Clinical Study Protocol——Title Page

A Randomized, Double-blind, Placebo-controlled, Parallel-group Phase II Clinical Study to Evaluate the Efficacy and Safety of GS1-144 Tablets in the Treatment of Moderate to Severe Vasomotor Symptoms in Chinese Postmenopausal Women

Protocol No.:	GenSci074-201
Amendment No.:	2
Version/Date:	Version 3.0, 10-Jan-2025
Test Drug Name:	GS1-144 tablet
Brief Title:	A Phase II Study to Evaluate GS1-144 Tablets for the Treatment of Moderate to Severe Vasomotor Symptoms in Postmenopausal Women
Study Phase:	Phase II
Regulatory Agency Identifier No.:	NMPA IND 2023LP02354
Principal Investigator Name and Affiliation:	Qi Yu Professor Peking Union Medical College Hospital Address: No. 41 Damucang Alley, Xicheng District, Beijing
Sponsor Name:	Changchun GeneScience Pharmaceuticals Co., Ltd.
Legal Registered Address:	No. 1718 Yueda Road, High-Tech Development Zone, Changchun, Jilin, China
Sponsor's Responsible Medical Officer:	Chao Pan Executive Medical Director

Protocol Amendment Summary of Changes Table

Document History	
Document	**Date**
Amendment 2 (Version 3.0)	10-Jan-2025
Amendment 1 (Version 2.0)	01-Sep-2024
Original Protocol (Version 1.0)	15-Aug-2024

Amendment 2 (10-Jan-2025)

Overall Rational for the Amendment:

To ensure the accuracy of endpoint definitions, efficacy difference analysis, and indication definitions, refine the protocol description, and improve clinical operability.

1. Update the Statistical Methods for the Primary Efficacy Endpoints
DESCRIPTION OF CHANGE
Replace "visit" with "week" in the Mixed-Effect Model Repeated Measure (MMRM) model. Update the calculation formula and its accompanying notes for VMS severity as the co-primary endpoint in Section 9.4.1.1.
BRIEF RATIONALE
To ensure the accuracy of the endpoint definitions and the analysis of efficacy differences, the calculation formula for the severity of VMS has been updated and further clarified. The average severity score of VMS for a single day is first calculated using the weighted formula, and then the mean value for the preceding 7 days is calculated correspondingly. Besides, replace "visit" with "week" in the analysis method for primary endpoints to maintain consistency with the actual analysis model.
2. Refine Study Indication
DESCRIPTION OF CHANGE
Indication "postmenopausal vasomotor symptoms" is updated to "moderate to severe postmenopausal vasomotor symptoms".
BRIEF RATIONALE
To further describe the study indication.
3. Add the Definition of QTcF Baseline Value for QTc Stopping Criteria
DESCRIPTION OF CHANGE
Add "the average of two QTcF values before dosing will be used as the baseline if only one ECG is captured within the latest single day prior to dosing, or the average of all the QTcF values will be used as the baseline if multiple ECGs are captured within the latest single day prior to dosing."

BRIEF RATIONALE
Additional clarification to enhance practical operability.
4. Update Collecting Time Requirements for Medical History/Comorbidities
DESCRIPTION OF CHANGE
Add "In addition to the requirements for collecting medical history related to inclusion/exclusion criteria, it is also routine to gather information on medical history/comorbidities within the 6 months prior to obtaining informed consent. However, if a more concerning AE occurs during the study or there is a need to trace the medical history/comorbidities, this collection can be done without being limited to the aforementioned time frame."
BRIEF RATIONALE
To improve data consistency and practical operability.
5. Update Collecting Requirements for Prior/Concomitant Treatments
DESCRIPTION OF CHANGE
Add non-drug therapy in addition to medication for medical conditions other than VMS to be documented from 90 days prior to the screening visit to the first dose of investigational product, and add the following: - "Non-drug therapies received by the participant from the first administration of the investigational medicinal product to the last study-related activity will be recorded in the eCRF as concomitant treatments. Prior and concomitant non-drug therapies to be documented include, but are not limited to, physical therapy (treatments using sound, light, electricity, and magnetic fields, etc.), traditional Chinese therapy (such as acupuncture and cupping), and surgical intervention, with the records including name of the non-drug thrapies, frequency (if applicable), treatment duration (start and end dates), and indication, etc." - "If a more concerning AE occurs or there is a need to trace the prior treatments for medical history during the study, the aforementioned time limits for collection may not apply." In addition, update the types of prior hormone therapies that need to be washed out before screening.
BRIEF RATIONALE
Appropriate updates for enhanced risk management of participants.
6. Refine the Requirements for ECG Capturing
DESCRIPTION OF CHANGE
Update "rest in supine position" for at least 5 minutes prior to ECG capturing to "rest in sitting/supine position".
BRIEF RATIONALE
To enhance the practical operability without compromising the scientific integrity of the data.

7. Update the Requirements for Assessment Sequence
DESCRIPTION OF CHANGE
Maintain the assessment sequence for scales, while removing the requirements for other procedures.
BRIEF RATIONALE
To further clarify the assessment sequence.
8. Update the Requirements for Laboratory Testing
DESCRIPTION OF CHANGE
Revise 2 test items and add a footnote "For some of the laboratory tests mentioned above that cannot be performed by the study site, it is acceptable to send them out to third-party laboratories and other hospitals for testing."
BRIEF RATIONALE
To improve practical operability.

Protocol Signature Page

(Sponsor)

Protocol Title:	A Randomized, Double-blind, Placebo-controlled, Parallel-group Phase II Clinical Study to Evaluate the Efficacy and Safety of GS1-144 Tablets in the Treatment of Moderate to Severe Vasomotor Symptoms in Chinese Postmenopausal Women
Protocol No.:	GenSci074-201
Protocol Version/Date:	Version 3.0, 10-Jan-2025

Sponsor:

I will conscientiously perform my duties as a sponsor according to current China GCP, and be responsible for initiating, applying for, organizing, funding and monitoring this clinical study.

I have participated in the development and discussion of this clinical study protocol and agree on the contents of this protocol. I have had a clear understanding of the sponsor's responsibilities in relation to the study protocol of this project and agree to conduct the clinical study in accordance with this protocol and all applicable laws and regulations.

Sponsor: Changchun GeneScience Pharmaceuticals Co., Ltd.

Sponsor's Responsible Medical Officer: Chao Pan

Title: Executive Medical Director

Chao Pan
Signature

2025. 2. 5
Date

Protocol Signature Page

(Investigator)

Protocol Title:	A Randomized, Double-blind, Placebo-controlled, Parallel-group Phase II Clinical Study to Evaluate the Efficacy and Safety of GS1-144 Tablets in the Treatment of Moderate to Severe Vasomotor Symptoms in Chinese Postmenopausal Women
Protocol No.:	GenSci074-201
Protocol Version/Date:	Version 3.0, 10-Jan-2025

Principal Investigator:

I will conscientiously assume the responsibilities of an investigator in accordance with the provisions of current GCP. I have received the Investigator's Brochure and understood its essential contents. I have been informed that I will receive the updated Investigator's Brochures in a timely manner. I have read and understood this study protocol, and the study will be conducted in accordance with the moral, ethical and scientific principles stipulated in the Declaration of Helsinki and current China GCP. I agree to conduct the clinical study according to the design and provisions of this protocol.

Principal Investigator Name:Qi Yu

Title:PI

Affiliation:Peking Union Medical College Hospital, Chinese Academy of Medical

Qi Yu
Signature

Feb. 8. 2025
Date

Table of Contents

List of Abbreviations and Definitions of Terms

Abbreviations	Full name in English
AE	Adverse Event
ALT	Alanine Aminotransferase
ASD	Amorphous Solid Dispersion
AST	Aspartate Transaminase
ATC	Anatomical Therapeutic Chemical Classification
AUC	Area under Curve
BALP	Bone Alkaline Phosphatase
BID	Bis in Die; Twice Daily
BI-RADS	Breast Imaging-Reporting and Data System
BMI	Body Mass Index
CI	Confidence Interval
C_{max}	Concentration of Peak
CRA	Clinical Research Associator
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organization
CS	Clinical Significance
CT	Computed Tomography
CTX	Cross Linked C-telopeptide of Type I Collagen
CYP1A2	Cytochrome P450 1A2
DM	Data Manager
DMP	Data Management Plan
DMR	Data Management Report
DVP	Data Verification Plan
Dyn	Dynorphin
E1	Estrone
E2	Estradiol
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
ED	Early Discontinuation
EDC	Electronic Data Collection
eGFR	Estimated Glomerular Filtration Rate
EOT	End of Treatment
FAS	Full Analysis Set
FSH	Follicle-stimulating Hormone
GCP	Good Clinical Practice
HBeAb	Hepatitis B Envelop Antibody
HBeAg	Hepatitis B Envelop Antigen
HBsAb	Hepatitis B Surface Antibody

Abbreviations	Full name in English
HBsAg	Hepatitis B Surface Antigen
HCV-Ab	Hepatitis C Virus-Antibody
HIV-Ab	Human Immunodeficiency Virus-Antibody
HRT	Hormone Replacement Therapy
IB	Investigator's Brochure
IC_{50}	Half-maximal Inhibitory Concentration
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IMP	Investigational Medicinal Product
IND	Investigational New Drug
IRB/IEC	Institutional Review Board/Independent Ethics Committee
IVRS/IWRS	Interactive Voice/Web Response System
Kiss	Kisspeptin
KNDy	Kisspeptin/Neurokinin B/Dynorphin neuron
LH	luteinizing Hormone
MedDRA	Medical Dictionary for Regulatory Activities
MENQOL	Menopause-specific Quality of Life
MM	Medical Monitor
MMRM	Mixed Model for Repeated Measure
MTD	Maximum Tolerated Dose
NCS	Non-clinical Significance
NDA	New Drug Application
NIMP/AxMP	Noninvestigational/Auxiliary Medicinal Product
NK3R	Neurokinin 3 Receptor
NKB	Neurokinin B
NOAEL	No Observed Adverse Effect Level
PD	Pharmacodynamics
PDAS	Pharmacodynamics Analysis Set
PDYN	Prodynorphin
PGI-C	Patient Global Impression of Change
PGI-S	Patient Global Impression of Severity
PINP	Type I procollagen N-terminal peptide
PKAS	Pharmacokinetics Analysis Set
PopPK	Population Pharmacokinetics
PPS	Per Protocol Set
PR	Progesterone Receptor
PT	Preferred Term
QA	Quality Assurance
QC	Quality Control
QD	Quaque Die; Once Daily

Abbreviations	Full name in English
QTcF	Corrected QT Interval for heart rate by Fridericia's cube root formula
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SHBG	Sex Hormone-binding Globulin
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operation Procedure
SS	Safety Set
$t_{1/2}$	Half-life
TAC3	Tachykinin 3
TBIL	Total Bilirubin
TEAE	Treatment Emergent Adverse Event
Teso	Testosterone
T_{max}	Time to Peak Concentration
TPPA	Treponema Pallidum Particle Agglutination
TVU	Trans-vaginal Ultrasound
ULN	Upper Limit of Normal
VMS	Vasomotor Syndrome
WHO Drug	WHO Drug Information

1. Protocol Summary

1.1. Synopsis

<table>
<tr><td colspan="2">Protocol No.:
GenSci074-201</td><td>Version and Date:
Version 3.0, 10-Jan-2025</td></tr>
<tr><td colspan="2">Test Drug Name:
GS1-144 tablet</td><td>Registration Classification:
Class 1 chemical drug</td></tr>
<tr><td colspan="2">Study Indication:
Moderate to severe postmenopausal vasomotor symptoms (VMS)</td><td>Study Phase:
Phase II</td></tr>
<tr><td colspan="3">Sponsor:
Changchun GeneScience Pharmaceuticals Co., Ltd.</td></tr>
<tr><td>Study Title:</td><td colspan="2">A Randomized, Double-blind, Placebo-controlled, Parallel-group Phase II Clinical Study to Evaluate the Efficacy and Safety of GS1-144 Tablets in the Treatment of Moderate to Severe Vasomotor Symptoms in Chinese Postmenopausal Women</td></tr>
<tr><td>Study Population:</td><td colspan="2">Postmenopausal women aged 40-64 (inclusive) years with moderate to severe VMS (an average of ≥7 episodes a day for 7 consecutive days)</td></tr>
<tr><td>Sample Size:</td><td colspan="2">About 268 participants are planned to be enrolled, with 67 participants randomized into each treatment group.</td></tr>
<tr><td>Study Sites:</td><td colspan="2">A total of about 30-46 sites, the leading site being Peking Union Medical College Hospital, the leading investigator being Professor Qi Yu</td></tr>
<tr><td colspan="3">Study Objectives and Endpoints:

<table>
<tr><th>Primary Objective</th><th>Co-primary Endpoints</th></tr>
<tr><td>• To evaluate the efficacy of GS1-144 in the treatment of moderate to severe VMS</td><td>• Changes from baseline in the frequency of moderate to severe VMS at Week 4
• Changes from baseline in the frequency of moderate to severe VMS at Week 12
• Changes from baseline in the severity of moderate to severe VMS at Week 4
• Changes from baseline in the severity of moderate to severe VMS at Week 12</td></tr>
<tr><th>Secondary Objectives</th><th>Secondary Endpoints</th></tr>
<tr><td>• To evaluate other efficacy of GS1-144 in the treatment of moderate to severe VMS
• To evaluate the safety and tolerability of GS1-144</td><td>• Changes from baseline in the frequency of moderate to severe VMS at each of the other treatment weeks over 12 weeks
• Changes from baseline in the severity of moderate to severe VMS at each of the other</td></tr>
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</td></tr>
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	treatment weeks over 12 weeks • Percentage decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks • Proportions of participants with ≥50% and 100% decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks • Incidence and severity of Adverse Events (AEs) • Changes from baseline at each time point in laboratory tests, vital signs, physical examination findings, 12-lead electrocardiogram (ECG), and transvaginal ultrasound (TVU), etc.
Exploratory Objectives	**Exploratory Endpoints**
• To characterize the population pharmacokinetics (PopPK) of GS1-144 and its metabolite M1 and to analyze its exposure-response relationship • To evaluate the improvement in sleep disturbance with GS1-144 • To evaluate the improvement in quality of life with GS1-144 • To evaluate the improvement in relevant postmenopausal symptoms with GS1-144 • To evaluate the effect of GS1-144 on the pharmacodynamics (PD) marker (luteinizing hormone [LH]) • To evaluate the effects of GS1-144 tablets on sex hormones (other than LH) and sex hormone-binding globulin • To evaluate the effect of GS1-144 tablets on bone metabolism	• This study will establish a PK model to characterize the PK profiles of GS1-144 and its metabolite M1. Then, based on the parameter estimates through the final PK modeling, individual exposure parameters for each participant will be estimated for further pharmacokinetic-pharmacodynamic (exposure-response and exposure-safety) analysis (if data available) • Scores on participant's Patient Global Impression of Change (PGI-C) in sleep disturbance at Weeks 4/8/12 from baseline • Changes from baseline on participant's Patient Global Impression of Severity (PGI-S) in sleep disturbance at Weeks 4/8/12 • Changes from baseline in modified Kupperman Index at Weeks 4/8/12 • Changes from baseline in Menopause-Specific Quality-of-Life (MENQOL) score at Weeks 4/8/12 • Changes from baseline in LH concentration; • Changes from baseline in sex hormones (other than LH) and sex hormone-binding globulin concentrations at D1 and Weeks 4/8/12 • Changes from baseline in serum concentrations of bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX) at Week 12.

Study Design:

This is a randomized, double-blind, placebo-controlled, parallel-group, 12-week treatment clinical study to evaluate the efficacy and safety of GS1-144 tablets in the treatment of moderate to severe VMS in postmenopausal women.

In this study, 268 postmenopausal female participants with moderate to severe VMS symptoms are planned to be enrolled through block randomization stratified by the body mass index (BMI, <28 kg/m^2 or ≥28 kg/m^2), and allocated to the GS1-144 30 mg QD, GS1-144 60 mg QD, GS1-144 30 mg BID or placebo group in a 1:1:1:1 ratio (67 participants each of these 4 treatment groups). Duration of treatment is 12 weeks. Following the completion of the treatment period or end of treatment (EOT) or early discontinuation from the study (ED), participant will complete the V9 (Day 85)/EOT/ED visit, and non-ED participants will also complete the final visit for safety and other assessments.

The study consists of 4 stages: screening period (D-30 to D-4), baseline period (D-3 to D-1), treatment period (D1 to D84), and follow-up period (D85 to D99). This study will be conducted in outpatients with a treatment duration up to 12 weeks, a study duration up to approximately 18 weeks, and a total of 10 visits.

Screening visit (V1) will be completed after the participant signs the informed consent form (ICF) and within 30 days prior to randomization. It will last for at least 9 days to collect baseline data on the frequency and severity of vasomotor symptoms, based on which a participant's eligibility for enrollment will be assessed together with the physical examinations, vital signs, clinical laboratory tests, ECGs, chest CTs or X-rays, breast ultrasounds, TVUs and endometrial biopsies, etc. If a participant has used any prohibited medication prior to screening, there should be a washout period of at least 5 half-lives of the drug(s) (see section 6.9.1 for washout period requirements).

Participants may be retested up to 1 time within the 30-day screening window, retaining the same participant number. Participants may be rescreened up to 1 time and must re-sign the ICF with a new participant number, which will result in a new 30-day screening window. The following assessments do not need to be repeated at re-screening if the assessment was done within the specified timeframe and its result meets all the inclusion criteria and none of the exclusion criteria: TVU (within 3 months prior to screening), endometrial biopsy (within 3 months prior to screening), breast ultrasound (within 6 months prior to enrollment with relevant record [including written or electronic report] indicating normal/negative or no clinically significant ultrasound findings), chest X-ray (anteroposterior) or chest CT (within 6 months prior to screening).

During the screening period, participants must have a minimum average of 7 episodes of moderate to severe VMS a day for 7 consecutive days prior to randomization. The VMS eDiary shall be reviewed by the designated site staff prior to randomization on D1 (V3) to confirm participant's compliance and eligibility. Participants not meeting the inclusion criteria upon the first assessment of VMS symptoms shall not be re-screened.

Participants will be randomized on D1 after completing the baseline tests/examinations/assessments and being confirmed eligible.

During the 12-week treatment period, the participant will take the investigational product, test drug or placebo, twice daily (2 tablets each in the morning and evening) for 84 consecutive days, and will return

to the study site for the corresponding tests/examinations, assessments, receiving and/or return of investigational product, and other procedures specified in Section 1.3 Schedule of Activities (SOA) every 2 weeks from V3 to V9 (D1, D15, D29, D43, D57, D71, and D85).

Participants must record their VMS episodes using the eDiary twice daily from 9 days prior to randomization to the last visit. Scale assessments (except for VMS diary) at the site visit must be completed after the participant's arrival at the study site and before other visit procedures. If a participant has discontinued treatment or discontinued from study, the participant should return to the study site to complete the scale assessments and other EOT/ED visit procedures as nearly as possible around the discontinuation.

The non-ED participant will need to return to the site on D99 or 14 days after EOT visit to complete the follow-up visit for safety, AEs and concomitant medications/therapies.

End of Study:

The end of study is defined as the date on which the last participant in the study completes the last visit.

A participant is considered to have completed the study if the participant has completed all periods of the study including the last visit or the last scheduled procedures shown in the SOA.

PK/PD Sampling:

LH is the PD marker for this study. The PK and PD samples should be taken at the same time.

Refer to Section 1.4 for detailed sampling time points.

Investigational Products:

All the study drugs in this study are investigational products, including the test drug GS1-144 30 mg tablet and its matching placebo tablet as a control, both manufactured by WuXi STA Pharmaceutical Co., Ltd. and supplied centrally by Changchun GeneScience Pharmaceutical Co., Ltd.

	Medication name	Dose formulation	Unit dose strength
Test drug	GS1-144	Tablet	30 mg/tablet
Control product	Placebo	Tablet	NA

Dosage Regimens:

The investigational products will be administrated orally.

GS1-144 30 mg QD group

Morning: one GS1-144 30 mg tablet + one placebo tablets

Evening: two placebo tablets

Daily dose level: 30 mg

GS1-144 60 mg QD group

Morning: two GS1-144 30 mg tablets

Evening: two placebo tablets

Daily dose level: 60 mg

GS1-144 30 mg BID group

Morning: one GS1-144 30 mg tablet + one placebo tablets

Evening: one GS1-144 30 mg tablet + one placebo tablets

Daily dose level: 60 mg

Placebo BID group

Morning: two placebo tablets

Evening: two placebo tablets

Daily dose level: NA

Dose modification is not allowed for the investigational products in this study.

In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose.

Treatment Duration:

Participants will take investigational products twice daily from day 1 (randomization) for a duration of 12 weeks.

Study Duration:

The screening period will last for up to about 30 days (including baseline period), the treatment period will last for 12 weeks, the follow-up period will last for 2 weeks, and the entire study will last for up to about 18 weeks.

Concomitant Medication Restrictions or Requirements:

Medication for VMS taken within the 12 months prior to screening and other medication/non-drug therapy taken from 90 days prior to the screening visit to the first dose of investigational product will be documented in the electronic case report form (eCRF) as prior treatment. If a more concerning AE occurs or there is a need to trace the prior treatments for medical history during the study, the aforementioned time limits for collection may not apply.

Medications taken after the first dose of investigational product through the last study-related activity will be documented in the eCRF as concomitant medication. Prior and concomitant medications to be

documented include, but are not limited to, vitamins, herbal remedies (e.g., St. John's wort, valerian) and over the counter and prescription medication, with the records including drug name, dose and frequency, dosing duration (start and end dates), route of administration, and reason for use, etc.

Non-drug therapies received by the participant from the first administration of the investigational medicinal product to the last study-related activity will be recorded in the eCRF as concomitant treatments. Prior and concomitant non-drug therapies to be documented include, but are not limited to, physical therapy (treatments using sound, light, electricity, and magnetic fields, etc.), traditional Chinese therapy (such as acupuncture and cupping), and surgical intervention, with the records including name of the non-drug therapy, frequency (if applicable), treatment duration (start and end dates), and indication, etc.

Participants will be instructed not to take any concomitant medication without first consulting the investigator throughout the study.

Prohibited Concomitant Medications:

The following medications and therapies are prohibited throughout the study (from signing of ICF through the last visit/follow-up):

- Medications for treatment of VMS such as hormone therapy, hormonal contraception or any treatment for menopausal vasomotor symptoms (prescription, over the counter or herbal). It is recommended that the medication for treating menopausal syndrome be taken consistently throughout the duration of the study.
- Investigational research products that have not been approved for any indication in Chinese Mainland.
- Moderate or strong CYP1A2 inhibitors.

Inclusion/Exclusion Criteria:

Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply:

Age

1. 40 to 64 years of age (inclusive) at the screening visit.

BMI

2. 18.5 to 30 kg/m^2 (inclusive).

Type of Participant and Disease Characteristics

3. Females meeting 1 of the following criteria of menopause at screening visit: spontaneous amenorrhea for ≥12 consecutive months, spontaneous amenorrhea for ≥ 6 consecutive months with serum follicle-stimulating hormone (FSH) > 40 IU/L, or 6 weeks past a postsurgical bilateral oophorectomy with or without hysterectomy;
4. Participants who are seeking treatment or relief for VMS and meet the criteria for moderate to severe VMS symptoms: during the 7 consecutive days prior to randomization, participants must have a minimum average of 7 episodes of moderate to severe VMS symptoms per day;
5. For females with uterus: endometrial thickness ≤ 4mm as shown by TVU at screening, or > 4mm without atypical hyperplasia or carcinogenesis of the endometrium from the subsequent biopsy

results (if the biopsy sample is insufficient or can't be obtained, it is considered normal and meeting this inclusion criterion);

Informed Consent

6. Volunteered to sign ICF and be able to understand and comply with the requirements of this study.

Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

Medical Conditions

1. Diseases or dysfunctions known to interfere with the clinical trial, including but not limited to: neuropsychiatric, cardiovascular, urological, digestive, respiratory, musculoskeletal, metabolic, endocrine, haematological, immune, dermatological and oncological conditions, etc., or poorly controlled chronic diseases with clinical significance;
2. Thyroid or parathyroid-related hormones abnormalities with clinical significance at screening or baseline;
3. Identified moderate to severe liver fatty at screening or baseline
4. Any surgical or medical conditions that may significantly affect the absorption, distribution, metabolism, and excretion of the drug, such as a history of gastrointestinal surgery (gastrectomy, gastroenterostomy, enterectomy, etc.), urinary tract obstruction, or dysuria
5. Current or prior history of malignancy (except for malignancies and basal cell carcinoma that have not received any antineoplastic treatment within 5 years prior to screening visit, or have currently recovered and have no risk of relapse during this study as assessed by the investigator);
6. Abnormal uterine bleeding with clinical significance during screening period or baseline period;
7. Participants who have attempted suicide within the last 1 year or are currently at risk of impulsive behavior or suicide;
8. Participants with a history of severe allergy to investigational products or any of their excipients or with allergic constitution (e.g., being allergic to two or more drugs or foods);
9. Participants who have positive serology results of hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV-Ab), human immunodeficiency virus antibody (HIV-Ab) or syphilis;
10. Abnormalities in vital signs during the screening period or baseline period, e.g., resting pulse rate < 55/min or > 105/min; systolic blood pressure < 90 mmHg or ≥ 160 mmHg; diastolic blood pressure < 60 mmHg or ≥ 100 mmHg, that upon evaluation by the investigator may interfere with this clinical study;
11. BI-RADS (Breast Imaging Reporting and Data System) Category ≥4 on breast ultrasounds within 6 months prior to randomization;
12. Participants who have positive pregnancy test during screening or baseline period.

Cardiac Safety

13. 12-lead electrocardiography (ECG) abnormalities during screening period or baseline period, e.g., heart rate-corrected QT interval QTcF absolute value > 470 ms (Fridericia's formula: $QTcF=QT/RR^{0.33}$) that upon evaluation by the investigator may interfere with this clinical study;

Liver Safety

14. Abnormalities in laboratory tests during screening period or baseline period, e.g., alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 2 × upper limit of normal (ULN), or total bilirubin (TBIL) > 1.5×ULN, that upon evaluation by the investigator may have interfere with this clinical study;

Renal Safety

15. Creatinine >1.5×ULN or estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73 m^2 based on modification of diet in renal disease (MDRD) during screening period or baseline period;

Prior/Concomitant Therapy

16. The participant has used or is using prohibited medications/therapies (moderate or strong CYP1A2 inhibitors, hormone replacement therapy or any VMS therapeutic agents [prescription, non-prescription or herbal medicines]) at screening and is unwilling to discontinue and wash out such medications throughout the study (see Section 6.9 for the washout intervals for prohibited concomitant/prior medications);

Prior/Concurrent Clinical Study Experience

17. Having participated in any other clinical trial within 3 months or any clinical study of fezolinetant or other treatments for VMS (except for participants who have not received any investigational product) within 1 year prior to screening, or planning to participate in any other clinical trial;

Other Exclusion Criteria

18. Current or prior history of drug use, drug abuse or alcohol abuse;
19. Any other conditions that are unsuitable for participating in this study in the opinion of the investigator.

Criteria for Treatment Discontinuation:

1. Hepatotoxicity: if laboratory tests indicate any of the following liver function conditions assessed by the investigator as related to the investigational product, safety management actions such as immediate discontinuation of treatment and close follow up should be taken:
   a. ALT or AST > 8 × ULN;
   b. ALT or AST > 5 × ULN for more than 2 weeks;
   c. ALT or AST > 3×ULN, and TBIL > 2 ×ULN or international normalized ratio (INR) > 1.5 ×ULN;
   d. ALT or AST > 3×ULN, accompanied by fatigue, nausea, vomiting, right upper abdomen pain or tenderness, fever, rash and/or eosinophilia (> 5%) and other symptoms that are thought to be associated with hepatic damage or allergy.
2. Cardiac toxicity: if a 12-lead ECG reveals QTcF >500 ms or QTcF prolonged by > 60 ms from baseline after enrollment, dosing should be suspended, and the examination should be immediately repeated twice (take the average of the 3 examinations); the average of two QTcF values before dosing will be used as the baseline if only one ECG is captured within the latest single day prior to dosing, or the average of all the QTcF values will be used as the baseline if multiple ECGs are captured within the latest single day prior to dosing. If the above criterion is still met and the condition is judged by the investigator to be related to the investigational product, the investigator will determine whether the participant should permanently discontinue study treatment and whether to change the participant management pattern;
3. If, for safety reasons, it is in the best interest of the participant that the study treatment be discontinued, in the investigator's opinion;
4. Development of a medical condition that requires concomitant treatment with a prohibited therapy;
5. Participants who have poor compliance, are not able to comply with the protocol during the trial, and are deemed inappropriate by the investigator to continue in the trial. This may include the following:
   a. Participants fail to take the drugs and/or receive examinations as specified;

b. Participants have used other drugs and/or food that affect the results of safety assessments and/or PK;
c. Participants have other behaviors that affect the trial results.

6. Unblinding of the randomization code during administration of the investigational products by the investigator or by designated study site staff.
7. Other reasons.

Criteria for Participant Withdrawal from the Study:

A participant may withdraw from the study at any time at the participant's own request for any reason (or without providing any reason) without any negative consequences, including: 1. withdrawal of consent, or 2. lost to follow-up which will also be considered as "withdrawal" when a participant no longer receive the procedures such as investigational product taking or blood sampling, although have not explicitly requested to withdraw from the trial.

Statistics

Sample Size Calculation

For the primary endpoint of mean change from baseline of daily frequency, the previous studies of fezolinetant showed that the treatment difference versus placebo ranged from -2.0 to -5.0, with similar results at Week 4 and Week 12. Using a 2-sample t-test at a two-sided 0.1 alpha, for a pairwise comparison of the primary endpoint of mean change from baseline of daily frequency, 55 participants in each group will provide 80% power to detect the difference from placebo of -2.4, assuming an SD of 5.

For the primary endpoint of mean change from baseline of severity, the previous studies of Fezolinetant showed that the treatment difference versus placebo ranged from -0.2 to -1.1, with similar results at Week 4 and Week 12. Using a 2-sample t-test at a two-sided 0.1 alpha, for a pairwise comparison of the primary endpoint of mean change from baseline of severity, 55 participants in each group will provide 80% power to detect the efficacy difference from placebo of -0.36, assuming an SD of 0.75.

Assuming approximately 17% drop-out rate (referring to Fezolinetant Phase III studies), the number of participants will be increased from 55 to 67 for each treatment group, totally 268 participants for 4 treatment groups. Note that the power for testing all 4 co-primary endpoints will be lower than the power for each one considered individually.

Analysis Datasets

- Full Analysis Set (FAS): including all participants who have been randomized and received at least one dose of the investigational products.
- Per Protocol Set (PPS): a subset of the FAS including all participants with valid primary endpoint data, good compliance (including study treatment compliance and vasomotor symptom diary recording compliance) and no important protocol deviations impacting the primary endpoint evaluation. There are two PPS: one specific to the co-primary endpoints at week 4 and another specific to week 12.
- Safety Set (SS): all participants who have received at least at least one dose of the investigational products.

- Pharmacokinetic analysis set (PKAS): including participants who have received at least one dose of GS1-144 and have at least one PK measurement.
- Pharmacodynamic analysis set (PDAS): a PDAS obtained from participants with at least 1 pre-dose and post-dose LH concentration.

Additional analysis sets may be defined as needed for analysis, and will be provided in a separate Statistical Analysis Plan (SAP).

General considerations for statistical analysis

Generally, descriptive summary of statistics, such as n, mean, SD, median, minimum, and maximum will be used for continuous variables, and counts and percentages will be for discrete variables.

Efficacy analysis

Efficacy analysis will be performed based on FAS, in addition, the analysis of co-primary endpoints will be conducted on PPS as well.

For each of the 4 co-primary efficacy endpoints, treatment comparison will be performed using a Mixed-Effect Model Repeated Measure (MMRM) model, with treatment group, week, and randomization stratification BMI (<28 kg/m^2 or ≥ 28 kg/m^2) as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction. Treatment effects will be estimated based on least-square (LS) means of the differences. The p-values for the LS mean differences along with the 2-sided 90% CI will be presented.

For other efficacy endpoints, unless otherwise specified, the MMRM model will be used for the analysis of continuous variables with repeated measures, and stratified CMH or Logistic regression model will be used for the analysis of binary variables. No adjustments for multiple comparisons will be made for the secondary endpoints and all p-values will be considered nominal.

Safety analysis

The safety analysis is based on the SS.

AEs will be coded with Medical Dictionary for Regulatory Activities (MedDRA). Any AEs occurring at or after the initial administration of investigational products or that are a consequence of a preexisting condition that has exacerbated after first study intervention are considered to be treatment emergent adverse events (TEAEs). Any TEAEs, serious TEAEs, and study drug-related TEAEs, etc., will be summarized and analyzed as classified by System Organ Class (SOC) and Preferred Term (PT), and all AEs will be listed. Other safety endpoints will also be summarized descriptively by treatment group.

PK Analysis

GS1-144 and M1 plasma concentrations at each dose will be summarized descriptively. Descriptive statistics include arithmetic mean, standard deviation, coefficient of variation, median, maximum, minimum, geometric mean, and geometric coefficient of variation, etc. Individual and mean plasma concentration-time curves will be plotted based on the blood sampling time points. The time used for individual participant's plasma concentration curves will be the actual blood sampling time, while the time used for the mean concentration-time curve will be the planned blood sampling time. Individual or mean plasma concentration-time curves will be displayed using both linear and semi-logarithmic plotting.

PD Analysis

Serum LH concentration and its change from baseline will be summarized by each planned blood sampling time point and actual treatment group with descriptive statistics, including arithmetic mean, standard deviation, coefficient of variation, median, maximum, minimum, geometric mean, and geometric coefficient of variation, etc. Individual and mean LH concentration-time curves will be plotted based on the blood sampling time points. The time used for individual participant's LH concentration curves will be the actual blood sampling time, while the time used for the mean concentration-time curve will be the planned blood sampling time.

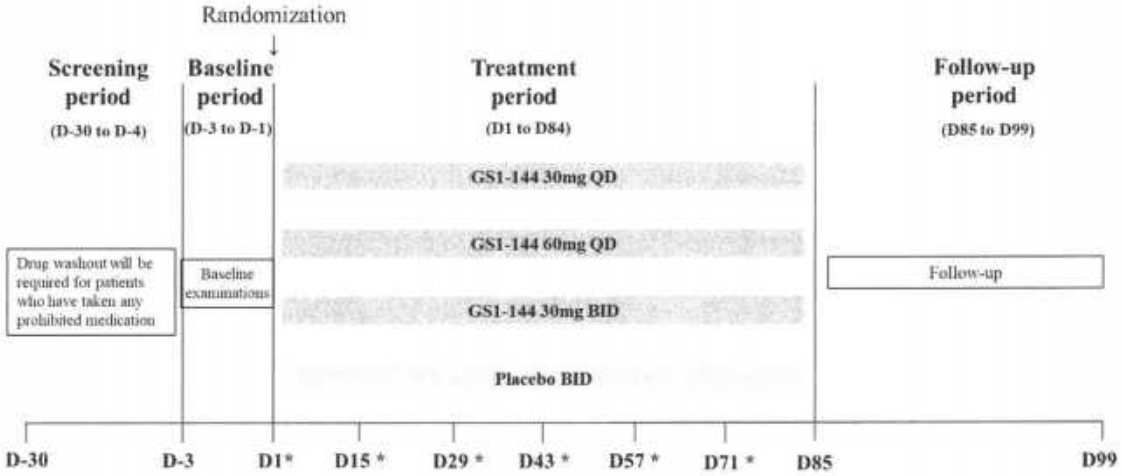
PopPK Analysis and Dose-Response Analysis

PopPK samples will be collected. The PK model will be established using the nonlinear mixed effect model, and participants' individual exposure parameters will be estimated based on the parameter estimates of the final PK model established for further dose-response (exposure-response) analysis, including analyses of the PK-efficacy and PK-safety correlations.

Interim Analysis:

To assist a timely internal decision making and adjustment to the development of the program, an interim analysis is planned after all randomized participants have completed the Week 4 visit (or participant's discontinuation/withdrawal from the study treatment earlier than that). To maintain the integrity of the blind, interim analysis will be performed by an independent un-blinded team, and the unblinded results will be restricted to a very small group independent of study team; Details will be documented in a separate charter to ensure the integrity of the study blinding maintenance.

1.2. Schema



Note: *The morning dose of investigational product will be taken at the study site, under the supervision of the designated study staff, after collection of predose blood samples.

1.3. Schedule of Activities (SOA)

	Screening period	Baseline period	Treatment period							Follow-up Period
Visit No.	V1	V2	V3 [22]	V4 [22]	V5 [22]	V6 [22]	V7 [22]	V8 [22]	V9/EOT/ED [22]	V10
Visit weeks	/	/	/	W2	W4	W6	W8	W10	W12	W14
Visit days	D-30 to D-4	D-3 to D-1	D1	D15	D29	D43	D57	D71	D85/day of treatment discontinuation/ day of discontinuation from study	D99/14 days after EOT
Visit window	/	/	/	± 3 days	± 3 days	± 3 days	± 3 days	± 3 days	± 3 days	± 3 days
Informed consent	X									
Inclusion/exclusion criteria	X		X							
Demographics [1]	X		X							
Medical history/concomitant diseases [2]	X		X							
PGI-C [3]					X		X		X	
PGI-S [3]		X			X		X		X	
Modified Kupperman Index [3]		X			X		X		X	
MENQOL questionnaire[3]		X			X		X		X	
Physical examination [4]	X				X		X		X	X
Vital signs [5]	X	X		X	X	X	X	X	X	X
Pregnancy test [6]	X	X								
Laboratory tests [7]	X	X [7]		X	X	X	X	X	X	X
Infectious disease screening [8]	X									
12-lead ECG [9]	X	X	X	X	X	X	X	X	X	X
Neck and abdominal ultrasound [10]	X									
Chest CT or X-ray (AP) [11]	X									
TVU and endometrial biopsy [12]	X								X	

	Screening period	Baseline period	Treatment period							Follow-up Period
Visit No.	**V1**	**V2**	**V3 [22]**	**V4 [22]**	**V5 [22]**	**V6 [22]**	**V7 [22]**	**V8 [22]**	**V9/EOT/ED [22]**	**V10**
Visit weeks	/	/	/	**W2**	**W4**	**W6**	**W8**	**W10**	**W12**	**W14**
Visit days	**D-30 to D-4**	**D-3 to D-1**	**D1**	**D15**	**D29**	**D43**	**D57**	**D71**	**D85/day of treatment discontinuation/ day of discontinuation from study**	**D99/14 days after EOT**
Visit window	/	/	/	**± 3 days**	**± 3 days**	**± 3 days**	**± 3 days**	**± 3 days**	**± 3 days**	**± 3 days**
Breast ultrasound [13]	X								X	
Train and/or review eDiary on VMS Symptoms [14]	X	X	X	X	X	X	X	X	X	X
Complete eDiary on VMS Symptoms [14]	D-9 to last visit: record VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) (within 7 consecutive days prior to randomization, participants must have: an average of ≥7 episodes of moderate to severe VMS a day)									
Sex hormone tests (other than LH) [15]	X	X	X	X	X	X	X	X	X	
Bone turnover marker tests [16]		X							X	
Randomization [17]			X							
PK/PD sampling [18]			X	X	X	X	X	X	X	
Dispense investigational products [19]			X	X	X	X	X	X		
Intake investigational products [20]			D1-D84: 2 tablets each in the morning and evening of a day (In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose)							
Investigational product accountability, medication diary and compliance check[21]				X	X	X	X	X	X	
Recording of adverse events	X									
Concomitant medications/non-drug therapy recording	X									

Note:

Abbreviations: PGI-C = patient global impression of change; PGI-S = patient global impression of severity; MENQOL = menopause-specific quality of life; ECG = electrocardiogram; CT = computed tomography; AP = anterior-posterior; TVU = transvaginal ultrasound; VMS = vasomotor syndrome; LH = luteinizing hormone; PK = pharmacokinetics; PD = pharmacodynamics; EOT = end of treatment; ED = early discontinuation; BID = bis in die (i.e., twice daily).

1. Demographics: including gender, ethnicity, age, date of birth, weight, height, and BMI. BMI=weight/height^2 (kg/m^2); only weight will be measured and BMI be calculated on Day1.
2. Medical history/concomitant diseases: general medical history, menstruation history, childbearing history, surgery history, allergy history, bleeding/blood donation history, smoking history, drinking history, caffeine and tea intake, drug abuse history, and participation in clinical trials, etc. In addition to the requirements for collecting medical history related to inclusion/exclusion criteria, it is also routine to gather information on medical history/comorbidities within the 6 months prior to obtaining informed consent. However, if a more concerning AE occurs during the study or there is a need to trace the medical history/comorbidities, this collection can be done without being limited to the aforementioned time frame. At V3, only medical histories/concurrent diseases or medical conditions (reported as an AE or SAE as appropriate) that have been exacerbated since the signing of ICF will be collected.
3. PGI-C, PGI-S, modified Kupperman Index and MENQOL: to be evaluated on the respective visit day upon arrival at the study site and prior to all other procedures.
4. Physical examination: skin, mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system.
5. Vital signs: ear temperature, pulse rate, sitting blood pressure (required to rest in sitting position for at least 5 minutes prior to measurement).
6. Pregnancy test: serum beta-human chorionic gonadotropin (β-hCG) test for screening period. If V2 is no more than 7 days after the V1 pregnancy test, there is no need for a repeat test at V2; otherwise, it needs to be repeated at V2. Urine pregnancy test is acceptable for baseline period.
7. Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (refer to Appendix 2: Study Items and Contents for specific test items). A laboratory test may not need to be repeated at V2 if the V1 test was done within the past 5 days. All samples for clinical laboratory tests should be taken predose at visits during treatment period.
8. Infectious disease screening: Hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), hepatitis B e antigen (HBeAg), hepatitis B e antibody (HBeAb), hepatitis B core antibody (HBcAb), hepatitis C virus antibody (HCV-Ab), human immunodeficiency virus antibody (HIV-Ab), and treponema pallidum particle agglutination (TPPA test).
9. 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest in sitting/supine position for at least 5 minutes prior to measurement). For V3, ECG must be done before pre-dose blood sampling and at 4 h post-dose (±30 min, before PK/PD blood sampling).
10. Abdominal ultrasound: in a fasted state.
11. Chest X-ray (AP) or chest CT: examination results obtained within 6 months prior to screening visit are acceptable, or to be examined only once during screening period or baseline period.
12. TVU and endometrial biopsy: uterus and adnexa are to be examined via TVU. For female participants with uterus: endometrial biopsy is required when endometrial thickness is > 4 mm revealed by TVU. Participants do not have to undergo a repeat TVU or biopsy at EOT/ED visit should it be no more than 1 month from the last TVU. TVU and endometrial biopsy is only to be done once at screening visit or baseline visit.
13. Breast ultrasound: The examination scope includes both breasts (if applicable) and both axillae; breast ultrasound is not required at EOT/ED visit if the visit is less than 1 month from the last breast ultrasound (including routine clinical examinations). Only one examination is needed at screening visit or baseline visit..

14. Vasomotor symptoms diary: the vasomotor symptoms diary is embedded electronically in participants' electronic device. From 9 days prior to randomization to the last visit (eligibility evaluation is based on the 7-day VMS data prior to randomization), the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening), and record the VMS symptoms immediately when waking up in the morning. The investigator or designated personnel must train/instruct the participant at the screening visit and complete review of VMS symptoms based on participant's eDiary prior to the administration of investigational product on the scheduled day during treatment period.
15. Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Blood samples will be collected predose only, and all be tested at central lab. During the screening period, only FSH should be tested at the study site when necessary to determine whether the participant meets the menopause criteria.
16. Bone turnover marker tests: bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX), all to be tested at the central lab.
17. Randomization: to be done on D-1 after all baseline assessments are completed.
18. PK/PD sampling: Pre-1st dose (within 4 h) blood samples of the day will all be collected at D1, D15, D29, D43, D57 and D71 visits, and 1.5 h (±10 min) and 4 h (±1 h) post-1st dose blood samples of the day will also be collected at D1, D29, and D57 visits. Post-dose sampling will also be done at D15, D43, or D71 visit when missing at D1, D29, or D57 visit. PK/PD samples also need to be collected at D85/EOT/ED visits.
19. Dispense investigational products: at V3-V8, the participant should return to the study site, where the designated site staff shall dispense to the participant the investigational products in the quantity for 2 weeks.
20. Intake Investigational products: the investigational product will be taken with water under the supervision of the investigator or the designated study staff (in the morning only; to be self-administered in the evening) on study visit days of V3-V8. Participants will take their dose of investigational product at home on all other days throughout the treatment period..
21. Investigational product accountability, medication eDiary and compliance check: the investigator or authorized staff must count the remaining unused investigational products returned by the participant (if any) and review the medication eDiary at V4-V9/EOT/ED visit. Participants should complete the medication compliance eDiary based on the actual daily use of the investigational product.
22. V3-V9/EOT/ED visits: participants will arrive at the study site as instructed in a fasted state (defined as having not consumed anything except water [within 1 hour prior to taking the investigational products] for at least 10 hours prior to the study visit). On all the other study days throughout the treatment period, participants will take the morning dose of the investigational products at home as instructed, at approximately the same time of a day, with an interval of as close to 12 hours as possible between the two doses for a day (preferably between 7:00 AM and 10:00 AM and between 7:00 PM and 10:00 PM). It is preferred to take the investigational products 1 hour before or 2 hours after a meal.

1.4. Schedule of PK/PD Sampling

Sampling visit	V3	V4	V5	V6	V7	V8	V9/EOT/ED
Sampling day	**D1**	**D15**	**D29**	**D43**	**D57**	**D71**	**D85/day of treatment discontinuation/day of discontinuation from study**
Sampling window	/	**±3 days**	**±3 days**	**±3 days**	**±3 days**	**±3 days**	**±3 days**
Pre-1st dose (within 4 h) of the day	X	X	X	X	X	X	X [2]
1.5 h (±10 min) post-1st dose of the day	X	(X) [1]	X	(X) [1]	X	(X) [1]	-
4 h (±1 h) post-1st dose of the day	X	(X) [1]	X	(X) [1]	X	(X) [1]	-

Note:

1. Only pre-dose sampling is scheduled at D15, D43, and D71 visits, yet post-dose sampling will be done at D15, D43, or D71 visit when missing at D1, D29, or D57 visit.
2. PK/PD samples are also needed at V9/EOT/ED visits (without administration of IMP).

2. Introduction

2.1. Background

2.1.1. Characteristics of Vasomotor Symptoms

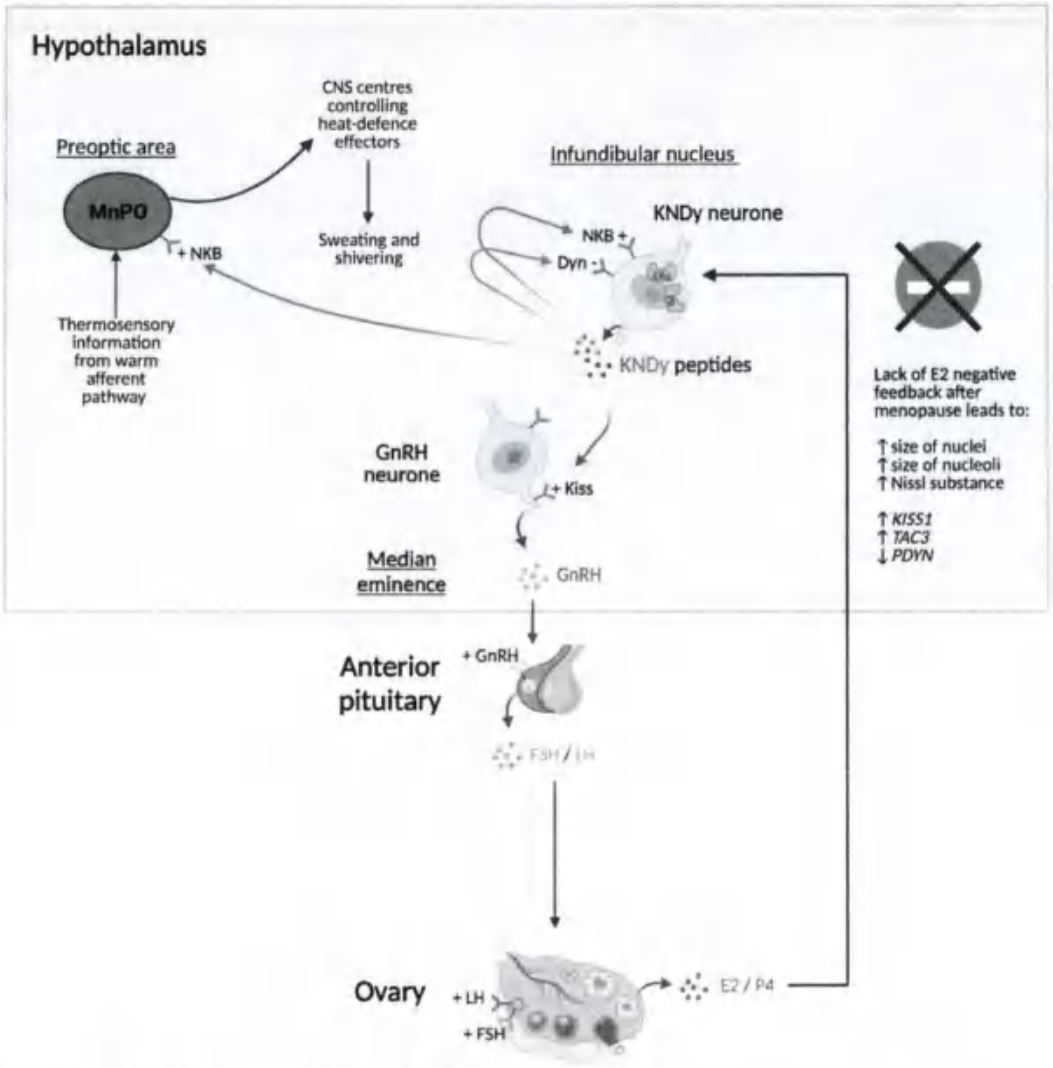
Vasomotor symptoms (VMS), or hot flashes and night sweats, are the most common symptoms of menopause. It feels like a sudden flare of heat (despite that there is only a very small increase, usually 0.1-0.3°C, in core or skin temperature). As a result, the heat dissipation effector is activated to lower the temperature, which is manifested as sweating, skin redness, coldness or tremble, as well as non-specific autonomic symptoms such as constriction of head or chest, restlessness, nausea, tachycardia, or shortness of breath. VMS affects as high as 70% of menopausal women, and 10% of these women would find VMS intolerable, significantly affecting their daily life including sleep, work, and social functioning, and could last for many years (median duration 7.4 years) [1-2].

2.1.2. Pathogenesis[3]

The pathological mechanism of VMS has not yet been fully elucidated. It is currently considered to be the result of multiple factors, among which the hypothalamic–pituitary–gonadal axis is crucial for regulating reproductive function. In primates, a subset of Kiss neurons located in the infundibular nucleus of hypothalamus co-express kisspeptin (Kiss), neurokinin B (NKB), and dynorphin (Dyn), and are therefore known as kisspeptin-neurokinin B-dynorphin (KNDy) neurons.

Kiss (encoded by the KISS1 gene), which is essential for human fertility, is a potent stimulator for the hypothalamic-pituitary-gonadal axis. NKB (encoded by the tachykinin 3 [TAC3] gene) and Dyn (encoded by the prokinin [PDYN] gene) stimulate and inhibit the release of Kiss at synapses through the neurokinin-3 receptor (NK3R) and Dyn (kappa opioid) receptor, respectively. Gonadal feedback is transmitted through estrogen receptor (ERα) and progesterone receptor (PR) expressed on KNDy neurons. Normally, KNDy neurons are activated by NK3R stimulation and inhibited by estrogen. At the same time, KNDy neurons are projected to the mammalian hypothalamic thermoregulatory center (median preoptic area and adjacent median preoptic nucleus) to regulate vasomotor activities.

The decline in estrogen levels during menopause leads to excessive secretion of NKB, especially excessive stimulation of KNDy neurons, which leads to increased activity of the thermoregulatory center, changes in the thermal neutral zone, increases sensitivity to external stimulation, and triggers more frequent heat dissipation responses, thereby inducing hot flashes.



Cited from MENOWN S J & TELLO J A, 2021 [3].

Figure 2-1 Schematic of Relationship Between KNDy Neurons, GnRH Neurons, and the Heat-Defense

2.1.3. Status Quo of Treatment

Hormone replacement therapy (HRT) remains the mainstay of treatment of menopausal vasomotor symptoms. It includes estrogen therapy alone or estrogen in combination with a progestogen. In addition to improving symptoms of hot flashes, vaginal dryness, and emotional disorder, HRT can also provide clinical benefits in reducing the risk of fractures and postmenopausal osteoporosis. Although HRT presents an effective and safe therapeutic approach in the short term, long-term (>5 years) use would be associated with an increased risk of venous thromboembolism, and caution should be exercised for use in patients at increased risk of cardiovascular and cerebrovascular diseases and certain malignancies (breast, endometrial). In addition, cancer patients who have received androgen deprivation therapy are not suitable for HRT, either, warranting alternative treatment strategies to be introduced. Nonhormonal therapeutic options include selective serotonin reuptake inhibitors, selective

serotonin norepinephrine reuptake inhibitors, gabapentin, cognitive behavioral therapy, Chinese herbal medicine, acupuncture, and dietary and lifestyle changes, etc. However, these options have provided varying efficacy across clinical studies. Therefore, developing new alternative therapeutic agents for the treatment of vasomotor symptoms has become the focus of clinical studies in recent years and has contributed to a better understanding of the underlying pathophysiological mechanism of vasomotor symptoms [4].

Antagonism of NKB/NK3R signaling pathway has attracted extensive attention as a potential therapeutic target. Blocking the NKB signaling pathway with NK3R antagonists can normalize KNDy neuron activity and thus may contribute to alleviating VMS in menopausal women. In May 2023, the FDA approved fezolinetant (brand name VEOZAH), the first NK3R antagonist, for the treatment of moderate to severe vasomotor symptoms in menopause. The results of two repeated double-blind, randomized, placebo-controlled phase III studies SKYLIGHT1 and SKYLIGHT2 showed that fezolinetant 45 mg had significantly reduced the frequency and severity of moderate to severe VMS at weeks 4 and 12 compared with placebo, and the incidence of TEAEs was low; results of a 52-week randomized, double-blind, placebo-controlled phase III study SKYLIGHT4 further confirmed the safety and tolerability of fezolinetant, supporting its use in continuous treatment.

2.2. **Study Rationale**

GS1-144 Tablets is an NK3R antagonist that normalizes the activity of KNDy neurons by blocking overactivated NK3 receptors on KNDy neurons and median preoptic nucleus, thereby regulating the body temperature. GS1-144 Tablets is intended to be developed as a treatment for menopausal vasomotor symptoms.

2.2.1. Results of Non-clinical Studies

A series of non-clinical studies have been completed with GS1-144 Tablets, including non-clinical pharmacology studies, *in vivo* PK and drug metabolism studies in animals, and toxicology studies, which evaluated its pharmacological actions (NK3R antagonism) at the receptor, cell and animal levels and derived its PK/PD profiles in animals, and confirmed its safety in animals as well.

Non-clinical *in vitro* PD results showed that the antagonistic activity of GS1-144 against human NK3R was about 12 folds that of the reference product fezolinetant, and the antagonistic activity of GS1-144 against rat NK3R was about 4 folds that of fezolinetant, indicating its good antagonistic selectivity; the antagonistic activity of GS1-144 against NK3R was all stronger than (5-18 folds) that of fezolinetant in monkeys, dogs and rabbits. *In vivo* PD results showed that GS1-144 when dosed at 3-18 mg/kg could reduce LH in castrated female rats in a dose-dependent manner, with the initial effective dose of 3 mg/kg and significantly effective dose of 6 mg/kg; the effect of GS1-144 for reducing LH in rat was 3-4 folds (regardless of plasma binding rate) that of fezolinetant; *in vivo* PK results showed that at the same dose, the *in vivo* exposure of fezolinetant was 1.34 folds that of GS1-144, and the C_{max} was comparable to that

of GS1-144; there were no significant differences in post-dose animal weight between various GS1-144 or fezolinetant dose groups and the modeling group, and the tolerability was good.

Non-clinical PK results indicated: after rats and dogs were treated with a single oral dose of GS1-144 2 mg/kg, 6 mg/kg and 20 mg/kg, respectively, the mean T_{max} was about 0.75-1.0 h, and the mean $t_{1/2}$ was about 1.5-1.8 h. There was a sex difference in the AUC of GS1-144 in rats, being about 3 folds higher in females than in males; C_{max} increased in a dose-proportional manner; AUC increased in a more than dose-proportional manner; following repeated doses, GS1-144 was not observed to have accumulated significantly in rats. The mean T_{max} of GS1-144 in dogs was about 0.75-1.0 h, and the mean $t_{1/2}$ was about 2.1-3.2 h, with no marked sex difference; C_{max} and AUC increased with dose in a less than dose-proportional manner; following repeated doses, GS1-144 was not observed to have accumulated significantly in dogs.

Non-clinical toxicology results showed that the maximum tolerated dose (MTD) for single-dose toxicity was 1000 mg/kg/day in both rats and dogs; after rats were intragastrically given GS1-144 30, 100, and 300 mg/kg for 4 consecutive weeks, the No Observed Adverse Effect Level (NOAEL) was 30 mg/kg; after dogs were intragastrically given GS1-144 10, 30, and 150 mg/kg for 4 consecutive weeks, the NOAEL was 10 mg/kg; genetic toxicity studies were negative.

Refer to the Investigator's Brochure (IB) of GS1-144 for more information.

2.2.2. Results of Clinical Studies

Two dose-escalating phase I clinical studies for GS1-144 tablets are ongoing in China (GenSci074-101) and Austria (GenSci074-102).

GenSci074-101 study consists of the following 3 parts:

- Part 1: SAD study in healthy adult participants
  - Study design: randomized, double-blinded, placebo-controlled
  - Escalating doses: 5 mg, 15 mg, 30 mg, 60 mg, 90 mg
  - Planned sample size: N=6, 8, 8, 8, 8 for different dose treatment arms, each with 2 participants receiving placebo
- Part 2: Food effect study in healthy adult participants
  - Study design: randomized, open-label, two-periods, within-participants crossover
  - Cohorts: cohort 1 is under fasting condition in the first period and then with high-fat meal in the next period, while cohort 2 is in the inverted sequence.
  - Planned sample size: N=12/cohort
- Part 3: MAD study in postmenopausal healthy female participants and healthy female participants of childbearing potential

Randomized, double-blinded, placebo-controlled cohorts: planned sample size is 12/cohort, and each cohort has 2 participants assigned to receive placebo

- Cohort 1: 15 mg, q24h, for 7 days; postmenopausal healthy female participants
- Cohort 2: 30 mg, q24h, for 7 days; postmenopausal healthy female participants
- Cohort 3: 60 mg, q24h, for 7 days; postmenopausal healthy female participants
- Cohort 4: 30 mg, q12h, for 7 days; postmenopausal healthy female participants

Randomized, open-label, single-arm cohort: planned sample size is 6

- Cohort 5: 60 mg, q24h, for 7 days; healthy female participants of childbearing potential

GenSci074-102 study consists of the following 2 parts:

- Part 1: SAD study in healthy adult participants
  - Study design: randomized, double-blinded, placebo-controlled
  - Escalating doses: 5 mg, 15 mg, 30 mg, 60 mg, 90 mg
  - Planned sample size: N=6, 8, 8, 8, 8 for different dose treatment arms, each with 2 participants receiving placebo
- Part 2: MAD study in postmenopausal healthy female participants
  - Study design: randomized, double-blinded, placebo-controlled
  - Escalating doses: 15 mg, 30 mg and 60 mg, q24h, for 7 days.
  - Planned sample size: N=12/arm, each arm has 2 participants assigned to receive placebo

2.2.2.1. PK/PD Results

In GenSci074-102 study, after a single dose of GS1-144 in Chinese healthy participants, PK exposure increased proportionally within the dose range from 5 to 90 mg. Median time to reach C_{max} and mean half-life are approximately 0.5-2 h and 2.5-4.3 h, respectively.

In Chinese postmenopausal healthy female participants, PK exposure increased proportionally within the dose range from 15 to 60 mg. Median time to reach C_{max} and mean half-life are approximately 0.5-2.25 h and 4.6-5.8 h, respectively.

After multiple administrations within the dose range from 15 to 60 mg in postmenopausal healthy female participants, GS1-144 showed almost no accumulation (accumulation ratios of C_{max} and AUC were within 0.9- to 1.1-fold). The accumulation ratios of C_{max} and AUC for metabolite M1 (QD administration) were within 1.0- to 1.2-fold and within 1.2- to 1.7-fold, respectively. The accumulation ratios of C_{max} and AUC for metabolite M1 (BID administration) were 1.3-fold and 1.5-fold, respectively.

When compared with fasting, healthy participants with a high-fat meal (800-1000 calories, 50% fat) showed a decrease of approximately 30% in C_{max}, delayed T_{max}, and comparable AUC and half-life of GS1-144 and M1. The above phenomenon may be due to the decrease in gastric emptying rate caused by food and the obstruction of drug diffusion to the gastrointestinal wall. Therefore, the decrease in C_{max} is not considered clinically significant.

In Chinese postmenopausal healthy female participants, the maximum decrease in LH relative to baseline increased with increasing doses within the range of 15-60 mg for GS1-144. After a single administration of 15, 30 and 60 mg, the average maximum %LH inhibition was 46%, 54%, and 65%, respectively, and the average maximum decrease in LH relative to baseline was 16, 18, and 21 IU/L, respectively. Among female participants with childbearing potential, GS1-144 showed a maximum %LH inhibition of about 80.2% at a dose of 60 mg, which is similar to that of Fezolinetant at the same dose and population (Figure 2-2).

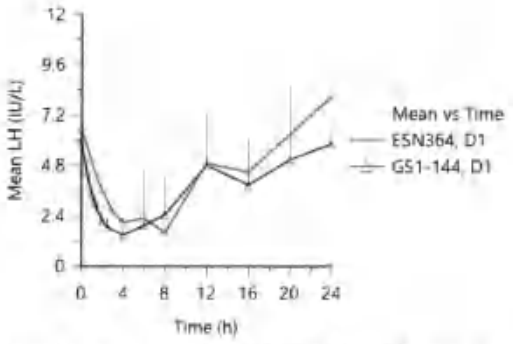


Figure 2-2 LH profiles of Fezolinetant and GS1-144 in Women with Childbearing Age

2.2.2.2. Safety Results

As of 31 July 2024, the occurrence of adverse events (AEs) in **GenSci074-101 study** is as follows:

In the SAD (single ascending dose) study, which has not yet been unblinded and includes 2 placebo participants in each dosage group, a total of 38 participants were enrolled, of which 8 participants (21.1%) experienced treatment-emergent adverse events (TEAEs), with 2, 1, 2, 1 and 2 participants in 5 mg, 15 mg, 30 mg, 60 mg and 90 mg groups, separately, 3 participants (7.9%) experienced TEAEs related to the investigational drug (1 participant each in the 15 mg, 60 mg and 90 mg groups). There were no serious TEAEs, TEAEs leading to discontinuation of the drug, TEAEs leading to withdrawal from study or TEAEs leading to death. All the TEAEs were mild in severity. TEAEs based on preferred term (PT, MedDRA 26.0) in descending order of occurrence rate included: blood parathyroid hormone increased (4 participants, 10.5%) and 1 participant each (2.6%) of alanine aminotransferase increased, neutrophil count increased, white blood cells urine positive, white blood cell count increased, and blood thyroid stimulating hormone increased. Among these, blood parathyroid hormone increased (2 participants, 5.3%, 1 participant each in 5 mg and 30 mg groups) and alanine aminotransferase increased (1 participant, 2.6%, 90 mg group) were determined by the investigators to be related to the investigational drug.

In the food effect study (open-label), a total of 24 participants were enrolled, with 12 each in fasting-high fat cohort and high fat-fasting cohort, of which 3 participants (12.5%)

experienced TEAEs, with 1 participant in fasting-high fat cohort and 2 participants in high fat-fasting cohort, 2 participants (8.3%) experienced TEAEs related to the investigational drug (1 participant each in these two cohorts). There were no serious TEAEs, TEAEs leading to discontinuation of the drug, TEAEs leading to withdrawal from study or TEAEs leading to death. All the TEAEs were mild (2 participants, 8.3%) to moderate (1 participant, 4.2%) in severity, no severe TEAEs occurred. TEAEs based on PT (MedDRA 26.0) in descending order of occurrence rate included: blood parathyroid hormone increased (2 participants, 8.3%) and 1 participant each (4.2%) of ventricular extrasystoles, neutrophil count decreased, white blood cell count decreased, noninfective gingivitis and abdominal pain. Among these, blood parathyroid hormone increased (2 participants, 8.3%, 1 participant each these two cohorts) were determined by the investigators to be related to the investigational drug.

In the MAD (multiple ascending dose) study, which has not yet been unblinded and includes 2 placebo participants in each dosage group, a total of 54 participants were enrolled, of which 29 participants (53.7%) experienced TEAEs, with 5, 9, 8, 0 and 7 participants in cohort 1-5, separately. There were no investigational-drug related TEAEs, serious TEAEs, TEAEs leading to discontinuation of the drug, TEAEs leading to withdrawal from study or TEAEs leading to death. All the TEAEs were mild (26 participant, 48.1%) to moderate (3 participant, 5.6%) in severity, no severe TEAEs occurred. TEAEs based on PT (MedDRA 26.0) in descending order of occurrence rate included: glomerular filtration rate decreased (5 participants, 9.3%), blood triglycerides increased (5 participants, 9.3%), atrioventricular block first degree (5 participants, 9.3%), neutrophil count decreased (3 participants, 5.3%), blood cholesterol increased (3 participants, 5.3%), nitrite urine present (2 participants, 3.7%), upper respiratory tract infection (2 participants, 3.7%) and 1 participant each (1.9%) of white blood cells urine positive, blood pressure systolic increased, lymphocyte count decreased, white blood cell count decreased, blood thyroid stimulating hormone increased, blood pressure increased, blood potassium increased, junctional ectopic tachycardia, oral herpes, mouth ulcer, diarrhoea, pain in extremity, thermal burn, headache, contact dermatitis, vertigo and anaemia.

As of 15 July 2024, the occurrence of adverse events (AEs) in **GenSci074-102 study** is as follows:

In the SAD (Single Ascending Dose) study, which has not yet been unblinded and includes 2 placebo participants in each dosage group, a total of 38 participants were enrolled, of which 8 particpants (21.1%) experienced TEAEs (1 case each in the 5 mg, 15 mg, 30 mg, and 90 mg arms, and 4 cases in the 60 mg arm). Two participants (5.3%) experienced TEAEs that were related to the investigational drug (1 case each in the 15 mg and 90 mg arms). There were no severe TEAEs, serious TEAEs, TEAEs leading to discontinuation of the drug, or TEAEs leading to death. TEAEs based on PT (MedDRA 26.0) in descending order of occurrence rate included: headache (2 cases, 5.3%) and one case each (2.6%) of presyncope, diarrhoea, dry mouth, vessel puncture site bruise, post procedural infection, and epistaxis. Among these,

diarrhea (1 case, 2.6%) and epistaxis (1 case, 2.6%) were determined by the investigators to be related to the investigational drug.

In the MAD study, which has not yet been unblinded and includes 2 placebo participants in each dosage group, the 15 mg arm has completed the enrollment of 10 participants including 2 receiving placebo, of which 8 participants (80.0%) experienced TEAEs. Three participants (30.0%) experienced TEAEs that were related to the investigational drug. There were no severe TEAEs, serious TEAEs, TEAEs leading to discontinuation of the drug, or TEAEs leading to death. TEAEs based on PT (MedDRA 26.0) in descending order of occurrence rate included: constipation (5 cases, 50.0%), catheter site bruise (2 cases, 20.0%), hot flush (2 cases, 20.0%), and one case each (10.0%) of diarrhoea, gastrooesophageal reflux disease, catheter site nodule, catheter site pain, mass, medical device site dermatitis, muscle discomfort, musculoskeletal discomfort, pain in extremity, hemangioma of skin, and dermatitis. Among these, constipation (1 case, 10.0%), skin hemangioma (1 case, 10.0%), and hot flush (1 case, 10.0%) were determined by the investigators to be related to the investigational drug.

Based on the above safety and PK/PD results, a phase II clinical study of GS1-144 tablet is currently planned to be conducted to evaluate its efficacy and safety, characterize its PopPK/PD profiles, and determine the dosage regimen for the intended population, so as to provide data supporting for its further development in the treatment of menopausal vasomotor symptoms.

2.3. **Benefit/risk assessment**

There is an unmet need for effective therapeutic options for menopausal vasomotor symptoms in Chinese women. Existing nonclinical and clinical study data on GS1-144 Tablets and fezolinetant, a drug with the same target as GS1-144, support its favorable risk/benefit profile, and it is anticipated that the expected AEs associated with GS1-144 Tablets will be manageable by the investigator through standard of care based on routine disease management guidelines. In conclusion, the currently available data and information support the conduct of this study.

2.3.1. Risk Assessment

With reference to the results of nonclinical study and clinical trial data of GS1-144 Tablets and the nonclinical data and adverse reaction data in clinical studies of fezolinetant, an overseas marketed product with the same target as GS1-144, the potential safety risks and their control measures for GS1-144 Tablets are summarized as follows:

Investigational drug GS1-144 Tablets		
Important potential risks	**Risk source and basis**	**Risk reduction measures**
Hepatic transaminase increased	Non-clinical data and clinical data of Fezolinetant, a drug with the same target, suggest that attention should be paid to hepatic transaminase increased during the study: 1. When SD rats were given GS1-144	1. The clinical study protocol and ICF cover this risk and provide guidelines for managing it, including but not limited to: • Strictly exclude individuals with underlying digestive

	amorphous solid dispersion (ASD) intragastrically once daily for 4 consecutive weeks for a total of 28 doses, ALT and AST increased at the 300 mg/kg dose, and slight to mild centrilobular hepatocellular hypertrophy were observed in the liver, and these changes were observed to have recovered or be recovering at the end of the recovery period. When Beagle dogs were given GS1-144 ASD intragastrically for 4 weeks followed by a 4-week recovery period, at the 150 mg/kg dose, hepatocellular hypertrophy was observed as a histopathological change in the liver, which had all recovered by the end of the recovery period. The content of major metabolite M1 was 33.2% after *in vitro* incubation in human hepatocytes, and was 42.3%, 59.1%, 1.21%, and 3.27% in *in vitro* incubation systems of monkey, dog, rat, and mouse hepatocytes, respectively. 2. In 3 clinical studies of fezolinetant, a drug with the same target as GS1-144 Tablets, serum transaminase (ALT and/or AST) elevated (> 3 * ULN) occurred in 2.3% and 0.9% of women in the VEOZAH treatment group (exposure-adjusted incidence rate [EAIR] 2.7/100 person-years) and placebo treatment group (EAIR 1.5 /100 person-years), respectively. No total serum bilirubin increased (> 2 * ULN) occurred. Women with ALT or AST increased were generally asymptomatic. The transaminase levels recovered to (or close to) the pre-treatment levels, and no sequelae was observed after the treatment was continued, interrupted or discontinued. 3. Blinded data from ongoing phase I studies of GS1-144 tablets showed that only 1 participant in the SAD 90 mg dose group of GenSci074-101 study in China reported 1 occurrence of the TEAE alanine aminotransferase increased, which was assessed by the investigator as related to the investigational product and was mild, and had the outcome of resolved without intervention.	system diseases or dysfunctions and/or drug abuse interfering with the clinical trial, and/or with hepatic function abnormal (ALT/AST >2×ULN, total bilirubin >1.5×ULN) in developing the in/exclusion criteria; exclude individuals with confirmed moderate to severe hepatic steatosis at screening or baseline; • Regularly monitor the liver function parameters; • Establish safe and reasonable criteria for treatment discontinuation; • Give corresponding treatment as appropriate for the liver function based on the clinical practice. 2. Perform routine medical surveillance and pharmacovigilance activities during the clinical study, including but not limited to targeted medical surveillance programs, comprehensive safety information collection and risk monitoring, identification, assessment and control, and assessment of the effectiveness of risk control measures; regular case review analysis and summarization of individual case reports, including serious adverse events and adverse events of special interest, periodic pooled analysis of AEs, and close monitoring, assessment and reporting of possible new safety risks.
Blood pressure decreased	Based on the mechanism of action of NK3R antagonists, non-clinical data of GS1-144 and	1. The clinical study protocol and ICF cover this risk and provide

	non-clinical data of fezolinetant, the drug with the same target, it is suggested that attention should be paid to blood pressure decreased during the course of the study: 1. In the brain, NK3R is mostly expressed in the pons, as well as in the amygdala, hypothalamus, midbrain and other sites. Among them, the hypothalamus regulates the autonomic nervous system by regulating the production and release of endocrine hormones, thereby unconsciously regulating the organism's blood pressure, respiration, heartbeat, digestion, pupillary response, and sexual arousal, etc. In the ventral tegmental area (VTA): NK3R antagonists can lower the blood pressure and increase the heart rate, which can be reversed by dopamine D2 receptor antagonists. 2. Non-clinical data suggest that when GS1-144 ASD was given intragastrically to conscious Beagle dogs at doses ≥ 30 mg/kg, blood pressure decreased with compensatory cardiac acceleration was observed in the animals at different time points over 0.5 to 8 h post-dose, and had generally normalized by 24 h post-dose. After Beagle dogs were given intragastrically a single dose of 1000 mg/kg/day and repeated doses of 150 and 500 mg/kg/day, heart rate increased was both observed at 2-4 h post-dose. When Beagle dogs were given GS1-144 ASD intragastrically for 4 weeks followed by a 4-week recovery period, at ≥30 mg/kg doses, RR interval shortened and heart rate increased were observed in female and male animals at 2-4 h post-dose, and had recovered by 24 h post-dose. The heart rate increased observed in the above animals was considered to be a compensatory response to blood pressure decreased. 3. In nonclinical studies of fezolinetant, the drug with the same target as GS1-144 Tablets, heart rate increased and blood pressure decreased were observed: +dP/dtmax, systolic blood pressure and mean atrial pressure decreased and heart rate increased were observed in all dose	guidelines for managing it, including but not limited to: • Strictly exclude individuals with underlying cardiovascular diseases or dysfunctions interfering with the clinical trial and exclude individuals with any abnormalities in, e.g., vital signs or 12-lead ECG assessed to potentially interfere with the clinical study during the screening period or baseline period in developing the in/exclusion criteria; • Regularly monitor blood pressure, heart rate and ECG and evaluate ECG parameters, and intervene early in the detection of any abnormality; • Establish safe and reasonable criteria for treatment discontinuation based on 12-lead ECG results; • Give timely clinical treatment as appropriate for the participant's actual condition, and actively pay attention to and treat associated complications. 2. Perform routine medical surveillance and pharmacovigilance activities during the clinical study, including but not limited to targeted medical surveillance programs, comprehensive safety information collection and risk monitoring, identification, assessment and control, and assessment of the effectiveness of risk control measures; regular case review analysis and summarization of individual case reports, including serious adverse events and adverse events of special interest, periodic pooled analysis of AEs,

	groups. As these changes were slight and did not indicate statistically significant differences, they were not considered to have affected the cardiovascular (CV) system. 4. Blinded data from ongoing phase I studies of GS1-144 tablets showed that no TEAEs with blood pressure decrease or compensatory cardiac acceleration were reported.	and close monitoring, assessment and reporting of possible new safety risks.
Other potential risks of clinical significance	**Risk source and basis**	**Risk reduction measures**
Thyroid and parathyroid function abnormal	1. Non-clinical data indicate: when SD rats were given GS1-144 ASD intragastrically once daily for 4 consecutive weeks for a total of 28 doses, at doses ≥100 mg/kg, absolute and relative (Organ/body weight ratio and organ-brain ratio) weights of thyroid and parathyroid glands increased, and histopathology revealed slight to mild diffuse follicular epithelial cell hypertrophy in thyroid gland; when Beagle dogs were given GS1-144 ASD intragastrically for 4 weeks followed by a 4-week recovery period, at 30 and 150 mg/kg doses, significantly increased weights of thyroid and parathyroid glands compared with the vehicle control group were observed in male animals. 2. Blinded data from ongoing phase I studies of GS1-144 tablets showed that a total of 6 participants in the GenSci074-101 study in China reported 6 occurrences of the TEAE parathyroid hormone increased, including 1 occurrence reported in 1 participant each in the SAD 5 mg, 15 mg, 60 mg, and 90 mg dose groups, 2 occurrences reported in 2 participants in FE Cohort A, and no occurrence reported in any MAD dose groups, all of which were mild and resolved without intervention; of them, the 4 occurrences reported in 4 participants were all assessed by the investigator as related to the investigational product. Two participants reported 2 occurrences of the TEAE thyroid-stimulating hormone increased, including 1 occurrence reported in 1 participant in the SAD 30 mg dose	1. Exclude individuals with underlying endocrine diseases or dysfunctions interfering with the clinical study in developing the in/exclusion criteria ; exclude individuals with thyroid or parathyroid-related hormones abnormal with clinical significance at screening or baseline. 2. Regularly monitor thyroid function and parathyroid function, as well as the relevant parameters (e.g., blood calcium and blood phosphorus), and intervene early in the detection of any abnormality.

	group and 1 occurrence reported in 1 participant in MAD Cohort 3, all of which were assessed by the investigator as unrelated to the investigational product, were mild, and resolved without intervention.	
Study Procedures		
Venipuncture will be performed during the study	There will be risks of bleeding, bruising, hematoma formation, and infection at the venipuncture site.	Only appropriately qualified personnel will obtain the blood draw.

In response to the above risks, the sponsor will pay continuous attention to and evaluate safety throughout the study. In addition, the safety and tolerability of GS1-144 in the participants will be closely monitored during the study, so as to ensure their safety.

2.3.2. Benefit Assessment

It is expected to contribute to the development of new therapies for menopausal vasomotor symptoms in women.

2.3.3. Overall benefit/risk conclusions

Given the measures taken to minimize the risks for participants in this study, the benefit/risk balance of GS1-144 for this study is for testing in Phase 2.

3. Objectives and Endpoints

Primary Objective	**Co-primary Endpoints**
• To evaluate the efficacy of GS1-144 in the treatment of moderate to severe VMS	• Changes from baseline in the frequency of moderate to severe VMS at Week 4; • Changes from baseline in the frequency of moderate to severe VMS at Week 12; • Changes from baseline in the severity of moderate to severe VMS at Week 4; • Changes from baseline in the severity of moderate to severe VMS at Week 12.
Secondary Objectives	**Secondary Endpoints**
• To evaluate other efficacy of GS1-144 in the treatment of moderate to severe VMS; • To evaluate the safety and tolerability of GS1-144.	• Changes from baseline in the frequency of moderate to severe VMS at each of the other treatment weeks over 12 weeks; • Changes from baseline in the severity of moderate to severe VMS at each of the other treatment weeks over 12 weeks; • Percentage decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks; • Proportions of participants with ≥50% and 100% decreases from baseline in the frequency of moderate to severe VMS at each treatment

	week over 12 weeks; • Incidence and severity of Adverse Events (AEs); • Changes from baseline at each time point in laboratory tests, vital signs, physical examination findings, 12-lead electrocardiogram (ECG), and transvaginal ultrasound (TVU), etc.
Exploratory Objectives	**Exploratory Endpoints**
• To evaluate the population pharmacokinetics (PopPK) of GS1-144 and its metabolite M1 and to analyze its exposure-response relationship; • To evaluate the improvement in sleep disturbance with GS1-144; • To evaluate the improvement in quality of life with GS1-144; • To evaluate the improvement in relevant postmenopausal symptoms with GS1-144; • To evaluate the effect of GS1-144 on the pharmacodynamics marker (luteinizing hormone [LH]); • To evaluate the effects of GS1-144 tablets on sex hormones (other than LH) and sex hormone-binding globulin; • To evaluate the effect of GS1-144 tablets on bone metabolism.	• This study will establish a PK model to characterize the PKprofiles of GS1-144 and its metabolite M1. Then, based on the parameter estimates through final PK modeling, individual exposure parameters for each participant will be estimated for further pharmacokinetic-pharmacodynamic (exposure-response and exposure-safety) analysis (if data available); • Scores on participant's Patient Global Impression of Change (PGI-C) in sleep disturbance at Weeks 4/8/12 from baseline • Changes from baseline on participant's Patient Global Impression of Severity (PGI-S) in sleep disturbance at Weeks 4/8/12; • Changes from baseline in modified Kupperman Index at Weeks 4/8/12; • Changes from baseline in Menopause-Specific Quality of Life (MENQOL) score at Weeks 4/8/12; • Changes from baseline in LH concentration; • Changes from baseline in sex hormones (other than LH) and sex hormone-binding globulin concentrations at D1 and Weeks 4/8/12; • Changes from baseline in serum concentrations of bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX) at Week 12.

4. Study Design

4.1. Overall design

This is a randomized, double-blind, placebo-controlled, parallel-group, 12-week treatment clinical study to evaluate the efficacy and safety of GS1-144 tablets in the treatment of moderate to severe VMS in postmenopausal women.

In this study, 268 postmenopausal female participants with moderate to severe VMS symptoms are planned to be enrolled through block randomization stratified by BMI (<28 kg/m^2 or ≥28 kg/m^2) and allocated to the GS1-144 30 mg QD, GS1-144 60 mg QD, GS1-144 30 mg BID or placebo group in a 1:1:1:1 ratio (67 participants each of these 4 treatment groups). Duration of treatment is 12 weeks. Following the completion of the treatment period or end of treatment (EOT) or early discontinuation from the sutdy (ED), the participant will complete the V9 (Day 85)/EOT/ED visit, and non-ED participants will also complete the final visit for safety and other assessments.

The study consists of 4 stages: screening period (D-30 to D-4), baseline period (D-3 to D-1), treatment period (D1 to D84), and follow-up period (D85 to D99). This study will be conducted in outpatients with a treatment duration up to 12 weeks, a study duration up to approximately 18 weeks, and a total of 10 visits.

Screening visit (V1) will be completed after the participant signs the informed consent form (ICF) and within 30 days prior to randomization; It will last for at least 9 days to collect baseline data on the frequency and severity of vasomotor symptoms, based on which participants' eligibility for enrollment will be assessed together with the physical examinations, vital signs, clinical laboratory tests, ECGs, chest CTs or X-rays, breast ultrasound, TVUs and endometrial biopsies, etc. If a participant has used any prohibited medication prior to screening, there should be a washout period of at least 5 half-lives of the drug (see section 6.9.1 for washout period requirements).

Participants may be retested up to 1 time within the 30-day screening window, retaining the same participant number. Participants may be rescreened up to 1 time and must re-sign the ICF with a new participant number, which will result in a new 30-day screening window. The following assessments do not need to be repeated at re-screening if the assessment was done within the following timeframe and its result meets all the inclusion criteria and none of the exclusion criteria: TVU (within 3 months prior to screening), endometrial biopsy (within 3 months prior to screening), breast ultrasound (within 6 months prior to enrollment with relevant record [including written or electronic report] indicating normal/negative or no clinically significant ultrasound findings), chest X-ray (anteroposterior) or chest CT (within 6 months prior to screening).

During the screening period, participants must have a minimun average of 7 episodes of moderate to severe VMS a day. The VMS eDiary will be reviewed by study site staff prior to randomization on D1 (V3) to confirm participant compliance and eligibility. Participants not meeting the inclusion criteria upon the first assessment of VMS symptoms shall not be re-screened.

Participants will be randomized on D1 after completing the baseline tests/examinations/ assessments and being deemed eligible.

During the 12-week treatment period, the participant will take the investigational product twice daily (2 tablets each in the morning and evening) for 84 consecutive days, and will return to the study site for the corresponding tests/examinations, assessments, receiving and/or return of investigational product, and other procedures specified in Section 1.3 SOA every 2 weeks from V3 to V9 (D1, D15, D29, D43, D57, D71, and D85).

Participants must record their VMS episodes using the eDiary twice daily from 9 days prior to randomization to the last visit. Scale assessments (excluding VMS diary) at the site visit must be completed after the participant's arrival at the study site and before the other visit procedures. If a participant has discontinued treatment or discontinued from study, the participant should return to the study site to complete the scale assessments and other EOT/ED visit procedures as nearly as possible around discontinuation.

The non-ED participant will need to return to the site on D99 or 14 days after EOT visit to complete the follow-up visit for safety, AEs and concomitant medications/therapies.

4.2. Scientific Rationale for Study Design

The study will be designed with reference to the *Technical Guidelines for Population Pharmacokinetic Studies* issued by the Center for Drug Evaluation (CDE) and based on the existing clinical data of GS1-144. All available nonclinical information and information on drugs with similar mechanism of action (approved fezolinetant) are also referenced.

4.3. Justification for Dose

4.3.1. GS1-144 PK Results

After a single dose of GS1-144 in Chinese healthy participants, PK exposure increased proportionally within the dose range from 5 to 90 mg. Median time to reach Cmax and mean half-life are approximately 0.5-2 h and 2.5-4.3 h, respectively.

In Chinese postmenopausal healthy female participants, PK exposure increased proportionally within the dose range from 15 to 60 mg. Median time to reach Cmax and mean half-life are approximately 0.5-2.25 h and 4.6-5.8 h, respectively.

Since GS1-144 is mainly metabolized by CYP1A2, and the female have weaker CYP1A2 activity, the exposure level is higher and the half-life is longer in female participants than in males. The activity of the metabolite M1 is weaker in antagonizing human NK3R, and its activity is 1/42 of that of GS1-144.

According to the established PopPK/PD model, there was no statistically significant effect of weight, age, ALT, AST, and CrCL, etc. on the PK parameters of GS1-144, except for the effect of food on Ka and gender on CL. Although food reduced the absorption rate of GS1-144, it has no effect on AUC, so GS1-144 can be administered with food or without food. Considering that the indication of GS1-144 is menopausal women with moderate to severe VMS, there is no need to adjust the dose according to gender.

4.3.2. GS1-144 PD Results

According to the established PopPK/PD model, there was no statistically significant effect of covariates (age, weight, baseline LH level, etc.) on PD concentration.

In postmenopausal healthy female participants, GS1-144 showed an increase in the maximum percentage reduction of LH relative to baseline with increasing doses within the range of 15-60 mg. After a single administration of 15, 30, and 60 mg, the average maximum percentage reductions of LH relative to baseline were 46%, 54%, and 65%, respectively, and the average maximum reductions of LH from baseline were 16, 18, and 21 IU/L, respectively.

After the daily administration of 30 mg GS1-144, the maximum %LH inhibition was comparable to Fezolinetant 180 mg QD and 90 mg BID in Chinese postmenopausal healthy female participants. According to LH maintenance time, LH AUEC of GS1-144 60 mg QD was comparable to that of Fezolinetant 180 mg QD (see Table 4-1 for details). Therefore, 30 mg QD and 60 mg QD were selected as the phase II study dose. And considering the half-life of GS1-144, 30 mg BID was also used to explore the different frequency of administration.

Table 4-1 LH data for GS1-144 and Fezolinetant

	GS1-144-D1			Fezolinetant	
	postmenopausal healthy women 30 mg QD	postmenopausal healthy women 30 mg BID	postmenopausal healthy women 60 mg QD	Japan phase I postmenopausal healthy women 180 mg QD-D1	US IIa moderate to severe VMS postmenopausal female 90 mg BID
Maximum %LH inhibition	54%	54%	65%	-	49.8%
Maximum LH inhibition (IU/L)	18	20	21	-	NA
Mean R_{min} (IU/L)	16	18	11	16	~20
Mean AUEC (h*IU/L)	-127	-152	-183	-194	-

4.3.3. Safety Results

In the ongoing studies of GS1-144, there have been no serious adverse events, and the adverse events were all mild or moderate (in a few cases), and its overall safety profile is good.In summary, the GS1-144 has demonstrated good safety and tolerability in the existing 5-90 mg SAD and 15-60 mg MAD studies. The doses of 30 mg QD, 60 mg QD, and 30 mg BID have been selected for Phase II studies to fully explore the efficacy of the product while ensuring the participants' safety.

4.4. Definition of end of study (EOS)

The end of study is defined as the date on which the last participant in the study completes the last visit.

A participants is considered to have completed the study if the participant has completed all periods of the study including the last visit or the last scheduled procedures shown in the SOA.

5. Study Population

Postmenopausal women aged 40-64 (inclusive) years with moderate to severe VMS (an average of ≥7 episodes a day for 7 consecutive days)

5.1. Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply:

Age

1. 40 to 64 years of age (inclusive) at the screening visit;

BMI

2. 18.5 to 30 kg/m^2 (inclusive);

Type of Participants and Disease Characteristics

3. Females meeting 1 of the following criteria of menopause at screening visit: spontaneous amenorrhea for ≥ 12 consecutive months, spontaneous amenorrhea for ≥ 6 consecutive months with serum follicle-stimulating hormone (FSH) > 40 IU/L, or 6 weeks past a postsurgical bilateral oophorectomy with or without hysterectomy;
4. Participants who are seeking treatment or relief for VMS and meet the criteria for moderate to severe VMS symptoms: during the 7 consecutive days prior to randomization, participants must have a minimum average of 7 episodes of moderate to severe VMS symptoms per day;
5. For females with uterus: endometrial thickness ≤ 4mm as shown by TVU at screening, or > 4mm without atypical hyperplasia or carcinogenesis of the endometrium from the subsequent biopsy results (If the biopsy sample is insufficient or can't be obtained, it is considered normal and meets this inclusion criterion);

Informed Consent

6. Volunteered to sign ICF and be able to understand and comply with the requirements of this study.

5.2. Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

Medical Conditions:

1. Diseases or dysfunctions known to interfere with the clinical trial, including but not limited to: neuropsychiatric, cardiovascular, urological, digestive, respiratory, musculoskeletal, metabolic, endocrine, haematological, immune, dermatological and oncological conditions, etc., or poorly controlled chronic diseases with clinical significance;

2. Thyroid or parathyroid-related hormones abnormalites with clinical significance at screening or baseline;
3. Confirmed moderate to severe liver fatty at screening or baseline;
4. Any surgical or medical conditions that may significantly affect the absorption, distribution, metabolism, and/or excretion of the drug, such as a history of gastrointestinal surgery (gastrectomy, gastroenterostomy, enterectomy, etc.), urinary tract obstruction, or dysuria;
5. Current or prior history of malignancy (except for malignancies and basal cell carcinoma that have not received any antineoplastic treatment within 5 years prior to screening visit, or have currently recovered or have no risk of relapse during this study as assessed by the investigator);
6. Abnormal uterine bleeding with clinical significance during screening period or baseline period;
7. Participants who have attempted suicide within the last 1 year or are currently at risk of impulsive behavior or suicide;
8. Participants with a history of severe allergy to investigational products or any of their excipients or with allergic constitution (e.g., being allergic to two or more drugs or foods);
9. Participants who have positive serology results of hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV-Ab), human immunodeficiency virus antibody (HIV-Ab) or syphilis;
10. Abnormalities in vital signs during the screening period or baseline period, e.g., resting pulse rate < 55/min or > 105/min; systolic blood pressure < 90 mmHg or ≥ 160 mmHg; diastolic blood pressure < 60 mmHg or ≥ 100 mmHg, that upon evaluation by the investigator may interfere with this clinical study;
11. BI-RADS (Breast Imaging Reporting and Data System) Category ≥ 4 on breast ultrasound within 6 months prior to randomization;
12. Participants who have positive pregnancy test during screening or baseline period.

Cardiac Safety

13. 12-lead electrocardiography (ECG) abnormalities during screening period or baseline period, e.g., heart rate-corrected QT interval QTcF absolute value >470 ms (Fridericia's formula: $QTcF=QT/RR^{0.33}$) that upon evaluation by the investigator may interfere with this clinical study;

Liver safety

14. Abnormalities in laboratory tests during screening period or baseline period, e.g., alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >2×upper limit of normal

(ULN), or total bilirubin (TBIL) >1.5×ULN, that upon evaluation by the investigator may interfere with this clinical study;

Renal Safety

15. Creatinine >1.5×ULN or estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2 based on modification of diet in renal disease (MDRD) during screening period or baseline period;

Prior/Concomitant Therapy

16. The participant has used or is using prohibited medications/therapies (moderate or strong CYP1A2 inhibitors, hormone replacement therapy or any VMS therapeutic agents [prescription, non-prescription or herbal medicines]) at screening and is unwilling to discontinue and wash out such medications throughout the study (see Section 6.9 for the washout intervals for prohibited concomitant medications and prior medications);

Prior/Concurrent Clinical Study Experience

17. Having participated in any other clinical trial within 3 months or any clinical study of fezolinetant or other treatments for VMS (except for participants who have not received any investigational product) within 1 year prior to screening, or planning to participate in any other clinical trial;

Other Exclusion Criteria

18. Current or prior history of drug use, drug abuse or alcohol abuse;
19. Any other conditions that are unsuitable for participating in this study in the opinion of the investigator.

5.3. Lifestyle Considerations

- Participants shall abstain from ingesting caffeine- or xanthine-containing products (e.g. coffee, tea, cola drinks, chocolate) for 12 h before each PK/PD blood sampling until collection of the 4 h post-dose blood sample.
- Use of tobacco products or alcohol will not be permitted during the study (from screening until after the final follow-up visit).

5.4. Screen Failures

A screen failure occurs when a participant has consented by signing ICF to participate in the clinical study is not subsequently randomized into this study. A minimal set of a patient's screen failure information must be collected, including demographics, specifics of screening failure, eligibility criteria, and any AE.

A participant not meeting the criteria for participating in this study (screen failure) may be re-screened up to 1 time, with a new written informed consent and a new participant number first, which will result in a new screening window. The following assessments do not need to be

repeated at re-screening provided they fall within the protocol-permitted procedure competed timeframe and all results meet inclusion and no exclusion criteria: TVU (within 3 months prior to screening), endometrial biopsy (within 3 months prior to screening), breast ultrasound (within 6 months prior to enrollment with relevant record [including written or electronic report] indicating normal/negative or no clinically significant ultrasound findings), chest X-ray (posterior-anterior view) or chest CT (within 6 months prior to screening visit). Participants not meeting the VMS eligibility criteria upon the first assessment for enrollment may not be re-screened.

Items out of the eligibility criteria may be repeated up to 1 time should they are within the same screening window, which with the same participant number retained will not be deemed as re-screening.

6. Study Intervention and Concomitant Intervention

The study interventions in this study will all be investigational products, including the investigational drug GS1-144 30 mg tablets and its matching placebo tablets as a control.

6.1. Study medications Administered

Table 6-1 Study Medications Administered

Medication Name	GS1-144	Placebo
Dose Formulation	Tablet	Tablet
Unit Dose Strength	30 mg/tablet	NA
Medication Description	30 mg QD, or 60 mg QD, or 30 mg BID for 12 weeks	Placebo group: 2 tablets BID Investigational drug group: to be supplemented as needed for 12 weeks
Dose Level (s)	30 mg/day, 60 mg/day, 60 mg/day	NA
Route of Administration	Oral	Oral
Use	Test Drug	Placebo control
IMP and NIMP/AxMP	IMP	IMP
Sourcing	Manufactured by WuXi STA Pharmaceutical Co., Ltd., centrally supplied by the sponsor	
Packaging and Labeling	All investigational products for this study will be provided in wallets, and each container will bear a label identifying the contents as the investigational product, including the study number and the statement "For clinical use only", etc. The preparation, packaging, labeling and release of the investigational products will all be performed in accordance with SOPs and relevant laws/regulations.	

Table 6-2 Study Arms

Arm Title	GS1-144 30 mg QD group	GS1-144 60 mg QD group	GS1-144 30 mg BID group	Placebo BID Group
Arm Type	Investigational drug group	Investigational drug group	Investigational drug group	Placebo control group
Arm Description	**Morning:** one 30 mg tablet + one placebo tablets **Evening:** two placebo tablets administrated orally for 12 weeks	**Morning:** two 30 mg tablets **Evening:** two placebo tablets administrated orally for 12 weeks	**Morning:** one 30 mg tablet + one placebo tablets **Evening:** one 30 mg tablet + one placebo tablets administrated orally for 12 weeks	**Morning:** two placebo tablets **Evening:** two placebo tablets administrated orally for 12 weeks
Medication(s)	GS1-144, placebo	GS1-144, placebo	GS1-144, placebo	Placebo

6.2. **Preparation, Handling, Storage and Accountability**

- In receiving any investigational products, the investigator or designee must confirm appropriate conditions (e.g. temperature) as required have been maintained during transit, and any discrepancies should be reported and resolved before use of the investigational products.
- All investigational products must be stored in a secure, environmentally controlled and monitored (manual or automated) area in accordance with the labeled storage conditions with access limited to the investigators and authorized site staff.
- Only randomized participants may receive the investigational products per protocol, and only authorized site staff may have access to the investigational products.
- Authorized pharmacist will be responsible for the accountability, reconciliation, and records maintenance (i.e., receipt, reconciliation, and final disposition records) of investigational products. When the investigational product is shipped to each study site, the authorized pharmacist should sign the drug receipt form to confirm the receipt of the investigational product. The contents of the drug receipt form should include, but are not limited to, the batch number, quantity, and date of receipt. The authorized pharmacist should record all dispensations on the corresponding form. At the end or termination of the study, the quantities of investigational products on the form should be consistent with the quantities of drugs kept at the site and the quantities dispensed. The dispensation records of the investigational products should be consistent with the used and returned investigational products or the discrepancies must be reasonably explained.
- Packages of all used drugs and unopened and unused investigational products, including products that have exceeded the expiration date (unless approved by the sponsor), should be returned, upon counting and signing by the authorized study site drug manager, to GeneScience, and the drug return form should be signed. The investigational products returned will be uniformly destructed at the GeneScience Pharmaceuticals factory. They should be destructed by authorized specially-assigned personnel who have certain preventive awareness of the possible dangers of drug destruction with a written authorization of GeneScience Pharmaceuticals. The whole process of drug destruction will be completely recorded and archived. See the Investigational Product Management Manual for more information.

6.3. **Participants Assignment to Study Treatment Groups**

Randomization and drug allocation management will be performed in the study using a randomization system. Using a block randomization method stratified by BMI (<28 kg/m^2 or ≥28 kg/m^2), all participants will be randomly assigned to a study treatment group in a 1:1:1:1 ratio in an interactive web response system (IWRS). Once a unique randomization number has

been assigned, it must not be re-assigned. The IWRS login information and directions will be provided to each study site prior to study initiation.

The designated study site staff will dispense investigational products based on the IWRS assignment.

The schedule of dispensing investigational products is specified in Section 1.3 SOA. Returned investigational products should not be dispensed to the participants.

6.4. Blinding

6.4.1. Blinding Method

This is a double-blind study in which participants will be randomly assigned to study treatment in a 1:1:1:1 ratio. The investigators, the sponsor's study management team, and the clinical staff will also remain blinded to the study treatment throughout the study. In keeping with the double-blind design, the administration of the investigational products will all be identical among treatment groups.

6.4.2. Confirmation of Indistinguishability of Investigational Products

The appearance, size, shape, smell and packaging of the test drug GS1-144 tablets are identical with those of its matching placebo.

6.4.3. Retention of the Assignment Schedule and Procedures for Treatment Group Unblinding

Storage of the randomization list and maintenance of blinding to investigational products will be performed through the IWRS.

6.4.4. Unblinding provisions

IWRS will be programmed according to the unblinding instructions. Unblinding will be performed after database lock, where the participant treatment group code and the corresponding dosing group will be revealed. At the interim analysis, unblinding will be performed for an independent un-blinded team, the details will be described in a separate charter.

6.4.5. Emergency unblinding

In case of an emergency, the investigator has the sole responsibility for determining if unblinding of participant's treatment assignment is warranted. In making this decision, the safety of the participant must be the primary consideration. If the investigator decides that unblinding is required, he/she will send an instruction to the IWRS, which executes a program according to the unblinding instruction and provides the participant's treatment group code. The investigator may contact the sponsor as far as possible to discuss the situation prior to unblinding the participant's treatment assignment without delaying any emergency treatment

for the participant. If a participant's treatment assignment has been unblinded, the sponsor must be notified immediately within 24 hours of the event, and the date, reason, and executor of the unblinding must be recorded. At the same time, the Clinical Monitor should be notified as early as possible, and a safety event report should be submitted to the Ethics Committee.

Participants on whom emergency unblinding has been performed should discontinue the study treatment. After the end of the trial, the number, reason, scope and time of emergency unblinding should be described and analyzed as a reference for safety evaluation.

6.4.6. Unblinding by the Sponsor

When a suspected unexpected serious adverse reaction (SUSAR) occurs, in order to meet the submission requirements of the regulatory agency, the drug safety department of the sponsor can unilaterally unblind the individual participant. During this process, the unblinding code will be provided only to limited people involved in unblinding, while others will remain blinded, and the participant will not be considered a withdrawal or dropout.

6.5. Study Treatment Compliance

It is necessary to ensure that the participants are fully informed of and fully understand the investigational product and the trial process; the participants should also be informed in detail of relevant precautions and possible adverse drug reactions. Participant education on compliance should be emphasized, informing them of the importance of 100% adherence to the study treatment regimens. Investigator or authorized person should ensure that study participants meet this goal throughout the study period. In addition, prior to the conduct of the study, the sponsor should formulate a detailed monitoring plan in strict accordance with the protocol requirements.

When investigational products administration is performed at the study site, it will be completed under the supervision of the investigator or designee. The date and time of each dose administered in the clinic will be recorded in the source document.

When participants self-administer investigational products at home, study medication compliance will be assessed at each visit. During the site visit, compliance will be assessed by direct inquiry, review of medication eDiary and counting of returned unused tablets, etc., which will be recorded in the source documents and related forms. Deviations from the prescribed dosing regimen should be recorded.

From randomization until after the final follow-up visit, if a participant has taken less than 12 study doses or completed the VMS diary less than 12 times for 7 consecutive days, and such a situation has occurred 3 times, the investigator should discuss with the sponsor on whether it is necessary for the participant to discontinue from study.

6.6. **Dose Modification**

No dose modification is allowed for investigational drugs in this study.

In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose.

Reasons for any missed doses and any deviations from the dosing schedule or dose discontinuation must be recorded in the medical records, source documents and electronic Case Report Form (eCRF).

6.7. **Continued access to study treatment after the end of study**

Not applicable.

6.8. **Treatment of overdose**

No data on overdose has been available for GS1-144, and the definition of overdose has not been established. In the event of an overdose, the investigator/attending physician should:

- Evaluate the participant and make every effort to consult with the sponsor to determine if study treatment should be interrupted.
- If required by the sponsor (as the case may be), blood sample for PK analysis will be collected within 3 days after the date of the last dose of study treatment.
- Closely monitor any AE/SAE and the abnormalities in laboratory examination of the participants.
- Record the overdose and duration of the overdose.

6.9. **Previous and Concomitant Treatment (drug/non-drug Therapy)**

Medication for VMS taken during the 12 months prior to screening and other medication/non-drug therapy taken from 90 days prior to the screening visit to the first dose of investigational product will be documented in the electronic case report form (eCRF) as prior treatment. If a more concerning AE occurs or there is a need to trace the prior treatments for medical history during the study, the aforementioned time limits for collection may not apply.

Medications taken after the first dose of investigational product through the last study-related activity will be documented in the eCRF as concomitant medication. Prior and concomitant medications to be documented include, but are not limited to, vitamins, herbal remedies (e.g., St. John's wort, valerian) and over the counter and prescription medication with the records including: drug name, dose and frequency, dosing duration (start and end dates), route of administration, and reason for use, etc.

Non-drug therapies received by the participant from the first administration of the investigational medicinal product to the last study-related activity will be recorded in the eCRF

as concomitant treatments. Prior and concomitant non-drug therapies to be documented include, but are not limited to, physical therapy (treatments using sound, light, electricity, and magnetic fields, etc.), traditional Chinese therapy (such as acupuncture and cupping), and surgical intervention, with the records including name of the non-pharmacological treatment, frequency (if applicable), treatment duration (start and end dates), and indication, etc.

Participants will be instructed not to take any concomitant medication without first consulting the investigator throughout the duration of the study.

6.9.1. Previous Medication (Drugs and Therapies)

For women who recently discontinued traditional Chinese medicine therapy for VMS, the interval from treatment discontinuation to the screening visit must be ≥1 month.

For women who recently discontinued hormone therapy, the interval from treatment discontinuation to the screening visit must meet the following criteria:

- ≥ 1 week for prior vaginal hormonal products (rings, creams, gels and inserts);
- ≥ 4 weeks for prior transdermal estrogen alone or estrogen/progestin products;
- ≥ 8 weeks for prior oral estrogen and/or progestin therapy;
- ≥ 8 weeks for prior intrauterine progestin therapy;
- ≥ 3 months for prior progestin implants and estrogen alone injectable drug therapy; or
- ≥ 6 months for prior progestin injectable drug therapy.

6.9.2. Concomitant Medications (Drugs and Therapies)

All concomitant medications (prescriptions, over the counter and herbal) and therapies, other than the investigational product, administered from ICF through D99/14 days after EOT/ED visit (inclusive) will be collected in the eCRF.

6.9.3. Prohibited Concomitant Medications

The following medications and therapies are prohibited throughout the study (from signing of ICF through the last visit/follow-up):

- Hormonal medications for treatment of VMS such as hormone therapy, hormonal contraception or any treatment for menopausal vasomotor symptoms (prescription, over the counter or herbal). It is recommended that the medication for treating menopausal syndrome be taken consistently throughout the duration of the study.
- Investigational research products that have not been approved for any indication in Chinese Mainland.
- Moderate or strong CYP1A2 inhibitors.

See Appendix 3: List of Prohibited Concomitant Medications for more information.

7. Treatment discontinuation and participant withdrawal from study

A discontinuation from treatment is a participant who enrolled in the study and for whom study treatment is permanently discontinued for any reason. Participants who discontinued treatment or withdrawal from study will not be substituted. The investigator should collect as much as possible the reason for the participant's treatment discontinuation or withdrawal from study.

See Section 12.1.9.2 for the specific information on terminating a specific study site or the whole study.

7.1. Treatment discontinuation

In rare cases, the participant may need to permanently discontinue study treatment. Permanently treatment discontinuation does not necessarily mean the participant has ended/discontinued from study. In case of permanent discontinuation of study treatment, the participant should still try to complete the EOT visit and safety follow-up 14 days after EOT visit as much as possible. See Section 1.3 SoA for data to be collected at the EOT and follow-up visits.

7.1.1. Treatment discontinuation criteria for hepatic events

If laboratory tests indicate any of the following liver function conditions assessed by the investigator as related to the investigational product, safety management actions such as immediate discontinuation of the treatment and close follow-up should be taken immediately.

a. ALT or AST > 8 × ULN;

b. ALT or AST >5 × ULN for more than 2 weeks;

c. ALT or AST >3×ULN, and TBIL > 2 ×ULN or international normalized ratio (INR) > 1.5 ×ULN;

d. ALT or AST > 3×ULN, accompanied by fatigue, nausea, vomiting, right upper abdomen pain or tenderness, fever, rash and/or eosinophilia (> 5%) and other symptoms that are thought to be associated with hepatic damage or allergy.

7.1.2. Treatment discontinuation criteria for QTc

If a post-enrollment 12-lead ECG reveals QTcF >500ms or QTcF prolonged by >60ms from baseline, dosing should be suspended, and the examination should be immediately repeated twice (take the average of the 3 examinations); the average of two QTcF values before dosing will be used as the baseline if only one ECG is captured within the latest single day prior to dosing, or the average of all the QTcF values will be used as the baseline if multiple ECGs are captured within the latest single day prior to dosing. If the above criterion is still met and the condition is judged by investigator to be related to the investigational product, the investigator

will determine whether the participant should permanently discontinue study treatment and whether to change the participant management pattern.

The investigator's ECG review results must be documented. Any new clinically relevant abnormal findings should be reported as an AE.

7.1.3. Other treatment discontinuation criteria

- If, for safety reasons, it is in the best interest of the participant that the study treatment be discontinued, in the investigator's opinion;
- Development of a medical condition that requires concomitant treatment with a prohibited therapy;
- Participants who have poor compliance, are not able to comply with the trial protocol during the trial, and are deemed inappropriate by the investigator to continue in the trial. This may include the following:
    a. Participants fail to take the drugs and/or receive examinations as specified;
    b. Participants have used other drugs and/or food that affect the results of safety assessments and/or PK;
    c. Participants have other behaviors that affect the trial results.
- Unblinding of the randomization code during administration of the investigational products by the investigator or by designated study site staff;
- Other reasons

7.2. Participant withdrawal from study

7.2.1. Criteria for Participant Withdrawal from the Study

A participant may withdraw from the study at any time at the participant's own request for any reason (or without providing any reason) without any negative consequences, including withdrawal of consent or lost to follow-up which will also be considered as "withdrawal" when a participant no longer receive the procedures such as investigational product taking or blood sampling, although have not explicitly requested to withdraw from the trial.

7.2.2. Procedure for Participant Withdrawal from the Study

When a participant has withdrawal from study, ED visit should be performed if possible, following the procedure specified in Section 1.3 SOA. The reason for a participant's decision to discontinue study treatment and follow-up assessments and whether any adverse event has occurred should be inquired and documented. Adverse events will be followed up (see Section 8.10.5). Participants or their guardian should return unused investigational products.

If a participant has discontinued from study, the participant may request that any samples collected but not tested be destroyed, and the investigator must indicate this in the site study records.

7.3. Lost to follow-up

Investigator or authorized person should make every effort to contact any participant lost to follow-up during the course of the study to complete study-related assessments, record outstanding data and retrieve investigational products. Measures to be taken include:

- If a participant fails to return to the clinic for a mandatory study visit, the study site should make effort to contact the participant to reschedule the missed visit as early as possible, emphasizing to the participant the importance of returning for visits as scheduled and determining the participant's willingness to continue participating in the study;
- At least 3 attempts to contact the participant via telephone or other local equivalent methods must be made at different times (at an interval greater than 24 hours between each two attempts) before the participant is deemed to have been lost to follow-up. The efforts made should be recorded in their medical records or study documents.

If the participant has repeatedly failed to return to the study site for a scheduled visit and the study site fails to contact the participant despite the best effort to do so, the participant will be considered to have discontinued from study, for the reason "loss to follow-up".

8. Study Assessments and Procedures

8.1. Study Flow

The study must be conducted in accordance with the protocol requirements, including the specifications in Section 1.3 SOA. All scheduled study procedures and their scheduling are summarized in the SOA.

The relevant study results that may unblind the study will not be reported to the study site or other blinded staff prior to the overall unblinding of the study.

8.1.1. Screening visit (D-30 to D-4, V1)

Following the signing of ICF, the following screening tests/examinations and procedures will be performed to determine whether the criteria for participating in the study are met.

1) Assigning participant numbers and collecting demographics: gender, ethnicity, age, date of birth, weight, height, and BMI. BMI=weight/height^2 (kg/m^2)
2) Medical history/concomitant disease inquiry: general medical history, menstruation history, childbearing history, surgery history, allergy history, bleeding/blood donation history, smoking history, drinking history, caffeine and tea consumption, drug abuse history, and participation in clinical trials, etc.

3) Physical examination: skin, mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system

4) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement)

5) Pregnancy test: blood beta-human chorionic gonadotropin (β-hCG) test

6) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents). During the screening period, only FSH should be tested at the study site when necessary to determine whether the participant meets the menopause criteria.

7) Infectious disease screening: Hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), hepatitis B e antigen (HBeAg), hepatitis B e antibody (HBeAb), hepatitis B core antibody (HBcAb), hepatitis C virus antibody (HCV Ab), human immunodeficiency virus antibody (HIV Ab), and treponema pallidum specific antibody (TPPA test).

8) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

9) Neck and abdominal ultrasound:

10) Chest X-ray (AP) or chest CT: examination results obtained within 6 months prior to Screening are acceptable; only to be done once during screening period or baseline period.

11) TVU and/or endometrial biopsy: uterus and appendages are to be examined for TVU. For female participants with uterus for whom TVU revealed endometrial thickness >4 mm, endometrial biopsy is required. Only to be done once during screening period or baseline period.

12) Breast ultrasoound: for bilateral breasts (if present) and bilateral axillae. Only to be done once during screening period or baseline period.

13) Instructions on VMS eDiary: the investigator or authorized staff must train/instruct the participant at the screening visit and inform the participant that VMS should be recorded twice daily from 9 days prior to randomization until the last visit.

14) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening). VMS symptoms should be recorded immediately when waking up in the morning;

15) Adverse event

16) Concomitant medications/non-drug therapy

17) Confirming eligibility of the participant to participate in this clinical study.

8.1.2. Baseline visit (D-3 to D-1, V2)

1) PGI-S, modified Kupperman Index and MENQOL: to be evaluated upon arrival at the study site and prior to all other procedures; no specific requirements for other procedures.

2) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement)

3) Pregnancy test: if a test is no more than 7 days apart from V1 pregnancy test, it is not necessary to be repeated; otherwise, it will need to be done at V2; urine pregnancy test is acceptable for baseline period.

4) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents). **A test may not be repeated if the last test was done in no more than 5 days.**

5) 12-lead ECG: heart rate, RR interval, PR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

6) Chest X-ray (AP) or chest CT: examination results obtained within 6 months prior to Screening are acceptable; only to be done once during screening period or baseline period.

7) TVU and/or endometrial biopsy: uterus and appendages are to be examined for TVU. For female participants with uterus for whom TVU revealed endometrial thickness >4 mm, endometrial biopsy is required. Only to be done once during screening period or baseline period.

8) Breast ultrasound: for bilateral breasts (if present) and bilateral axillae. Only to be done once during screening period or baseline period.

9) VMS diary: it will be stored electronically in participants' electronic device. From 7 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

10) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary on the day of visit.

11) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Only pre-

dose blood samples will be collected, and they will all be tested at central lab.

12) Bone turnover marker tests: bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX), all to be tested at the central lab.

13) Adverse event

14) Concomitant medications/non-drug therapy

8.1.3. Treatment period (D1 to D84, V3 to V9)

8.1.3.1. Medication visit D1 (V3)

1) Weight, BMI

2) Medical history/concurrent diseases: only medical histories/concurrent diseases or medical conditions that have changed since the signing of ICF will be collected, and they will be reported as an AE or SAE as appropriate.

3) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement). ECG will be done before pre-1st dose blood sampling and at 4 h post-1st dose (±30 minutes, to be completed before PD blood sampling) of the day at V3.

4) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

5) Review of VMS ediary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary before dosing on the day of visit.

6) Confirming eligibility of the participant to participate in this clinical study.

7) Randomization: to be done after all baseline examinations/assessments are completed and qualified;

8) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Only pre-dose blood samples will be collected, and they will all be tested at central lab.

9) PK/PD sampling: to be collected pre-1st dose (within 4 h) and at 1.5 h (±10 min) and 4 h (±1 h) post-1st dose of the day.

10) Dispensing investigational products: the relevant site staff should dispense to the participant the investigational products in the quantity for 2 weeks.

11) Medication: 2 tablets each in the morning and evening, taken with water. The 2 tablets in the morning should be taken under the supervision of the investigator or the relevant nursing staff, and the 2 tablets in the evening will be self-administered by the participant. Participants should self-administer doses at home outside of the D1-D84 scheduled visits. In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose. Dose adjustment will not be allowed for the investigational product; see Section 6.1 for the specific information on treatment.

12) Adverse event

13) Concomitant medications/non-drug therapy

8.1.3.2. Medication visit on D15 (±3 days, V4)

1) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement).

2) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents). To be done pre-dose.

3) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

4) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

5) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary before dosing on the day of visit.

6) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Only pre-dose blood samples will be collected, and they will all be tested at central lab.

7) PK/PD sampling: blood samples will be collected pre-1st dose (within 4 h) of the day. Blood samples both at 1.5 h (±10 min) and 4 h (±1 h) post-1st dose of the day also need to be collected if missing on D1.

8) Dispensing investigational products: the relevant site staff should dispense to the participant the investigational products in the quantity for 2 weeks.

9) Medication: 2 tablets each in the morning and evening, taken with water. The 2 tablets in the morning should be taken under the supervision of the investigator or the relevant

nursing staff, and the 2 tablets in the evening will be self-administered by the participant. Participants should self-administer doses at home outside of the D1-D84 scheduled visits. In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose. See Section 6.1 for the details of study treatments.

10) Investigational product accountability, Medication eDiary and compliance check: the investigator or authorized staff must count the remaining unused investigational products returned by the participant (if any) and review the medication eDiary. Participants should complete the medication compliance eDiary based on the actual daily use of the investigational product.

11) Adverse event

12) Concomitant medications/non-drug therapy

8.1.3.3. Medication visit on D29 (±3 days, V5)

1) PGI-C, PGI-S, modified Kupperman Index and MENQOL: to be evaluated upon arrival at the study site and prior to all other procedures; no specific requirements for other procedures.

2) Physical examination: skin, mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system.

3) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement).

4) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents). To be done pre-dose.

5) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

6) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

7) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary before dosing on the day of visit.

8) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Only pre-dose blood samples will be collected, and they will all be tested at central lab.

9) PK/PD sampling: blood samples will be collected pre-1st dose (within 4 h) and at 1.5 h (±10 min) and 4 h (±1 h) post-1st dose of the day.

10) Dispensing investigational products: the relevant site staff should dispense to the participant the investigational products in the quantity for 2 weeks.

11) Medication: 3 tablets each in the morning and evening, taken with water. The 3 tablets in the morning should be taken under the supervision of the investigator or the relevant nursing staff, and the 3 tablets in the evening will be self-administered by the participant. Participants should self-administer doses at home outside of the D1-D84 scheduled visits. In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose. See Section 6.1 for the details of study treatments.

12) Investigational product accountability, medication eDiary and compliance check: the investigator or authorized staff must count the remaining unused investigational products returned by the participant (if any) and review the medication eDiary. Participants should complete the medication compliance eDiary based on the actual daily use of the investigational product.

13) Adverse event

14) Concomitant medications/non-drug therapy

8.1.3.4. Medication visit on D43 (±3 days, V6)

1) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement).

2) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents). To be done pre-dose.

3) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

4) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

5) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary before dosing on the day of visit.

6) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Only pre-

dose blood samples will be collected, and they will all be tested at central lab.

7) PK/PD sampling: blood samples will be collected pre-1st dose (within 4 h) of the day. Blood samples both at 1.5 h (±10 min) and 4 h (±1 h) post-1st dose of the day also need to be collected if missing on D29.

8) Dispensing investigational products: the relevant site staff should dispense to the participant the investigational products in the quantity for 2 weeks.

9) Medication: 2 tablets each in the morning and evening, taken with water. The 2 tablets in the morning should be taken under the supervision of the investigator or the relevant nursing staff, and the 2 tablets in the evening will be self-administered by the participant. Participants should self-administer doses at home outside of the D1-D84 scheduled visits. In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose. See Section 6.1 for the details of study treatments.

10) Investigational product accountability, medication eDiary and compliance check: the investigator or authorized staff must count the remaining unused investigational products returned by the participant (if any) and review the medication eDiary. Participants should complete the medication compliance eDiary based on the actual daily use of the investigational product.

11) Adverse event

12) Concomitant medications/non-drug therapy

8.1.3.5. Medication visit on D57 (±3 days, V7)

1) PGI-C, PGI-S, modified Kupperman Index and MENQOL: to be evaluated upon arrival at the study site and prior to all other procedures; no specific requirements for other procedures.

2) Physical examination: skin, mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system.

3) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement).

4) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents). To be done pre-dose.

5) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

6) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete

recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

7) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary before dosing on the day of visit.

8) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Only pre-dose blood samples will be collected, and they will all be tested at central lab.

9) PK/PD sampling: blood samples will be collected pre-1st dose (within 4 h) and at 1.5 h (±10 min) and 4 h (±1 h) post-1st dose of the day.

10) Dispensing investigational products: the relevant site staff should dispense to the participant the investigational products in the quantity for 2 weeks.

11) Medication: 2 tablets each in the morning and evening, taken with water. The 2 tablets in the morning should be taken under the supervision of the investigator or the relevant nursing staff, and the 2 tablets in the evening will be self-administered by the participant. Participants should self-administer doses at home outside of the D1-D84 scheduled visits. In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose. See Section 6.1 for the details of study treatments.

12) Investigational product accountability, medication eDiary and compliance check: the investigator or authorized staff must count the remaining unused investigational products returned by the participant (if any) and review the medication eDiary. Participants should complete the medication compliance eDiary based on the actual daily use of the investigational product.

13) Adverse event

14) Concomitant medications/non-drug therapy

8.1.3.6. Medication visit on D71 (±3 days, V8)

1) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement).

2) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents). To be done pre-dose.

3) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

4) VMS diary: it will be stored electronically in participants' electronic device. From 9 days

prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

5) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary before dosing on the day of visit.

6) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Only pre-dose blood samples will be collected, and they will all be tested at central lab.

7) PK/PD sampling: blood samples will be collected pre-1st dose (within 4 h) of the day. Blood samples both at 1.5 h (±10 min) and 4 h (±1 h) post-1st dose of the day also need to be collected if missing on D57.

8) Dispensing investigational products: the relevant site staff should dispense to the participant the investigational products in the quantity for 2 weeks.

9) Medication: 2 tablets each in the morning and evening, taken with water. The 2 tablets in the morning should be taken under the supervision of the investigator or the relevant nursing staff, and the 2 tablets in the evening will be self-administered by the participant. Participants should self-administer doses at home outside of the D1-D84 scheduled visits. In the case of a missed dose, the participant should skip the missed dose and continue with the next scheduled dose. See Section 6.1 for the details of study treatments.

10) Investigational product accountability, medication eDiary and compliance check: the investigator or authorized staff must count the remaining unused investigational products returned by the participant (if any) and review the medication eDiary. Participants should complete the medication compliance eDiary based on the actual daily use of the investigational product.

11) Adverse event

12) Concomitant medications/non-drug therapy

8.1.4. D85/End of Treatment/early discontinuation visit (±3 days, V9/day of treatment discontinuation/day of discontinuation from study)

1) PGI-S, PGI-C, modified Kupperman Index and MENQOL: to be evaluated upon arrival at the study site and prior to all other procedures; no specific requirements for other procedures.

2) Physical examination: skin, mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system.

3) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement).

4) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents).

5) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

6) TVU and endometrial biopsy: uterus and appendages are to be examined for TVU. For female participants with uterus for whom TVU revealed endometrial thickness >4 mm, endometrial biopsy is required. No need to be repeated if EOT/ED visit is no more than 1 month apart from the last TVU.

7) Breast ultrasound: for bilateral breasts (if present) and bilateral axillae. Breast ultrasound is not required if EOT/ED visit is less than 1 month apart from the last breast ultrasound (including that included in routine clinical examinations).

8) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS synptoms immediately when waking up in the morning.

9) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary before dosing on the day of visit.

10) Sex hormone tests (other than LH): follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E2), estrone (E1), sex hormone-binding globulin (SHBG). Pre-dose blood samples will be collected and will all be tested at central lab.

11) Bone turnover marker tests: bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX), all to be tested at the central lab.

12) PK/PD sampling.

13) Investigational product accountability, medication eDiary and compliance check: the investigator or authorized staff must count the remaining unused investigational products returned by the participant (if any) and review the medication eDiary. Participants should complete the medicationcompliance eDiary based on the actual daily use of the investigational product.

14) Adverse event

15) Concomitant medications/non-drug therapy

8.1.5. Follow-up period (D85 to D99)

Follow-up visit (V10, D99±3 days/14±3 days after EOT)

1) Physical examination: skin, mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system.

2) Vital signs: ear temperature, pulse rate, sitting blood pressure (rest sitting for at least 5 minutes before measurement).

3) Laboratory tests: hematology, blood chemistry, urinalysis, coagulation function, thyroid function, and parathyroid function (the specific test items are presented in Appendix 2: Study Items and Contents).

4) 12-lead ECG: heart rate, PR interval, RR interval, QRS duration, QT interval, and QTcF interval (rest sitting/lying for at least 5 minutes before measurement).

5) VMS diary: it will be stored electronically in participants' electronic device. From 9 days prior to randomization to the last scheduled visit, the participant should complete recording of VMS symptoms twice a day (when waking up in the morning and before going to bed in the evening) and recording of status of VMS symptoms immediately when waking up in the morning.

6) Review of VMS eDiary: the investigator or authorized staff must complete review of VMS symptoms in participant's eDiary on the day of visit.

7) Adverse event

8) Concomitant medications/non-drug therapy

8.2. Efficacy assessment

8.2.1. Vasomotor Symptom Diary

Daily VMS data will be collected using an electronic VMS diary (see Appendix 4: VMS Diary), which participants should complete twice daily (after waking up in the morning and before going to bed in the evening) from 9 days prior to randomization to the follow-up visit (V10). The VMS diary is a validated, interactive, real-time vendor hosted system available for use 24 hours per day for data entry. This electronic diary will be the only source document for the 4 co-primary endpoints. Participants will be provided with a reference guide within the VMS diary, which includes the definitions of mild, moderate and severe VMS. These definitions per FDA Guidance for Industry 2003 [5] are as follows:

- Mild: sensation of heat without sweating
- Moderate: sensation of heat with sweating, able to continue activity

- Severe: sensation of heat with sweating, causing cessation of activity

The real-time system will generate daily compliance reports for each participant. The compliance reports tabulate the date and time of each VMS item entry and the number of VMSs entered at each time point.

8.3. Exploratory Efficacy Assessment

8.3.1. Patient Global Impression Scale

The Patient Global Impression (PGI) scale (see Appendix 5: Patient Global Impression Score) [6], including (a) Global Impression-Severity (PGI-S) and (b) Patient Global Impression-Change (PGI-C), provides a brief overall assessment before and after starting study treatment. In this study, PGI scales (PGI-S and PGI-C) will be used to evaluate meaningful self-changes over time in sleep disturbance.

The PGI-C asks: Since the start of the study, my overall status is?" The participant can choose from [1] very much improved to [7] very much worse. The PGI-S asks the participant to choose none to very severe that best describes the severity of the participant's overall status over the past week.

8.3.2. Modified Kupperman Index

The modified Kupperman Index (see Appendix 6: Modified Kupperman Index) [7] provides a brief assessment of comprehensive menopausal symptoms before and after the initiation of study treatment, covering 13 most common perimenopausal symptoms; the 13 items (weighting factor) include: sweating hot flushes (4), paresthesia (2), insomnia (2), irritability (2), melancholia (1), vertigo (1), fatigue (1), myalgia, arthralgia (1), headache (1), heart palpitation (1), formication (1), sexual pain (2), and urinary system symptoms (2). Participant's symptom scores for each item range from (0) None or Normal to (3) Severe symptoms, and the total score is the weighted sum of the weighting factor, ranging from 0 to 63 and classified as "normal" (total score of < 6), "mild" (total score 6-15), "moderate" (total score 16-30), and severe (total score >30), where a higher total score would indicate more severe menopause-related symptoms.

8.3.3. MENQOL Questionnaire

The MENQOL questionnaire (see Appendix 7: MENQOL Questionnaire) [8] is a 29-item Pro measure that assesses the impact of 4 domains of menopausal symptoms, as experienced over the last week: vasomotor (items 1 to 3), psychosocial (items 4 to 10), physical (items 11 to 26) and sexual (items 27 to 29). Items pertaining to a specific symptom are rated as present or not present, and if present, how bothersome on a zero (not bothersome) to 6 (extremely bothersome) scale.

The raw data scores for each of the above items should be converted as described below for

further analysis, and the converted score ranges from 1 to 8 points. Each domain is scored separately. The mean of the converted scores for each item in a domain will be the score for the respective domain, ranging from 1 to 8 points [8, 9]. The overall questionnaire score is the mean of the domain means. Higher scores represent more bothersome menopausal symptoms.

Subject Response	Conversion Score
No	1
Yes 0	2
1	3
2	4
3	5
4	6
5	7
6	8

The questionnaire should take, on average, 7 minutes to complete with a range of 5 to 15 minutes based on the original English and French Canadian pre-test results [8, 9].

8.4. **Pharmacodynamic Assessments**

Venous blood samples will be collected from D1 (V3) to D85 (V9/EOT) for pharmacodynamics evaluation. The marker is LH.

Pre-1st dose (within 4 h) blood samples of the day will all be collected at D1, D15, D29, D43, D57 and D71 visits, and 1.5 h (±10 min) and 4 h (±1 h) post-1st dose blood samples of the day will also be collected at D1, D29, and D57 visits. Post-1st dose sampling of the day will also be done at D15, D43, or D71 visit when missing at D1, D29, or D57 visit. PD samples also need to be collected at V85/EOT/ED visits. See Section 1.3 SOA for details. The PK sample and PD sample should be taken at the same time.

The exact date and time of blood sampling must be recorded in the source documents and on the eCRF. Serum will be collected, handled and labeled as specified in the central laboratory manual.

Detailed procedures for sample collection, shipment, processing and storage are described in the laboratory manual.

8.5. **Exploratory Pharmacodynamics Assessments**

Venous blood samples will be collected from V2 to V9 (D85)/EOT/ED for exploratory pharmacodynamics evaluation. The markers are sex hormones other than LH, including FSH, Testo, E2, E1, and SHBG.

Pre-1st dose blood samples of the day for tests of non-LH sex hormones will be collected at D-3 to -1 (V2), D1 (V3), D15 (V4), D29 (V5), D43 (V6), D57 (V7), D71 (V8), and D85

(V9)/EOT/ED visits. Exploratory pharmacodynamics sampling scheduled at the same time point as PD/PK sampling will be performed immediately after completion of PD/PK sampling.

The exact date and time of blood sampling must be recorded in the source documents and on the eCRF. Samples will be collected and presented for testing according to the regulations of each study site.

8.6. **Pharmacokinetic Assessments**

Pre-1st dose (within 4 h) venous blood samples of the day will be collected at D1, D15, D29, D43, D57, D71 and D85 visits, and 1.5 h (±10 min) and 4 h (±1 h) post-1st dose blood samples of the day will also be collected at D1, D29, D57 visits. Post-1st dose sampling of the day will also be done at D15, D43, or D71 visit when missing at D1, D29, or D57 visit for pharmacokinetics analysis of plasma GS1-144 and its metabolite M1 (see Section 1.3 SOA). The PK samples and PD sample should be taken at the same time.

The exact date and time of the blood sampling must be recorded in the source documents and eCRF. The blood shall be collected, processed and labeled according to the procedures outlined in the central laboratory manual.

Further procedures for sample collection, shipment, processing, and storage are described in the laboratory manual.

8.7. **Safety assessment**

Safety will be assessed by the occurrence of AEs and changes over time in physical examination results, vital signs, 12-lead ECG, clinical laboratory tests, breast ultrasound, TVU, and endometrial biopsy.

8.7.1. Physical examination

A full physical examination will be performed at screening (V1), D29 (V5), D57 (V7), D85 (V9)/EOT/ED and D99 (V10)/14 days after EOT visit, including: skin and mucosa, lymph nodes, head, neck, chest, abdomen, musculoskeletal system/limbs, and nervous system. At the same time, from D1 (V3) to last visit, unscheduled symptom-oriented physical examination will be performed.

8.7.2. Vital Signs

Vital signs will be assessed at each study visit (except for V3, see Section 1.3 SOA), including: ear temperature, pulse rate and blood pressure (in sitting position; required to rest sitting for at least 5 minutes before measurement).

Any change from baseline in vital sign values occurring during the study that is considered to be clinically relevant or that requires concomitant medication, as judged by the investigator, should be recorded in the source documents and the AE module of the eCRF.

8.7.3. 12-Lead Electrocardiogram

One 12-lead ECG (rest sitting/lying at least 5 minutes before measurement) will be performed on each of the time points shown in the SOA (see section 1.3). The following ECG parameters should be recorded: heart rate, RR interval, PR interval, QRS duration, QT interval, and QTcF interval.

The investigator or the designated qualified personnel by the investigator should evaluate 12-lead ECG finding to determine whether it is normal or abnormal. If abnormal, it is necessary to judge whether the abnormality is clinically significant (CS/NCS). The investigator's evaluation of the ECG must also be recorded in the source document and eCRF.

For the discontinuation criteria concerning QTc, see Section 7.1.2.

8.7.4. Clinical safety laboratory tests

Laboratory tests will be carried out in the laboratories of study sites. The collection and analysis of samples will follow the requirements of the laboratory; the test items can be found in Appendix 2: Study Items and Contents; the sampling schedule and frequency can be found in the SOA (Section 1.3).

If the clinical laboratory results are outside the normal range, the investigator will document his/her assessment as clinically significant or not clinically significant, and any clinically significant changes that occurred during the study will be recorded as AE. The laboratory results must be retained with the source documents.

For all laboratory tests with clinically significant abnormalities during study participation or within 14 days following the last study treatment, unscheduled tests may be performed or the laboratory tests with abnormality may be repeated, and suspected AEs may be followed up until the value has normalized or recovered to baseline level, or is considered by the investigator or Medical Monitor as no longer clinically significant.

8.7.5. Imaging

8.7.5.1. Breast ultrasound

For participants with breasts only, breast ultrasonography shall be done at screening (V1) or baseline (V2) as well as D85 (V9)/EOT/ED visits, covering bilateral breasts (if present) and bilateral axillae. Breast ultrasound results must show no clinically significant findings in order for participants to be included in the study. Breast ultrasound is not required if EOT/ED visit is no more than 1 month apart from the last examination (including routine clinical screening for the participant).

8.7.5.2. Transvaginal ultrasound

All participants with uterus will undergo a TVU to assess endometrial thickness at screening

(V1) or baseline (V2) as well as D85 (V9)/EOT/ED visits. The endometrium should be measured in the long axis or sagittal plane. The measurement is of the thickest echogenic area from 1 basal endometrial interface across the endometrial canal to the other basal surface. Care should be taken not to include the hypoechoic myometrium in this measurement. TVU is not required if EOT/ED visit is no more than 1 month apart from the last examination (including routine clinical screening for the participant).

8.7.6. Endometrial biopsy

Only for participants with TVU revealing endometrial thickness >4 mm, endometrial aspiration biopsy will be performed at the following points:

- At screening or baseline period (Endometrial biopsy within 3 months prior to enrollment is acceptable)
- At D85/EOT/ED visits

Individuals with uterine myoma who do not require any treatment during the study as determined by the investigator and meet the inclusion criteria related to TVU may be included in the study.

From randomization until after the final follow-up visit,, any woman with an abnormal endometrial biopsy reported as disordered proliferative endometrium, endometrial hyperplasia or endometrial cancer will be referred to standard of care clinical management and followed to resolution, and the report of any medical or surgical procedures and the resultant pathology will be obtained.

All pathology reports should be filed in the participant's source document.

8.8. Exploratory Safety Assessments

8.8.1. Exploratory Bone Turnover Markers Testing

Blood sampling for bone turnover markers will be performed at V2 and V9/EOT/ED visit. Bone turnover marker samples should be collected at the same time as sex hormone (other than LH) samples. Bone turnover markers including: BALP, PINP, and CTX will be tested at the central laboratory.

8.9. Order of Assessments

When more than one examination/assessment needs to be done at the same point, it is recommended to follow the order below:

Screening (day -30 to day -4)

1) All screening procedures (except biopsy)
2) Endometrial biopsy

Baseline and after randomization (D-3 to D99)

PGI-C, PGI-S, modified Kupperman Index and MENQOL evaluations must be completed after arrival at the study site and before all the other procedures. No specific requirements for other procedures.

Scale assessments will be performed at baseline (D-3 to D-1), D29, D57, D85, EOT and ED visits in the following order:

- PGI-C
- PGI-S
- Modified Kupperman Index
- MENQOL questionnaire

8.10. AEs, SAEs, and other safety reports

8.10.1. Definition of AEs

An AE refers to any untoward medical occurrence following the use of the investigational product in a participant. It can therefore be any symptom, sign, disease or abnormal laboratory finding, which does not necessarily have a causal relationship with the investigational product. An AE can be any unfavorable and unintended sign including an abnormal laboratory finding, symptom, or disease temporally associated with the use of the investigational product, whether or not related to the investigational product. Thus, an AE can be any of the following:

- Any new disease or exacerbation of an existing disease (worsening in nature, increased frequency or worsening in severity of a known disease), except for those conditions that are excludable as specified in the protocol.
- Worsening in a laboratory test value or other clinical assessment results (e.g., ECG, X-ray) that are associated with symptoms or have led to change to the investigational product or concomitant therapies or discontinuation of the investigational product. If it is judged as medically significant by the investigator, it is usually considered clinically significant (CS) and needs to be recorded as an AE.
- Adverse events related to the interventions required in the protocol.
- Other medical occurrences, e.g., accidents, falls and any injuries resulting therefrom, regardless of whether or not related to the investigational product.

The safety information from signing ICF to the start of study treatment is important for evaluation of the safety of the investigational product (for example, knowing whether the participants experience some adverse symptom before taking the investigational product, which serves as the baseline status compared with the status after administration). In addition,

it is helpful to evaluate whether the obtained safety information is related to the study process and operation (washout and tissue biopsy). Therefore, this study stipulates that the collection of AEs begins with **the signing of ICF by participants**.

Here are the criteria for differentiation between medical history and AEs. The "conditions" mentioned below may refer to abnormal physical examination results, symptoms, diseases, laboratory tests, or imaging examinations:

- Conditions that have existed prior to the signing of ICF and are not symptomatic or untreated at the time of signing the ICF should be recorded as medical history (e.g., seasonal allergy without acute chief complaints).
- Conditions that have existed prior to the signing of ICF but present symptoms or do not change in severity upon treatment at the time of signing the ICF should be recorded as medical history (e.g., allergic pollinosis).
- Conditions that have existed prior to the signing of ICF but are found or diagnosed at screening can be recorded as medical history (e.g., hyperlipidaemia, gallstones, etc.) according to medical judgment by the investigator.
- Conditions that arise or worsen after signing the ICF are recorded as AEs.

It should be noted that any surgery planned prior to the initiation of the study by the doctor for a participant should not be recorded as an AE.

8.10.2. Definition of SAEs

An SAE refers to an untoward medical occurrence that at any dose meets any of the following criteria:

1) Results in death.
2) Is life-threatening: The term "life-threatening" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
3) Requires inpatient hospitalization or prolongation of existing hospitalization.

   However, it will not be reported as an SAE if at least one of the following criteria are met:

   - The length of hospital stay is less than 24 hours;
   - The hospitalization is pre-planned (e.g., the scheduled elective surgery or the originally planned surgery before the first dose of the IP; or admission as part of the study process);
   - The hospitalization is not associated with an AE (e.g., hospitalization or prolonged hospitalization for diagnosis or elective surgical treatment of an

existing disease; hospitalization or prolonged hospitalization for efficacy evaluation required for the study; hospitalization or prolonged hospitalization for the prescribed course of treatment for the target disease of the study; hospitalization for complete medical examination/physical examination; admission to a social welfare institute for temporary care).

However, it should be emphasized that if an SAE meets other seriousness criteria during hospitalization, it should be reported according to clinical judgment.

4) Results in persistent or significant disability/incapacity, where a disability refers to a substantial impairment of a person's ability to perform normal living functions.

5) Is a congenital anomaly/birth defect.

6) Is an important medical event: it may not immediately lead to death, life-threatening or hospitalization/prolongation of existing hospitalization, but may require medical intervention to prevent above conditions according to medical judgment.

If an adverse event that meets the Hy's law does not meet one of the five criteria for an SAE, it will be reported according to SAE requirements as an "important medical event", as detailed in Appendix 8: Reporting and Evaluation Process for Hy's Law Cases.

8.10.3. Content of AE assessment

All AEs will be evaluated and recorded by the investigator based on the following classification, which are described in detail as below.

8.10.3.1. Seriousness

Refer to the SAE definition to determine and evaluate the seriousness of each AE one by one.

8.10.3.2. Severity

The severity of AE will be classified by the following categories during the study:

- Mild: slight or transient discomfort that requires little or no treatment and does not affect participants' daily activities.
- Moderate: resulting in some obstruction to daily activities, requiring treatment, and possibly exerting partial impacts on functions.
- Severe: unable to carry out normal daily activities, requiring systemic medication or other treatment measures, and possibly leading to life-threatening or disability.

It should be noted that distinguishing severe AE and serious AE is very important: "severe" is not necessarily equal to "serious", and there is no necessary connection between severity and seriousness. Severity is an intensity parameter, while seriousness is defined by the criteria of SAE in the Section 8.10.2. A severe AE is not necessarily a serious AE.

8.10.3.3. Causality

The investigators shall comprehensively assess the causal relationship (**Related/Unrelated**) between AEs and IP according to the understanding of participants, the clinical background of events and any alternative reasons. "Related" means that there is a reasonable correlation between AE and IP, while "Unrelated" means that there is no reasonable correlation between AE and IP, but there are also alternative explanations, such as pre-existing disease, concomitant treatment and other risk factors.

In assessing the causality, comprehensive analysis and consideration from the following five core aspects are desired:

- Whether there was a reasonable temporal relationship between investigational product and occurrence of AE;
- Whether the AE conforms to the known mechanism of action, properties of IMP or known adverse reactions;
- de-challenge result (if applicable): de-challenge refers to suspension of clinical treatment. During a clinical trial, the phenomenon that an AE naturally disappears or alleviates after treatment suspension for a participant would be considered positive for de-challenge; otherwise, it would be considered negative for de-challenge. If the AE alleviates after treatment suspension and receiving targeted treatment, the de-challenge result should be considered unknown, as accurate judgment cannot be made in such case;
- re-challenge result (if applicable): re-challenge refers to treatment resumption after treatment suspension. If an AE that has disappeared or alleviated reappears or worsens after treatment resumption, it would be considered positive for re-challenge; otherwise, it would be considered negative for re-challenge.
- whether the AE can be explained by the participant's disease progression (including concurrent diseases), the effect of concomitant medications, other therapeutic measures, or interfering factors.

Note: The criteria for determining the relevance of adverse events may vary across different centers. The five-point scale method is acceptable for such determinations. If a center uses the five-point scale method to assess relevance, the correspondence between the five-point scale and the binary scale can be found in the "Technical Guidelines for the Evaluation of Adverse Event Relevance in Drug Clinical Trials (Trial)" issued by the CDE in June 2024 [10].

Table 8-1 Classification and Criteria for Determining the Relevance of Adverse Events in Drug Clinical Trials

Five-point Method	Criteria for Determination	Two-point Method
Definitely Related	● There is a reasonable temporal relationship ● Consistent with known mechanisms of action, characteristics, or known adverse reactions ● De-challenge is positive ● Re-challenge is positive ● No other reasonable explanation	Related
Probably Related	● There is a reasonable temporal relationship ● Consistent with known mechanisms of action, characteristics, or known adverse reactions ● De-challenge is positive ● Lack of positive re-challenge evidence ● No other reasonable explanation	
Possibly Related	● There is a reasonable temporal relationship ● Lack of positive re-challenge evidence ● Characterized by any of the following: ①Consistent with known mechanisms of action, characteristics, or known adverse reactions; de-challenge is positive, but can also be explained by other reasonable factors; ②Consistent with known mechanisms of action, characteristics, or known adverse reactions; lack of positive de-challenge evidence, and no other reasonable explanation; ③Inconsistent with known mechanisms of action, characteristics, or known adverse reactions; de-challenge is positive, with no other reasonable explanation; ④Inconsistent with known mechanisms of action, characteristics, or known adverse reactions; lack of positive de-challenge evidence, and no other reasonable explanation.	
Unlikely Related	● Temporal relationship cannot be ruled out ● Lack of positive de-challenge evidence ● Lack of positive re-challenge evidence ● characterized by any of the following: ①Consistent with known mechanisms of action, characteristics, or known adverse reactions, but can be explained by other more reasonable factors; ②Inconsistent with known mechanisms of action, characteristics, or known adverse reactions, and can be explained by other reasonable factors.	Unrelated
Unrelated	● No reasonable temporal relationship ● inconsistent with known mechanisms of action, characteristics, or known adverse reactions ● Lack of positive de-challenge evidence ● Lack of positive re-challenge evidence ● Can be explained by other reasonable factors	

Causal Relationship between AE and Study Procedures

The causal relationship between AE and the study procedures should be evaluated based on whether there is a reasonable causal relationship with the procedures required by the protocol. The method for assessing causality between AE and investigational product can be referenced for this assessment.

8.10.3.4. Actions taken with IPs

After an AE occurs, any action taken with the IPs should be recorded according to the following classification criteria:

- Dose not changed
- Dose interrupted
- Temporarily discontinued
- Drug withdrawn
- Not applicable
- Unknown

8.10.3.5. Actions taken for AEs

Targeted treatment for AEs during the study should be recorded as below:

- None
- Drug therapy
- Other treatment measures

8.10.3.6. Outcome

The outcome of an AE should be recorded according to the following criteria:

- Recovered / resolved
- Recovering / resolving
- Recovered / resolved with sequelae
- Not recovered / not resolved
- Fatal
- Unknown

8.10.4. Recording of AEs

All AEs, including those observed or obtained through inquiries by the investigator and those spontaneously reported by the participants, from the participant's signing of the ICF until D99/14 days after EOT/ED visit (inclusive) should be fully recorded in case report forms/eCRFs of the participants. Clinically significant laboratory test abnormalities and symptoms/signs should be recorded as AEs. Any SAE that occurs beyond the safety information collection window specified above and is determined to be related to the investigational product by the investigator should be reported to the sponsor in accordance with the SAE reporting standards.

The names of AEs should be in medical terminology, preferably medical diagnoses. If no definite diagnosis can be made, symptoms/signs will be used. The record should be updated when a diagnosis becomes available at a later time, and the diagnosis should replace the previously recorded symptoms/signs. For determination of AE terms, it should be ensured that each AE term consists of a single event and that a diagnosis, sign/symptom is an AE.

The investigator is responsible for grading the AE according to the severity mentioned above. At the same time, the investigator will evaluate the **seriousness** of the event. If it is an SAE, it should be filled in the eCRF according to SAE criteria.

Detailed documentation of all AEs should include the start and end dates (the time of event onset and resolution; the onset time of an SAE is the date on which an AE is escalated to an SAE), severity, causality with the IMPs and/or study procedures, potential alternative explanations (underlying diseases, concomitant therapy, other risk factors, etc.), actions taken with the IMPs, actions taken with the AEs, and the final outcomes of the AEs.

All deaths that occur during study or during the safety information collection window as defined in this study protocol must be reported in the following manner:

- Death should be seen as an outcome, not an exact event. The cause of death, instead of "death", should be recorded as the term of the AE, and "death" should be the outcome of the AE that leads to death. If the cause of death is unknown and cannot be determined at the time of reporting, the death may be reported as an SAE "unexplained death", and the investigator is required to follow up as much as possible to obtain and assess the cause of death. An autopsy may assist in the assessment of the cause of death of participants, and if an autopsy is performed, a copy of the autopsy results should be submitted to the sponsor.
- Deaths occurring after the safety information collection window specified in the protocol should be recorded on the Deaths page of eCRF. If the death is due to an event that began after the safety follow-up period specified in the protocol and is believed to be caused by delayed toxicity of the IP, it should be reported as an SAE.

8.10.5. Follow-up of AEs

The investigator should continuously follow up all AEs and SAEs until they recover, return to baseline or reach a stable state, death or no further information is available. The investigator should monitor and record the outcome of AEs in the source documents of participants. The investigator is not obliged to proactively collect AEs or SAEs that occur beyond the safety information collection window specified in the protocol, but if any SAE that occurs during this period is considered related to the investigational product by the investigator, it should be reported to the sponsor in accordance with the SAE reporting standards.

8.10.6. SAE reporting

Notification to Sponsor

The investigator is obliged to report all SAEs that meet the seriousness criteria specified in the protocol to the drug safety department of the sponsor. The investigator should report each SAE to the sponsor within 24 hours after learning of the SAE, according to the reporting format specified by the sponsor. All investigators should be trained in this aspect. Relevant contact information, report forms, and other information will be summarized in the investigator management documents and updated as needed.

The investigator is obliged to respond to safety queries raised by the sponsor in a timely manner. After obtaining new information, the investigator should submit an SAE follow-up report, which should follow the same reporting time limit and format requirements as the initial report.

All SAEs should be evaluated separately by the sponsor, including the expectedness, seriousness and causal relationship with the IPs.

Notification to Ethics Committee/Institution

The sponsor and/or the investigator will notify the EC/Institution of all relevant events (such as SUSARs, etc.) in accordance with regulatory requirements.

Notification to Study Sites

The sponsor should notify all study sites of relevant reported events (e.g., SUSARs) in accordance with applicable regulations.

Submission to Regulatory Authorities

The sponsor should report SUSARs to the drug regulatory authorities and the health authorities.

8.11. Total blood collection volume

Blood samples will be collected for clinical laboratory tests, serological tests (screening period only), pharmacokinetics analysis, pharmacodynamics analysis, exploratory sex hormones (other than LH) analysis, and bone markers analysis. Repeat and additional blood samples may be taken if required. A total of approximately 207 mL of blood samples are expected to be

collected from an individual participant during the clinical study.

9. Statistical Methods

9.1. General considerations of Statistical Analysis

In general, continuous data will be summarized with descriptive statistics (number of participants, mean, SD, minimum, median and maximum) and frequency and percentage for categorical data.

9.1.1. Statistical Hypothesis

This is a multicenter, randomized, double-blind, placebo-controlled, parallel-group phase II study with a superiority design. The statistical hypothesis for pairwise comparisons between different GS1-144 groups and placebo group is as follows:

$$H_0: \mu_T-\mu_C=0$$

$$H_1: \mu_T-\mu_C\neq0$$

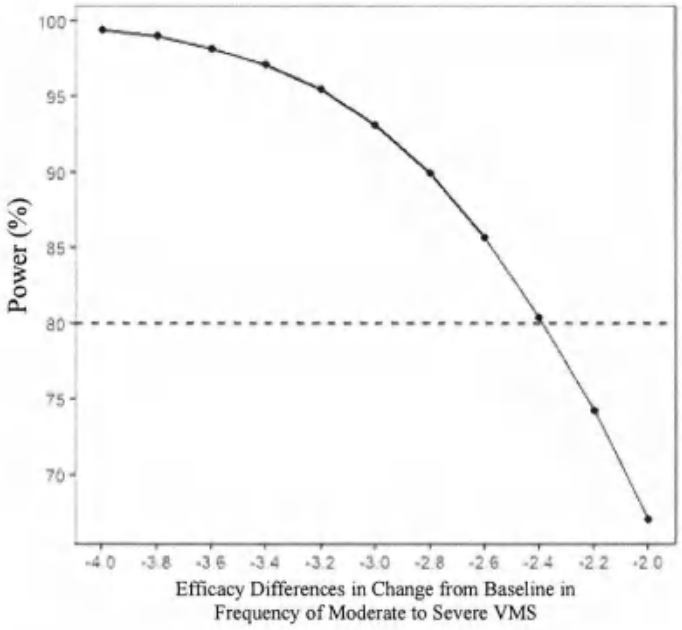
Significance level $\alpha = 0.1$(two-sided). μ_T and μ_C are change from baseline in VMS frequency (or severity) at Week 4 (or Week 12) in a test group and placebo group, respectively.

9.1.2. Multiplicity adjustment

This is a phase II exploratory study. Tests of the primary endpoint between different treatment groups or tests of other secondary endpoints will not be adjusted for multiplicity.

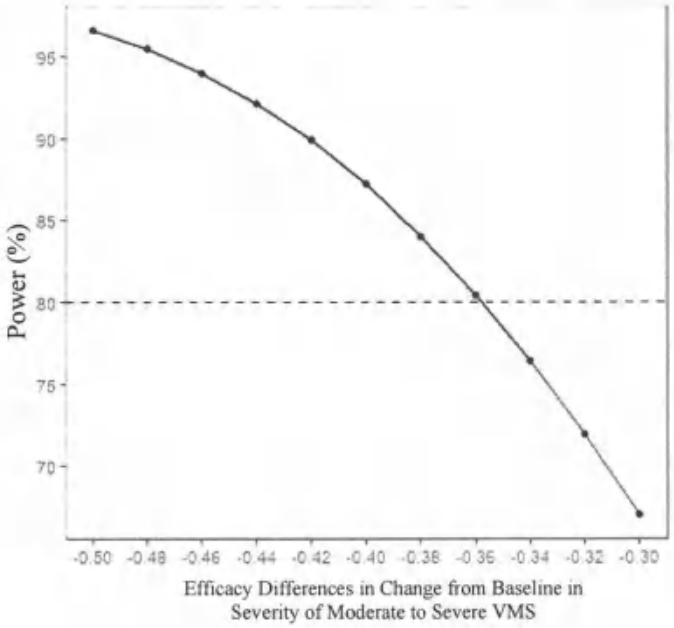
9.2. Sample Size

For the primary endpoint of mean change from baseline of daily frequency, the previous studies



of fezolinetant showed the treatment difference ranged from -2.0 to -5.0, with similar results at Week 4 and Week 12. Using a 2-sample t-test at a two-sided 0.1 alpha, for a pairwise comparison of the primary endpoint of mean change from baseline of daily frequency, 55 participants in each group will provide 80% power to detect the difference from placebo of -2.4, assuming an SD of 5.

For the primary endpoint of mean change from baseline of severity, the previous studies of Fezolinetant showed the treatment difference ranged from -0.2 to -1.1, with similar results at Week 4 and Week 12. Using a 2-sample t-test at a two-sided 10% alpha, for a pairwise comparison of the primary endpoint of mean change from baseline of severity, 55 participants in each group will provide 80% power to detect the efficacy difference from placebo of -0.36, assuming an SD of 0.75.



Assuming approximately 17% drop out rate (referring to Fezolinetant Phase III studies), the number of participants will be increased from 55 to 67 for each treatment group, totally 268 participants. Note that the power for testing all 4 co-primary endpoints will be lower than the power for each considered individually.

9.3. **Analysis Sets**

- Full analysis set (FAS): including all participants who have been randomized and used at least one dose of the investigational products.
- Per Protocol Set (PPS): a subset of the FAS including all participants with valid primary

endpoint data, good compliance (including compliance to dosage regimen and vasomotor symptom diary recording) and no significant protocol deviations interfering with primary endpoint evaluation. Two PPS datasets will be defined based on different co-primary endpoints, one to be used for analysis of the Week 4 co-primary endpoints and the other to be used for analysis of the Week 12 co-primary endpoints.

- Safety set (SS): all participants who have taken at least one dose of the investigational products.
- Pharmacokinetic analysis set (PKAS): it is a pharmacokinetic concentration data set obtained from participants who have received at least one dose of GS1-144.
- Pharmacodynamic analysis set (PDAS): it is a PDAS obtained from participants with at least 1 pre-dose and post-dose LH concentration.

Additional analysis sets may be defined as needed for analysis, and will be provided in a separate Statistical Analysis Plan (SAP).

9.4. Efficacy Analysis

9.4.1. Primary Endpoints

There are 4 co-primary endpoints for this study:

- Changes from baseline in the frequency of moderate to severe VMS at Week 4;
- Changes from baseline in the frequency of moderate to severe VMS at Week 12;
- Changes from baseline in the severity of moderate to severe VMS at Week 4;
- Changes from baseline in the severity of moderate to severe VMS at Week 12.

9.4.1.1. Primary estimand

The primary objective of the study is to evaluate the efficacy of GS1-144 for the treatment of moderate to severe VMS. Based on the primary objective, the primary estimand for this study is defined as follows:

Population: postmenopausal women with moderate to severe VMS.

Variables/endpoints: there are 4 co-primary endpoints, change from baseline in the mean daily frequency of moderate to severe VMS over 7 days before Week 4 (Week 12) and change from baseline in the mean daily severity of moderate to severe VMS over 7 days before Week 4 (Week 12). The change from baseline will be regarded as 0 in the occurrence of intercurrent events 1 and 2. Post-baseline frequency and severity will be calculated based on the daily mean over 7 days prior to a visit; baseline frequency and severity will be calculated based on the daily mean over 7 days prior to randomization. Severity will be calculated using a weighed mean method with the following formula

$$\frac{\text{number of mild VMS} \times 1 + \text{number of moderate VMS} \times 2 + \text{number of severe VMS} \times 3}{\textit{total number of mild, moderate, and severe VMS episodes on that day}}$$

Notes:

1) the calculation for severity at baseline uses a similar formula, but does not include mild VMS events in the numerator or denominator.
2) At baseline, when no moderate or severe VMS are reported for a particular day, the mean severity for that day will be set to 0. At post-baseline, when no VSM are reported for a particular day, the mean severity for that day will be set to 0. The mean severity will be aggregated by averaging the mean daily severity of VMS of the available days during specific week.

Treatments: the following treatments will be administered for different groups:

- GS1-144 30 mg QD
- GS1-144 60 mg QD
- GS1-144 30 mg BID
- Placebo BID

Intercurrent events and corresponding strategies:

1. receiving protocol-prohibited concomitant medications prior to Week 4 (Week 12) which had an impact on the efficacy assessments
2. discontinuing study treatment early due to lack of efficacy prior to Week 4 (Week 12)
3. discontinuing study treatment early for other reasons prior to Week 4 (Week 12)

A composite strategy will be applied for intercurrent events 1 and 2, data collected after the occurrence of the intercurrent event will be imputed with the baseline value, that is, the value will be regarded as having no change from baseline. A hypothetical strategy will be used for intercurrent event 3, data after occurrence of the intercurrent event will be considered as missing and handled by MMRM model assuming missing at random.

Population-level summary: difference of least square mean between active groups and placebo group for change from baseline in the mean daily frequency of moderate to severe VMS over 7 days before Week 4 (Week 12), and change from baseline in the mean daily severity of moderate to severe VMS over 7 days before Week 4 (Week 12).

9.4.1.2. Primary analysis method

Efficacy analyses will be performed based on FAS; co-primary efficacy endpoints will also be analyzed based on PPS.

For each of the 4 co-primary efficacy endpoints, treatment comparison will be performed using a Mixed-Effect Model Repeated Measure (MMRM) model, with treatment group, week, and

randomization stratification BMI (<28 kg/m^2 or ≥28 kg/m^2) as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction. Treatment effects will be estimated based on least-square (LS) means of the differences. The p-values for the LS mean differences along with the 2-sided 90% CI will be presented.

Other supplementary estimands (if applicable) and sensitivity analysis will be specified in the SAP.

9.4.2. Secondary Endpoints and Exploratory Endpoints

For other efficacy endpoints, unless otherwise specified, the MMRM model will be used for the analysis of continuous variables with repeated measures, and stratified CMH or Logistic regression model will be used for the analysis of binary variables. No adjustments for multiple comparisons will be made for the secondary endpoints and all p-values will be considered nominal.

9.5. Safety analysis

The safety analysis is based on the SS.

AEs will be coded with Medical Dictionary for Regulatory Activities (MedDRA). Any AEs occurring at or after the initial administration of study intervention or that are a consequence of a preexisting condition that has worsened after first study intervention is considered to be treatment emergent adverse events (TEAEs). Any TEAEs, serious TEAEs, and study drug-related TEAEs, etc., will be summarized and analyzed as classified by System Organ Class (SOC) and Preferred Term (PT), and all AEs will be listed. Other safety endpoints will also be summarized descriptively by treatment group.

9.6. PK Analysis

GS1-144 and M1 plasma concentrations will be summarized descriptively. Descriptive statistics include arithmetic mean, standard deviation, coefficient of variation, median, maximum, minimum, geometric mean, and geometric coefficient of variation, etc. Individual and mean plasma concentration-time curves will be plotted based on the blood sampling time points. The time used for individual participant's plasma concentration curves will be the actual blood sampling time, while the time used for the mean concentration-time curve will be the planned blood sampling time. Individual or mean plasma concentration-time curves will be displayed using both linear and semi-logarithmic plotting.

Refer to the SAP for details.

9.7. PD Analysis

Serum LH concentration and the its change from baseline will be summarized by each planned blood sampling time point and actual treatment group with descriptive statistics, including

arithmetic mean, standard deviation, coefficient of variation, median, maximum, minimum, geometric mean, and geometric coefficient of variation, etc. Individual and mean LH concentration-time curves will be plotted based on the blood sampling time points. The time used for individual participant's LH concentration curves will be the actual blood sampling time, while the time used for the mean concentration-time curve will be the planned blood sampling time. Descriptive statistical analysis will also be conducted on other biomarkers such as sex hormones: FSH, Testo, E2, E1, SHBG, etc.

Refer to the SAP for details.

9.8. PopPK Analysis and Dose-Response Analysis

PopPK samples will be collected. The PK model will be established using the nonlinear mixed effect model, and participants' individual exposure parameters will be estimated based on the parameter estimates of the final PK model established for further dose-response (exposure-response) analysis, including analyses of the PK-efficacy and PK-safety correlations.

9.9. Interim Analysis

To assist a timely internal decision making and adjustment to the development of the program, an interim analysis is planned after all randomized participants have completed the Week 4 visit (or participant's discontinuation/withdrawal from the study treatment earlier than that). To maintain the integrity of the blind, interim analysis will be performed by an independent un-blinded team, and the unblinded results will be restricted to a very small group independent of study team; Details will be documented in a separate charter to ensure the integrity of the study blinding maintenance..

10. Operational Considerations

10.1. Electronic Clinical Outcome Assessments

Participant VMS diary will be completed by the participant on an electronic device and the collected electronic source data will be hosted at the vendor. The investigator or site designee will review the diary data throughout the study to ensure completion and protocol compliance.

The VMS diary data will be transferred electronically to sponsor or designee at predefined intervals during the study. The vendor will provide the investigator with a complete and clean copy of their site's data and will provide the sponsor or designee with a complete and clean copy of all study data. The data will be owned by the investigator.

10.2. Important Protocol Deviations

A protocol deviation is generally an unexpected deviation from the protocol, and all protocol deviations should be recorded.

The investigator is responsible for ensuring the study is conducted in accordance with the

procedures and evaluations described in this protocol and must protect the rights, safety and well-being of participants. The investigator should not implement any deviation from, or changes of, the protocol, unless it is necessary to eliminate an immediate hazard to participants.

An important protocol deviation is one that may potentially impact the completeness, accuracy or reliability of data contributing to the primary endpoint or affect the rights, safety or well-being of a participant. The reporting requirements for important protocol deviations will be specified in the Medical Monitoring Plan.

When a participant is found to have an important protocol deviation, the investigator or authorized staff must ensure the sponsor is notified. The sponsor will follow up with the investigator to assess the deviation and the possible impact to the safety and/or efficacy or pharmacokinetic parameters of the participant to determine participant continuation in the study. The investigator should also assure that protocol deviations meeting the criteria of the institutional review board (IRB)/independent ethics committee (IEC) and competent authorities. All documentations and communications with the IRB/IEC and competent authorities should be provided to the sponsor and maintained within the trial master file.

11. Study Organization

11.1. Independent Data Safety Monitoring Board

Safety monitoring for this study will be performed by an independent DSMB. The DSMB is responsible for performing regular safety reviews. The DSMB will be independent of the sponsor and has the right to recommend suspension of the study or termination of a dose for safety reasons at any time. The DSMB will perform safety data review based on the cumulative summary tables and/or listings of AEs, SAEs, clinical laboratory results, concomitant medications, medical histories, and study treatments. After the review, the DSMB will advise the sponsor on whether to continue the study (or terminate a certain dose), and the sponsor will make decisions based on the DSMB's advice.

DSMB members will be selected based on their experience in clinical trial methodology and/or the disease area. The DSMB Charter will include specific information on the pre-specified frequency of safety reviews, the data required for reviews, and the procedure for negotiating with the sponsor.

12. Appendices

12.1. Appendix 1: Regulatory, Ethical, and Study Oversight Considerations

12.1.1. Regulatory and Ethical Considerations of Study Conduct

The study will be conducted in accordance with the protocol, ICH guidelines, applicable laws/regulations and guidelines governing clinical study conduct and the ethical principles stipulated in the Declaration of Helsinki.

12.1.2. Institutional Review Board/Independent Ethics Committee/Competent Authorities

The investigator must submit the clinical study protocol, any protocol amendment(s), the IB, the ICF, and any other relevant documents (e.g., participant recruitment advertisement) and essential documents to the IEC/IRB prior to the conduct of the study. The IEC/IRB will review the ethical, scientific and medical appropriateness of the study. The IEC/IRB approval of the protocol, the ICF and information sheet for participants, and/or advertisement (if relevant) should be obtained before authorizing shipping of the investigational products to the study site.

Any amendment to the protocol must be approved by the IRB/IEC prior to implementation; for any substantial amendment, approval of the competent authorities must also be obtained prior to implementation, unless for changes necessary for eliminating immediate hazards to participants.

The investigator will be responsible for the following:

- Providing written summaries of the status of the study to the IRB/IEC annually or more frequently in accordance with the requirements, policies and procedures established by the IRB/IEC;
- Notifying the IRB/IEC of SAEs or other significant safety findings as required by IRB/IEC procedures;
- Supervising the study conduct at the site and the compliance with NMPA GCP 2020, ICH guidelines, IRB/IEC requirements, and any other applicable local laws/regulations.

12.1.3. Protocol Amendments

Any changes to the study that arise after approval of the protocol must be documented as protocol amendments: substantial amendments and/or non-substantial amendments. Approval or notification of the IRB/IEC and competent authorities may be required depending on the nature of the amendment. The changes will become effective only after the approval of the sponsor, the investigator, the regulatory authority and the IRB/IEC.

Amendments to this protocol must be signed by the sponsor and the investigator. Written verification of IRB/IEC approval must be obtained before any amendment is implemented.

12.1.4. Participant Information and Consent

The investigator or authorized personnel will explain to the potential participant or his/her guardian the nature of the study (including risks and benefits), and answer all study-related questions. Potential participants must be informed that their participation is fully voluntary. Before a participant undergoes any study-related screening procedures, the participant or participant's guardian should read the informed consent statement that complies with the local regulations, ICH guidelines, and IRB/IEC or site requirements before signing and dating it. The investigator or authorized person who administered ICF must also sign the ICF.

Participants must be reconsented to the most current effective version of the ICF during their participation in the study. Re-screened participants are required to sign a new ICF.

After the ICF is signed in duplicate, one copy will be retained in the participant's medical records by the investigator and made available for review upon request of the study monitors or inspectors of regulatory authorities; the other copy must be provided to the participant or his/her guardian. A statement that the participant has signed ICF prior to enrollment in the study, the date of obtaining the written ICF, and the fact that participants have received the signed ICF should be documented in the medical records.

12.1.5. Source Documents

Source data must be archived at the investigator's study site to document participants' conditions and confirm the integrity of the study data collected. Source data must include the original documents relating to the study, as well as the medical treatment and medical history of the participant.

The investigator is responsible for ensuring the source data are attributable, legible, contemporaneous, original, accurate and complete whether the data are hand-written on paper or entered electronically. CRF data transcribed from source data or data entered into the eCRF must be consistent with the source data, and any discrepancies must be justified.

As needed for the study, in addition to having current, available medical records, the investigator may require access to the Previous medical records or transfer records of a participant. The investigator must ensure that the source data documents for CRF information entry are properly preserved.

The sponsor or designee will carry out monitoring to ensure that the data entered by the authorized site staff into CRF are accurate, complete, and verifiable from the source documents; that the safety and rights of participants are protected; and that the study is being conducted in accordance with the currently approved protocol and any other study agreements, ICH GCP, and all applicable regulatory requirements.

12.1.6. Retention of Records

The investigator should archive all study data (e.g., participant identification code list, source data, eCRFs and investigator's file) and relevant correspondence records. After the end of the study, the investigator must preserve the records and documents (including signed ICFs) related to the conduct of this study for 5 years, unless local regulations or the institution's policy requires longer duration of retention. The sponsor will notify the site and investigator if the NDA is approved or if the IND is discontinued. During the preservation period, no records may be destroyed without the written permission of the sponsor. No records may be transferred to another location or party without written notification to the sponsor. The investigator agrees to obtain the sponsor's agreement prior to disposal, moving or transferring of any study-related records. The sponsor will archive and retain all documents pertaining to the study according to local regulations.

Data generated by the methods described in the protocol will be recorded in the participants' medical records and/or study progress notes.

12.1.7. Privacy of Participants and Confidentiality

The privacy of participants must always be respected. Every possible measure should be taken to ensure the privacy of participants and to minimize the potential impact of the clinical study on the participant.

Each participant will be assigned a unique identifier by the sponsor. Any participant records or datasets transferred to the sponsor will only contain the identifier; neither the participant's name nor any information that reveals the participant's identity will be transferred. The sponsor shall not disclose any confidential information on participants obtained during the performance of their duties in the clinical study without justifiable reasons.

The participant must be informed that his/her medical records may be viewed by Clinical Quality Assurance auditors or other authorized personnel appointed by the sponsor, by IRB/IEC members, and by inspectors from regulatory authorities.

If any individuals involved in the study, including the study monitors and auditors, may get to know matters related to participant's privacy due to direct access to source documents, or from other sources, they may not leak the content to third parties.

12.1.8. Procedure for Clinical Study Quality Control

12.1.8.1. Clinical Study Monitoring

The sponsor or delegated CRO is responsible for monitoring the clinical study to ensure that participant's rights and safety are protected, that the study is properly conducted in adherence to the current protocol and GCP, and study data reported by the investigator/subinvestigator are accurate and complete and that they are verifiable with source data. The sponsor is

responsible for assigning study monitor(s) to this study for proper monitoring. They will monitor the study in accordance with planned monitoring procedures.

12.1.8.2. Direct Access to Source Data/Documents

The investigator and the study site must accept monitoring and auditing by the sponsor or delegated CRO, as well as inspections from the IRB/IEC and relevant regulatory authorities. In these instances, they must provide all study-related records including source documents when they are requested by the sponsor monitors and auditors, the IRB/IEC or regulatory authorities. The participant's privacy shall be well protected consistent with local and national regulations when the source documents are participant to direct access.

12.1.8.3. Data Management

The data manager (DM) of sponsor will develop a data management plan (DMP) based on the clinical trial protocol and SOP requirements for data management. As a guiding document for the entire data management process, the DMP provides guidance on the entire process of data management through the time/frequency, contents and procedures defined therein.

12.1.8.3.1. CRF design and database establishment

This clinical trial adopts an electronic data capture (EDC) system to collect clinical trial data. The DM will design the eCRF in the EDC based on the clinical trial protocol and CDISC standards, and complete annotation of the CRF.

The DM will draft a data validation plan (DVP) based on the clinical trial protocol and annotated CRF, and database programmers will design the systemic edit check in the EDC based on the DVP. The edit check is conducted by the DM for the integrity, consistency, and accuracy of database data.

The DM will organize internal and external users to conduct a user acceptance testing on the database. After passing the testing, the EDC system can be launched only after approval is obtained from the sponsor.

All users accessing the EDC must receive relevant trainings and fill out the user permission management form. After confirmation and approval by the DM and the sponsor, the system administrator will create accounts. The system administrator will create accounts and grant different permissions based on the user permission management form, including different roles such as DM, investigators (principal), CRA, medical monitor (MM), and clinical research coordinator (CRC).

12.1.8.3.2. Data cleansing

The investigator or the trained CRC authorized by the investigator will accurately, promptly, completely, and normatively fill out the eCRF based on raw data and eCRF completion guidelines.

The primary responsibility of the investigator is to ensure that the data reported in the eCRF or other forms are accurate, complete, and timely, and he/she should also ensure that the data on the eCRF are derived from the participant's source data and any discrepancies are justified.

After the data are filled into the EDC database, the system will automatically verify the data according to the set systemic edit check procedures and generate system queries for problematic data. The DM will conduct the manual data check based on the DVP and external data check requirements. For problematic data, a manual query will be sent in the EDC database.

Other members of the project team, such as CRA and MM, will also check the data in the EDC system according to their respective responsibilities, and send a query promptly in the EDC system about any inconsistent or questionable data identified during the check. The investigator or the authorized person can modify or confirm the data after verification. The reason for modification should be filled out in the eCRF for the modified data, and the audit trails should be left in the database. The investigator will review all final data. Before the lock of database, the electronic signature of the principal investigator should be obtained for all eCRFs so as to confirm the authenticity and accuracy of the data.

12.1.8.3.3. Data coding

The DM is also responsible for medical coding in this trial. The coded information includes medical history, prior medications, concomitant medications/non-drug therapies and AEs. Medical history, AEs and non-drug therapies will be coded according to the MedDRA, and prior medications and concomitant medications will be coded according to the World Health Organization Drug Dictionary (WHO Drug) using the Anatomical Therapeutic Chemical Classification System (ATC). All versions of the dictionaries used should be confirmed by the sponsor.

During the coding process, the DM will ask the investigator, in the form of data queries, to verify and confirm any data problems such as failure to code due to improper, inaccurate, and vague medical terms provided.

Before database lock, the DM will send the medical coding report to the project team of the sponsor for review.

12.1.8.3.4. Data lock and handover

At the EOS, a data (blind) review meeting will be held, at which the principal investigator, investigators, sponsor, project manager, statistician, MM (if applicable), and DM will jointly review the data, divide the statistical analysis populations according to the clinical trial protocol, and verify the SAE reporting and handling records.

After all data are reviewed to be correct and all parties approve the data lock, the DM will proceed with database lock. If any modification is required after database lock, an application should be submitted, and its necessity should be discussed by the sponsor, principal investigator,

project manager, medical monitor (if applicable), DM, and statistician. The modification may be implemented after confirmation by their signatures.

After the database is locked, the DM will hand over the data to the statistical analyst, who will perform the statistical analysis according to the SAP. The data management party will write a data management report (DMR).

12.1.8.3.5. Archiving of data and data materials

After the EOS, all parties will archive and save the involved data and data materials.

The project data management documents should be saved according to regulatory requirements for at least 5 years after the IP is approved for marketing.

12.1.8.4. Quality Assurance

The sponsor is implementing and maintaining quality assurance (QA) and quality control (QC) systems with written SOPs to ensure that studies are conducted and data are generated, documented, recorded and reported in compliance with the protocol, GCP and applicable regulatory requirement(s).

The sponsor or sponsor's designee may arrange to audit the study at any or all study sites and facilities. The audit may include on-site review of regulatory documents, CRFs and source documents. Direct access to these documents will be required by the auditors.

12.1.9. Study and Site Start and Closure

12.1.9.1. Study Initiation Date

Study initiation date refers to the date of the first participant of the first site signing the informed consent form.

12.1.9.2. Study and Site Discontinuation

The sponsor or its designee reserves the right to close the study site or terminate the study at any time, for any reason, and at the sole discretion of the sponsor. Study sites will be closed upon study completion. A study site will be considered to have been closed when all essential documents and study supplies have been collected and the site closure visit has been completed.

The investigator may initiate the site closure process at any time, provided that there is a reasonable reason and adequate notice has been given before the anticipated discontinuation.

Reasons for the early closure of a study site by the sponsor or investigator may include but are not limited to:

Study Discontinuation:

- Discontinuation of further study intervention and development

Discontinuation of the site:

- The investigator fails to comply with the protocol, the requirements of the IRB/IEC or local regulatory authorities, the sponsor's procedures, or GCP guidelines;
- Upon evaluation, an insufficient number of or no participants have been recruited by the investigator after an appropriate period of time;
- All participants have been enrolled before the expected time point.

If the study is prematurely terminated or suspended by the sponsor, the sponsor should promptly inform the investigators, the IEC/IRB, the regulatory authorities, and any contract research organizations involved in the study of the reason for termination or suspension, as specified by the applicable regulatory requirements. The investigator should promptly inform the participant and assure appropriate participant therapy and/or follow-up.

12.1.10. Publication Policy

The results of this study may be published or presented at scientific meetings. If there is such a plan, the investigator agrees to submit all manuscripts or abstracts to the sponsor prior to submission, so that the sponsor can protect intellectual properties and provide opinions.

The sponsor will comply with the requirements for publication of study results. Based on the standard editing and ethical practices, the sponsor generally only supports the publication of multicenter study data as a whole rather than for individual study sites. In this case, a coordinating investigator will be designated by mutual agreement.

Authorship will be negotiated between the two parties and be determined in accordance with the requirements of the International Committee of Medical Journal Editors on authorship.

12.2. Appendix 2: Study Items and Contents

Item	Requirement and items
Demographics	Gender, age, ethnicity, date of birth, height, weight, body mass index (BMI)
Inquiry	General medical history, menstruation history, childbearing history, surgery history, allergy history, bleeding/blood donation history, smoking history, drinking history, drug abuse history, caffeine/tea consumption, and participation in clinical trials, etc.
Physical examination	Skin, mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system
Vital Signs	Ear temperature, pulse rate, and sitting blood pressure (rest sitting for at least 5 minutes before measurement)
Pregnancy test	Serum or urine beta-human chorionic gonadotropin (β-HCG)
Hematology	Red blood cell count, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, hemoglobin, platelet count, mean platelet volume, white blood cell count, white blood cell count and differential (lymphocyte percentage, monocyte percentage, neutrophil percentage, eosinophil percentage, basophil percentage, absolute eosinophil count, absolute basophil count, absolute neutrophil count, absolute lymphocyte count, and absolute monocyte count)
Blood chemistry	Alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyltransferase (GGT), alkaline phosphatase (ALP), lactate dehydrogenase (LDH), total bilirubin (TBIL), direct bilirubin (DBIL), total protein (TP), albumin (ALB), globulin (GLO), creatinine (CRE), urea (UREA)/blood urea nitrogen (BUN), uric acid (UA), cholesterol (CHO), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), potassium (K), sodium (NA), chloride (CL), blood calcium (CA), inorganic phosphorus (PHO), magnesium (MG), glucose (GLU), and estimated glomerular filtration rate (eGFR)
Coagulation	Prothrombin time (PT), activated partial thromboplastin time (APTT), thrombin time (TT), fibrinogen (FIB) quantification and international normalized ratio (INR).
Thyroid and parathyroid function	Free triiodothyronine (FT3), free thyroxine (FT4), thyroid stimulating hormone (TSH), and parathyroid hormone (IPTH/PTH)
Urinalysis	pH, urine glucose, specific gravity, urine occult blood, urine protein, urine bilirubin, urobilinogen, urine ketones, urine leukocyte, and urine erythrocyte
Infectious disease screening	Hepatitis B serologic test [hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), hepatitis B e antigen (HBeAg), hepatitis B e antibody (HBeAb), and hepatitis B core antibody (HBcAb)], hepatitis C virus antibody (HCV Ab), human immunodeficiency virus antibody (HIV Ab), and Treponema pallidum Specific Antibody (TPPA test). Note: if TPPA result is positive, TRUST may be additionally done, and the patient will not be allowed to be enrolled if the TRUST remains positive.
ECG examination	12-lead ECG (rest lying for at least 5 minutes before measurement); ECG parameters include heart rate, RR interval, PR interval, QRS duration, QT interval, and QTcF interval
Chest CT or X-ray	For chest x-ray (P-A) or chest CT, examination results within 6 months prior to the screening are acceptable

Transvaginal ultrasound (TVU) or endometrial biopsy	Uterus and appendages; endometrial biopsy is to be done if TVU reveals endometrial thickness >4mm
Breast ultrasound	Bilateral breasts (if present) and bilateral axillae
Ultrasound neck	Thyroid gland and parathyroid gland examination
Ultrasound abdomen	Liver, gallbladder, pancreas, kidneys and spleen in a fasted state
Sex hormone test	Follicle stimulating hormone (FSH), testosterone (Testo), estradiol (E_2), estrone (E_1), luteinizing hormone (LH, as the PD parameter), and sex hormone binding globulin (SHBG), to be tested at the central lab
Bone turnover marker tests	Bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX) (all to be tested at the central lab)

Note: For some of the laboratory tests mentioned above that cannot be performed by the study site, it is acceptable to send them out to third-party laboratories and other hospitals for testing.

12.3. Appendix 3: List of Prohibited Concomitant Medications

These lists are not inclusive of all possible prohibited medications. In case of doubt, the Investigator must contact the local medical monitor.

- Use of hormonal medications such as hormone therapy, HRT or hormonal contraception or any treatment for menopausal symptoms (prescription, over the counter or herbal) is not allowed during the study.
- Investigational research products that have not been approved for any indication in China.

Strong CYP1A2 Inhibitors (AUCr > 5)	
Inhibitor	**Therapeutic Class**
Angelica root - Bai Zhi (Angelica dahurica radix)	Herbal Medications
ciprofloxacin	Antibiotics
clinafloxacin	Antibiotics
enoxacin	Antibiotics
fluvoxamine	SSRI
oltipraz	Cancer Chemopreventive Agents
rofecoxib	NSAIDS
zafirlukast	Antiasthmatics
Moderate CYP1A2 Inhibitors (AUCr ≥ 2 and AUCr ≤ 5)	
Inhibitor	**Therapeutic Class**
MDMA	Recreational Drugs
etintidine	H-2 Receptor Antagonists
genistein	Food Products
idrocilamide	Muscle relaxants
methoxsalen (8-methoxypsoralen)	Antipsoriatics
mexiletine	Antiarrhythmics
osilodrostat	Adrenal Steroidogenesis Inhibitors
Oral contraception	Oral contraception
phenylpropanolamine	Vasoconstrictors
pipemidic acid	Antibiotics
propafenone	Antiarrhythmics
propranolol	Alpha/Beta Adrenergic Antagonists
troleandomycin	Antibiotics
vemurafenib	Kinase Inhibitors

AUCr: area under the concentration-time curve ratio: CYP: cytochrome P450: MDMA: 3,4-methylene-dioxymethamphetamine; NSAID: nonsteroidal anti-inflammatory drugs; SSRI: Selective serotonin reuptake inhibitors

12.4. Appendix 4: VMS Diary

Complete this section in the evening	
Have you taken your study medication today?	Yes O No O
No hot flushes during the day	O
Total **number** of hot flushes of **each severity** during the day:	
MILD: *Sensation of heat without sweating*	⌊⌋⌋ Mild
MODERATE: *Sensation of heat with sweating, but able to continue activity.*	⌊⌋⌋ Moderate
SEVERE: *Sensation of heat with sweating, causing cessation (stopping) of activity.*	⌊⌋⌋ Severe

Complete this section in the morning	
Total **number** of times you woke up last night:	⌊⌋⌋ "0" if none
No hot flushes during the night	O
Total **number** of hot flushes of **each severity** during the night:	
MILD: *Sensation of heat without sweating*	⌊⌋⌋ Mild
MODERATE: *Sensation of heat with sweating, but able to continue activity.*	⌊⌋⌋ Moderate
SEVERE: *Sensation of heat with sweating, causing cessation (stopping) of activity.* **Note**: *A night-time hot flush that wakes you up (stops you sleeping) is a severe hot flush. If you had more hot flushes once you were awake, record these too.*	⌊⌋⌋ Severe

12.5. Appendix 5: Patient Global Impression Score

PATIENT GLOBAL IMPRESSION OF CHANGE (PGIC)

Since the start of the study, my overall status is:

✓one box only:

- [1] ☐ Very Much Improved
- [2] ☐ Much Improved
- [3] ☐ Minimally Improved
- [4] ☐ No Change
- [5] ☐ Minimally Worse
- [6] ☐ Much Worse
- [7] ☐ Very Much Worse

(US/English)

PGIC - USA/English – Original version
PGI-C_T01.E_eng-USA.doc

PATIENT GLOBAL IMPRESSION OF SEVERITY (PGIS)

Please choose the response below that best describes the severity of your overall status over the past week.

☐ None

☐ Mild

☐ Moderate

☐ Severe

☐ Very severe

PGI-S - United States/English - Map
C0021-TR-0007 / PGI-S_TS1.0.0_eng-USA.doc

12.6. Appendix 6: Modified Kupperman Index

Scale for Evaluation of Female Menopausal Syndrome: Modified Kupperman Index

Symptoms	Weighting factor	Severity scale				Symptom score
		0	1	2	3	
Sweating hot flushes	4	None	<3 times/day	3-9 times/day	≥10 times/day	
Paresthesia	2	None	Once in a while	Feel tingling, numbness or tinnitus etc. frequently	Frequent, severe	
Insomnia	2	None	Once in a while	Frequent	Frequent, severe Needing sleep medications	
Irritability	2	None	Once in a while	Frequent	Frequent, cannot control	
Melancholia	1	None	Once in a while	Frequent, can self-control	Losing faith in life	
Vertigo	1	None	Once in a while	Frequent, not affecting daily life	Affects life and work	
Fatigue	1	None	Once in a while	Frequent	Restricted daily life	
Myalgia, arthralgia	1	None	Once in a while	Frequent, not affecting function	Dysfunction	
Headache	1	None	Once in a while	Frequent, can endure	Needing medication	
Heart Palpitation	1	None	Once in a while	Frequent, not affecting work	Requires treatment	
Formication	1	None	Once in a while	Frequent, can endure	Requires treatment	
Sexual pain	2	None	Once in a while	Frequent, can endure	Affects daily life	
Urinary system symptoms	2	None	Once in a while	Frequent, not affecting life	Affects life and work	

Notes: weighted score, symptom score × weighting factor; total score, sum of the weighted score, ranging 0-63.

Classification of the modified Kupperman Index is "normal" (total score < 6), "mild" (total score 6-15), "moderate" (total score 16-30); or "severe" (total score >30)

Reference: Yu Qi. Menopause [M]. Beijing: People's Medical Publishing House. 2013: 106-11. Chinese.

12.7. Appendix 7: MENQOL Questionnaire

Study Specifics:

Subject ID # :_____ **Date :** ____/____/____
yy mm dd

THE MENOPAUSE-SPECIFIC

QUALITY-OF-LIFE QUESTIONNAIRE

MENQOL™

Primary Care Research Unit
Department of Family and Community Medicine
Sunnybrook Health Sciences Centre
University of Toronto

Authors: John R. Hilditch, Jacqueline E. Lewis, Peter G. Norton, Earl V. Dunn

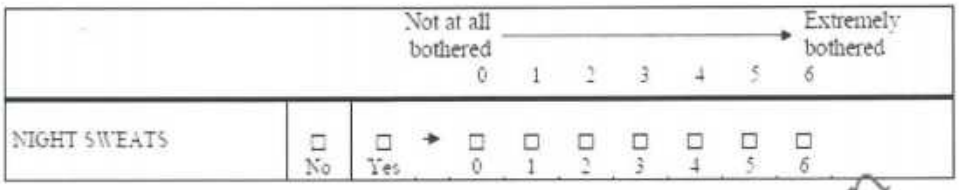
The development of the MENQOL™ questionnaire was funded by CIBA-GEIGY Canada Ltd., Mississauga, Canada.

The authors request citation of the 1996 and 2005 development papers whenever MENQOL or MENQOL-I is used or otherwise acknowledged.

For information or permission to use the questionnaire, please submit a request through ePROVIDE™, Mapi Research Trust online platform.

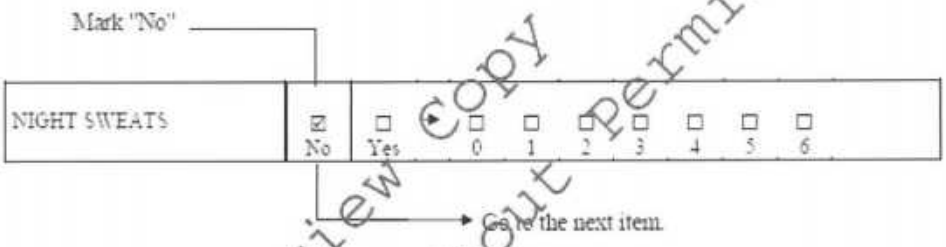
INSTRUCTIONS

Each of the items in the questionnaire is in the form of the examples below:



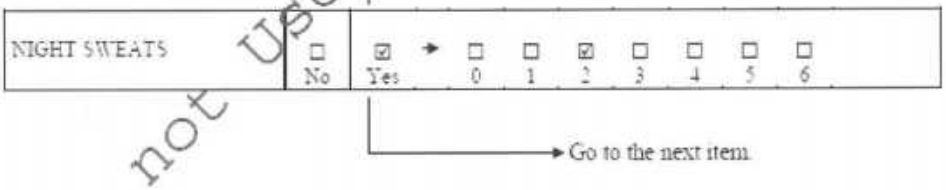
Indicate whether or not you have experienced this problem in the **PAST MONTH**.

IF YOU ***HAVE NOT*** EXPERIENCED THE PROBLEM:



IF YOU ***HAVE*** EXPERIENCED THE PROBLEM:

Mark "Yes", then check off how bothered you were by the problem.



This questionnaire is completely confidential. Your name will not be associated with your responses. However, if for any reason you do not wish to complete an item, please leave it and go on to the next one.

Date : ____ ____ ____ Subject ID = : _____
yy mm dd

For each of the following items, indicate whether you have experienced the problem in the **PAST MONTH**. If you have, rate how much you have been ***bothered*** by the problem.

			Not at all bothered → Extremely bothered						
			0	1	2	3	4	5	6
1. HOT FLUSHES OR FLASHES	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
2. NIGHT SWEATS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
3. SWEATING	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
4. DISSATISFACTION WITH MY PERSONAL LIFE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
5. FEELING ANXIOUS OR NERVOUS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
6. POOR MEMORY	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
7. ACCOMPLISHING LESS THAN I USED TO	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
8. FEELING DEPRESSED, DOWN OR BLUE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
9. BEING IMPATIENT WITH OTHER PEOPLE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. FEELINGS OF WANTING TO BE ALONE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. FLATULENCE (WIND) OR GAS PAINS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
12. ACHING IN MUSCLES AND JOINTS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
13. FEELING TIRED OR WORN OUT	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
14. DIFFICULTY SLEEPING	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
15. ACHES IN BACK OF NECK OR HEAD	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
16. DECREASE IN PHYSICAL STRENGTH	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

The Menopause-Specific Quality of Life Questionnaire *Page 4 of 4*

Date: ____ ____ ____ (yy mm dd) Subject ID = : _____

			Not at all bothered → Extremely bothered						
			0	1	2	3	4	5	6
17. DECREASE IN STAMINA	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
18. LACK OF ENERGY	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
19. DRY SKIN	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
20. WEIGHT GAIN	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
21. INCREASED FACIAL HAIR	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
22. CHANGES IN APPEARANCE, TEXTURE OR TONE OF MY SKIN	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
23. FEELING BLOATED	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
24. LOW BACKACHE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
25. FREQUENT URINATION	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
26. INVOLUNTARY URINATION WHEN LAUGHING OR COUGHING	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
27. DECREASE IN MY SEXUAL DESIRE	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
28. VAGINAL DRYNESS	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
29. AVOIDING INTIMACY	☐ No	☐ Yes →	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

MENQOL™ (1 month recall)
MENQOL - Canada/English - Mapi
ID0296-TR-72179 / MENQOL_A02.2_1month-recall_eng-CAen.doc

INSTRUCTIONS FOR USE AND SCORING OF THE MENOPAUSE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE MENQOL™

USE:

1. The title page, subject questionnaire instruction and 29 items constitute the official MENQOL™.
2. Pages i, ii, and iii inclusive contain information for the researchers only.
3. Ensure you have the correct questionnaire recall period based upon your study need.
4. The MENQOL™ questionnaire is designed to be self-administered either in person or by mail.
5. Use of electronic, verbal, Braille, sign language or other delivery methods require pre-testing.
6. Researchers are advised to pre-test the average time required by subjects to complete the questionnaire.

REFERENCES :

Hilditch JR, Lewis J, Peter A, van Maris B, Ross A, Franssen E, Guyatt GH, Norton PG, Dunn E. A Menopause-Specific Quality of Life Questionnaire: development and psychometric properties. Maturitas 1996;24: 161-75

Lewis JE, Hilditch JR, Wong CJ. Further psychometric property development of the Menopause-Specific Quality of Life questionnaire and development of a modified version, the MENQOL-Intervention questionnaire. Maturitas 2005; 50:209-221.

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SCORING:

1. Convert the Subject Response (the item raw data score) to a Conversion Score (a score for further analyses), in the following manner:

Subject Response	Conversion Score
No	1
Yes 0	2
1	3
2	4
3	5
4	6
5	7
6	8

2. a) The MENQOL™ contains four domains.
   - i Vasomotor - Items 1 to 3
   - ii Psychosocial - Items 4 to 10
   - iii Physical - Items 11 to 26
   - iv Sexual - Items 27 to 29

   b) Each domain is scored separately.

   c) After conversion, each domain mean ranges from 1 to 8.

3. The overall questionnaire score is the mean of the domain means.

4. Interpretation of results:
   a) The questionnaire instructions ask the subject to check the "No" box if she does not experience the item. The Conversion Score, '1', means the individual does not experience the item.

   b) The Subject Response, "Yes" with a raw data score '0', has an important meaning in the MENQOL™ because it permits the subject to experience the item, "Yes", BUT to be "Not at all bothered" by the item's occurrence. The Conversion Score '2' means the subject experiences the item BUT is "Not at all bothered" by the experience.

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c) Conversion score '3' means the subject experiences the item, "Yes" and is minimally bothered, raw score '1'.
Conversion score '4' is the equivalent of a bothersome raw score of '2'.
Conversion score '5' is the equivalent of a bothersome raw score of '3'.
Conversion score '6' is the equivalent of a bothersome raw score of '4'.
Conversion score '7' is the equivalent of a bothersome raw score of '5'.
Conversion score '8' means the subject experiences the item and is 'Extremely bothered', reflecting a raw data score of '6'.

d) Hence, the Conversion score ranges from 1 to 8; whereas, the questionnaire raw data score is NO or Yes, with a bothersome score of '0' "Not at all bothered" worsening to '6', "Extremely bothered".

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12.8. Appendix 8: Reporting and Evaluation Process for Hy's Law Cases

This appendix describes the process to be followed to identify, report, and evaluate Hy's Law cases, and is not intended as a comprehensive guideline for the management of increased liver biochemistry indicators.

Hy's Law cases refer to those cases meeting all the following conditions:

① ALT or AST >3×ULN along with TBIL >2×ULN or clinical jaundice;

② New R value (nR) ≥ 5 [new R value is the ratio of the ULN multiple of ALT or AST (the higher one) to the ULN multiple of ALP];

③ The simultaneous increase in aminotransferase and TBIL cannot be justified by other causes (such as cholestasis, viral hepatitis, or other acute liver disease, or concomitant use of other drugs that can cause liver damage).

The investigator should stay alert to increases in liver biochemistry indicators during the study. In the detection of a liver biochemistry indicator meeting both of the ① and ② criteria, the investigator and sponsor should jointly review and evaluate the case and strengthen safety monitoring for such participants. Based on results of review and assessment, the investigator will operate according to the following instructions.

- If it is agreed that the case can be explained by any other reason, it should be determined whether the reason fulfills an AE and, if yes, whether the AE meets any SAE criterion. If it is an AE/SAE, the reason should be recorded/reported as the AE/SAE term;
- If it is agreed that the case cannot be explained by any other reason than the investigational products, an SAE should be reported as per the following requirements:
  - The reported term should be "Hy's Law case" or "drug-induced liver injury";
  - If none of the seriousness criteria 1) to 5) for SAE definition in Section 8.10.2 are met, the criterion "important medical events" should be used;
  - The causality should be assessed as "related" as the case cannot be explained by any other reasons;
  - Timely record information related to Hy's Law cases and follow them up closely. Once necessary supplementary information becomes available, another review and evaluation are required; if the abnormality in liver biochemistry indicators can be explained by any other reason, the SAE report should be updated based on the review result.

For participants with baseline hepatic function abnormal, it should be reviewed whether there have been "significant changes" in the participant's condition. Significant changes refer to a

clinically significant increase from baseline in the participant's liver biochemistry indicators, or clinically significant changes in the clinical symptoms. It will be at the investigator's discretion whether the participant has experienced significant changes, and the investigator may discuss with the sponsor when there is any uncertainty. If the review conclusion is that there have been "significant changes" in the participant's condition, proceed following the above procedures.

12.9. Appendix 9: Protocol Amendment History

Amendment 1 (01-Sep-2024)

Overall Rational for the Amendment:

Based on the review opinion from IEC of leading site, the high-dose group of 90 mg QD group will not be studied for the time being. Accordingly, the justification for dose, the study dose group information, and the sample size as well as the wording have been revised throughout the protocol.

1. Update Justification for Dose, and Remove 90 mg QD Group
DESCRIPTION OF CHANGE
Remove Table 4-2 GS1-144 Safety Margin（based on animal models）and the information pertaining to 90 mg QD group, and modify the morning- or evening-dose of IMP to 2 tablets accordingly.
BRIEF RATIONALE
According to the overall development plan of this product, the highest dose is set to be 60 mg.
2. Update Sample Size
DESCRIPTION OF CHANGE
A total of 285 participants with 57 each in 5 groups were updated to be a total 268 participants with 67 each in 4 groups, and the sample size determination is updated accordingly.
BRIEF RATIONALE
To ensure the statistical power is relatively high.
3. Update the Dietary Requirements for Drug Administration
DESCRIPTION OF CHANGE
Remove the fasting requirement for drug administration.
BRIEF RATIONALE
Although food reduced the absorption rate of GS1-144, it has no effect on AUC, so GS1-144 can be administered with food or without food. Only fasting requirement for examinations/tests at scheduled visits needs to be maintained.
4. Update Sex Hormone (other than LH) Test Requirements
DESCRIPTION OF CHANGE
Remove the fasting requirement for sex hormone (other than LH) test.
BRIEF RATIONALE
Sex hormone (other than LH) test can be done both in a fasted state or after meal.

5. Update PK/PD Sampling Requirements
DESCRIPTION OF CHANGE
Add language to clarify the PK/PD sampling time points are all pertaining to the 1st dose of the day.
BRIEF RATIONALE
Only pre- and post-1st dose samples of the day are needed for PK/PD analysis.
6. Add FSH Test during Screening
DESCRIPTION OF CHANGE
Add *During the screening period, only FSH should be tested at the study site when necessary to determine whether the participant meets the menopause criteria* in section 1.3 (SOA) and section 8.1.1.
BRIEF RATIONALE
FSH test is needed in some circumstance for inclusion criteria #3（menopause criteria）.
7. Remove Pregnancy Reporting and Pregnancy Related Discontinuation Criteria
DESCRIPTION OF CHANGE
Remove section 8.10.7 Pregnancy Reporting and pregnancy related discontinuation criteria in Abstract and section 7.1.3 Other Treatment Discontinuation Criteria。
BRIEF RATIONALE
The study population are all menopausal women without child-bearing potential, removal of the above-mentioned content could avoid any ambiguity.
8. Update Schema in Section 1.2
DESCRIPTION OF CHANGE
Removing the 90 mg QD group from this protocol to clarify that no drug administrations are scheduled on D85, and update the note *Returning to the research center to receive the investigational medication and undergo examination/evaluation* to *The morning dose of investigational product will be taken at the study site, under the supervision of the designated study staff, after collection of predose blood samples* at D1 to D71 visits.
BRIEF RATIONALE
Modifying the wording to keep consistency throughout the protocol.
9. Update the Abdominal Ultrasound Requirement in SOA
DESCRIPTION OF CHANGE

Add note #10 following SOA to clarify that the abdominal ultrasound is conducted in a fasted state as stated in Appendix 2.
BRIEF RATIONALE
To keep consistency with Appendix 2 Study Items and Contents.
10. Update the Pregnancy Test in Appendix 2
DESCRIPTION OF CHANGE
The items/contents of pregnancy test are updated from *Blood beta-human chorionic gonadotropin (β-HCG)* to *Serum or urine beta-human chorionic gonadotropin (β-HCG).*
BRIEF RATIONALE
The pregnancy test during screening is based on serum, while urine can be chosen for the Day1 test.

13. References

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Statistical Analysis Plan

A Randomized, Double-blind, Placebo-controlled, Parallel-group Phase II Clinical Study to Evaluate the Efficacy and Safety of GS1-144 Tablets in the Treatment of Moderate to Severe Vasomotor Symptoms in Chinese Postmenopausal Women

Protocol GenSci074-201; **Phase II**

GS1-144

Status:	Approved
Date:	13May2025
Prepared by:	Changchun GeneScience Pharmaceuticals Co., Ltd.

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VERSION HISTORY

Table 1 – SAP Version History Summary

SAP Version	Approval Date	Change	Rationale
1.0	19Feb2025	Not Applicable	Final Version 1.0
2.0	13May2025	1. Section 5.7.4: Add baseline VMS frequency for subgroup analysis 2. Section 5.5.2: Add "For sex hormones (other than LH) and sex hormone-binding globulin concentrations, mean concentration-time curves (for both absolute value and change from baseline) will be plotted based on the nominal blood sampling time points." 3. Section 4: Add following criteria to exclude participants from PPS4 and PPS12 respectively: • Participants didn't take any investigational products within Day 22 to 28 • Participants didn't take any investigational products within Day 78 to 84 4. Section 5.3.3.1: Add "except that analysis at Week 4 based on PPS4 will only include Week 2 and Week 4 in the model" in sensitivity analysis for PPS4 5. Section 6.8: Add "Transaminases increased" and "Transaminases abnormal" 6. Section5.7.4 and 6.3 BMI subgroup was updated	1. To further explore the treatment effect of different subgroups 2. To create the linear plot for sex hormones and sex hormone-binding globulin to clearly reflect the changes overtime through plots. 3. Participants who didn't take any dose during the week prior to primary analysis timepoint may greatly impact the primary efficacy evaluation, consider to exclude those kind of participants from PPS 4. Add clarification that analysis for PPS4 will only include data up to Week 4, which is different with primary analysis method up to Week 12. 5. Update the rule for AESI 6. Update the BMI classification criterion to reflect China standard.

1. INTRODUCTION

This statistical analysis plan (SAP) provides a technical elaboration of the statistical methods to be used in the interim and final analyses in order to answer the study objectives outlined in the protocol.

The plan may change due to unforeseen circumstances; any changes made after the plan has been finalized will be documented. No revision to the SAP is required for changes which do not affect the statistical analysis methods, definitions, or rules defined in this document.

Shells for tables, figures and listings are contained in a separate document.

1.1. Objectives and Endpoints

Primary Objective	**Co-primary Endpoints**
• To evaluate the efficacy of GS1-144 in the treatment of moderate to severe VMS	• Changes from baseline in the frequency of moderate to severe VMS at Week 4 • Changes from baseline in the frequency of moderate to severe VMS at Week 12 • Changes from baseline in the severity of moderate to severe VMS at Week 4 • Changes from baseline in the severity of moderate to severe VMS at Week 12
Secondary Objectives	**Secondary Endpoints**
• To evaluate other efficacy of GS1-144 in the treatment of moderate to severe VMS • To evaluate the safety and tolerability of GS1-144	• Changes from baseline in the frequency of moderate to severe VMS at each of the other treatment weeks over 12 weeks • Changes from baseline in the severity of moderate to severe VMS at each of the other treatment weeks over 12 weeks • Percentage decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks • Proportions of participants with ≥50% and 100% decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks • Incidence and severity of Adverse Events (AEs) • Changes from baseline at each time point in laboratory tests, vital signs, physical examination findings, 12-lead electrocardiogram (ECG), and transvaginal ultrasound (TVU), etc.

Exploratory Objectives	Exploratory Endpoints
• To characterize the population pharmacokinetics (PopPK) of GS1-144 and its metabolite M1 and to analyze its exposure-response relationship • To evaluate the improvement in sleep disturbance with GS1-144 • To evaluate the improvement in quality of life with GS1-144 • To evaluate the improvement in relevant postmenopausal symptoms with GS1-144 • To evaluate the effect of GS1-144 on the pharmacodynamics (PD) marker (luteinizing hormone [LH]) • To evaluate the effects of GS1-144 tablets on sex hormones (other than LH) and sex hormone-binding globulin • To evaluate the effect of GS1-144 tablets on bone metabolism	• A PK model will be established to characterize the PK profiles of GS1-144 and its metabolite M1. Then, based on the parameter estimates derived from the final PK modeling, individual exposure parameters for each participant will be estimated for further exposure-response (exposure-efficacy and exposure-safety) analysis (if data available) • Scores on participant's Patient Global Impression of Change (PGI-C) in sleep disturbance at Weeks 4/8/12 from baseline • Changes from baseline on participant's Patient Global Impression of Severity (PGI-S) in sleep disturbance at Weeks 4/8/12 • Changes from baseline in modified Kupperman Index at Weeks 4/8/12 • Changes from baseline in Menopause-Specific Quality-of-Life (MENQOL) score at Weeks 4/8/12 • Changes from baseline in LH concentration; • Changes from baseline in sex hormones (other than LH) and sex hormone-binding globulin concentrations at D1 and Weeks 4/8/12 • Changes from baseline in serum concentrations of bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX) at Week 12.

1.2. Study Design

This is a randomized, double-blind, placebo-controlled, parallel-group, 12-week treatment clinical study to evaluate the efficacy and safety of GS1-144 tablets in the treatment of moderate to severe VMS in postmenopausal women.

In this study, 268 postmenopausal female participants with moderate to severe VMS symptoms are planned to be enrolled through block randomization stratified by the body mass index (BMI, <28 kg/m^2 or ≥ 28 kg/m^2), and allocated to the GS1-144 30 mg QD, GS1-144 60 mg QD, GS1-144 30 mg BID or placebo group in a 1:1:1:1ratio (67 participants each of these 4 treatment groups). Duration of treatment is 12 weeks. Following the completion of the treatment period or end of treatment (EOT) or early discontinuation from the study (ED), participant will complete the V9 (Day 85)/EOT/ED visit, and non-ED participants will also complete the final visit for safety and other assessments.

The study consists of 4 stages: screening period (D-30 to D-4), baseline period (D-3 to D-1), treatment period (D1 to D84), and follow-up period (D85 to D99). This study will be conducted in outpatients with a treatment duration up to 12 weeks, a study duration up to approximately 18 weeks, and a total of 10 visits. For an overview of the study design, see **Figure 1**.

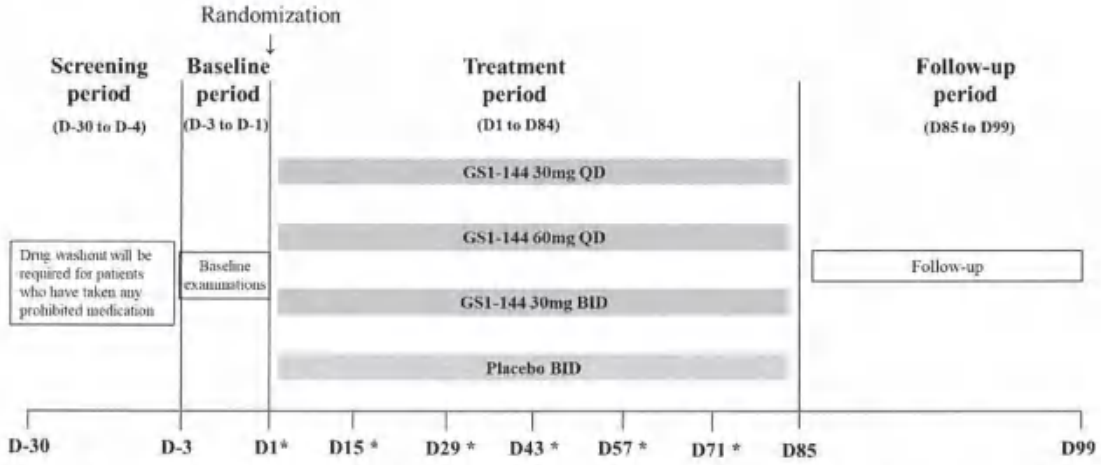
Screening visit (V1) will be completed after the participant signs the informed consent form (ICF) and within 30 days prior to randomization.

Participants will be randomized on D1 after completing the baseline tests during the screening period and being confirmed eligible.

During the 12-week treatment period, the participant will take the investigational products twice daily (2 tablets each in the morning and evening) for 84 consecutive days, and will return to the study site for the corresponding tests/examinations, assessments, receiving and/or return of investigational products, and other procedures specified in Protocol every 2 weeks from V3 to V9 (D1, D15, D29, D43, D57, D71, and D85).

The non-ED participant will need to return to the site on D99 or 14 days after EOT visit to complete the follow-up visit for safety, AEs and concomitant medications/therapies.

Figure 1 Study Schema



Note: *The morning dose of investigational product will be taken at the study site, under the supervision of the designated study staff, after collection of predose blood samples.

2. STATISTICAL HYPOTHESES

This is a multicenter, randomized, double-blind, placebo-controlled, parallel-group phase II study with a superiority design. The statistical hypothesis for pairwise comparisons between different GS1-144 groups and placebo group is as follows:

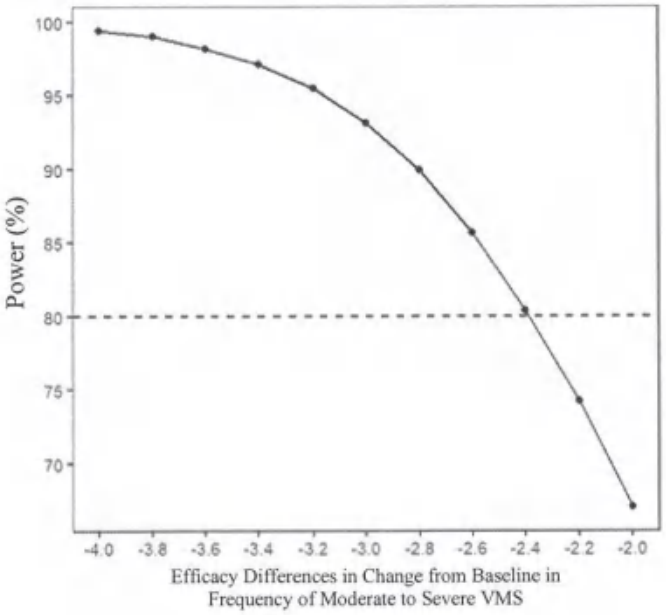
$$H_0: \mu_T - \mu_C = 0$$

$$H_1: \mu_T - \mu_C \neq 0$$

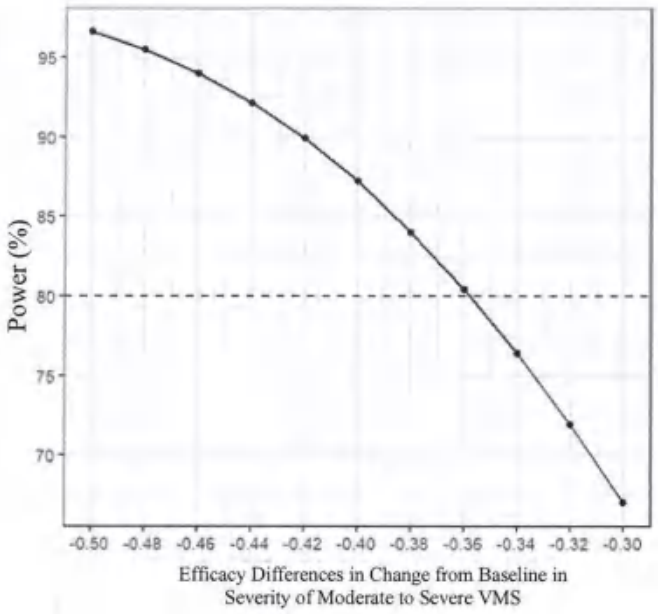
Significance level $\alpha = 0.1$(two-sided). μ_T and μ_C are change from baseline in VMS frequency (or severity) at Week 4 (or Week 12) in a test group and placebo group, respectively.

3. SAMPLE SIZE DETERMINATION

For the primary endpoint of mean change from baseline of daily frequency, the previous studies of fezolinetant showed the treatment difference ranged from -2.0 to -5.0, with similar results at Week 4 and Week 12. Using a 2-sample t-test at a two-sided 0.1 alpha, for a pairwise comparison of the primary endpoint of mean change from baseline of daily frequency, 55 participants in each group will provide 80% power to detect the difference from placebo of -2.4, assuming an SD of 5.



For the primary endpoint of mean change from baseline of severity, the previous studies of fezolinetant showed the treatment difference ranged from -0.2 to -1.1, with similar results at Week 4 and Week 12. Using a 2-sample t-test at a two-sided 10% alpha, for a pairwise comparison of the primary endpoint of mean change from baseline of severity, 55 participants in each group will provide 80% power to detect the efficacy difference from placebo of -0.36, assuming an SD of 0.75.



Assuming approximately 17% drop out rate (referring to Fezolinetant Phase III studies), the number of participants will be increased from 55 to 67 for each treatment group, totally 268 participants. Note that the power for testing all 4 co-primary endpoints will be lower than the power for each considered individually.

4. POPULATIONS (ANALYSIS SETS) FOR ANALYSIS

Following analysis sets are defined for purpose of analysis.

Analysis Sets	Description
Randomized	The randomized analysis set includes all participants who were randomized in the study.
Full Analysis Set (FAS)	Including all participants who have been randomized and used at least one dose of the investigational products. Participants will be analyzed according to their randomized study medication assignment, irrespective of the treatment actually received.
Per Protocol Set (PPS)	A subset of the FAS including all participants with valid primary endpoint data, good compliance (including compliance to dosage regimen and vasomotor symptom diary recording) and no important protocol deviations impacting primary endpoint evaluation. Two PPS datasets will be defined based on different co-primary endpoints, one to be used for analysis of the Week 4 co-primary endpoints (PPS4) and the other to be used for analysis of the Week 12 co-primary endpoints (PPS12).
Safety Set (SS)	All participants who have taken at least one dose of the investigational products.
Pharmacokinetic Analysis Set (PKAS)	Including all participants who have received at least one dose of GS1-144 and have evaluable PK measurements.

Analysis Sets	Description
Pharmacodynamic Analysis Set (PDAS)	Including all participants who have at least one pre-dose and post-dose LH concentration.

The following reasons may lead to participant's exclusion from PPS4:

- VMS missing for more than 2 days within 7 days during Week 4.
- <85% VMS diary compliance during the 4 week treatment period (Day 1 to Day 28).
- Treatment compliance less than or equal to 80% during the 4 week treatment period (Day 1 to Day 28).
- Treatment duration (days) is less than 23 days.
- Participants didn't take any investigational products within Day 22 to 28
- Other important protocol deviations which impact primary endpoint evaluation at Week 4.

The following reasons may lead to participant's exclusion from PPS12:

- VMS missing for more than 2 days within 7 days during Week 12.
- <85% VMS diary compliance during the 12 week treatment period (Day 1 to Day 84).
- Treatment compliance less than or equal to 80% during the 12 week treatment period (From Day 1 to last treatment date).
- Treatment duration (days) are less than 68 days.
- Participants didn't take any investigational products within Day 78 to 84
- Other important protocol deviations which impact primary endpoint evaluation at Week 12.

The number of participants in each analysis sets will be summarized based on randomized analysis set. A by-participant listing of analysis sets details will be provided based on randomized sets, including inclusion/exclusion flag for each analysis set and reason for exclusion from specific analysis set.

5. STATISTICAL ANALYSES

5.1. General Considerations

Descriptive statistics (i.e., N, mean, median, standard deviation (SD), Q1-Q3, minimum, and maximum) will be used to summarize continuous variables. Counts and percentages will be used to summarize categorical variables. Graphical data displays may also be used to summarize the data.

The study day is relative to first treatment date unless otherwise specified:

- If the date of the event/assessments is on or after the first treatment date, then:

  Study Day = (date of event/assessments – first treatment date) + 1

- If the date of the event/assessments is prior to the first treatment date, then:

  Study Day = (date of event/assessments – first treatment date)

This is a phase II exploratory study. Tests of the primary endpoint between different treatment groups or tests of other secondary endpoints will not be adjusted for multiplicity.

5.1.1. Visit Windows

For VMS diary data, the study week determination for the vasomotor symptoms data is based on the following.

Table 2 –Analysis Windows

Analysis study week	Analysis window*
Baseline	D-7 to D-1
Week 1	D2 to D8
Week 2	D8 to D14
Week 3	D15 to D21
Week 4	D22 to D28
Week 5	D29 to D35
Week 6	D36 to D42
Week 7	D43 to D49
Week 8	D50 to D56
Week 9	D57 to D63
Week 10	D64 to D70
Week 11	D71 to D77
Week 12	D78 to D84

*Baseline was relative to randomization date, other Visit was relative to Study Day 1, where Day 1 corresponds to start of treatment.

For other efficacy and safety assessments, unless specified otherwise, data to be analyzed or presented over time will be presented by nominal visits. Visit "D85/EOT/ED" will be mapped to "D85" if participants complete the study treatment (according to CRF form "End of Treatment"), otherwise visit "D85/EOT/ED" will be mapped to the scheduled visits (if the specific scheduled visit not occurred) if it's allocated within the visit window in protocol.

5.1.2. Baseline

Unless otherwise specified, the baseline value will be defined as the last available measurement value prior to the first study treatment administration, or prior to randomization for participants randomized but not treated. The baseline of VMS assessments is as specified in Section 5.1.1.

5.2. Participant Disposition

Screened participants and reason for screen failures will be summarized overall.

Based on the randomized analysis set, the number of participants in the following disposition categories will be summarized throughout the study by treatment group and overall:

- Participants randomized
- Participants who received study treatment
- Participants who completed the study treatment
- Participants who discontinued study treatment
- Reasons for discontinuation of study treatment
- Participants who completed study treatment before Week 4
- Participants who discontinued study treatment before Week 4
- Reasons for discontinuation of study treatment before Week 4
- Participants who completed the study
- Participants who terminated study prematurely
- Reasons for termination of study

A listing of participant disposition will also be provided.

5.3. Primary Endpoints Analysis

5.3.1. Definitions of Primary Endpoints

There are 4 co-primary endpoints for this study:

- Changes from baseline in the frequency of moderate to severe VMS at Week 4;
- Changes from baseline in the frequency of moderate to severe VMS at Week 12;
- Changes from baseline in the severity of moderate to severe VMS at Week 4;
- Changes from baseline in the severity of moderate to severe VMS at Week 12.

Baseline value of frequency of moderate to severe VMS:

The baseline value will be calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).

Note: participants missed either daytime or nighttime VMS collection at a particular day will be regarded as missing for the day. This rule applies to other VMS missing definition for particular day.

Frequency of moderate to severe VMS during treatment:

The frequency of moderate to severe VMS for each week during the treatment period will be calculated using the available data during that particular week. Specifically, for Week 2 Days 8-

14 will be used, for Week 4 Days 22-28 will be used, for Week 6 Days 36-42, for Week 8 Days 50-56 will be used, for Week 10 Days 64-70 will be used, and for Week 12 Days 78-84 will be used (Day 1 corresponds to start of treatment). These data will be aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week). In case data is missing for more than 2 days within a week, the value for that particular week will be set to missing.

Mean change in frequency of moderate to severe VMS from baseline to Week 4 and Week 12:

This will be calculated as the difference in the mean daily frequency of moderate to severe VMS at Week 4 or Week 12, respectively, from the baseline value of the mean daily frequency of moderate to severe VMS.

Baseline value of severity of moderate to severe VMS:

Baseline severity will be calculated based on the daily mean over 7 days prior to randomization, Daily mean severity for available days will be calculated using a weighed mean method with the following formula:

$$\frac{\text{number of moderate VMS} \times 2 + \text{number of severe VMS} \times 3}{\textit{total number of moderate, and severe VMS episodes on that day}}$$

When no moderate or severe VMS are reported for a particular day, the mean severity for that day will be set to 0.

The baseline value will be calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization.

Severity of VMS during treatment:

Post-baseline severity will be calculated based on the daily mean over 7 days during particular week; Daily mean severity for available days will be calculated using a weighed mean method with the following formula:

$$\frac{\text{number of mild VMS} \times 1 + \text{number of moderate VMS} \times 2 + \text{number of severe VMS} \times 3}{\textit{total number of mild, moderate, and severe VMS episodes on that day}}$$

When no VMS are reported for a particular day, the mean severity for that day will be set to 0.

To obtain the post-baseline severity of VMS during a particular week, the weekly data will be aggregated by averaging the mean daily severity of VMS of the available days during that week.

In case data is missing for more than 2 days within 7 days, the value for that particular week will be set to missing; if data is missing for less than or equal to 2 days, data with non-missing information will be used in the derivation, and formula will be adjusted using the number of non-missing days as denominator.

Similar to the frequency, the severity of VMS for each week during the treatment period will be calculated using the available data during that particular week. Specifically, for Week 2 Days 8-14 will be used, for Week 4 Days 22-28 will be used, for Week 6 Days 36-42, for Week 8 Days 50-56 will be used, for Week 10 Days 64-70 will be used, and for Week 12 Days 78-84 will be used (Day 1 corresponds to start of treatment).

5.3.2. Estimand

5.3.2.1. Primary Estimand

The primary objective of the study is to evaluate the efficacy of GS1-144 for the treatment of moderate to severe VMS. Based on the primary objective, the primary estimands for this study is defined as follows:

Population: postmenopausal women with moderate to severe VMS.

Variables/Endpoints: There are 4 co-primary endpoints:

- Changes from baseline in the frequency of moderate to severe VMS at Week 4;
- Changes from baseline in the frequency of moderate to severe VMS at Week 12;
- Changes from baseline in the severity of moderate to severe VMS at Week 4;
- Changes from baseline in the severity of moderate to severe VMS at Week 12.

The change from baseline will be regarded as 0 in the occurrence of intercurrent events 1 and 2 (see intercurrent events defined below).

Treatments: the following treatments will be administered for different groups:

- GS1-144 30 mg QD
- GS1-144 60 mg QD
- GS1-144 30 mg BID
- Placebo BID

Intercurrent events and corresponding strategies:

1) receiving protocol prohibited concomitant medications prior to Week 4 (Week 12) which impact the efficacy assessment (ICE 1).

2) discontinuing study treatment early due to lack of efficacy prior to Week 4 (Week 12) (ICE 2)

3) discontinuing study treatment early for other reasons prior to Week 4 (Week 12) (ICE 3)

A composite strategy will be used for intercurrent events 1 and 2, data collected after the occurrence of the intercurrent event (for the ICE 1, only value between the initialization of prohibited medication and end of washout period) will be imputed with the baseline value, that is, the value will be regarded as having no change from baseline. A hypothetical strategy will be used for intercurrent event 3, data after occurrence of the intercurrent event will be considered as missing during calculation and handled by Mixed-Effect Model Repeated Measure (MMRM) model assuming missing at random.

Note: the ICEs rule will be handled for post-baseline records based on calculated daily average VMS score during specific week. That is, after calculation of daily average VMS score for specific week:

- For ICE 1, if a specific Week is overlapped with the period of prohibited medication (from initialization of prohibited medication to end of washout period), then values for the specific Week will be handled by the ICEs rule.
- For ICE 2 and 3, if ICEs occurred during a specific Week, then values on or after the specific Week will be handled by the ICEs rules.
- If subject has experienced ICE 1 first and ICE 2/3 later， then value before ICE 2/3 will follow the strategy of ICE 1, value on or after ICE 2/3 handled by ICE 2/3; if subjects experienced ICE 2/3 on or before ICE 1, then value will be handled by the strategy of ICE 2/3 (This rule will also apply to other estimand defined for this study).

The list of prohibited concomitant medications together with the pre-defined washout period for their effect will be reviewed during blind review of the data and finalized prior to unblinding.

Population-level summary: difference of least square mean between active group and placebo group for change from baseline in the mean daily frequency of moderate to severe VMS at Week 4 (Week 12), and active group and placebo group for change from baseline in the mean daily severity of moderate to severe VMS at Week 4 (Week 12).

5.3.2.2. Supplementary Estimands

Following supplementary estimands will be defined:

- Supplementary Estimand 1: All intercurrent events will be handled by composite strategy:

  Data collected after the occurrence of the intercurrent events will be imputed with the baseline value, that is, the value will be regarded as having no change from baseline.

- Supplementary Estimand 2: All intercurrent events will be handled by treatment policy strategy:

  Data collected after occurrence of the intercurrent events will be used if available.

- Supplementary Estimand 3: Hypothetical strategy for ICE 1, other ICEs will be handled with same strategy as primary estimands:

Data after occurrence of ICE 1 (from initialization of prohibited medication to end of washout period) will be considered as missing and handled by Mixed-Effect Model Repeated Measure (MMRM) model assuming missing at random.

5.3.3. Analysis Methods

5.3.3.1. Analysis Method for Primary estimand

Primary analysis method:

The primary analysis will be performed based on FAS.

The frequency and severity of moderate to severe VMS and the change from baseline at Week 4 and Week 12 will be summarized using descriptive statistics.

For each of the 4 co-primary efficacy endpoints, treatment comparison will be performed using an MMRM model, with treatment group, stratification factor BMI (< 28 kg/m^2; ≥ 28 kg/m^2) and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction. The Week included in the MMRM model for primary analysis will include Week 2, Week 4, Week 6, Week 8, Week 10 and Week 12. The Kenward-Roger approximation will be used to estimate denominator degrees of freedom and adjust standard errors. This analysis will use a restricted maximum likelihood–based repeated-measures approach. An unstructured covariance matrix for repeated measures within a participant will be used. In case of lack of convergence, empirical structured covariances will be used in the following order until convergence is reached: 1) Toeplitz 2) first order Autoregressive Moving Average. Treatment

effects will be estimated based on least-square (LS) means of the differences. The p-values for the LS mean differences along with the 2-sided 90% CI will be presented.

Sensitivity analysis methods:

For primary estimand, following sensitivity analysis will be performed:

- Missing values (after handling of ICEs) be imputed by multiple imputation (MI) method. The MI method will be applied as follows:
  1. **For the intermittent missing values**, the missing value will be filled in using the MCMC method with multiple chains, monotone missing data imputing pattern. A total of 100 sets of imputations will be performed. The seed used for these imputations will be 1234 and all other multiple imputation procedures described in this SAP will use this same seed as well.
  2. The resulting 100 imputed data sets will have a monotone missing pattern and will be imputed using a method for monotone missingness:

     monotone regression will be used to impute missing data. The procedure will be based on the 100 imputed datasets generated from the MCMC procedure and will be performed by Imputation. This approach imputes missing data in a sequential manner, for each time point, a regression model based on all available data at this timepoint (either observed or imputed) is fitted and used to impute values still missing at this timepoint. The ancillary variable includes in the model will be treatment group, the stratification factors, and the value of different timepoint. This will be based on 100 sets of imputations.
  3. The SAS® PROC MI procedure will be used for the imputation.
- A tipping point analysis will be applied to assess the sensitivity assuming missing not at random (MNAR), this will be done by applying an unfavorable additive shift (delta adjustment) to the values imputed by the MI method in the GS1-144 arm. For the endpoints related to the frequency of VMS, the adjustments will be applied with delta values of 1,2,3,4,etc. in each successive tipping point iteration until a tipping point is attached. For the endpoints related to severity of VMS, the adjustments will be applied with delta values of 0.2, 0.4, 0.6, etc. in each successive tipping point iteration until a tipping point is attained.
- In case data is missing for more than 3 days within 7 days, the value for that particular week will be set to missing, if data is missing for less than or equal to 3 days, data with non-missing information will be used in the calculation of primary VMS endpoints.
- All collected data within 7 days will be used for VMS primary endpoints calculation
- Sensitivity analysis for mean severity: same as primary analysis, except for the formula of mean severity calculation change as below:

$$\frac{\text{number of mild VMS over 7 days} \times 1 + \text{number of moderate VMS over 7 days} \times 2 + \text{number of severe VMS over 7 days} \times 3}{\textit{total number of mild, moderate, and severe VMS episodes} \text{ over 7 days}}$$

Note: the baseline will not include mild VMS in the formula.

- Analysis for endpoints at Week 4 will be performed based on PPS for Week 4, and analysis for endpoints at Week 12 based on PPS for Week 12. Analysis method will be the same as primary analysis method, except that analysis at Week 4 based on PPS4 will only include Week 2 and Week 4 in the model.

Subgroup analysis

If data allows, the subgroup analysis will be performed for primary endpoints with same ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) will be used for subgroup analysis.

The subgroups for subgroup analysis are defined in Section 5.7.4. Forest plot will be generated to include all subgroups for each of the 4 co-primary endpoints.

5.3.3.2. Analysis Method for Supplementary estimands:

Same analysis method as primary analysis method for the primary estimand will be used for other supplementary estimands.

5.4. Secondary Endpoints Analysis

To evaluate other efficacy of GS1-144 in the treatment of moderate to severe VMS:

- Changes from baseline in the frequency of moderate to severe VMS at each of the other treatment weeks over 12 weeks.
- Changes from baseline in the severity of moderate to severe VMS at each of the other treatment weeks over 12 weeks.
- Percentage decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks.
- Proportions of participants with $\geqslant$50% and 100% decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks.

5.4.1. Definitions of Secondary Endpoints

The percentage change from baseline in the frequency of moderate to severe VMS at each week is derived as follows, using Week 12 as an example:

Percentage change= (VMSweek12 - VMSBL)/ VMSBL

where VMSweek12 and VMSBL are the frequency of moderate and severe VMS at week 12 and baseline, respectively.

- Participants with a percentage change ≤-50% are considered to have a ⩾ 50% reduction from baseline.
- Participant has 100% reduction from baseline if frequency of moderate to severe VMS at specific Week = 0.

5.4.2. Estimands

The components of estimands for secondary endpoints are same as primary estimand except below:

Variables and Population-level Summary:

Variable (Endpoint)	**Population-level Summary**	**ICEs and handling rules**
Changes from baseline in the frequency of moderate to severe VMS at each of the other treatment weeks over 12 weeks	Difference of least square mean between active group and placebo group at each Week	Same as primary estimand except for timepoint change accordingly (e.g., change Week 12 to specific timepoint)
Changes from baseline in the severity of moderate to severe VMS at each of the other treatment weeks over 12 weeks.	Difference of least square mean between active group and placebo group at each Week	Same as primary estimand except for timepoint change accordingly (e.g., change Week 12 to specific timepoint)
Percentage decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks.	Difference of least square mean between active group and placebo group at each Week	Same as primary estimand
Proportions of participants with ⩾50% decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks.	Difference of proportion between active group and placebo group at each Week	ICE1 and 2 will handled by composite strategy, data collected after occurrence of ICEs will be considered as non-responder; ICE3 will be handled by treatment policy, data collected after ICE occurrence will be used if available.
Proportions of participants with 100% decreases from baseline in the frequency of moderate to severe VMS at each treatment week over 12 weeks.	Difference of proportion between active group and placebo group at each Week	ICE1 and 2 will handled by composite strategy, data collected after occurrence of ICEs will be considered as non-responder;

		ICE3 will be handled by treatment policy, data collected after ICE occurrence will be used if available.

5.4.3. Analysis Methods

Analysis will be based on FAS unless otherwise specified.

For continuous endpoints, the same MMRM model as primary analysis method used for primary estimand will be applied, the Week included in the model will include each week from Week 1 to Week 12, with the analysis window specified at 5.1.1. The nominal p-values for the LS mean differences along with the 2-sided 90% CI will be presented. The frequency and severity of moderate to severe VMS and the change from baseline as well as the percentage change (%) from baseline will be summarized using descriptive statistics by treatment group and by week. The change from baseline over time for each endpoint will be shown using line plots for LSMeans together with 90% CIs by treatment group.

For binary endpoint, a CMH stratified by stratification factor BMI (< 28 kg/m^2; ≥ 28 kg/m^2) will be used, the adjusted risk difference between active group and placebo group will be calculated using the common stratified Cochran-Mantel-Haenszel (CMH) test and 90% Mantel-Haenszel CIs will be presented. Participants with missing values (after handling of ICEs) will be considered as non-responder.

No adjustments for multiple comparisons will be made for the secondary endpoints and all p-values will be considered nominal.

5.5. Exploratory Endpoints Analysis

- Scores on participant's Patient Global Impression of Change (PGI-C) in sleep disturbance at Weeks 4/8/12 from baseline.
- Changes from baseline on participant's Patient Global Impression of Severity (PGI-S) in sleep disturbance at Weeks 4/8/12.
- Changes from baseline in modified Kupperman Index at Weeks 4/8/12.
- Changes from baseline in Menopause-Specific Quality of Life (MENQOL) score at Weeks 4/8/12.
- Changes from baseline in sex hormones (other than LH) and sex hormone-binding globulin concentrations at D1 and Weeks 4/8/12.
- Changes from baseline in serum concentrations of bone-specific alkaline phosphatase (BALP), procollagen type I N-propeptide (PINP), and collagen type I C-terminal telopeptide (CTX) at Week 12.

5.5.1. Definition of Endpoints

Patient Global Impression Scale

The Patient Global Impression (PGI) scale, including (a) patient global impression of severity (PGI-S) and (b) patient global impression of change (PGI-C), provides a brief overall assessment before and after starting study treatment. In this study, PGI scales (PGI-S and PGI-C) will be used to evaluate meaningful self-changes over time in sleep disturbance.

The PGI-C asks: Since the start of the study, my overall status is?" The participant can choose from [1] very much improved to [7] very much worse as details below:

1 = Very Much Improved

2 = Much Improved

3 = Minimally Improved

4 = No change

5 = Minimally Worse

6 = Much Worse

7 = Very Much worse

The PGI-S asks the participant to choose none to very severe that best describes the severity of the participant's overall status over the past week. The scoring method is as below:

1 = None

2 = Mild

3 = Moderate

4 = Severe

5 = Very severe

Modified Kupperman Index

The modified Kupperman Index (see protocol 12.6) provides a brief assessment of comprehensive menopausal symptoms before and after the initiation of study treatment, covering 13 most common perimenopausal symptoms; the 13 items (weighting factor) include: sweating hot flushes (4), paresthesia (2), insomnia (2), irritability (2), melancholia (1), vertigo (1), fatigue (1), myalgia, arthralgia (1), headache (1), heart palpitation (1), formication (1), sexual pain (2), and urinary system symptoms (2). Participant's symptom scores for each item range from (0) None or Normal to (3) Severe symptoms, and the total score is the weighted sum of the weighting factor, ranging

from 0 to 63 and classified as "normal" (total score of < 6), "mild" (total score 6-15), "moderate" (total score 16-30), and severe (total score >30), where a higher total score would indicate more severe menopause-related symptoms.

MENQOL score

The MENQOL questionnaire (see protocol 12.7) is a 29-item Pro measure that assesses the impact of 4 domains of menopausal symptoms, as experienced over the last week: vasomotor (items 1 to 3), psychosocial (items 4 to 10), physical (items 11 to 26) and sexual (items 27 to 29). Items pertaining to a specific symptom are rated as present or not present, and if present, how bothersome on a zero (not bothersome) to 6 (extremely bothersome) scale.

The raw data scores for each of the above items should be converted as described below for further analysis, and the converted score ranges from 1 to 8 points.

Participant response	Analysis score
No	1
0	2
1	3
2	4
3	5
4	6
5	7
6	8

The score for each domain is calculated by the mean of the items contained in each, ranging from 1 to 8 points. The overall questionnaire score is the mean of the domain means. Higher scores represent more bothersome menopausal symptoms.

5.5.2. Analysis Methods

All exploratory endpoints will be analyzed based on observed data, missing values will not be imputed.

PGI-C and PGI-S

Absolute values of the PGI-C will be summarized using descriptive statistics by treatment group and scheduled visit. In addition, the similar approach as primary analysis method (MMRM incorporating post-baseline data collected up to Week 12, with treatment group, stratification factor BMI (< 28 kg/m^2; ≥ 28 kg/m^2), week as factors, as well as treatment by week interaction) will be used to provide estimates of the absolute values at Week 4/8/12. The answers to PGI-C items will also be summarized in frequency tables for each post-baseline visit by treatment group.

Absolute and changes from baseline values of the PGI-S will be summarized using descriptive statistics by treatment group and scheduled visit. In addition, the similar approach as primary analysis method (MMRM incorporating post-baseline data collected up to Week 12) will be used to provide estimates of the changes from baseline at Week 4/8/12. The PGI-S items will be summarized accordingly in frequency tables for baseline and each post-baseline visits by treatment groups. The change from baseline in PGI-S individual scores will be analyzed using shift tables (observed frequencies at baseline versus post-baseline weeks).

Modified Kupperman Index

Absolute and changes from baseline values of the total score will be summarized using descriptive statistics by treatment group and scheduled visit. In addition, the same approach as primary analysis method (MMRM incorporating post-baseline data collected up to Week 12) will be used to provide estimates of the changes from baseline at Week 4/8/12. The category "normal" (total score of < 6), "mild" (total score 6-15), "moderate" (total score 16-30), and severe (total score >30) will be summarized accordingly in frequency tables for baseline and each post-baseline visits by treatment groups, and shift table will be provided for frequencies at baseline versus post-baseline weeks.

MENQOL score

For the 4 domain scores and the overall score, absolute and changes from baseline will be summarized using descriptive statistics by treatment group and scheduled visit. In addition, the same approach as primary analysis method (MMRM incorporating post-baseline data collected up to Week 12) will be used to provide estimates of the change from baseline to Week 4/8/12.

Other Exploratory Endpoints

Absolute and changes from baseline will be summarized using descriptive statistics by treatment group and scheduled visit. For sex hormones (other than LH) and sex hormone-binding globulin concentrations, mean concentration-time curves (for both absolute value and change from baseline) will be plotted based on the nominal blood sampling time points.

5.6. Safety Analyses

All safety analyses will be based on the safety analysis set based on actual treatment received, unless otherwise specified.

5.6.1. Extent of Exposure

Unless otherwise specified, the analysis of extent of exposure will be summarized based on SS.

Treatment duration will be defined as the number of days from the day of first study drug intake up to and including the day of last study drug intake and will be summarized using descriptive statistics by treatment group.

The extent of exposure will be summarized as the cumulative dose and the average daily dose in mg using descriptive statistics per treatment group. For Placebo group, the cumulative dose and average daily dose is 0. For GS1-144 groups, the cumulative dose (mg) will be calculated as below:

- For GS1-144 30 mg QD group, the cumulative dose (mg)= (number of tablets taken / 4) * 30
- For GS1-144 60 mg QD group, the cumulative dose (mg)= (number of tablets taken / 2) * 30
- For GS1-144 30 mg BID group, the cumulative dose (mg)= (number of tablets taken / 2) * 30

The average daily dose (mg/day) = The cumulative dose (mg) / Treatment Duration in Days.

The above analysis will be performed for time up to Week 4 (Day 28) and Week 12 (day of last treatment) separately.

The treatment compliance (%) was defined in appendix 7, which will be summarized based on FAS.

5.6.2. Adverse Events

AEs will be coded with the Medical Dictionary for Regulatory Activities (MedDRA). Any AEs occurring at or after the initial administration of study treatment or that are a consequence of a preexisting condition that has worsened after first study treatment is considered to be treatment emergent adverse events (TEAEs). If the event occurs on the day of the initial study treatment, the event will be assumed to be treatment emergent if the item "Did it occur prior to first dose?" at eCRF "Adverse Event" page is answered as "No". If the event date is recorded as partial or completely missing, then the event will be considered to be treatment emergent unless it is known to be prior to the first administration of study treatment based on partial onset date or resolution date. All reported treatment-emergent adverse events will be included in the analysis.

Relationship to study treatment is indicated as "Related" or "Unrelated" by investigators. TEAEs with missing relationship to study treatment will be regarded as 'Related' to study treatment.

The number and percentage of participants with any TEAEs (and number of TEAEs), treatment-related adverse events (TRAEs), procedure-related adverse events, treatment emergent serious adverse events (SAEs), treatment-related serious adverse events, TEAEs leading to drug interruption and TEAEs leading to drug withdrawn will be summarized and analyzed as classified by SOC and PT by treatment groups. Descriptive analysis for adverse events will include but not limited to:

- Any TEAEs summarized by SOC and PT
- Severity of TEAEs summarized by SOC and PT
- Severe TEAEs summarized by SOC and PT
- Any TRAEs summarized by SOC and PT

- Severity of TRAEs summarized by SOC and PT
- Severe TRAEs summarized by SOC and PT
- Severity of procedure-related AEs summarized by SOC and PT
- Any treatment emergent SAEs and treatment-related SAEs summarized by SOC and PT
- Severity of treatment emergent SAEs and treatment-related SAEs summarized by SOC and PT
- All TEAEs and TRAEs leading to drug interruption summarized by SOC and PT
- All TEAEs and TRAEs leading to drug withdrawn summarized by SOC and PT
- All TEAEs and TRAEs leading to drug interruption summarized by Severity by SOC and PT
- All TEAEs and TRAEs leading to drug withdrawn summarized by Severity by SOC and PT

In order to identify potential drug-induced liver injury, the TEAE of special interest (AESI) of hepatotoxic events are classified according to PT (see Appendix 8) and will be summarized by treatment group. Descriptive analysis for AESI will include but not limited to:

- Any AESIs and drug-related AESIs summarized by SOC and PT
- Severity of AESIs and drug-related AESIs summarized by SOC and PT
- Any serious AESIs and drug-related serious AESIs summarized by SOC and PT
- Severity of serious AESIs and drug-related serious summarized by SOC and PT
- All AESIs and serious AESIs leading to drug interruption summarized by Severity by SOC and PT
- All AESIs and serious AESIs leading to drug withdrawn summarized by Severity by SOC and PT

For each participant and each adverse event, the worst severity recorded will be attributed and used in the by-severity summaries.

In addition to the summary tables, listings will be provided for:

- Any AEs
- Any SAEs
- Severe TEAEs
- TEAE of special interest - All hepatotoxic events
- TEAEs leading to drug withdrawn
- TEAEs leading to drug interruption
- AE leading to death

5.6.3. Additional Safety Assessments

5.6.3.1. Clinical Laboratory Tests

For continuous clinical laboratory parameters, including hematology, blood chemistry, coagulation function, thyroid function, and parathyroid function, the descriptive statistics of the observed value and change from baseline will be provided by treatment groups and time point for each parameter. Each clinical laboratory result will be classified as normal (N), or abnormal and clinically significant (CS), abnormal but not clinically significant (NCS), a shift table to compare the laboratory result at baseline versus result at each post-baseline visit and worst post-baseline result will be produced (note: unless otherwise specified, the shift table will base on subjects with non-missing values at both baseline and specific visit, this rule also applies to other safety shift tables). The worst result according to the degree of clinically significance from high to low is: abnormal, clinically significant > abnormal, not clinically significant > normal.

If a lab test result is recorded as "<10", then it will be summarized as a value of "10", if applicable; and likewise, ">10" will be summarized as "10".

Data listings will be provided for all laboratory test results. Separate listings will be provided for participants with significant abnormal values.

Hepatotoxic events will be analyzed based on liver function parameters in laboratory tests. Liver function parameters of interest are ALT, AST, TBIL, γ -GGT, ALP and INR. Grading of laboratory values of liver function parameters will be assigned programmatically as National Cancer Institute (NCI) CTCAE version 5.0 (see Appendix 9). CTCAE Grade 0 will be assigned for all non-missing values not graded as 1 or higher. Grade 5 will not be used.

For the above liver function parameters, shift tables using CTCAE grades to compare baseline with the worst post-baseline grades will be produced by treatment groups. The number and percentage of patients with baseline values and the worst post-baseline values will be summarized by treatment groups, with the worst value being the highest value for each parameter.

Baseline value categories will include but not limited to:

- ALT or AST > 1×Upper Limit of Normal (ULN) to ≤ 1.5 × ULN
- ALT or AST > 1.5 × ULN
- TBIL > 1 × ULN to ≤ 1.5 × ULN
- TBIL > 1.5 × ULN

The worst post-baseline value categories will include but not limited to:

- ALT > 8 × ULN
- ALT > 5 × ULN
- ALT > 3 × ULN
- ALT > 2 × ULN
- ALT > 1.5 × ULN

- AST > 8 × ULN
- AST > 5 × ULN

- AST > 3 × ULN
- AST > 2 × ULN
- AST > 1.5 × ULN

- ALT or AST > 20 × ULN
- ALT or AST > 10 × ULN
- ALT or AST > 8 × ULN
- ALT or AST > 5 × ULN
- ALT or AST > 3 × ULN
- TBIL > 2 × ULN
- ALP > 2 × ULN
- (ALT or AST > 3 × ULN) and (TBIL > 1.5 × ULN)
- (ALT or AST > 3 × ULN) and (TBIL > 2 × ULN or INR>1.5)

The observed value and change from baseline over time for AST, ALT, ALP and TBIL will be shown using line plots for Mean (+/- SD) by treatment group.

Data listing will be provided for all visits where the worst post-treatment value meets the classification criteria above.

5.6.3.2. Vital Signs and Physical Examination Findings

Vital signs parameters include ear temperature, pulse rate, systolic blood pressure and diastolic blood pressure. Descriptive statistics of observed value and change from baseline will be presented for vital signs by scheduled visit. A shift table to compare the vital signs result at baseline versus result at each post-baseline visit and worst post-baseline result will be produced. The worst result according to the degree of clinically significance from high to low is abnormal, clinically significant > abnormal, not clinically significant > normal.

Physical examination includes a review of skin and mucous membranes, lymph nodes, head, neck, chest, abdomen, muscle and bone/limbs, and nervous system. A shift table to compare the physical examination result at baseline versus worst post-baseline result will be produced by body system. The worst result according to the degree of clinically significance from high to low is abnormal, clinically significant > abnormal, not clinically significant > normal.

All vital signs and physical examination data will be listed by participant and visit.

Separate listings will be provided for participants with significant abnormal values.

5.6.3.3. 12-Lead Electrocardiogram

The following ECG parameters will be included: RR interval, PR interval, QRS duration, QT interval, and QTcF interval. ECG parameters will be examined for trends using descriptive statistics of observed value and change from baseline for each post-baseline visit over time. A shift table to compare the interpretation result at baseline versus result at each post-baseline visit and worst post-baseline result will be produced. The worst result according to the degree of clinically

significance from high to low is: abnormal, clinically significant > abnormal, not clinically significant > normal.

Note: the baseline value for ECG parameters will use the average value of last two measurements prior to first study treatment, the interpretation will use the worst result of the two measurements. If only one assessment was taken prior to first study treatment, then it will be considered as baseline.

The number and percentage of patients will be summarized by treatment groups for each post-treatment visit and worst values (based on maximum observed value), categorized as follows:

- QTcF
  - ≤ 450 msec
  - > 450 to ≤ 480 msec
  - > 480 to ≤ 500 msec
  - > 500 msec
- QTcF change from baseline
  - ≤ 0 msec
  - > 0 to ≤ 30 msec
  - > 30 to ≤ 60 msec
  - > 60 msec

All 12-lead ECG data will be listed by participant and visit.

Separate listings will be provided for participants with significant abnormal values.

5.6.3.4. Other Safety Parameters

Listing of other safety data collected in eCRF will be presented by participant level. In addition, following summary analysis will be performed:

- **Breast Ultrasound**
  - ✓ A shift table to compare the result (Normal, NCS, CS) at baseline versus result at Week 12 will be produced by body system/organ.
  - ✓ BI-RADS Category will be summarized at baseline and Week 12.
- **Transvaginal Ultrasound (TVU) and Endometrial biopsy**
  - ✓ A shift table to compare the result (Normal, NCS, CS) of TVU at baseline versus result at Week 12 will be produced by body system/organ.
  - ✓ Endometrial thickness will be summarized at baseline and Week 12. The result (Normal, NCS, CS) of endometrial biopsy will be summarized at baseline and Week 12 (based on subjects with endometrial thickness >4 mm).

5.7. Other Analyses

5.7.1. Pharmacokinetics

Descriptive statistical analysis will be performed for the PK concentrations, including arithmetic mean, standard deviation, coefficient of variation, median, maximum, minimum, geometric mean, and geometric coefficient of variation, etc. For descriptive statistical analysis of PK concentrations, the mean, SD, and CV will be calculated only if at least two-thirds of the individual data at a time point equal to or higher than the LLOQ, otherwise, only the minimum and maximum values will be reported (pre-dose was not applicable for the above rules). Only mean, SD, minimum and maximum values will be reported for the pre-dose time points. Plasma concentration-time profiles (linear) will be plotted by the nominal blood sampling time points and either individual or mean concentrations. One or more values below the LLOQ occur in a profile before the first measurable concentration will be assigned a value of zero concentration; other values below the LLOQ will be set as missing.

5.7.2. Pharmacodynamics

Serum LH concentration and change from baseline will be summarized by each planned blood sampling time point and actual treatment group with descriptive statistics, including arithmetic mean, standard deviation, coefficient of variation, median, maximum, minimum, geometric mean, and geometric coefficient of variation, etc. Mean observed maximum change from baseline (the smallest negative value of the change from baseline) and mean maximum percentage of changes from baseline (absolute maximum change from baseline/baseline) for serum LH will be summarized by treatment and visit. Individual and mean LH concentration-time curves will be plotted based on the nominal blood sampling time points.

5.7.3. PopPK Analysis and Dose-Response Analysis

The plan and details for PopPK and dose-response analysis will be provided in separate documents.

5.7.4. Definition of Subgroups

Subgroup	Variant	Definition
Age Group	1	• <55 • >=55
BMI	1	• normal 18.5-<24 kg/m^2 • overweight 24-<28 kg/m^2 • obese >=28 kg/m^2
	2	• <28 kg/m^2 • >=28 kg/m^2
Smoking Status	1	• current • former/never
Baseline Moderate to Severe VMS Frequency	1	• <=12 • >12
	2	• <=10

Subgroup	Variant	Definition
		• >10 to <=13 • >13

5.8. Interim Analyses

To assist a timely internal decision making and adjustment to the development of the program, an interim analysis is planned after all randomized participants have completed the Week 4 visit (or participant's discontinuation/withdrawal from the study treatment earlier than that). To maintain the integrity of the blind, interim analysis will be performed by an independent un-blinded team, and the unblinded results will be restricted to a very small group independent of study team; details will be documented in a separate charter to ensure the integrity of the study blinding maintenance.

The interim analysis will mainly be focused on following major efficacy endpoints and safety endpoints analysis (include data up to Week 4 for each participant):

- Demographic and baseline characteristics
- Participant Disposition prior to Week 4
- Prior and concomitant medications within Week 4 treatment period
- Extent of exposure and treatment compliance prior to Week 4
- Co-primary endpoints at Week 4
- VMS frequency and severity change from baseline at each week through Week 4
- Selected analysis for adverse events occurrence within Week 4 treatment period
- Summaries of Liver function parameters in laboratory tests within Week 4 treatment period
- Selected other important safety analysis

5.9. Data Safety Monitoring Board (DSMB)

Safety monitoring for this study will be performed by an independent DSMB. The DSMB is responsible for performing regular safety reviews. The DSMB will be independent of the sponsor and has the right to recommend suspension of the study or termination of a dose for safety reasons at any time. The DSMB will perform safety data review based on the cumulative summary tables and/or listings of AEs, SAEs, clinical laboratory results, concomitant medications, medical histories, and study treatments. The analysis details will be provided in the separate DSMB SAP. After the review, the DSMB will advise the sponsor on whether to continue the study (or terminate a certain dose), and the sponsor will make decisions based on the DSMB's advice.

DSMB members will be selected based on their experience in clinical trial methodology and/or the disease area. The DSMB Charter will include specific information on the pre-specified

frequency of safety reviews, the data required for reviews, and the procedure for negotiating with the sponsor.

6. SUPPORTING DOCUMENTATION

6.1. Appendix 1 List of Abbreviations

AE	Adverse Event
AESI	Adverse Event of Special Interest
ALP	Alkaline Phosphatase
ALT/SGPT	Alanine Aminotransferase
ANCOVA	Analysis of Covariance
AST/SGOT	Aspartate Aminotransferase
ATC	Anatomic and Therapeutic Class
AUC	Area Under the Curve
BALP	Bone-Specific Alkaline Phosphatase
BID	Twice Daily
BMI	Body Mass Index
BQL	Below the Quantification Limit
BSA	Body Surface Area
CI	Confidence Interval
CL	Total Systemic Clearance
CMH	Cochran-Mantel-Haenszel Test
CRF	Case Report Form
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
CTX	Cross Linked C-telopeptide of Type Ⅰ Collagen
CV	Coefficient of Variation
DSMB	Data Safety Monitoring Board
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
ED	Early Discontinuation
EOT	End of Treatment
FAS	Full Analysis Set
FDA	Food and Drug Administration
ICH	International Conference on Harmonisation
ICE	Intercurrent Events
LH	Luteinizing Hormone
LLOQ	Lower Limit of Quantification
LOCF	Last Observation Carried Forward
LS Mean	Least Square Mean
MedDRA	Medical Dictionary for Regulatory Activities
MENQOL	Menopause-Specific Quality-of-Life
MI	Multiple Imputation
MMRM	Mixed-Effect Model Repeated Measure
M0	Metabolite
NCS	Not Clinically Significant
PD	Pharmacodynamics
PDAS	Pharmacodynamic Analysis Set
PGI	Patient Global Impression
PGI-C	Patient Global Impression of Change
PGI-S	Patient Global Impression of Severity
PI	Principal Investigator
PINP	Type Ⅰ procollagen N-terminal peptide
PK	Pharmacokinetics

PKAS	Pharmacokinetic Analysis Set
PopPK	Population Pharmacokinetics
PPS	Per Protocol Set
PT	Preferred Term
QD	Once Daily
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SMQs	Standardised MedDRA Queries
SOC	System Organ Class
SS	Safety Set
TEAE	Treatment-Emergent Adverse Event
TVU	Transvaginal Ultrasound
ULN	Upper Limit of Normal
VMS	Vasomotor Symptoms
WHO-DD	World Health Organization Drug Dictionary

6.2. Appendix 2 Changes to Protocol-Planned Analyses

Not applicable.

6.3. Appendix 3 Demographics and Baseline Characteristics

Demographic variables and baseline characteristics that will be summarized by treatment group, and overall for the FAS and PPS.

Demographic and baseline assessments to be summarized will include:

- Age (at inclusion),
- Ethnicity (The Han Nationality, and Other),
- Categorized age (<55, >=55)
- Weight (kg), height (cm), body mass index (BMI; kg/m^2)
- Categorized BMI (<28 kg/m^2, >=28 kg/m^2; 18.5-<24 kg/m^2, 24-<28 kg/m^2, >=28 kg/m^2)
- Smoking history (Never, Former, Current; Former/never, Current)

A listing will be provided for above demographic and baseline assessments based on FAS.

In addition, the distribution of participants by site ID will be presented unless otherwise noted (based on FAS).

6.4. Appendix 4 Protocol Deviations

Participants with important protocol deviations will be identified prior to database lock, important deviations from the protocol and the resulting assignment of participants to the analysis sets (see Section 4) are agreed upon in the blind review meeting (BRM). The participants with important protocol deviations will be summarized by category and listed.

6.5. Appendix 5 Prior and Concomitant Medications/therapy

- A prior medication/non-drug therapy is defined as any medication/non-drug therapy that ended prior to the date of the initial dose; a concomitant medication/non-drug therapy is defined as any medication/non-drug therapy that is either ongoing or has ended at or after the date of initial dose.

- All medications will be coded using the latest version of WHO-DD. Prior and concomitant medications will be summarized by treatment group, presenting the number and percentage of participants by the Anatomical Therapeutic Chemical (ATC) classification system and the preferred name (PN); each participant could have medications under multiple ATC Level 3 groups and/or multiple preferred drug names, but each participant will be counted only once within each ATC Level 2 group and preferred name class.
- Prior and concomitant non-drug therapy will be summarized by treatment group, presenting the number and percentage of participants by the System Organ Class (SOC) and the Preferred Term (PT); each participant could have treatments under multiple SOCs and/or PTs, but each participant will be counted only once within each SOC and PT. If any PT is linked to multiple SOCs, the primary SOC will be used for summarization.

  The above analysis will be performed based on FAS.

6.6. Appendix 6 Medical History

Medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). All medical history will be listed, and the number and percentage of participants with any medical history will be summarized for the FAS by system organ class (SOC) and preferred term (PT) for each treatment group.

6.7. Appendix 7 Treatment Compliance

The compliance (as percentage) will be calculated as:

100 * Number of tablets taken / Number of planned tablets

The number of planned tablets is calculated as: treatment duration * 4. All tablets, including the placebo tablets, will be counted.

For participants who withdraw prematurely from the study drug, compliance will be calculated up to the time of last dose. The compliance will be summarized descriptively by treatment group. In addition, percentage of compliance will be categorized into 3 groups, less than 80%, 80 to 120% and greater than 120%, and the categories will be summarized by treatment group.

The above analysis will be performed for time up to Week 4 (Day 28) and Week 12 (day of last treatment) separately.

6.8. Appendix 8 Adverse Events of Special Interest

Adverse events of special interest are defined as follows:

AE Special Interest Category	MedDRA Preferred Term
Hepatotoxic Events	Hepatic function abnormal, Liver function test abnormal, Hepatic enzyme abnormal, Hepatic enzyme increased, Alanine aminotransferase abnormal, Alanine aminotransferase increased, Ammonia abnormal, Ammonia increased, Aspartate aminotransferase abnormal, Aspartate aminotransferase increased, Blood bilirubin increased, Bilirubin conjugated increased, Bilirubin conjugated abnormal, Blood bilirubin unconjugated increased, Blood bilirubin unconjugated increased, Hyperbilirubinaemia, Gamma-glutamyltransferase abnormal, Gamma-glutamyltransferase increased, Hepatocellular injury, Drug-induced liver injury, Suspected drug-induced liver injury, Hepatic failure, Acute hepatic failure, Liver injury, Transaminases increased, Transaminases abnormal

6.9. Appendix 9 Laboratory Toxicity Grading

The grading scale use for lab assessments is based on 'Common Terminology Criteria for Adverse Events (CTCAE) v5.0'.

In case a test has two sets of ranges – one for baseline normal and one for baseline abnormal, the one for baseline normal will be applied for all measurements taken on baseline.

Investigations					
CTCAE Term	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Alanine aminotransferase increased	>ULN -3.0 x ULN if baseline was normal; 1.5 -3.0 x baseline if baseline was abnormal	>3.0 -5.0 x ULN if baseline was normal; >3.0-5.0 x baseline if baseline was abnormal	>5.0 -20.0 x ULN if baseline was normal; >5.0-20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	-
Definition: A finding based on laboratory test results that indicate an increase in the level of alanine aminotransferase (ALT or SGPT) in the blood specimen.					
Aspartate aminotransferase increased	>ULN -3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 -5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 -20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	-
Definition: A finding based on laboratory test results that indicate an increase in the level of aspartate aminotransferase (AST or SGOT) in a blood specimen.					
Blood bilirubin increased	>ULN - 1.5 x ULN if baseline was normal; >1.0 - 1.5 x baseline if baseline was abnormal	>1.5 - 3.0 x ULN if baseline was normal; > 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 10.0 x ULN if baseline was normal; > 3.0 - 10.0 x baseline if baseline was abnormal	> 10.0 x ULN if baseline was normal; > 10.0 x baseline if baseline was abnormal	-
Definition: A finding based on laboratory test results that indicate an abnormally high level of bilirubin in the blood. Excess bilirubin is associated with jaundice					
Alkaline phosphatase increased	>ULN - 2.5 x ULN if baseline was normal; 2.0 - 2.5 x baseline if baseline was abnormal	> 2.5 – 5.0 x ULN if baseline was normal; > 2.5 – 5.0 x baseline if baseline was abnormal	>5.0 -20.0 x ULN if baseline was normal: >5.0-20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal: >20.0 x baseline if baseline was abnormal	-
Definition: A finding based on laboratory test results that indicate an increase in the level of alkaline phosphatase in a blood specimen.					
GGT increased	>ULN -2.5 x ULN if baseline was normal; 2.0 -2.5 x baseline if baseline was abnormal	>2.5 -5.0 x ULN if baseline was normal; >2.5 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; > 5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; > 20.0 x baseline if baseline was abnormal	-
Definition: A finding based on laboratory test results that indicate higher than normal levels of the enzyme gamma-glutamyltransferase in the blood specimen. GGT (gamma-glutamyltransferase) catalyzes the transfer of a gamma glutamyl group from a gamma glutamyl peptide to another peptide, amino acids or water.					

* Grade 0 is assigned to a lab assessment when the lab test is described in the table, but the lab value is not assigned a grade 1 or higher.

7. REFERENCES

Not applicable

Protocol: GenSci074-201

Data Extract: 2025-05-15

Contents

Table 14.1.1.1
Subject Enrollment and Disposition
All Screened Subjects

	Placebo	GS1-144 30 mg QD	GS1-144 60 mg QD	GS1-144 30 mg BID	Combined GS1-144	Overall
All Screened Subjects	NA	NA	NA	NA	NA	615
Screen Failure	NA	NA	NA	NA	NA	339
Eligibility Criteria Not Met	NA	NA	NA	NA	NA	326
Withdrawal By Subject	NA	NA	NA	NA	NA	13
Adverse Event or Serious Adverse Event	NA	NA	NA	NA	NA	0
Other	NA	NA	NA	NA	NA	0
Enrolled	NA	NA	NA	NA	NA	276
Randomized, n (%)	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)
Not Dosed	0	0	0	0	0	0
Dosed	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)

Data Source: Listing 16.2.1.1, Listing 16.2.1.2, Listing 16.2.1.3

All Screened Subjects, re-screened subjects were counted only once. Percentages were based on the number of randomized subjects.

SS: all subjects who have taken at least one dose of the investigational products.

FAS: including all subjects who have been randomized and used at least one dose of the investigational products.

PPS4: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 4.

PPS12: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 12.

PKAS: including all subjects who have received at least one dose of GS1-144 and have evaluable PK measurements.

PDAS: including all subjects who have at least one pre-dose and post-dose LH concentration.

Table 14.1.1.1
Subject Enrollment and Disposition
All Screened Subjects

	Placebo	GS1-144 30 mg QD	GS1-144 60 mg QD	GS1-144 30 mg BID	Combined GS1-144	Overall
Completed Treatment before Week 4, n (%)	67 (97.1)	69 (98.6)	67 (97.1)	68 (100)	204 (98.6)	271 (98.2)
Discontinued Treatment before Week 4, n (%)	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
Meet the treatment discontinuation criteria for hepatic events	0	0	0	0	0	0
Meet the treatment discontinuation criteria for QTc	0	0	0	0	0	0
For safety reasons, treatment discontinued as per the investigator's opinion	0	0	0	0	0	0
Lack of Efficacy	0	0	0	0	0	0
Development of a medical condition that requires concomitant treatment with a prohibited therapy	0	0	0	0	0	0
Participants who have poor compliance, are not able to comply with the trial protocol during the trial, and are deemed inappropriate by the investigator to continue in the trial	0	0	0	0	0	0
Emergency Unblinding	0	0	0	0	0	0
Withdrawal By Subject	2 (2.9)	0	2 (2.9)	0	2 (1.0)	4 (1.4)
Lost to Follow-up	0	0	0	0	0	0
Death	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0
Other	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.1.1, Listing 16.2.1.2, Listing 16.2.1.3

All Screened Subjects, re-screened subjects were counted only once. Percentages were based on the number of randomized subjects.

SS: all subjects who have taken at least one dose of the investigational products.

FAS: including all subjects who have been randomized and used at least one dose of the investigational products.

PPS4: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 4.

PPS12: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 12.

PKAS: including all subjects who have received at least one dose of GS1-144 and have evaluable PK measurements.

PDAS: including all subjects who have at least one pre-dose and post-dose LH concentration.

Table 14.1.1.1
Subject Enrollment and Disposition
All Screened Subjects

	Placebo	GS1-144 30 mg QD	GS1-144 60 mg QD	GS1-144 30 mg BID	Combined GS1-144	Overall
Completed the Study Treatment, n (%)	64 (92.8)	66 (94.3)	65 (94.2)	63 (92.6)	194 (93.7)	258 (93.5)
Discontinued the Study Treatment, n (%)	5 (7.2)	4 (5.7)	4 (5.8)	5 (7.4)	13 (6.3)	18 (6.5)
Meet the treatment discontinuation criteria for hepatic events	0	0	0	0	0	0
Meet the treatment discontinuation criteria for QTc	0	0	0	0	0	0
For safety reasons, treatment discontinued as per the investigator's opinion	2 (2.9)	2 (2.9)	0	1 (1.5)	3 (1.4)	5 (1.8)
Lack of Efficacy	0	0	0	0	0	0
Development of a medical condition that requires concomitant treatment with a prohibited therapy	0	0	0	0	0	0
Participants who have poor compliance, are not able to comply with the trial protocol during the trial, and are deemed inappropriate by the investigator to continue in the trial	0	0	0	0	0	0
Emergency Unblinding	0	0	0	0	0	0
Withdrawal By Subject	3 (4.3)	0	4 (5.8)	4 (5.9)	8 (3.9)	11 (4.0)
Lost to Follow-up	0	0	0	0	0	0
Death	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0
Other	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)

Data Source: Listing 16.2.1.1, Listing 16.2.1.2, Listing 16.2.1.3

All Screened Subjects, re-screened subjects were counted only once. Percentages were based on the number of randomized subjects.

SS: all subjects who have taken at least one dose of the investigational products.

FAS: including all subjects who have been randomized and used at least one dose of the investigational products.

PPS4: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 4.

PPS12: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 12.

PKAS: including all subjects who have received at least one dose of GS1-144 and have evaluable PK measurements.

PDAS: including all subjects who have at least one pre-dose and post-dose LH concentration.

Table 14.1.1.1
Subject Enrollment and Disposition
All Screened Subjects

	Placebo	GS1-144 30 mg QD	GS1-144 60 mg QD	GS1-144 30 mg BID	Combined GS1-144	Overall
Completed the Study, n (%)	64 (92.8)	68 (97.1)	66 (95.7)	63 (92.6)	197 (95.2)	261 (94.6)
Discontinued the Study, n (%)	5 (7.2)	2 (2.9)	3 (4.3)	5 (7.4)	10 (4.8)	15 (5.4)
Withdrawal By Subject	5 (7.2)	1 (1.4)	3 (4.3)	4 (5.9)	8 (3.9)	13 (4.7)
Lost to Follow-up	0	0	0	0	0	0
Death	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0
Other	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Safety Set (SS), n (%)	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)
Full Analysis Set (FAS), n (%)	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)
Per Protocol Set at Week 4 (PPS4), n (%)	66 (95.7)	67 (95.7)	66 (95.7)	65 (95.6)	198 (95.7)	264 (95.7)
Per Protocol Set at Week 12 (PPS12), n (%)	63 (91.3)	64 (91.4)	65 (94.2)	60 (88.2)	189 (91.3)	252 (91.3)
Pharmacokinetic Analysis Set (PKAS), n (%)	0	70 (100)	69 (100)	68 (100)	207 (100)	207 (75.0)
Pharmacodynamic Analysis Set (PDAS), n (%)	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)

Data Source: Listing 16.2.1.1, Listing 16.2.1.2, Listing 16.2.1.3

All Screened Subjects, re-screened subjects were counted only once. Percentages were based on the number of randomized subjects.

SS: all subjects who have taken at least one dose of the investigational products.

FAS: including all subjects who have been randomized and used at least one dose of the investigational products.

PPS4: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 4.

PPS12: a subset of the FAS including all subjects with valid primary endpoint data, good compliance and no important protocol deviations impacting primary endpoint evaluation at Week 12.

PKAS: including all subjects who have received at least one dose of GS1-144 and have evaluable PK measurements.

PDAS: including all subjects who have at least one pre-dose and post-dose LH concentration.

Table 14.1.1.2
Subject Disposition by Site
FAS

Site ID	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
001	4 (5.8)	3 (4.3)	3 (4.3)	0	6 (2.9)	10 (3.6)
002	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
003	2 (2.9)	1 (1.4)	3 (4.3)	0	4 (1.9)	6 (2.2)
004	1 (1.4)	0	0	2 (2.9)	2 (1.0)	3 (1.1)
005	3 (4.3)	0	3 (4.3)	0	3 (1.4)	6 (2.2)
006	1 (1.4)	6 (8.6)	1 (1.4)	2 (2.9)	9 (4.3)	10 (3.6)
007	0	3 (4.3)	2 (2.9)	3 (4.4)	8 (3.9)	8 (2.9)
008	2 (2.9)	1 (1.4)	3 (4.3)	3 (4.4)	7 (3.4)	9 (3.3)
009	5 (7.2)	1 (1.4)	3 (4.3)	3 (4.4)	7 (3.4)	12 (4.3)
010	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
011	2 (2.9)	1 (1.4)	3 (4.3)	1 (1.5)	5 (2.4)	7 (2.5)
012	0	3 (4.3)	2 (2.9)	0	5 (2.4)	5 (1.8)
013	2 (2.9)	0	2 (2.9)	1 (1.5)	3 (1.4)	5 (1.8)
014	2 (2.9)	0	1 (1.4)	0	1 (0.5)	3 (1.1)
015	0	2 (2.9)	1 (1.4)	2 (2.9)	5 (2.4)	5 (1.8)
016	0	0	2 (2.9)	2 (2.9)	4 (1.9)	4 (1.4)
017	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
018	4 (5.8)	1 (1.4)	0	2 (2.9)	3 (1.4)	7 (2.5)
019	2 (2.9)	3 (4.3)	2 (2.9)	2 (2.9)	7 (3.4)	9 (3.3)
020	2 (2.9)	1 (1.4)	3 (4.3)	1 (1.5)	5 (2.4)	7 (2.5)
021	2 (2.9)	2 (2.9)	0	1 (1.5)	3 (1.4)	5 (1.8)
022	0	2 (2.9)	3 (4.3)	2 (2.9)	7 (3.4)	7 (2.5)

Data Source: Listing 16.2.1.3

Table 14.1.1.2
Subject Disposition by Site
FAS

Site ID	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
023	2 (2.9)	3 (4.3)	3 (4.3)	2 (2.9)	8 (3.9)	10 (3.6)
024	3 (4.3)	3 (4.3)	2 (2.9)	2 (2.9)	7 (3.4)	10 (3.6)
025	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
026	0	3 (4.3)	1 (1.4)	2 (2.9)	6 (2.9)	6 (2.2)
027	1 (1.4)	2 (2.9)	1 (1.4)	2 (2.9)	5 (2.4)	6 (2.2)
028	1 (1.4)	2 (2.9)	3 (4.3)	2 (2.9)	7 (3.4)	8 (2.9)
029	2 (2.9)	2 (2.9)	1 (1.4)	2 (2.9)	5 (2.4)	7 (2.5)
030	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
031	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
033	3 (4.3)	0	2 (2.9)	6 (8.8)	8 (3.9)	11 (4.0)
034	3 (4.3)	2 (2.9)	1 (1.4)	0	3 (1.4)	6 (2.2)
035	2 (2.9)	3 (4.3)	0	2 (2.9)	5 (2.4)	7 (2.5)
036	3 (4.3)	2 (2.9)	2 (2.9)	1 (1.5)	5 (2.4)	8 (2.9)
037	1 (1.4)	3 (4.3)	3 (4.3)	1 (1.5)	7 (3.4)	8 (2.9)
038	3 (4.3)	2 (2.9)	2 (2.9)	3 (4.4)	7 (3.4)	10 (3.6)
039	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
040	7 (10.1)	5 (7.1)	5 (7.2)	3 (4.4)	13 (6.3)	20 (7.2)
041	0	0	0	3 (4.4)	3 (1.4)	3 (1.1)
042	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
044	1 (1.4)	2 (2.9)	1 (1.4)	2 (2.9)	5 (2.4)	6 (2.2)
045	1 (1.4)	2 (2.9)	0	2 (2.9)	4 (1.9)	5 (1.8)
046	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.1.3

Table 14.1.1.3
Important Protocol Deviations
FAS

Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Subjects with any Important Protocol Deviation	2 (2.9)	3 (4.3)	1 (1.4)	3 (4.4)	7 (3.4)	9 (3.3)
1. Informed consent	0	0	0	0	0	0
2. Eligibility	0	3 (4.3)	0	2 (2.9)	5 (2.4)	5 (1.8)
3. Study drug administration	0	0	0	0	0	0
4. Study schedule	1 (1.4)	0	0	0	0	1 (0.4)
5. Concomitant medications and therapies	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
6. Biological samples	0	0	0	0	0	0
7. Adverse events	0	0	0	0	0	0
8. Maintenance of blinding	0	0	0	0	0	0
9. Randomization	0	0	0	0	0	0
10. Study facility	0	0	0	0	0	0
11. Study management	0	0	0	0	0	0
12. Others	0	0	0	0	0	0

Data Source: Listing 16.2.2
Subjects were counted only once per treatment per category.

Table 14.1.2.1
Demographic and Baseline Characteristics
FAS

	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Age (years)						
n	69	70	69	68	207	276
Mean (SD)	54.5 (4.40)	55.0 (4.00)	53.8 (3.46)	54.7 (3.92)	54.5 (3.82)	54.5 (3.96)
Median	55.0	55.0	54.0	54.0	54.0	54.5
Q1 - Q3	51.0 - 57.0	52.0 - 58.0	51.0 - 56.0	51.0 - 57.5	52.0 - 57.0	51.5 - 57.0
Min - Max	46 - 64	41 - 64	47 - 62	48 - 64	41 - 64	41 - 64
Age Group (years), n (%)						
<55	34 (49.3)	29 (41.4)	40 (58.0)	35 (51.5)	104 (50.2)	138 (50.0)
>=55	35 (50.7)	41 (58.6)	29 (42.0)	33 (48.5)	103 (49.8)	138 (50.0)
Height (cm)						
n	69	70	69	68	207	276
Mean (SD)	155.70 (6.108)	157.02 (6.559)	158.88 (5.634)	157.77 (5.349)	157.89 (5.898)	157.34 (6.015)
Median	155.00	156.50	159.00	156.50	157.50	157.00
Q1 - Q3	152.50 - 160.50	153.00 - 162.10	155.00 - 162.10	154.00 - 161.25	154.00 - 161.90	153.25 - 161.50
Min - Max	137.0 - 172.0	143.5 - 174.3	143.0 - 172.5	148.0 - 171.0	143.0 - 174.3	137.0 - 174.3
Weight (kg)						
n	69	70	69	68	207	276
Mean (SD)	57.44 (7.995)	59.32 (7.192)	58.83 (7.668)	58.79 (6.656)	58.98 (7.156)	58.60 (7.390)
Median	56.50	59.40	57.00	58.75	58.50	58.00
Q1 - Q3	52.00 - 63.00	53.50 - 63.50	53.50 - 65.10	54.15 - 62.95	53.50 - 64.20	53.10 - 63.50
Min - Max	42.0 - 78.3	44.0 - 77.7	45.0 - 75.5	43.5 - 76.2	43.5 - 77.7	42.0 - 78.3

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.1
Demographic and Baseline Characteristics
FAS

	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
BMI (kg/m²)						
n	69	70	69	68	207	276
Mean (SD)	23.64 (2.489)	24.04 (2.363)	23.27 (2.530)	23.59 (2.193)	23.64 (2.376)	23.64 (2.400)
Median	23.50	24.25	23.10	23.35	23.60	23.55
Q1 - Q3	21.80 - 25.30	22.30 - 25.20	21.50 - 25.00	22.05 - 25.25	21.80 - 25.10	21.80 - 25.15
Min - Max	18.8 - 29.7	19.0 - 29.4	18.8 - 28.8	19.0 - 28.7	18.8 - 29.4	18.8 - 29.7
BMI (kg/m²) Group[1], n (%)						
<28	65 (94.2)	65 (92.9)	66 (95.7)	65 (95.6)	196 (94.7)	261 (94.6)
>=28	4 (5.8)	5 (7.1)	3 (4.3)	3 (4.4)	11 (5.3)	15 (5.4)
BMI (kg/m²) Group[2], n (%)						
>=18.5 to <24	40 (58.0)	32 (45.7)	44 (63.8)	43 (63.2)	119 (57.5)	159 (57.6)
>=24 to <28	25 (36.2)	33 (47.1)	22 (31.9)	22 (32.4)	77 (37.2)	102 (37.0)
>=28	4 (5.8)	5 (7.1)	3 (4.3)	3 (4.4)	11 (5.3)	15 (5.4)
Sex, n (%)						
Female	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)
Ethnicity, n (%)						
Han	66 (95.7)	68 (97.1)	66 (95.7)	61 (89.7)	195 (94.2)	261 (94.6)
Other	3 (4.3)	2 (2.9)	3 (4.3)	7 (10.3)	12 (5.8)	15 (5.4)

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.1
Demographic and Baseline Characteristics
FAS

	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Smoking History, n (%)						
Never	69 (100)	70 (100)	67 (97.1)	66 (97.1)	203 (98.1)	272 (98.6)
Former	0	0	0	0	0	0
Current	0	0	2 (2.9)	2 (2.9)	4 (1.9)	4 (1.4)
Smoking History Group, n (%)						
Never/Former	69 (100)	70 (100)	67 (97.1)	66 (97.1)	203 (98.1)	272 (98.6)
Current	0	0	2 (2.9)	2 (2.9)	4 (1.9)	4 (1.4)

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.2
Demographic and Baseline Characteristics
PPS4

	Placebo N = 66	GS1-144 30 mg QD N = 67	GS1-144 60 mg QD N = 66	GS1-144 30 mg BID N = 65	Combined GS1-144 N = 198	Overall N = 264
Age (years)						
n	66	67	66	65	198	264
Mean (SD)	54.5 (4.49)	54.9 (4.04)	53.8 (3.42)	54.9 (3.90)	54.6 (3.81)	54.5 (3.98)
Median	54.5	55.0	54.0	55.0	55.0	55.0
Q1 - Q3	51.0 - 58.0	52.0 - 58.0	51.0 - 56.0	51.0 - 58.0	52.0 - 57.0	51.5 - 57.5
Min - Max	46 - 64	41 - 64	47 - 62	48 - 64	41 - 64	41 - 64
Age Group (years), n (%)						
<55	33 (50.0)	28 (41.8)	38 (57.6)	32 (49.2)	98 (49.5)	131 (49.6)
>=55	33 (50.0)	39 (58.2)	28 (42.4)	33 (50.8)	100 (50.5)	133 (50.4)
Height (cm)						
n	66	67	66	65	198	264
Mean (SD)	155.56 (6.124)	156.96 (6.580)	158.93 (5.754)	157.86 (5.382)	157.91 (5.958)	157.32 (6.075)
Median	154.75	156.50	159.25	156.50	157.50	157.00
Q1 - Q3	152.50 - 160.00	153.00 - 161.50	155.00 - 163.00	154.50 - 161.00	154.00 - 161.60	153.50 - 161.50
Min - Max	137.0 - 172.0	143.5 - 174.3	143.0 - 172.5	148.0 - 171.0	143.0 - 174.3	137.0 - 174.3
Weight (kg)						
n	66	67	66	65	198	264
Mean (SD)	57.63 (8.015)	58.98 (6.965)	59.06 (7.764)	58.73 (6.799)	58.93 (7.154)	58.60 (7.384)
Median	56.20	59.30	57.10	58.50	58.50	58.00
Q1 - Q3	52.00 - 63.00	53.50 - 63.10	53.50 - 65.40	53.80 - 63.00	53.50 - 64.20	53.00 - 63.75
Min - Max	42.0 - 78.3	44.0 - 77.7	45.0 - 75.5	43.5 - 76.2	43.5 - 77.7	42.0 - 78.3

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.2
Demographic and Baseline Characteristics
PPS4

	Placebo N = 66	GS1-144 30 mg QD N = 67	GS1-144 60 mg QD N = 66	GS1-144 30 mg BID N = 65	Combined GS1-144 N = 198	Overall N = 264
BMI (kg/m²)						
n	66	67	66	65	198	264
Mean (SD)	23.75 (2.466)	23.92 (2.229)	23.35 (2.560)	23.54 (2.215)	23.60 (2.341)	23.64 (2.369)
Median	23.65	24.20	23.25	23.30	23.60	23.60
Q1 - Q3	22.00 - 25.30	22.30 - 25.20	21.50 - 25.10	22.00 - 24.90	21.80 - 25.10	21.85 - 25.15
Min - Max	18.8 - 29.7	19.0 - 29.4	18.8 - 28.8	19.0 - 28.7	18.8 - 29.4	18.8 - 29.7
BMI (kg/m²) Group[1], n (%)						
<28	62 (93.9)	64 (95.5)	63 (95.5)	62 (95.4)	189 (95.5)	251 (95.1)
>=28	4 (6.1)	3 (4.5)	3 (4.5)	3 (4.6)	9 (4.5)	13 (4.9)
BMI (kg/m²) Group[2], n (%)						
>=18.5 to <24	37 (56.1)	31 (46.3)	41 (62.1)	42 (64.6)	114 (57.6)	151 (57.2)
>=24 to <28	25 (37.9)	33 (49.3)	22 (33.3)	20 (30.8)	75 (37.9)	100 (37.9)
>=28	4 (6.1)	3 (4.5)	3 (4.5)	3 (4.6)	9 (4.5)	13 (4.9)
Sex, n (%)						
Female	66 (100)	67 (100)	66 (100)	65 (100)	198 (100)	264 (100)
Ethnicity, n (%)						
Han	63 (95.5)	65 (97.0)	63 (95.5)	58 (89.2)	186 (93.9)	249 (94.3)
Other	3 (4.5)	2 (3.0)	3 (4.5)	7 (10.8)	12 (6.1)	15 (5.7)

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.2
Demographic and Baseline Characteristics
PPS4

	Placebo N = 66	GS1-144 30 mg QD N = 67	GS1-144 60 mg QD N = 66	GS1-144 30 mg BID N = 65	Combined GS1-144 N = 198	Overall N = 264
Smoking History, n (%)						
Never	66 (100)	67 (100)	64 (97.0)	64 (98.5)	195 (98.5)	261 (98.9)
Former	0	0	0	0	0	0
Current	0	0	2 (3.0)	1 (1.5)	3 (1.5)	3 (1.1)
Smoking History Group, n (%)						
Never/Former	66 (100)	67 (100)	64 (97.0)	64 (98.5)	195 (98.5)	261 (98.9)
Current	0	0	2 (3.0)	1 (1.5)	3 (1.5)	3 (1.1)

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.3
Demographic and Baseline Characteristics
PPS12

	Placebo N = 63	GS1-144 30 mg QD N = 64	GS1-144 60 mg QD N = 65	GS1-144 30 mg BID N = 60	Combined GS1-144 N = 189	Overall N = 252
Age (years)						
n	63	64	65	60	189	252
Mean (SD)	54.4 (4.56)	55.0 (4.00)	53.8 (3.45)	55.1 (3.96)	54.6 (3.83)	54.6 (4.02)
Median	54.0	55.0	54.0	55.0	55.0	55.0
Q1 - Q3	51.0 - 58.0	52.0 - 58.0	51.0 - 56.0	52.0 - 58.0	52.0 - 58.0	52.0 - 58.0
Min - Max	46 - 64	41 - 64	47 - 62	48 - 64	41 - 64	41 - 64
Age Group (years), n (%)						
<55	32 (50.8)	27 (42.2)	37 (56.9)	29 (48.3)	93 (49.2)	125 (49.6)
>=55	31 (49.2)	37 (57.8)	28 (43.1)	31 (51.7)	96 (50.8)	127 (50.4)
Height (cm)						
n	63	64	65	60	189	252
Mean (SD)	155.76 (6.160)	156.94 (6.669)	158.90 (5.793)	157.91 (5.537)	157.92 (6.050)	157.38 (6.138)
Median	155.00	156.30	159.00	156.55	157.50	157.00
Q1 - Q3	152.50 - 160.50	153.00 - 161.25	155.00 - 163.00	154.25 - 161.25	154.00 - 161.60	153.50 - 161.50
Min - Max	137.0 - 172.0	143.5 - 174.3	143.0 - 172.5	148.0 - 171.0	143.0 - 174.3	137.0 - 174.3
Weight (kg)						
n	63	64	65	60	189	252
Mean (SD)	57.82 (8.147)	58.65 (6.703)	58.97 (7.788)	58.78 (6.964)	58.80 (7.137)	58.55 (7.398)
Median	56.50	58.90	57.00	58.75	58.50	58.05
Q1 - Q3	51.90 - 64.00	53.50 - 62.70	53.50 - 65.40	53.65 - 63.25	53.50 - 63.50	53.00 - 63.75
Min - Max	42.0 - 78.3	44.0 - 73.0	45.0 - 75.5	43.5 - 76.2	43.5 - 76.2	42.0 - 78.3

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.3
Demographic and Baseline Characteristics
PPS12

	Placebo N = 63	GS1-144 30 mg QD N = 64	GS1-144 60 mg QD N = 65	GS1-144 30 mg BID N = 60	Combined GS1-144 N = 189	Overall N = 252
BMI (kg/m^2)						
n	63	64	65	60	189	252
Mean (SD)	23.77 (2.518)	23.79 (2.160)	23.32 (2.571)	23.54 (2.213)	23.55 (2.321)	23.60 (2.369)
Median	23.60	24.05	23.20	23.35	23.50	23.55
Q1 - Q3	21.80 - 25.40	22.30 - 25.15	21.50 - 25.00	22.05 - 24.85	21.80 - 25.00	21.80 - 25.10
Min - Max	18.8 - 29.7	19.0 - 28.5	18.8 - 28.8	19.0 - 28.7	18.8 - 28.8	18.8 - 29.7
BMI (kg/m^2) Group[1] , n (%)						
<28	59 (93.7)	62 (96.9)	62 (95.4)	57 (95.0)	181 (95.8)	240 (95.2)
>=28	4 (6.3)	2 (3.1)	3 (4.6)	3 (5.0)	8 (4.2)	12 (4.8)
BMI (kg/m^2) Group[2] , n (%)						
>=18.5 to <24	36 (57.1)	31 (48.4)	41 (63.1)	39 (65.0)	111 (58.7)	147 (58.3)
>=24 to <28	23 (36.5)	31 (48.4)	21 (32.3)	18 (30.0)	70 (37.0)	93 (36.9)
>=28	4 (6.3)	2 (3.1)	3 (4.6)	3 (5.0)	8 (4.2)	12 (4.8)
Sex, n (%)						
Female	63 (100)	64 (100)	65 (100)	60 (100)	189 (100)	252 (100)
Ethnicity, n (%)						
Han	60 (95.2)	62 (96.9)	62 (95.4)	53 (88.3)	177 (93.7)	237 (94.0)
Other	3 (4.8)	2 (3.1)	3 (4.6)	7 (11.7)	12 (6.3)	15 (6.0)

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.2.3
Demographic and Baseline Characteristics
PPS12

	Placebo N = 63	GS1-144 30 mg QD N = 64	GS1-144 60 mg QD N = 65	GS1-144 30 mg BID N = 60	Combined GS1-144 N = 189	Overall N = 252
Smoking History, n (%)						
Never	63 (100)	64 (100)	63 (96.9)	59 (98.3)	186 (98.4)	249 (98.8)
Former	0	0	0	0	0	0
Current	0	0	2 (3.1)	1 (1.7)	3 (1.6)	3 (1.2)
Smoking History Group, n (%)						
Never/Former	63 (100)	64 (100)	63 (96.9)	59 (98.3)	186 (98.4)	249 (98.8)
Current	0	0	2 (3.1)	1 (1.7)	3 (1.6)	3 (1.2)

Data Source: Listing 16.2.4.1
[1] Data is the stratification factor from CRF Randomization page.
[2] Data is from CRF Body Measurements page.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Subjects with any Medical History	58 (84.1)	59 (84.3)	60 (87.0)	53 (77.9)	172 (83.1)	230 (83.3)
Hepatobiliary disorders	34 (49.3)	20 (28.6)	29 (42.0)	29 (42.6)	78 (37.7)	112 (40.6)
Hepatic steatosis	17 (24.6)	12 (17.1)	19 (27.5)	14 (20.6)	45 (21.7)	62 (22.5)
Hepatic cyst	12 (17.4)	7 (10.0)	9 (13.0)	9 (13.2)	25 (12.1)	37 (13.4)
Gallbladder polyp	7 (10.1)	3 (4.3)	3 (4.3)	7 (10.3)	13 (6.3)	20 (7.2)
Cholelithiasis	3 (4.3)	2 (2.9)	3 (4.3)	5 (7.4)	10 (4.8)	13 (4.7)
Bile duct stone	1 (1.4)	0	2 (2.9)	2 (2.9)	4 (1.9)	5 (1.8)
Gallbladder enlargement	0	0	0	2 (2.9)	2 (1.0)	2 (0.7)
Hepatic calcification	2 (2.9)	0	0	0	0	2 (0.7)
Cholecystitis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Hepatic function abnormal	1 (1.4)	0	0	0	0	1 (0.4)
Hepatic mass	1 (1.4)	0	0	0	0	1 (0.4)
Hyperplastic cholecystopathy	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Reproductive system and breast disorders	28 (40.6)	26 (37.1)	28 (40.6)	26 (38.2)	80 (38.6)	108 (39.1)
Breast mass	14 (20.3)	14 (20.0)	13 (18.8)	12 (17.6)	39 (18.8)	53 (19.2)
Breast hyperplasia	9 (13.0)	11 (15.7)	11 (15.9)	11 (16.2)	33 (15.9)	42 (15.2)
Menopausal symptoms	4 (5.8)	1 (1.4)	3 (4.3)	3 (4.4)	7 (3.4)	11 (4.0)
Cervical cyst	3 (4.3)	3 (4.3)	1 (1.4)	3 (4.4)	7 (3.4)	10 (3.6)
Breast cyst	3 (4.3)	3 (4.3)	2 (2.9)	1 (1.5)	6 (2.9)	9 (3.3)
Ovarian cyst	4 (5.8)	2 (2.9)	2 (2.9)	1 (1.5)	5 (2.4)	9 (3.3)
Adenomyosis	0	1 (1.4)	5 (7.2)	0	6 (2.9)	6 (2.2)
Uterine polyp	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
Adnexa uteri cyst	2 (2.9)	0	0	1 (1.5)	1 (0.5)	3 (1.1)
Abnormal uterine bleeding	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Adnexa uteri mass	2 (2.9)	0	0	0	0	2 (0.7)
Breast calcifications	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Hydrometra	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mammary duct ectasia	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Vaginal prolapse	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Breast pain	1 (1.4)	0	0	0	0	1 (0.4)
Cervical polyp	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Galactocele	1 (1.4)	0	0	0	0	1 (0.4)
Ovarian failure	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Pelvic adhesions	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Uterine prolapse	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Endocrine disorders	22 (31.9)	27 (38.6)	29 (42.0)	22 (32.4)	78 (37.7)	100 (36.2)
Thyroid mass	22 (31.9)	22 (31.4)	26 (37.7)	21 (30.9)	69 (33.3)	91 (33.0)
Thyroid cyst	0	4 (5.7)	4 (5.8)	1 (1.5)	9 (4.3)	9 (3.3)
Hyperthyroidism	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Adrenal mass	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Goitre	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Hypothyroidism	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Parathyroid hyperplasia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Thyroid calcification	1 (1.4)	0	0	0	0	1 (0.4)
Metabolism and nutrition disorders	22 (31.9)	18 (25.7)	25 (36.2)	19 (27.9)	62 (30.0)	84 (30.4)
Hyperlipidaemia	14 (20.3)	14 (20.0)	18 (26.1)	10 (14.7)	42 (20.3)	56 (20.3)
Hyperuricaemia	10 (14.5)	3 (4.3)	4 (5.8)	5 (7.4)	12 (5.8)	22 (8.0)
Hypercholesterolaemia	5 (7.2)	2 (2.9)	3 (4.3)	6 (8.8)	11 (5.3)	16 (5.8)
Hypertriglyceridaemia	3 (4.3)	3 (4.3)	1 (1.4)	2 (2.9)	6 (2.9)	9 (3.3)
Diabetes mellitus	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Dyslipidaemia	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Glucose tolerance impaired	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Type 2 diabetes mellitus	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	22 (31.9)	19 (27.1)	17 (24.6)	14 (20.6)	50 (24.2)	72 (26.1)
Uterine leiomyoma	21 (30.4)	19 (27.1)	17 (24.6)	13 (19.1)	49 (23.7)	70 (25.4)
Haemangioma of liver	0	0	1 (1.4)	2 (2.9)	3 (1.4)	3 (1.1)
Breast cancer	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Ovarian germ cell teratoma	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Parathyroid tumour	1 (1.4)	0	0	0	0	1 (0.4)
Renal perivascular epithelioid cell tumour	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Respiratory, thoracic and mediastinal disorders	10 (14.5)	17 (24.3)	16 (23.2)	14 (20.6)	47 (22.7)	57 (20.7)
Pulmonary mass	6 (8.7)	11 (15.7)	14 (20.3)	13 (19.1)	38 (18.4)	44 (15.9)
Cough	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Interstitial lung abnormality	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
Pneumonitis	0	3 (4.3)	0	0	3 (1.4)	3 (1.1)
Bronchitis chronic	2 (2.9)	0	0	0	0	2 (0.7)
Cystic lung disease	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Lung opacity	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Bronchiectasis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Epiglottic cyst	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Nasal septum deviation	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Pleural thickening	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Respiratory, thoracic and mediastinal disorders (con'd)						
Pleurisy	1 (1.4)	0	0	0	0	1 (0.4)
Pulmonary artery dilatation	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Pulmonary calcification	1 (1.4)	0	0	0	0	1 (0.4)
Reflux laryngitis	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Rhinitis allergic	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Infections and infestations	16 (23.2)	10 (14.3)	13 (18.8)	8 (11.8)	31 (15.0)	47 (17.0)
Urinary tract infection	7 (10.1)	2 (2.9)	5 (7.2)	3 (4.4)	10 (4.8)	17 (6.2)
Vaginal infection	1 (1.4)	4 (5.7)	2 (2.9)	0	6 (2.9)	7 (2.5)
Rhinitis	2 (2.9)	1 (1.4)	0	1 (1.5)	2 (1.0)	4 (1.4)
Papilloma viral infection	0	1 (1.4)	2 (2.9)	0	3 (1.4)	3 (1.1)
Pelvic inflammatory disease	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Bronchitis	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Pharyngitis	2 (2.9)	0	0	0	0	2 (0.7)
Pneumonia	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Upper respiratory tract infection	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Appendicitis	1 (1.4)	0	0	0	0	1 (0.4)
Bacterial vulvovaginitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Dermatophytosis of nail	1 (1.4)	0	0	0	0	1 (0.4)
Folliculitis	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Furuncle	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Infections and infestations (con'd)						
Herpes simplex	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Herpes virus infection	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Laryngopharyngitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Otitis media chronic	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Pelvic infection	1 (1.4)	0	0	0	0	1 (0.4)
Periodontitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Peritonsillar abscess	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Pulmonary tuberculosis	1 (1.4)	0	0	0	0	1 (0.4)
Salpingitis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Sinusitis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Soft tissue infection	1 (1.4)	0	0	0	0	1 (0.4)
Syphilis	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Musculoskeletal and connective tissue disorders	10 (14.5)	14 (20.0)	15 (21.7)	7 (10.3)	36 (17.4)	46 (16.7)
Arthralgia	2 (2.9)	5 (7.1)	3 (4.3)	3 (4.4)	11 (5.3)	13 (4.7)
Back pain	2 (2.9)	5 (7.1)	4 (5.8)	1 (1.5)	10 (4.8)	12 (4.3)
Osteoporosis	1 (1.4)	2 (2.9)	2 (2.9)	2 (2.9)	6 (2.9)	7 (2.5)
Spinal osteoarthritis	2 (2.9)	0	5 (7.2)	0	5 (2.4)	7 (2.5)
Intervertebral disc protrusion	1 (1.4)	2 (2.9)	2 (2.9)	0	4 (1.9)	5 (1.8)
Myalgia	1 (1.4)	3 (4.3)	0	1 (1.5)	4 (1.9)	5 (1.8)
Arthritis	0	0	0	2 (2.9)	2 (1.0)	2 (0.7)
Arthropathy	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Neck pain	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Osteoarthritis	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Periarthritis	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Bone cyst	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Bursitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Exostosis	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Gouty arthritis	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Joint effusion	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Lumbar spinal stenosis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Osteoporosis postmenopausal	1 (1.4)	0	0	0	0	1 (0.4)
Pain in extremity	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Rotator cuff syndrome	1 (1.4)	0	0	0	0	1 (0.4)
Sacral pain	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Renal and urinary disorders	13 (18.8)	6 (8.6)	15 (21.7)	6 (8.8)	27 (13.0)	40 (14.5)
Nephrolithiasis	8 (11.6)	3 (4.3)	6 (8.7)	4 (5.9)	13 (6.3)	21 (7.6)
Renal cyst	3 (4.3)	2 (2.9)	9 (13.0)	2 (2.9)	13 (6.3)	16 (5.8)
Haematuria	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Stress urinary incontinence	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Nephrocalcinosis	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Urinary incontinence	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Pollakiuria	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Renal mass	1 (1.4)	0	0	0	0	1 (0.4)
Ureterolithiasis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Urethral syndrome	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Urge incontinence	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Vascular disorders	11 (15.9)	9 (12.9)	11 (15.9)	6 (8.8)	26 (12.6)	37 (13.4)
Hypertension	7 (10.1)	8 (11.4)	8 (11.6)	5 (7.4)	21 (10.1)	28 (10.1)
Aortic arteriosclerosis	4 (5.8)	0	4 (5.8)	1 (1.5)	5 (2.4)	9 (3.3)
Venous thrombosis limb	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Gastrointestinal disorders	6 (8.7)	4 (5.7)	9 (13.0)	8 (11.8)	21 (10.1)	27 (9.8)
Chronic gastritis	2 (2.9)	1 (1.4)	3 (4.3)	2 (2.9)	6 (2.9)	8 (2.9)
Gastrooesophageal reflux disease	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.9)	4 (1.9)	5 (1.8)
Abdominal distension	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Functional gastrointestinal disorder	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Gastritis	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Haemorrhoids	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Large intestine polyp	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Abdominal adhesions	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Abdominal pain	1 (1.4)	0	0	0	0	1 (0.4)
Constipation	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Diverticulum intestinal	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Gastritis erosive	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Inguinal hernia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Nausea	1 (1.4)	0	0	0	0	1 (0.4)
Oesophageal wall hypertrophy	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Rectal polyp	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Toothache	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Vomiting	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Psychiatric disorders	8 (11.6)	7 (10.0)	6 (8.7)	4 (5.9)	17 (8.2)	25 (9.1)
Insomnia	4 (5.8)	2 (2.9)	4 (5.8)	2 (2.9)	8 (3.9)	12 (4.3)
Sleep disorder	3 (4.3)	5 (7.1)	2 (2.9)	2 (2.9)	9 (4.3)	12 (4.3)
Anxiety	1 (1.4)	0	0	0	0	1 (0.4)
Major depression	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Investigations	4 (5.8)	9 (12.9)	7 (10.1)	4 (5.9)	20 (9.7)	24 (8.7)
Urinary occult blood positive	2 (2.9)	2 (2.9)	1 (1.4)	0	3 (1.4)	5 (1.8)
Aspartate aminotransferase increased	1 (1.4)	2 (2.9)	1 (1.4)	0	3 (1.4)	4 (1.4)
White blood cell count decreased	0	2 (2.9)	1 (1.4)	0	3 (1.4)	3 (1.1)
Alanine aminotransferase increased	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Blood pressure increased	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Electrocardiogram T wave abnormal	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
White blood cells urine positive	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Blood glucose increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Blood triglycerides increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Electrocardiogram ST segment abnormal	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Electrocardiogram U wave present	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Gamma-glutamyltransferase increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Human papilloma virus test positive	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Neutrophil count decreased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Protein urine present	1 (1.4)	0	0	0	0	1 (0.4)
Transaminases increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Ultrasound thyroid abnormal	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Cardiac disorders	5 (7.2)	3 (4.3)	5 (7.2)	4 (5.9)	12 (5.8)	17 (6.2)
Sinus bradycardia	1 (1.4)	1 (1.4)	0	3 (4.4)	4 (1.9)	5 (1.8)
Arrhythmia	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
Supraventricular extrasystoles	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Arteriosclerosis coronary artery	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Cardiomegaly	1 (1.4)	0	0	0	0	1 (0.4)
Coronary artery stenosis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Left ventricular enlargement	1 (1.4)	0	0	0	0	1 (0.4)
Myocardial ischaemia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Palpitations	1 (1.4)	0	0	0	0	1 (0.4)
Ventricular extrasystoles	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
General disorders and administration site conditions	3 (4.3)	2 (2.9)	7 (10.1)	2 (2.9)	11 (5.3)	14 (5.1)
Fatigue	2 (2.9)	2 (2.9)	4 (5.8)	1 (1.5)	7 (3.4)	9 (3.3)
Chest discomfort	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Asthenia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Chronic fatigue syndrome	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Nodule	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Oedema peripheral	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Blood and lymphatic system disorders	2 (2.9)	4 (5.7)	4 (5.8)	3 (4.4)	11 (5.3)	13 (4.7)
Lymphadenopathy	0	2 (2.9)	3 (4.3)	2 (2.9)	7 (3.4)	7 (2.5)
Anaemia	2 (2.9)	2 (2.9)	1 (1.4)	1 (1.5)	4 (1.9)	6 (2.2)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Skin and subcutaneous tissue disorders	1 (1.4)	2 (2.9)	5 (7.2)	3 (4.4)	10 (4.8)	11 (4.0)
Rash	0	0	2 (2.9)	1 (1.5)	3 (1.4)	3 (1.1)
Eczema	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Pruritus	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Chloasma	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Neurodermatitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Seborrhoeic dermatitis	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Skin mass	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Nervous system disorders	4 (5.8)	3 (4.3)	3 (4.3)	0	6 (2.9)	10 (3.6)
Headache	2 (2.9)	3 (4.3)	2 (2.9)	0	5 (2.4)	7 (2.5)
Carotid arteriosclerosis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Dizziness	1 (1.4)	0	0	0	0	1 (0.4)
Hypoaesthesia	1 (1.4)	0	0	0	0	1 (0.4)
Vertebral artery stenosis	1 (1.4)	0	0	0	0	1 (0.4)
Ear and labyrinth disorders	3 (4.3)	2 (2.9)	0	0	2 (1.0)	5 (1.8)
Tinnitus	1 (1.4)	2 (2.9)	0	0	2 (1.0)	3 (1.1)
Deafness neurosensory	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Motion sickness	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.3
Medical History
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Injury, poisoning and procedural complications	0	1 (1.4)	3 (4.3)	1 (1.5)	5 (2.4)	5 (1.8)
Animal scratch	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Ankle fracture	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Ligament injury	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Tendon injury	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Tendon rupture	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Uterine scar diverticulum	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Eye disorders	2 (2.9)	0	1 (1.4)	1 (1.5)	2 (1.0)	4 (1.4)
Cataract	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Narrow anterior chamber angle	1 (1.4)	0	0	0	0	1 (0.4)
Trichiasis	1 (1.4)	0	0	0	0	1 (0.4)
Xerophthalmia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Congenital, familial and genetic disorders	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Aberrant aortic arch	1 (1.4)	0	0	0	0	1 (0.4)
Patent ductus arteriosus	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Pregnancy, puerperium and perinatal conditions	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Ectopic pregnancy	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.4.3
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Subjects with any Prior Medication	12 (17.4)	13 (18.6)	19 (27.5)	13 (19.1)	45 (21.7)	57 (20.7)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	2 (2.9)	4 (5.7)	6 (8.7)	4 (5.9)	14 (6.8)	16 (5.8)
TRADITIONAL CHINESE MEDICINE (TCM) DECOCTION	0	2 (2.9)	3 (4.3)	2 (2.9)	7 (3.4)	7 (2.5)
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE TUBER;ANEMARRHENA ASPHODELOIDES RHIZOME;CORNUS OFFICINALIS FRUIT;DIOSCOREA OPPOSITIFOLIA RHIZOME;PAEONIA X SUFFRUTICOSA ROOT BARK;PHELLODENDRON CHINENSE BARK; PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT TUBER	0	0	1 (1.4)	2 (2.9)	3 (1.4)	3 (1.1)
HERBAL PREPARATION	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
ANEMARRHENA ASPHODELOIDES RHIZOME;PAEONIA LACTIFLORA ROOT;PHELLODENDRON AMURENSE BARK;REHMANNIA GLUTINOSA ROOT TUBER;TORTOISE CARAPACE AND PLASTRON	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE (con'd)						
ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA RHIZOME;BUPLEURUM SPP. ROOT;GARDENIA JASMINOIDES FRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;PAEONIA LACTIFLORA ROOT;PAEONIA X SUFFRUTICOSA ROOT BARK; PORIA COCOS SCLEROTIUM	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ASTRAGALUS MONGHOLICUS ROOT;LIGUSTRUM LUCIDUM RIPE FRUIT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ATRACTYLODES MACROCEPHALA RHIZOME;CITRUS X AURANTIUM FRUIT PEEL;POLYGALA TENUIFOLIA ROOT;REHMANNIA GLUTINOSA PROCESSED ROOT TUBER;REYNOUTRIA MULTIFLORA STEM;SALVIA MILTIORRHIZA ROOT;ZIZIPHUS JUJUBA FRUIT	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE (con'd)						
FAGOPYRUM CYMOSUM RHIZOME	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
TIGER BONE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ANTIBACTERIALS FOR SYSTEMIC USE	3 (4.3)	4 (5.7)	3 (4.3)	4 (5.9)	11 (5.3)	14 (5.1)
CEFDINIR	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
CEFUROXIME AXETIL	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
CEFUROXIME	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
AMOXICILLIN	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CALLICARPA NUDIFLORA LEAF	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CEFACLOR	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CEFALEXIN	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CEFMETAZOLE SODIUM	1 (1.4)	0	0	0	0	1 (0.4)
CEFRADINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CEFUROXIME SODIUM	1 (1.4)	0	0	0	0	1 (0.4)
LEVOFLOXACIN	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Table 14.1.4.1
Prior Medication
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANESTHETICS	1 (1.4)	2 (2.9)	5 (7.2)	2 (2.9)	9 (4.3)	10 (3.6)
PROPOFOL	0	1 (1.4)	1 (1.4)	2 (2.9)	4 (1.9)	4 (1.4)
ETOMIDATE	0	0	3 (4.3)	0	3 (1.4)	3 (1.1)
CIPROFOL	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
LIDOCAINE HYDROCHLORIDE	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
DYCLONINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
FENTANYL CITRATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
LIDOCAINE	1 (1.4)	0	0	0	0	1 (0.4)
ROPIVACAINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
OTHER GYNECOLOGICALS	1 (1.4)	4 (5.7)	2 (2.9)	1 (1.5)	7 (3.4)	8 (2.9)
ASINI CORII COLLA;COPTIS SPP. RHIZOME;PAEONIA LACTIFLORA ROOT;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA PROCESSED ROOT TUBER;SCUTELLARIA BAICALENSIS ROOT	0	2 (2.9)	1 (1.4)	0	3 (1.4)	3 (1.1)

Data Source: Listing 16.2.5.1.1
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Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
OTHER GYNECOLOGICALS (con'd)						
ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA RHIZOME;BUPLEURUM SPP. ROOT;CARTHAMUS TINCTORIUS FLOWER;CODONOPSIS SPP. ROOT;CORYDALIS YANHUSUO TUBER;CYPERUS ROTUNDUS RHIZOME;GENTIANA MACROPHYLLA ROOT;LYCIUM CHINENSE ROOT BARK;PAEONIA OFFICINALIS SUBSP. OFFICINALIS ROOT;PANAX NOTOGINSENG ROOT;PLANTAGO SPP. SEED;PORIA COCOS SCLEROTIUM;PORTULACA OLERACEA HERB;REHMANNIA GLUTINOSA PROCESSED ROOT TUBER;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SARGASSUM PALLIDUM;SONCHUS ARVENSIS;TARAXACUM SPP. HERB;TURTLE CARAPACE	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Table 14.1.4.1
Prior Medication
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
OTHER GYNECOLOGICALS (con'd)						
ANDROGRAPHIS PANICULATA HERB;ANGELICA SINENSIS ROOT;BERBERIS SPP. STEM;CODONOPSIS SPP. ROOT;FLEMINGIA SPP. ROOT;ROSA SPP. ROOT;SPATHOLOBUS SUBERECTUS STEM;ZANTHOXYLUM DISSITUM ROOT WITH STEM	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CIBOTIUM BAROMETZ RHIZOME;LEONURUS JAPONICUS HERB;LIGUSTICUM CHUANXIONG RHIZOME;LONICERA JAPONICA STEM;PAEONIA SPP. ROOT;PLANTAGO SPP. WHOLE PLANT;SPATHOLOBUS SUBERECTUS STEM;TARAXACUM SPP. WHOLE PLANT	1 (1.4)	0	0	0	0	1 (0.4)
MISOPROSTOL	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

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WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
DRUGS FOR ACID RELATED DISORDERS	1 (1.4)	3 (4.3)	2 (2.9)	1 (1.5)	6 (2.9)	7 (2.5)
RABEPRAZOLE SODIUM	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CITRUS X AURANTIUM UNRIPE FRUIT;ISODON AMETHYSTOIDES WHOLE PLANT;PANAX GINSENG ROOT WITH RHIZOME	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ESOMEPRAZOLE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
MONTMORILLONITE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
PERIPLANETA AMERICANA	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
RABEPRAZOLE	1 (1.4)	0	0	0	0	1 (0.4)
VONOPRAZAN FUMARATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	3 (4.3)	0	2 (2.9)	1 (1.5)	3 (1.4)	6 (2.2)
ANGELICA DAHURICA ROOT;CALCIUM SULFATE DIHYDRATE;CHRYSANTHEMUM X MORIFOLIUM FLOWER;COPTIS SPP. RHIZOME;FORSYTHIA SUSPENSA FRUIT;GARDENIA JASMINOIDES FRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;INULA JAPONICA FLOWER HEAD;LIGUSTICUM CHUANXIONG RHIZOME;MENTHA CANADENSIS HERB;NEPETA TENUIFOLIA SPIKE;PHELLODENDRON CHINENSE BARK;PLATYCODON GRANDIFLORUS ROOT;RHEUM SPP. ROOT WITH RHIZOME;SAPOSHNIKOVIA DIVARICATA ROOT;SCUTELLARIA BAICALENSIS ROOT;VITEX TRIFOLIA FRUIT	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Prior medication was defined as any medication that ended prior to the date of first study drug administration.
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Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS (con'd)						
ANGELICA SINENSIS ROOT;ASTRAGALUS SPP. ROOT;BOSWELLIA SPP. RESIN;CARTHAMUS TINCTORIUS FLOWER;CLEMATIS SPP. ROOT WITH RHIZOME;COMMIPHORA SPP. GUM RESIN;CURCUMA LONGA RHIZOME;CYATHULA OFFICINALIS ROOT; CYPERUS ROTUNDUS RHIZOME;LIGUSTICUM CHUANXIONG RHIZOME;SALVIA MILTIORRHIZA ROOT WITH RHIZOME	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ANGELICA SINENSIS ROOT;CARTHAMUS TINCTORIUS FLOWER;CINNAMOMUM CASSIA STEM BARK;COW BEZOAR;GASTRODIA ELATA TUBER;LIGUSTICUM CHUANXIONG RHIZOME;PANAX NOTOGINSENG ROOT WITH RHIZOME	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS (con'd)						
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;LONICERA JAPONICA FLOWER	1 (1.4)	0	0	0	0	1 (0.4)
CELECOXIB	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
IBUPROFEN	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
NIMESULIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
PARECOXIB SODIUM	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
PSYCHOLEPTICS	3 (4.3)	0	1 (1.4)	2 (2.9)	3 (1.4)	6 (2.2)
ALPRAZOLAM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ESTAZOLAM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ORYZANOL	1 (1.4)	0	0	0	0	1 (0.4)
OXAZEPAM	1 (1.4)	0	0	0	0	1 (0.4)
PODOSORDARIA NIGRIPES MYCELIUM	1 (1.4)	0	0	0	0	1 (0.4)
REMIMAZOLAM BESYLATE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

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Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANALGESICS	2 (2.9)	0	1 (1.4)	2 (2.9)	3 (1.4)	5 (1.8)
ANGELICA SINENSIS ROOT;GASTRODIA ELATA TUBER;MESOBUTHUS MARTENSII;REYNOUTRIA MULTIFLORA ROOT TUBER;SAPOSHNIKOVIA DIVARICATA ROOT;SMILAX GLABRA RHIZOME	1 (1.4)	0	0	0	0	1 (0.4)
ARCTIUM LAPPA FRUIT;ARTEMISIA ANNUA HERB;CHRYSANTHEMUM X MORIFOLIUM FLOWER;FORSYTHIA SUSPENSA FRUIT;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;MENTHA CANADENSIS HERB;MORUS ALBA LEAF;MORUS ALBA TWIG;NEPETA TENUIFOLIA SPIKE;PERSICARIA HYDROPIPER;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS RHIZOME;PRUNUS SPP. SEED;VIGNA SPP. SEED;XANTHIUM STRUMARIUM HERB	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
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Prior Medication
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANALGESICS (con'd)						
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DEXTROMETHORPHAN HYDROBROMIDE;DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DEZOCINE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
TRAMADOL HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
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Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
COUGH AND COLD PREPARATIONS	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
AMMONIUM CHLORIDE;PROMETHAZINE HYDROCHLORIDE;SULFOGAIACOL	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ANGELICA DAHURICA ROOT;CINNAMOMUM CASSIA TWIG;CITRUS X AURANTIUM FRUIT PEEL;EPHEDRA SPP. STEM;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;PERILLA FRUTESCENS LEAF;PLATYCODON GRANDIFLORUS ROOT;PRUNUS SPP. SEED; PUERARIA MONTANA VAR. LOBATA ROOT;SAPOSHNIKOVIA DIVARICATA ROOT;ZINGIBER OFFICINALE RHIZOME	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
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Table 14.1.4.1
Prior Medication
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
COUGH AND COLD PREPARATIONS (con'd)						
ASTER AGERATOIDES WHOLE PLANT;FIRMIANA SIMPLEX ROOT;KITAGAWIA PRAERUPTORA ROOT;METAGENTIANA RHODANTHA WHOLE PLANT;SCLEROMITRION DIFFUSUM WHOLE PLANT;SCUTELLARIA BAICALENSIS ROOT;STEMONA SPP. ROOT TUBER	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CAMPHOR;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;ILLICIUM VERUM OIL;PAPAVER SOMNIFERUM LATEX;SODIUM BENZOATE	1 (1.4)	0	0	0	0	1 (0.4)
ERIOBOTRYA JAPONICA LEAF;MENTHOL;MORUS ALBA ROOT BARK;PAPAVER SOMNIFERUM PERICARP;PLATYCODON GRANDIFLORUS ROOT;STEMONA SPP. ROOT TUBER;VINCETOXICUM SPP. ROOT WITH RHIZOME	1 (1.4)	0	0	0	0	1 (0.4)

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Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
SODIUM CHLORIDE	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
ALANINE;ARGININE;ASPARTIC ACID;CYSTEINE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE; LYSINE ACETATE;METHIONINE;PHENYLALANINE;PROLINE;S ERINE;THREONINE;TRYPTOPHAN;TYROSINE;VALINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	1 (1.4)	0	0	0	0	1 (0.4)
GLUCOSE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
POTASSIUM CHLORIDE	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
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Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	0	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	4 (1.4)
METRONIDAZOLE	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
CHLORHEXIDINE DIACETATE;CLOTRIMAZOLE;METRONIDAZOLE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CLOTRIMAZOLE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	0	0	1 (1.4)	2 (2.9)	3 (1.4)	3 (1.1)
ALLISARTAN ISOPROXIL	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ENALAPRIL MALEATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
VALSARTAN	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
AMINOPHYLLINE;CHLORPHENAMINE MALEATE;METHOXYPHENAMINE HYDROCHLORIDE;NOSCAPINE	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
BUDESONIDE	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
BERBERINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ANTITHROMBOTIC AGENTS	2 (2.9)	0	0	0	0	2 (0.7)
ACETYLSALICYLIC ACID	1 (1.4)	0	0	0	0	1 (0.4)
CLOPIDOGREL BISULFATE	1 (1.4)	0	0	0	0	1 (0.4)
ENOXAPARIN SODIUM	1 (1.4)	0	0	0	0	1 (0.4)
HEPARIN SODIUM	1 (1.4)	0	0	0	0	1 (0.4)
CORTICOSTEROIDS FOR SYSTEMIC USE	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
BETAMETHASONE DIPROPIONATE;BETAMETHASONE SODIUM PHOSPHATE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
DEXAMETHASONE SODIUM PHOSPHATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
ATRACTYLODES MACROCEPHALA RHIZOME;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;LEVOGLUTAMIDE;PANAX GINSENG ROOT WITH RHIZOME;PORIA COCOS SCLEROTIUM	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
DIMETICONE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
MOSAPRIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
SIMETICONE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
DYDROGESTERONE	1 (1.4)	0	0	0	0	1 (0.4)
ESTRADIOL VALERATE	1 (1.4)	0	0	0	0	1 (0.4)
PROMESTRIENE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
THROAT PREPARATIONS	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
ALISMA PLANTAGO-AQUATICA TUBER;CARTHAMUS TINCTORIUS FLOWER;CHICKEN'S GIZZARD-MEMBRANE;CICADA SLOUGH;CURCUMA SPP. RHIZOME;FRITILLARIA THUNBERGII BULB;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;LASIOSPHAERA FENZLII;LONICERA JAPONICA FLOWER BUD;OPHIOPOGON JAPONICUS ROOT TUBER;OROXYLUM INDICUM SEED;PRUNUS SPP. SEED;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SCROPHULARIA NINGPOENSIS ROOT;SPARGANIUM STOLONIFERUM RHIZOME;TARAXACUM SPP. WHOLE PLANT	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
THROAT PREPARATIONS (con'd)						
GARDENIA JASMINOIDES FRUIT;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;PHELLODENDRON CHINENSE BARK;SCAPHIUM AFFINE SEED;SCUTELLARIA BAICALENSIS ROOT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN (con'd)						
ACHYRANTHES BIDENTATA ROOT;ANGELICA DAHURICA ROOT;AQUILARIA SINENSIS WOOD;ARDISIA CRENATA ROOT;ARDISIA LINDLEYANA HERB;ASARUM SPP. ROOT WITH RHIZOME;CAMPHOR;CINNAMOMUM CASSIA TWIG;CURCUMA SPP. RHIZOME;DOLOMIAEA COSTUS ROOT;ELEUTHEROCOCCUS NODIFLORUS ROOT BARK;FIBRAUREA RECISA STEM;GARDENIA JASMINOIDES;LIGUSTICUM CHUANXIONG RHIZOME;MENTHOL;NEPETA TENUIFOLIA HERB;SAPOSHNIKOVIA DIVARICATA ROOT;SPARGANIUM STOLONIFERUM RHIZOME;URCEOLA SPP. BARK;VINCETOXICUM MUKDENENSE ROOT WITH RHIZOME;ZANTHOXYLUM NITIDUM ROOT	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN (con'd)						
MENTHOL;METHYL SALICYLATE	1 (1.4)	0	0	0	0	1 (0.4)
ANTIANEMIC PREPARATIONS	1 (1.4)	0	0	0	0	1 (0.4)
ASTRAGALUS MONGHOLICUS ROOT;BLOOD, PIG;ZIZIPHUS JUJUBA FRUIT	1 (1.4)	0	0	0	0	1 (0.4)
IRON POLYSACCHARIDE COMPLEX	1 (1.4)	0	0	0	0	1 (0.4)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
GANCICLOVIR	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ANTIHISTAMINES FOR SYSTEMIC USE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
DESLORATADINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ANTISEPTICS AND DISINFECTANTS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
POVIDONE-IODINE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ANTIVIRALS FOR SYSTEMIC USE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
OSELTAMIVIR	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
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*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
CALCIUM CHANNEL BLOCKERS	1 (1.4)	0	0	0	0	1 (0.4)
AMLODIPINE BESILATE	1 (1.4)	0	0	0	0	1 (0.4)
CONTRAST MEDIA	1 (1.4)	0	0	0	0	1 (0.4)
IOHEXOL	1 (1.4)	0	0	0	0	1 (0.4)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CAMPHOR;DEXAMETHASONE ACETATE;MENTHOL	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
DIGESTIVES, INCL. ENZYMES	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ASPERGILLUS ORYZAE ENZYME;PANCREATIN	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DIURETICS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
HYDROCHLOROTHIAZIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
DRUGS FOR CONSTIPATION	1 (1.4)	0	0	0	0	1 (0.4)
MAGNESIUM SULFATE;POTASSIUM SULFATE;SODIUM SULFATE	1 (1.4)	0	0	0	0	1 (0.4)
DRUGS FOR TREATMENT OF BONE DISEASES	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
DENOSUMAB	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
DRUGS USED IN DIABETES	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
METFORMIN HYDROCHLORIDE;SAXAGLIPTIN MONOHYDRATE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
LIPID MODIFYING AGENTS	1 (1.4)	0	0	0	0	1 (0.4)
ROSUVASTATIN CALCIUM	1 (1.4)	0	0	0	0	1 (0.4)
MINERAL SUPPLEMENTS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CALCIUM GLUCONATE;CALCIUM PHOSPHATE DIBASIC;ERGOCALCIFEROL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
MUSCLE RELAXANTS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
EPERISONE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
NASAL PREPARATIONS	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
AZELASTINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
LEVOFLOXACIN	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Prior medication was defined as any medication that ended prior to the date of first study drug administration.
*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
OPHTHALMOLOGICALS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CARBOMER	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
MACROGOL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
OTHER NERVOUS SYSTEM DRUGS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
MECOBALAMIN	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
OTHER RESPIRATORY SYSTEM PRODUCTS	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
AMBROXOL HYDROCHLORIDE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	1 (1.4)	0	0	0	0	1 (0.4)
NEPIDERMIN	1 (1.4)	0	0	0	0	1 (0.4)
RESPIRATORY SYSTEM*	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
RESPIRATORY SYSTEM	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
VACCINES	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
RABIES VACCINE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
VASOPROTECTIVES	1 (1.4)	0	0	0	0	1 (0.4)
AESCULUS HIPPOCASTANUM SEED	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
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*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.1
Prior Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
VITAMINS	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ERGOCALCIFEROL	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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*: There was no ATC Level 2, supplemented with the Preferred Name.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Subjects with any Concomitant Medication	26 (37.7)	28 (40.0)	32 (46.4)	23 (33.8)	83 (40.1)	109 (39.5)
ANTIBACTERIALS FOR SYSTEMIC USE	8 (11.6)	9 (12.9)	8 (11.6)	3 (4.4)	20 (9.7)	28 (10.1)
CEFUROXIME AXETIL	2 (2.9)	2 (2.9)	3 (4.3)	0	5 (2.4)	7 (2.5)
CEFIXIME	2 (2.9)	1 (1.4)	1 (1.4)	0	2 (1.0)	4 (1.4)
AMOXICILLIN	0	1 (1.4)	2 (2.9)	0	3 (1.4)	3 (1.1)
CEFDINIR	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
LEVOFLOXACIN	0	2 (2.9)	1 (1.4)	0	3 (1.4)	3 (1.1)
CEFACLOR	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
AMOXICILLIN;CLAVULANATE POTASSIUM	1 (1.4)	0	0	0	0	1 (0.4)
AZITHROMYCIN	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
BENZATHINE BENZYLPENICILLIN	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
BENZYLPENICILLIN SODIUM	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CEFOPERAZONE SODIUM;SULBACTAM SODIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
CEFUROXIME SODIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
FENBUFEN;METRONIDAZOLE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
FOSFOMYCIN TROMETAMOL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
METRONIDAZOLE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
METRONIDAZOLE BENZOATE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
MOXIFLOXACIN HYDROCHLORIDE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
NORFLOXACIN	1 (1.4)	0	0	0	0	1 (0.4)
ORNIDAZOLE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ROXITHROMYCIN	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANALGESICS	6 (8.7)	3 (4.3)	7 (10.1)	4 (5.9)	14 (6.8)	20 (7.2)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE MALEATE;CHRYSANTHEMUM INDICUM FLOWER;ILEX ASPRELLA ROOT;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS OIL;PARACETAMOL	1 (1.4)	2 (2.9)	3 (4.3)	1 (1.5)	6 (2.9)	7 (2.5)
AMANTADINE HYDROCHLORIDE;CAFFEINE;CHLORPHENAMINE MALEATE;COW BEZOAR;PARACETAMOL	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
AMINOPHENAZONE;CAFFEINE;CHLORPHENAMINE MALEATE;PARACETAMOL	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ANDROGRAPHIS PANICULATA HERB;GARDENIA JASMINOIDES FRUIT;OPHIOPOGON JAPONICUS ROOT TUBER	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANALGESICS (con'd)						
ANGELICA DAHURICA ROOT;ARISAEMA SPP. TUBER;BOMBYX MORI;GASTRODIA ELATA TUBER;NOTOPTERYGIUM SPP. ROOT WITH RHIZOME;PANAX NOTOGINSENG ROOT;SAPOSHNIKOVIA DIVARICATA ROOT;SAUROMATUM GIGANTEUM TUBER	1 (1.4)	0	0	0	0	1 (0.4)
CAFFEINE;CHLORPHENAMINE MALEATE;COW BEZOAR;PARACETAMOL	1 (1.4)	0	0	0	0	1 (0.4)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.4)	0	0	0	0	1 (0.4)
CHLORPHENAMINE MALEATE;PARACETAMOL	1 (1.4)	0	0	0	0	1 (0.4)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANALGESICS (con'd)						
DIOXOPROMETHAZINE HYDROCHLORIDE;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;PARACETAMOL;ZINC GLUCONATE	1 (1.4)	0	0	0	0	1 (0.4)
PARACETAMOL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
SUFENTANIL CITRATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
CALCIUM CHANNEL BLOCKERS	6 (8.7)	4 (5.7)	4 (5.8)	3 (4.4)	11 (5.3)	17 (6.2)
AMLODIPINE BESILATE	4 (5.8)	1 (1.4)	2 (2.9)	3 (4.4)	6 (2.9)	10 (3.6)
LEVAMLODIPINE BESILATE	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
NIFEDIPINE	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
FELODIPINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
LERCANIDIPINE HYDROCHLORIDE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
NITRENDIPINE	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	2 (2.9)	2 (2.9)	3 (4.3)	4 (5.9)	9 (4.3)	11 (4.0)
IBUPROFEN	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
ACECLOFENAC	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS (con'd)						
ANGELICA DAHURICA ROOT;CALCIUM SULFATE DIHYDRATE;CHRYSANTHEMUM X MORIFOLIUM FLOWER;COPTIS SPP. RHIZOME;FORSYTHIA SUSPENSA FRUIT;GARDENIA JASMINOIDES FRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;INULA JAPONICA FLOWER HEAD;LIGUSTICUM CHUANXIONG RHIZOME;MENTHA CANADENSIS HERB;NEPETA TENUIFOLIA SPIKE;PHELLODENDRON CHINENSE BARK;PLATYCODON GRANDIFLORUS ROOT;RHEUM SPP. ROOT WITH RHIZOME;SAPOSHNIKOVIA DIVARICATA ROOT;SCUTELLARIA BAICALENSIS ROOT;VITEX TRIFOLIA FRUIT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Concomitant Medication
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS (con'd)						
ANGELICA SINENSIS ROOT;ASTRAGALUS MONGHOLICUS ROOT;COIX LACRYMA-JOBI VAR. MA-YUEN KERNEL;CYATHULA OFFICINALIS ROOT;ILEX CORNUTA LEAF;LIGUSTRUM LUCIDUM FRUIT;LUFFA AEGYPTIACA FRUIT;LYCOPUS LUCIDUS VAR. HIRTUS HERB;PRUNELLA VULGARIS SPIKE;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SIGESBECKIA SPP. HERB;SMILAX GLABRA RHIZOME;STEPHANIA TETRANDRA ROOT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
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ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS (con'd)						
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;LONICERA JAPONICA FLOWER	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CALCIUM CARBONATE;CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
DICLOFENAC SODIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
GLUCOSAMINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
NABUMETONE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
PAEONOL	1 (1.4)	0	0	0	0	1 (0.4)
PARECOXIB SODIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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Concomitant Medication
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIVIRALS FOR SYSTEMIC USE	4 (5.8)	2 (2.9)	2 (2.9)	2 (2.9)	6 (2.9)	10 (3.6)
CALCIUM SULFATE DIHYDRATE;DRYOPTERIS CRASSIRHIZOMA RHIZOME;EPHEDRA SPP. HERB;FORSYTHIA SUSPENSA FRUIT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HOUTTUYNIA CORDATA HERB;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT; LONICERA JAPONICA FLOWER;MENTHOL;POGOSTEMON CABLIN HERB;PRUNUS SPP. SEED;RHEUM SPP. ROOT WITH RHIZOME;RHODIOLA CRENULATA ROOT WITH RHIZOME	2 (2.9)	0	1 (1.4)	0	1 (0.5)	3 (1.1)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIVIRALS FOR SYSTEMIC USE (con'd)						
ACORUS CALAMUS VAR. ANGUSTATUS RHIZOME;ANEMARRHENA ASPHODELOIDES RHIZOME;CALCIUM SULFATE DIHYDRATE;CURCUMA SPP. ROOT TUBER;FORSYTHIA SUSPENSA FRUIT;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS RHIZOME;POGOSTEMON CABLIN HERB;REHMANNIA GLUTINOSA ROOT TUBER	2 (2.9)	0	0	0	0	2 (0.7)
OSELTAMIVIR PHOSPHATE	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
ACICLOVIR	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
AMANTADINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
RIBAVIRIN	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
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ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	3 (4.3)	3 (4.3)	3 (4.3)	1 (1.5)	7 (3.4)	10 (3.6)
AESCULUS HIPPOCASTANUM EXTRACT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANGELICA SINENSIS ROOT;CITRUS X AURANTIUM UNRIPE FRUIT;SANGUISORBA OFFICINALIS ROOT;SAPOSHNIKOVIA DIVARICATA ROOT;SCUTELLARIA BAICALENSIS ROOT;STYPHNOLOBIUM JAPONICUM FRUIT	1 (1.4)	0	0	0	0	1 (0.4)
ASTRAGALUS MONGHOLICUS ROOT;CIBOTIUM BAROMETZ RHIZOME;ECLIPTA PROSTRATA HERB;LIGUSTRUM LUCIDUM FRUIT;MORUS ALBA FRUIT;PAEONIA LACTIFLORA ROOT;REYNOUTRIA MULTIFLORA ROOT TUBER	1 (1.4)	0	0	0	0	1 (0.4)

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UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE (con'd)						
BORNEOL;CNIDIUM MONNIERI FRUIT;PUNICA GRANATUM PEEL;QUERCUS INFECTORIA;SOPHORA ALOPECUROIDES HERB;ZANTHOXYLUM BUNGEANUM PEEL	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
BUPLEURUM SPP. ROOT;CODONOPSIS SPP. ROOT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;PINELLIA TERNATA TUBER;SCUTELLARIA BAICALENSIS ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CENTIPEDE;FORSYTHIA SUSPENSA FRUIT;LONICERA JAPONICA FLOWER BUD;PHELLODENDRON CHINENSE BARK;TARAXACUM SPP. WHOLE PLANT	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

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UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE (con'd)						
CLEMATIS ARMANDI STEM;DIANTHUS SUPERBUS HERB;JUNCUS EFFUSUS HERB;LONICERA JAPONICA FLOWER BUD;LOPHATHERUM GRACILE HERB;PLANTAGO ASIATICA SEED;POLYGONUM AVICULARE HERB;PYRROSIA LINGUA LEAF;SCUTELLARIA BARBATA HERB;TAXILLUS CHINENSIS HERB	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
GINKGO BILOBA LEAF EXTRACT	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
PERSICARIA CAPITATA WHOLE PLANT	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
TRADITIONAL CHINESE MEDICINE (TCM) DECOCTION	1 (1.4)	0	0	0	0	1 (0.4)

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COUGH AND COLD PREPARATIONS	1 (1.4)	3 (4.3)	2 (2.9)	3 (4.4)	8 (3.9)	9 (3.3)
AMBROXOL HYDROCHLORIDE	0	2 (2.9)	0	1 (1.5)	3 (1.4)	3 (1.1)
ANGELICA DAHURICA ROOT;ARECA CATECHU FRUIT PEEL;ATRACTYLODES MACROCEPHALA RHIZOME;CITRUS X AURANTIUM FRUIT PEEL;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;MAGNOLIA OFFICINALIS BARK;PERILLA FRUTESCENS LEAF; PINELLIA TERNATA TUBER;PLATYCODON GRANDIFLORUS ROOT;POGOSTEMON CABLIN HERB;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)

Data Source: Listing 16.2.5.1.1
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COUGH AND COLD PREPARATIONS (con'd)						
ANGELICA DAHURICA ROOT;BUPLEURUM SPP. ROOT;CORYDALIS BUNGEANA HERB;MENTHA CANADENSIS HERB;NEPETA TENUIFOLIA SPIKE;PERILLA FRUTESCENS LEAF;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS RHIZOME;PLATYCODON GRANDIFLORUS ROOT;PRUNUS SPP. SEED;PUERARIA MONTANA VAR. LOBATA ROOT;SAPOSHNIKOVIA DIVARICATA ROOT	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
ACETYLCYSTEINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ANDROGRAPHIS PANICULATA	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

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COUGH AND COLD PREPARATIONS (con'd)						
ARCTIUM LAPPA FRUIT;CICADA SLOUGH;EPHEDRA SPP. HERB;ERIOBOTRYA JAPONICA LEAF;KITAGAWIA PRAERUPTORA ROOT;PERILLA FRUTESCENS FRUIT;PERILLA FRUTESCENS LEAF;PHERETIMA SPP.;SCHISANDRA CHINENSIS FRUIT	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
BERBERIS KANSUENSIS BARK;CORYDALIS HENDERSONII HERB;FRITILLARIA SPP. BULB;GENTIANA SCABRA ROOT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;INULA RACEMOSA ROOT;PHLOMOIDES YOUNGHUSHANDII;PRZEWALSKIA TANGUTICA ROOT;PSEUDOCODON CONVOLVULACEUS TUBER;RHODODENDRON SPP. LEAF WITH FLOWER	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
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COUGH AND COLD PREPARATIONS (con'd)						
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ERIOBOTRYA JAPONICA LEAF;MENTHOL;MORUS ALBA ROOT BARK;PAPAVER SOMNIFERUM PERICARP;PLATYCODON GRANDIFLORUS ROOT;STEMONA SPP. ROOT TUBER;VINCETOXICUM SPP. ROOT WITH RHIZOME	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	1 (1.4)	2 (2.9)	2 (2.9)	3 (4.4)	7 (3.4)	8 (2.9)
ALLISARTAN ISOPROXIL	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
AMLODIPINE BESILATE;PERINDOPRIL ARGININE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
AMLODIPINE;VALSARTAN	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
BENAZEPRIL HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
HYDROCHLOROTHIAZIDE;IRBESARTAN	1 (1.4)	0	0	0	0	1 (0.4)
HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
LOSARTAN POTASSIUM	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
PERINDOPRIL ERBUMINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

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BILE AND LIVER THERAPY	2 (2.9)	1 (1.4)	2 (2.9)	2 (2.9)	5 (2.4)	7 (2.5)
BICYCLOL	2 (2.9)	0	1 (1.4)	0	1 (0.5)	3 (1.1)
POLYENE PHOSPHATIDYLCHOLINE	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
SCHISANDRA SPHENANTHERA FRUIT	2 (2.9)	0	0	0	0	2 (0.7)
ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA RHIZOME;BUPLEURUM SPP. ROOT;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;MENTHA CANADENSIS HERB;PAEONIA LACTIFLORA ROOT;PORIA COCOS SCLEROTIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
GLUTATHIONE	1 (1.4)	0	0	0	0	1 (0.4)
MAGNESIUM ISOGLYCYRRHIZINATE	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
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VITAMINS	0	3 (4.3)	2 (2.9)	2 (2.9)	7 (3.4)	7 (2.5)
ASCORBIC ACID	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
ADENINE PHOSPHATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHROMIUM; COLECALCIFEROL;COPPER;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SELENIUM; VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN E NOS;VITAMIN K NOS;ZINC	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
BIOTIN;CYANOCOBALAMIN;FOLIC ACID;GLYCINE;NICOTINAMIDE;PANTOTHENATE SODIUM;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;SODIUM ASCORBATE;THIAMINE MONONITRATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ERGOCALCIFEROL	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

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Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
VITAMINS (con'd)						
ERGOCALCIFEROL;PHYTOMENADIONE;RETINOL;VITAMIN E NOS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
PYRIDOXINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
RETINOL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
VITAMIN B COMPLEX	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
VITAMIN B1 NOS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	2 (2.9)	1 (1.4)	1 (1.4)	2 (2.9)	4 (1.9)	6 (2.2)
LEVOCETIRIZINE DIHYDROCHLORIDE	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
LORATADINE	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. (con'd)						
ANGELICA DAHURICA ROOT;ARTEMISIA ARGYI LEAF;BASSIA SCOPARIA FRUIT;CNIDIUM MONNIERI FRUIT;DICTAMNUS DASYCARPUS ROOT BARK;HONEYCOMB;LIGUSTICUM CHUANXIONG RHIZOME;NEPETA TENUIFOLIA HERB;PORTULACA OLERACEA HERB;PRUNUS PERSICA TWIG;SALIX BABYLONICA TWIG;SOPHORA FLAVESCENS ROOT;SOPHORA TONKINENSIS;STEMONA SPP. ROOT TUBER;TAMARIX CHINENSIS;TRIBULUS TERRESTRIS FRUIT	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CETIRIZINE HYDROCHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DESLORATADINE CITRATE DISODIUM	1 (1.4)	0	0	0	0	1 (0.4)

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CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	1 (1.4)	1 (1.4)	1 (1.4)	3 (4.4)	5 (2.4)	6 (2.2)
HALOMETASONE	0	0	0	2 (2.9)	2 (1.0)	2 (0.7)
HYDROCORTISONE BUTYRATE	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
CLOBETASOL PROPIONATE;UREA	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
DEXAMETHASONE ACETATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
HYDROCORTISONE ACETATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
PREDNISONE ACETATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DRUGS FOR ACID RELATED DISORDERS	2 (2.9)	0	2 (2.9)	2 (2.9)	4 (1.9)	6 (2.2)
OMEPRAZOLE	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
AMOMUM SPP. FRUIT;CAMPYLOTROPIS HIRTELLA ROOT;COPTIS SPP. RHIZOME;CORYDALIS YANHUSUO TUBER;DOLOMIAEA COSTUS ROOT;FAGOPYRUM CYMOSUM RHIZOME;PAEDERIA FOETIDA HERB WITH ROOT;POTENTILLA FULGENS ROOT	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
CIMETIDINE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
HYDROTALCITE	1 (1.4)	0	0	0	0	1 (0.4)
OMEPRAZOLE SODIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

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DRUGS FOR ACID RELATED DISORDERS (con'd)						
REBAMIPIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
SODIUM BICARBONATE	1 (1.4)	0	0	0	0	1 (0.4)
LIPID MODIFYING AGENTS	1 (1.4)	2 (2.9)	2 (2.9)	1 (1.5)	5 (2.4)	6 (2.2)
ROSUVASTATIN CALCIUM	0	1 (1.4)	2 (2.9)	0	3 (1.4)	3 (1.1)
ATORVASTATIN	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
ATORVASTATIN CALCIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
FENOFIBRATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
FISH OIL;VITAMIN E NOS	1 (1.4)	0	0	0	0	1 (0.4)
MINERAL SUPPLEMENTS	0	4 (5.7)	0	2 (2.9)	6 (2.9)	6 (2.2)
CALCIUM CARBONATE;COLECALCIFEROL	0	4 (5.7)	0	0	4 (1.9)	4 (1.4)
CALCIUM GLUCONATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
CALCIUM;COLECALCIFEROL;MAGNESIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
PSYCHOLEPTICS	1 (1.4)	1 (1.4)	1 (1.4)	3 (4.4)	5 (2.4)	6 (2.2)
ESTAZOLAM	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
ALPRAZOLAM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DEXMEDETOMIDINE HYDROCHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DIAZEPAM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ESZOPICLONE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

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ANESTHETICS	0	2 (2.9)	1 (1.4)	2 (2.9)	5 (2.4)	5 (1.8)
ROPIVACAINE HYDROCHLORIDE	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
ARTICAINE HYDROCHLORIDE;EPINEPHRINE BITARTRATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
LIDOCAINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
LIDOCAINE HYDROCHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
OXYBUPROCAINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
PROPOFOL	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.9)	4 (1.9)	5 (1.8)
BACILLUS LICHENFORMIS	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
BERBERINE HYDROCHLORIDE;DOLOMIAEA COSTUS ROOT;PAEONIA LACTIFLORA ROOT;TETRADIUM RUTICARPUM FRUIT	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

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ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS (con'd)						
MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE ANHYDROUS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
MONTMORILLONITE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
RIFAXIMIN	1 (1.4)	0	0	0	0	1 (0.4)
CARDIAC THERAPY	1 (1.4)	2 (2.9)	1 (1.4)	1 (1.5)	4 (1.9)	5 (1.8)
BORNEOL;CINNAMOMUM CASSIA BARK;COW BEZOAR;LIQUIDAMBAR ORIENTALIS BALSAM;MUSK;PANAX GINSENG ROOT WITH RHIZOME;TOAD VENOM	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

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CARDIAC THERAPY (con'd)						
CRATAEGUS PINNATIFIDA FRUIT;DOLOMIAEA COSTUS ROOT;PANAX NOTOGINSENG ROOT WITH RHIZOME;PUERARIA MONTANA VAR. LOBATA ROOT;SALVIA MILTIORRHIZA ROOT WITH RHIZOME	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
EPINEPHRINE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
GLYCERYL TRINITRATE	1 (1.4)	0	0	0	0	1 (0.4)
NOREPINEPHRINE BITARTRATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
TRIMETAZIDINE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

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OTHER GYNECOLOGICALS	1 (1.4)	2 (2.9)	1 (1.4)	1 (1.5)	4 (1.9)	5 (1.8)

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OTHER GYNECOLOGICALS (con'd)						
ANGELICA SINENSIS ROOT;ATRACTYLODES MACROCEPHALA RHIZOME;BUPLEURUM SPP. ROOT;CARTHAMUS TINCTORIUS FLOWER;CODONOPSIS SPP. ROOT;CORYDALIS YANHUSUO TUBER;CYPERUS ROTUNDUS RHIZOME;GENTIANA MACROPHYLLA ROOT;LYCIUM CHINENSE ROOT BARK;PAEONIA OFFICINALIS SUBSP. OFFICINALIS ROOT;PANAX NOTOGINSENG ROOT;PLANTAGO SPP. SEED;PORIA COCOS SCLEROTIUM;PORTULACA OLERACEA HERB;REHMANNIA GLUTINOSA PROCESSED ROOT TUBER;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SARGASSUM PALLIDUM;SONCHUS ARVENSIS;TARAXACUM SPP. HERB;TURTLE CARAPACE	1 (1.4)	2 (2.9)	1 (1.4)	0	3 (1.4)	4 (1.4)

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OTHER GYNECOLOGICALS (con'd)						
ANDROGRAPHIS PANICULATA HERB;ANGELICA SINENSIS ROOT;BERBERIS SPP. STEM;CODONOPSIS SPP. ROOT;FLEMINGIA SPP. ROOT;ROSA SPP. ROOT;SPATHOLOBUS SUBERECTUS STEM;ZANTHOXYLUM DISSITUM ROOT WITH STEM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANGELICA SINENSIS ROOT;FICUS SIMPLICISSIMA ROOT;MACLURA SPP. ROOT;MELASTOMA DODECANDRUM WHOLE PLANT;ZANTHOXYLUM NITIDUM ROOT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

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TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	1 (1.4)	0	2 (2.9)	2 (2.9)	4 (1.9)	5 (1.8)
ACONITUM KUSNEZOFFII ROOT TUBER;ACONITUM SPP. ROOT TUBER;HERBAL NOS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ACONITUM KUSNEZOFFII ROOT TUBER;HERBAL NOS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DICLOFENAC DIETHYLAMINE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
KETOPROFEN	1 (1.4)	0	0	0	0	1 (0.4)
LOXOPROFEN SODIUM	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	0	1 (1.4)	1 (1.4)	2 (2.9)	4 (1.9)	4 (1.4)
SODIUM CHLORIDE	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
ALANINE;ARGININE HYDROCHLORIDE;ASPARTIC ACID;CYSTINE;GLUTAMIC ACID;GLYCINE;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;METHIONINE;PHENYLALANINE;PRO LINE;SERINE;THREONINE;TRYPTOPHAN; TYROSINE;VALINE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

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BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS (con'd)						
ALANINE;ARGININE;ASPARTIC ACID;CALCIUM CHLORIDE;GLUCOSE;GLUTAMIC ACID;GLYCINE;GLYCINE MAX SEED OIL;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM SULFATE;METHIONINE;PHENYLALANINE; POTASSIUM CHLORIDE;PROLINE;SERINE;SODIUM ACETATE;SODIUM GLYCEROPHOSPHATE;THREONINE;TRYPTOPHAN;TYRO SINE;VALINE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ALBUMIN HUMAN	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

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BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS (con'd)						
AMMONIUM MOLYBDATE;CHROMIC CHLORIDE;COBALT GLUCONATE;COPPER GLUCONATE;FERROUS GLUCONATE;MANGANESE GLUCONATE;SODIUM FLUORIDE;SODIUM IODIDE;SODIUM SELENITE;ZINC GLUCONATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
GLUCOSE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
POTASSIUM CHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
RED BLOOD CELLS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
SUCCINYLATED GELATIN	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

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DRUGS FOR CONSTIPATION	1 (1.4)	0	0	3 (4.4)	3 (1.4)	4 (1.4)
GLYCEROL	0	0	0	2 (2.9)	2 (1.0)	2 (0.7)
BACILLUS CEREUS;BIFIDOBACTERIUM INFANTIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
CANNABIS SATIVA FRUIT;CITRUS X AURANTIUM SUBMATURE FRUIT;MAGNOLIA OFFICINALIS BARK;PAEONIA LACTIFLORA ROOT;PRUNUS SPP. SEED;RHEUM SPP. ROOT WITH RHIZOME	1 (1.4)	0	0	0	0	1 (0.4)
DRUGS USED IN DIABETES	0	0	2 (2.9)	2 (2.9)	4 (1.9)	4 (1.4)
GLIMEPIRIDE	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
METFORMIN HYDROCHLORIDE	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
INSULIN NOS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
METFORMIN HYDROCHLORIDE;PIOGLITAZONE HYDROCHLORIDE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

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GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	0	2 (2.9)	1 (1.4)	1 (1.5)	4 (1.9)	4 (1.4)
METRONIDAZOLE	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
CHLORHEXIDINE DIACETATE;CLOTRIMAZOLE;METRONIDAZOLE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CLINDAMYCIN PHOSPHATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
MICONAZOLE NITRATE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
POVIDONE-IODINE	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
OPHTHALMOLOGICALS	1 (1.4)	1 (1.4)	0	2 (2.9)	3 (1.4)	4 (1.4)
DEXAMETHASONE;TOBRAMYCIN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
AZELASTINE HYDROCHLORIDE	1 (1.4)	0	0	0	0	1 (0.4)
BOVINE BASIC FIBROBLAST GROWTH FACTOR	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CALCIUM CHLORIDE;GLUCOSE;MAGNESIUM SULFATE;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
THROAT PREPARATIONS	1 (1.4)	1 (1.4)	0	2 (2.9)	3 (1.4)	4 (1.4)
IBUPROFEN	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
GARDENIA JASMINOIDES FRUIT;ISATIS TINCTORIA SUBSP. TINCTORIA ROOT;PHELLODENDRON CHINENSE BARK;SCAPHIUM AFFINE SEED;SCUTELLARIA BAICALENSIS ROOT	1 (1.4)	0	0	0	0	1 (0.4)
ANTITHROMBOTIC AGENTS	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
ENOXAPARIN SODIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
HEPARIN SODIUM	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
LEECH	1 (1.4)	0	0	0	0	1 (0.4)
RIVAROXABAN	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
CORTICOSTEROIDS FOR SYSTEMIC USE	1 (1.4)	0	0	2 (2.9)	2 (1.0)	3 (1.1)
BETAMETHASONE DIPROPIONATE;BETAMETHASONE SODIUM PHOSPHATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DEXAMETHASONE SODIUM PHOSPHATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
HYDROCORTISONE SODIUM SUCCINATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
METHYLPREDNISOLONE	1 (1.4)	0	0	0	0	1 (0.4)
METHYLPREDNISOLONE SODIUM SUCCINATE	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
CENTIPEDE;FORSYTHIA SUSPENSA FRUIT;LONICERA JAPONICA FLOWER BUD;PHELLODENDRON CHINENSE BARK;TARAXACUM SPP. WHOLE PLANT	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
CHITOSAN OLIGOSACCHARIDE NOS	1 (1.4)	0	0	0	0	1 (0.4)
PERIPLANETA AMERICANA	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
ERYTHROMYCIN	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
INTERFERON ALFA-2B	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
MUPIROCIN	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIHYPERTENSIVES	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
ACHYRANTHES BIDENTATA ROOT;ANGELICA SINENSIS ROOT;ILEX PUBESCENS ROOT;PANAX NOTOGINSENG ROOT;PRUNELLA VULGARIS SPIKE;PUERARIA MONTANA VAR. LOBATA ROOT;SALVIA MILTIORRHIZA ROOT WITH RHIZOME;SENNA OBTUSIFOLIA SEED;STYPHNOLOBIUM JAPONICUM FLOWER BUD;UNCARIA SPP. HOOK	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
DIHYDRALAZINE SULFATE;HYDROCHLOROTHIAZIDE;RESERPINE;TRIAMTERENE	1 (1.4)	0	0	0	0	1 (0.4)
BETA BLOCKING AGENTS	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
METOPROLOL SUCCINATE	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
EMOLLIENTS AND PROTECTIVES	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
TOCOPHEROL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
UREA	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
OTHER RESPIRATORY SYSTEM PRODUCTS	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
AMBROXOL	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
AMBROXOL HYDROCHLORIDE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
VASOPROTECTIVES	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
CHONDRUS CRISPUS;TITANIUM DIOXIDE;ZINC OXIDE	1 (1.4)	0	0	0	0	1 (0.4)
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ALL OTHER NON-THERAPEUTIC PRODUCTS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
WATER FOR INJECTION	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ALL OTHER THERAPEUTIC PRODUCTS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ASCORBIC ACID	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANTIANEMIC PREPARATIONS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANGELICA SINENSIS;ASTRAGALUS SPP.;ATRACTYLODES MACROCEPHALA;FERROUS SULFATE;FOLIC ACID;YEAST DRIED	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ASTRAGALUS MONGHOLICUS ROOT;BLOOD, PIG;ZIZIPHUS JUJUBA FRUIT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ANTIEMETICS AND ANTINAUSEANTS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
DIPHENHYDRAMINE HYDROCHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ONDANSETRON HYDROCHLORIDE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANTIEPILEPTICS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
MAGNESIUM SULFATE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANTIHEMORRHAGICS	1 (1.4)	0	0	0	0	1 (0.4)
PANAX NOTOGINSENG ROOT WITH RHIZOME	1 (1.4)	0	0	0	0	1 (0.4)
ANTIMYCOTICS FOR SYSTEMIC USE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
FLUCONAZOLE	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANTINEOPLASTIC AGENTS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
CARBOPLATIN	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
PACLITAXEL	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
ANTISEPTICS AND DISINFECTANTS	1 (1.4)	0	0	0	0	1 (0.4)
ORGANOSILICON QUATERNARY AMMONIUM SALT NOS	1 (1.4)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
DIGESTIVES, INCL. ENZYMES	1 (1.4)	0	0	0	0	1 (0.4)
ANGELICA DAHURICA ROOT;ARECA CATECHU FRUIT PEEL;ATRACTYLODES MACROCEPHALA RHIZOME;CITRUS X AURANTIUM FRUIT PEEL;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;MAGNOLIA OFFICINALIS BARK;PERILLA FRUTESCENS LEAF; PINELLIA TERNATA TUBER;PLATYCODON GRANDIFLORUS ROOT;POGOSTEMON CABLIN HERB;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT	1 (1.4)	0	0	0	0	1 (0.4)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
DOMPERIDONE	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.2
Concomitant Medication
FAS

ATC Classification (ATC Level 2) Preferred Name (PN)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
DRUGS FOR TREATMENT OF BONE DISEASES	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
ALENDRONATE SODIUM	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
IMMUNOSTIMULANTS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
GANODERMA SPP. SPORE OIL	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
OTHER DERMATOLOGICAL PREPARATIONS	1 (1.4)	0	0	0	0	1 (0.4)
CRISABOROLE	1 (1.4)	0	0	0	0	1 (0.4)
OTHER NERVOUS SYSTEM DRUGS	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
MECOBALAMIN	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
THYROID THERAPY	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
LEVOTHYROXINE SODIUM	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
TONICS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
TOCOPHEROL	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
UROLOGICALS	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
PERSICARIA CAPITATA WHOLE PLANT	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.1.1
WHODrug version WHODrug Global B3 Sep 1, 2024 applied.
Subjects were counted only once per treatment per category.
Concomitant medication was defined as any medication that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.3
Prior Non-drug Therapy
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Subjects with any Prior Non-drug Therapy	1 (1.4)	3 (4.3)	3 (4.3)	1 (1.5)	7 (3.4)	8 (2.9)
Surgical and medical procedures	1 (1.4)	3 (4.3)	3 (4.3)	0	6 (2.9)	7 (2.5)
Acupuncture	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Acupoint application therapy	1 (1.4)	0	0	0	0	1 (0.4)
Cupping therapy	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Intra-uterine contraceptive device removal	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Pelvic floor stimulation	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Physiotherapy	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Uterine dilation and curettage	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Investigations	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Hysteroscopy	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.2
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.
Prior non-drug therapy was defined as any non-drug therapy that ended prior to the date of first study drug administration.

Table 14.1.4.4
Concomitant Non-drug Therapy
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Subjects with any Concomitant Non-drug Therapy	3 (4.3)	2 (2.9)	2 (2.9)	2 (2.9)	6 (2.9)	9 (3.3)
Surgical and medical procedures	3 (4.3)	2 (2.9)	2 (2.9)	2 (2.9)	6 (2.9)	9 (3.3)
Tooth restoration	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Acupuncture	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Breast operation	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Cervix tumour excision	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Drainage	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Endocervical curettage	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Infrared therapy	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Intestinal anastomosis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Laparotomy	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Laser therapy	1 (1.4)	0	0	0	0	1 (0.4)
Ovarian operation	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Oxygen therapy	1 (1.4)	0	0	0	0	1 (0.4)
Pelvic fluid collection drainage	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Peritonectomy	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Proctocolectomy	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Salpingo-oophorectomy unilateral	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Ultrasound therapy	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Uterine polypectomy	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.2
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.
Concomitant non-drug therapy was defined as any non-drug therapy that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.1.4.4
Concomitant Non-drug Therapy
FAS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Investigations	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Laparoscopy	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.5.2
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.
Concomitant non-drug therapy was defined as any non-drug therapy that is either ongoing or has ended at or after the date of first study drug administration.

Table 14.2.1
Intercurrent Events
FAS

Intercurrent Events (ICEs)	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)
ICE1	0	0	0	0
ICE2	0	0	0	0
ICE3	5 (7.2)	4 (5.7)	4 (5.8)	5 (7.4)

Data Source: Listing 16.2.1.3 and Listing 16.2.5.1.2
ICE1 = receiving protocol prohibited concomitant medications prior to Week 12 which impact the efficacy assessment.
ICE2 = discontinuing study treatment early due to lack of efficacy prior to Week 12.
ICE3 = discontinuing study treatment early for other reasons prior to Week 12.
Subjects were counted only once per treatment per ICE.

Table 14.2.2.1.1

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	12.628 (2.5693)	12.957 (3.7763)	12.883 (4.4260)	12.979 (3.6833)
	Median	12.000	12.571	11.571	12.429
	Q1 - Q3	11.143 - 13.571	10.429 - 13.857	10.000 - 13.571	10.714 - 14.786
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	7.436 (3.6916)	6.803 (3.9056)	6.711 (4.2475)	6.345 (4.2275)
	Median	8.143	6.143	6.429	6.214
	Q1 - Q3	5.429 - 9.857	4.000 - 9.571	3.571 - 9.286	2.857 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.1

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-5.204 (4.0472)	-6.166 (4.6777)	-6.249 (4.2264)	-6.634 (3.9523)
	Median	-4.000	-5.143	-4.857	-6.429
	Q1 - Q3	-7.714 - -2.429	-9.286 - -2.571	-8.857 - -3.000	-8.857 - -3.357
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43
	LS Mean (SE)	-5.281 (0.5496)	-6.123 (0.5486)	-6.216 (0.5578)	-6.586 (0.5572)
	90% CI (2-sided)	-6.187, -4.374	-7.028, -5.218	-7.136, -5.296	-7.505, -5.667
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.842 (0.6295)	-0.935 (0.6324)	-1.305 (0.6319)
	90% CI (2-sided)		-1.881, 0.197	-1.979, 0.109	-2.348, -0.263
	P-value		0.1819	0.1403	0.0398

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.1

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	3.620 (3.2846)	3.323 (3.6159)	2.272 (2.3579)	2.324 (2.6140)
	Median	2.857	2.071	1.667	1.429
	Q1 - Q3	1.000 - 5.500	0.143 - 5.857	0.143 - 3.429	0.143 - 4.000
	Min - Max	0 - 12.43	0 - 14.00	0 - 9.71	0 - 11.57

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.1

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-8.997 (4.1162)	-9.716 (4.6916)	-10.748 (5.1597)	-10.625 (4.5897)
	Median	-8.643	-10.000	-10.000	-10.714
	Q1 - Q3	-11.857 - -6.214	-13.000 - -6.714	-11.714 - -8.000	-12.571 - -7.714
	Min - Max	-21.71 - -0.43	-22.43 - 1.00	-31.71 - -1.98	-31.00 - 2.57
	LS Mean (SE)	-9.219 (0.4896)	-9.639 (0.4874)	-10.637 (0.4966)	-10.626 (0.4997)
	90% CI (2-sided)	-10.027, -8.411	-10.443, -8.834	-11.456, -9.818	-11.450, -9.801
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.420 (0.5205)	-1.418 (0.5239)	-1.407 (0.5274)
	90% CI (2-sided)		-1.279, 0.440	-2.283, -0.553	-2.277, -0.536
	P-value		0.4209	0.0072	0.0081

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.2

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.313 (0.2072)	2.315 (0.2042)	2.345 (0.2127)	2.302 (0.2180)
	Median	2.287	2.249	2.335	2.296
	Q1 - Q3	2.131 - 2.474	2.169 - 2.498	2.215 - 2.484	2.092 - 2.471
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.880 (0.4237)	1.843 (0.4337)	1.781 (0.5313)	1.744 (0.4669)
	Median	1.931	1.878	1.879	1.871
	Q1 - Q3	1.714 - 2.124	1.617 - 2.128	1.596 - 2.062	1.506 - 2.092
	Min - Max	0 - 2.67	0 - 2.58	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.2

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.428 (0.4101)	-0.477 (0.3937)	-0.568 (0.4871)	-0.558 (0.4697)
	Median	-0.398	-0.419	-0.405	-0.424
	Q1 - Q3	-0.574 - -0.156	-0.636 - -0.247	-0.812 - -0.210	-0.766 - -0.255
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.23 - 0.03
	LS Mean (SE)	-0.469 (0.0681)	-0.518 (0.0679)	-0.603 (0.0693)	-0.605 (0.0690)
	90% CI (2-sided)	-0.581, -0.356	-0.630, -0.406	-0.718, -0.489	-0.719, -0.491
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.049 (0.0747)	-0.135 (0.0753)	-0.136 (0.0750)
	90% CI (2-sided)		-0.173, 0.074	-0.259, -0.011	-0.260, -0.012
	P-value		0.5087	0.0744	0.0706

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.2

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	1.519 (0.6539)	1.411 (0.6623)	1.366 (0.6864)	1.288 (0.6991)
	Median	1.642	1.505	1.371	1.429
	Q1 - Q3	1.181 - 2.000	1.000 - 1.938	1.000 - 1.879	1.000 - 1.740
	Min - Max	0 - 2.67	0 - 2.60	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.2

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-0.777 (0.6425)	-0.905 (0.6659)	-0.982 (0.6290)	-1.004 (0.7272)
	Median	-0.586	-0.743	-0.952	-0.888
	Q1 - Q3	-1.054 - -0.296	-1.286 - -0.381	-1.404 - -0.417	-1.370 - -0.410
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02
	LS Mean (SE)	-0.829 (0.0920)	-0.954 (0.0909)	-1.021 (0.0927)	-1.066 (0.0933)
	90% CI (2-sided)	-0.981, -0.677	-1.104, -0.804	-1.174, -0.868	-1.220, -0.912
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.125 (0.1144)	-0.192 (0.1154)	-0.237 (0.1158)
	90% CI (2-sided)		-0.314, 0.064	-0.382, -0.001	-0.428, -0.046
	P-value		0.2744	0.0980	0.0418

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.3

Primary Endpoint Analysis (Primary Estimand)

Change from Baseline in the Frequency of Mild to Severe VMS at Week 4 and Week 12

FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	14.816 (3.8226)	14.878 (4.0525)	14.924 (5.6488)	15.492 (5.2379)
	Median	13.714	14.286	13.429	14.286
	Q1 - Q3	12.571 - 16.571	11.571 - 16.571	11.429 - 16.000	11.929 - 16.929
	Min - Max	9.17 - 29.86	9.00 - 24.57	8.71 - 39.86	8.33 - 42.43
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	9.599 (4.1143)	9.203 (4.9338)	8.920 (4.9114)	8.926 (4.9063)
	Median	10.286	9.143	8.714	8.857
	Q1 - Q3	7.143 - 12.571	5.857 - 11.857	6.000 - 11.429	5.857 - 11.643
	Min - Max	0 - 17.71	0 - 31.29	0 - 24.57	0 - 25.71

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.3
Primary Endpoint Analysis (Primary Estimand)
Change from Baseline in the Frequency of Mild to Severe VMS at Week 4 and Week 12
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-5.224 (4.9265)	-5.714 (5.1469)	-6.090 (4.8326)	-6.566 (4.4968)
	Median	-3.143	-4.429	-4.214	-5.857
	Q1 - Q3	-6.714 - -1.857	-9.143 - -2.429	-8.429 - -2.857	-9.714 - -3.071
	Min - Max	-25.57 - 2.43	-20.00 - 7.14	-23.00 - 0.43	-21.29 - 0.71
	LS Mean (SE)	-5.193 (0.6313)	-5.716 (0.6299)	-6.042 (0.6412)	-6.262 (0.6425)
	90% CI (2-sided)	-6.234, -4.151	-6.755, -4.677	-7.100, -4.985	-7.322, -5.202
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.523 (0.7095)	-0.849 (0.7130)	-1.069 (0.7132)
	90% CI (2-sided)		-1.694, 0.648	-2.026, 0.327	-2.246, 0.108
	P-value		0.4616	0.2346	0.1349

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.3
Primary Endpoint Analysis (Primary Estimand)
Change from Baseline in the Frequency of Mild to Severe VMS at Week 4 and Week 12
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	5.602 (4.0876)	5.209 (4.8345)	4.063 (2.8621)	4.029 (3.3014)
	Median	4.857	4.357	3.714	3.857
	Q1 - Q3	2.214 - 8.857	1.429 - 7.857	1.667 - 6.000	1.429 - 5.429
	Min - Max	0 - 17.43	0 - 24.86	0 - 10.86	0 - 12.43

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.1.3
Primary Endpoint Analysis (Primary Estimand)
Change from Baseline in the Frequency of Mild to Severe VMS at Week 4 and Week 12
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-9.095 (5.1891)	-9.763 (5.1809)	-10.958 (5.8461)	-11.493 (6.4032)
	Median	-8.643	-9.571	-10.143	-10.714
	Q1 - Q3	-12.000 - -6.143	-13.429 - -5.857	-12.000 - -7.714	-13.429 - -7.571
	Min - Max	-28.43 - 1.14	-20.86 - 1.86	-34.29 - -1.71	-40.00 - 0.71
	LS Mean (SE)	-9.241 (0.6016)	-9.781 (0.5984)	-10.910 (0.6098)	-11.019 (0.6159)
	90% CI (2-sided)	-10.234, -8.249	-10.769, -8.794	-11.916, -9.904	-12.035, -10.003
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.540 (0.6549)	-1.669 (0.6590)	-1.778 (0.6640)
	90% CI (2-sided)		-1.621, 0.541	-2.757, -0.581	-2.874, -0.682
	P-value		0.4100	0.0119	0.0079

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.1

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	12.628 (2.5693)	12.957 (3.7763)	12.883 (4.4260)	12.979 (3.6833)
	Median	12.000	12.571	11.571	12.429
	Q1 - Q3	11.143 - 13.571	10.429 - 13.857	10.000 - 13.571	10.714 - 14.786
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	7.436 (3.6916)	6.803 (3.9056)	6.711 (4.2475)	6.345 (4.2275)
	Median	8.143	6.143	6.429	6.214
	Q1 - Q3	5.429 - 9.857	4.000 - 9.571	3.571 - 9.286	2.857 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.1

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-5.204 (4.0472)	-6.166 (4.6777)	-6.249 (4.2264)	-6.634 (3.9523)
	Median	-4.000	-5.143	-4.857	-6.429
	Q1 - Q3	-7.714 - -2.429	-9.286 - -2.571	-8.857 - -3.000	-8.857 - -3.357
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43
	LS Mean (SE)	-5.280 (0.5497)	-6.122 (0.5486)	-6.215 (0.5578)	-6.586 (0.5573)
	90% CI (2-sided)	-6.187, -4.374	-7.027, -5.218	-7.135, -5.295	-7.505, -5.666
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.842 (0.6295)	-0.935 (0.6324)	-1.305 (0.6319)
	90% CI (2-sided)		-1.881, 0.197	-1.979, 0.109	-2.348, -0.263
	P-value		0.1819	0.1403	0.0398

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.1

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	3.620 (3.2846)	3.323 (3.6159)	2.272 (2.3579)	2.324 (2.6140)
	Median	2.857	2.071	1.667	1.429
	Q1 - Q3	1.000 - 5.500	0.143 - 5.857	0.143 - 3.429	0.143 - 4.000
	Min - Max	0 - 12.43	0 - 14.00	0 - 9.71	0 - 11.57

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.1

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-8.997 (4.1162)	-9.716 (4.6916)	-10.748 (5.1597)	-10.625 (4.5897)
	Median	-8.643	-10.000	-10.000	-10.714
	Q1 - Q3	-11.857 - -6.214	-13.000 - -6.714	-11.714 - -8.000	-12.571 - -7.714
	Min - Max	-21.71 - -0.43	-22.43 - 1.00	-31.71 - -1.98	-31.00 - 2.57
	LS Mean (SE)	-9.218 (0.4896)	-9.638 (0.4875)	-10.636 (0.4966)	-10.625 (0.4998)
	90% CI (2-sided)	-10.026, -8.411	-10.442, -8.834	-11.456, -9.817	-11.450, -9.800
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.420 (0.5205)	-1.418 (0.5239)	-1.407 (0.5274)
	90% CI (2-sided)		-1.279, 0.440	-2.283, -0.553	-2.277, -0.536
	P-value		0.4209	0.0073	0.0081

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.2

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.313 (0.2072)	2.315 (0.2042)	2.345 (0.2127)	2.302 (0.2180)
	Median	2.287	2.249	2.335	2.296
	Q1 - Q3	2.131 - 2.474	2.169 - 2.498	2.215 - 2.484	2.092 - 2.471
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.880 (0.4237)	1.843 (0.4337)	1.781 (0.5313)	1.744 (0.4669)
	Median	1.931	1.878	1.879	1.871
	Q1 - Q3	1.714 - 2.124	1.617 - 2.128	1.596 - 2.062	1.506 - 2.092
	Min - Max	0 - 2.67	0 - 2.58	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.2

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.428 (0.4101)	-0.477 (0.3937)	-0.568 (0.4871)	-0.558 (0.4697)
	Median	-0.398	-0.419	-0.405	-0.424
	Q1 - Q3	-0.574 - -0.156	-0.636 - -0.247	-0.812 - -0.210	-0.766 - -0.255
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.23 - 0.03
	LS Mean (SE)	-0.469 (0.0681)	-0.518 (0.0679)	-0.603 (0.0693)	-0.605 (0.0690)
	90% CI (2-sided)	-0.581, -0.356	-0.630, -0.406	-0.718, -0.489	-0.719, -0.491
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.049 (0.0747)	-0.135 (0.0753)	-0.136 (0.0750)
	90% CI (2-sided)		-0.173, 0.074	-0.259, -0.011	-0.260, -0.012
	P-value		0.5087	0.0744	0.0706

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.2

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	1.519 (0.6539)	1.411 (0.6623)	1.366 (0.6864)	1.288 (0.6991)
	Median	1.642	1.505	1.371	1.429
	Q1 - Q3	1.181 - 2.000	1.000 - 1.938	1.000 - 1.879	1.000 - 1.740
	Min - Max	0 - 2.67	0 - 2.60	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.2

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 1: Non-missing >=4 Days Within a Week)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-0.777 (0.6425)	-0.905 (0.6659)	-0.982 (0.6290)	-1.004 (0.7272)
	Median	-0.586	-0.743	-0.952	-0.888
	Q1 - Q3	-1.054 - -0.296	-1.286 - -0.381	-1.404 - -0.417	-1.370 - -0.410
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02
	LS Mean (SE)	-0.829 (0.0920)	-0.954 (0.0909)	-1.021 (0.0927)	-1.066 (0.0933)
	90% CI (2-sided)	-0.981, -0.677	-1.104, -0.804	-1.173, -0.868	-1.220, -0.912
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.125 (0.1144)	-0.192 (0.1154)	-0.237 (0.1158)
	90% CI (2-sided)		-0.314, 0.064	-0.382, -0.001	-0.428, -0.046
	P-value		0.2745	0.0980	0.0418

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 3 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.3
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	12.628 (2.5693)	12.957 (3.7763)	12.883 (4.4260)	12.979 (3.6833)
	Median	12.000	12.571	11.571	12.429
	Q1 - Q3	11.143 - 13.571	10.429 - 13.857	10.000 - 13.571	10.714 - 14.786
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	7.436 (3.6916)	6.803 (3.9056)	6.711 (4.2475)	6.345 (4.2275)
	Median	8.143	6.143	6.429	6.214
	Q1 - Q3	5.429 - 9.857	4.000 - 9.571	3.571 - 9.286	2.857 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.3
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-5.204 (4.0472)	-6.166 (4.6777)	-6.249 (4.2264)	-6.634 (3.9523)
	Median	-4.000	-5.143	-4.857	-6.429
	Q1 - Q3	-7.714 - -2.429	-9.286 - -2.571	-8.857 - -3.000	-8.857 - -3.357
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43
	LS Mean (SE)	-5.272 (0.5517)	-6.116 (0.5507)	-6.301 (0.5583)	-6.579 (0.5594)
	90% CI (2-sided)	-6.182, -4.362	-7.024, -5.207	-7.222, -5.380	-7.501, -5.656
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.844 (0.6321)	-1.029 (0.6334)	-1.307 (0.6345)
	90% CI (2-sided)		-1.887, 0.200	-2.074, 0.017	-2.354, -0.259
	P-value		0.1831	0.1055	0.0405

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.3
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	3.620 (3.2846)	3.323 (3.6159)	2.272 (2.3579)	2.324 (2.6140)
	Median	2.857	2.071	1.667	1.429
	Q1 - Q3	1.000 - 5.500	0.143 - 5.857	0.143 - 3.429	0.143 - 4.000
	Min - Max	0 - 12.43	0 - 14.00	0 - 9.71	0 - 11.57

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.3
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-8.997 (4.1162)	-9.716 (4.6916)	-10.748 (5.1597)	-10.625 (4.5897)
	Median	-8.643	-10.000	-10.000	-10.714
	Q1 - Q3	-11.857 - -6.214	-13.000 - -6.714	-11.714 - -8.000	-12.571 - -7.714
	Min - Max	-21.71 - -0.43	-22.43 - 1.00	-31.71 - -1.98	-31.00 - 2.57
	LS Mean (SE)	-9.210 (0.4904)	-9.630 (0.4883)	-10.662 (0.4970)	-10.617 (0.5006)
	90% CI (2-sided)	-10.019, -8.401	-10.435, -8.824	-11.482, -9.842	-11.443, -9.791
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.420 (0.5207)	-1.452 (0.5236)	-1.407 (0.5276)
	90% CI (2-sided)		-1.280, 0.440	-2.316, -0.588	-2.278, -0.536
	P-value		0.4207	0.0060	0.0081

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.4
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.313 (0.2072)	2.315 (0.2042)	2.345 (0.2127)	2.302 (0.2180)
	Median	2.287	2.249	2.335	2.296
	Q1 - Q3	2.131 - 2.474	2.169 - 2.498	2.215 - 2.484	2.092 - 2.471
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.880 (0.4237)	1.843 (0.4337)	1.781 (0.5313)	1.744 (0.4669)
	Median	1.931	1.878	1.879	1.871
	Q1 - Q3	1.714 - 2.124	1.617 - 2.128	1.596 - 2.062	1.506 - 2.092
	Min - Max	0 - 2.67	0 - 2.58	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.4
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.428 (0.4101)	-0.477 (0.3937)	-0.568 (0.4871)	-0.558 (0.4697)
	Median	-0.398	-0.419	-0.405	-0.424
	Q1 - Q3	-0.574 - -0.156	-0.636 - -0.247	-0.812 - -0.210	-0.766 - -0.255
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.23 - 0.03
	LS Mean (SE)	-0.468 (0.0684)	-0.517 (0.0682)	-0.613 (0.0695)	-0.604 (0.0693)
	90% CI (2-sided)	-0.581, -0.355	-0.630, -0.405	-0.728, -0.499	-0.718, -0.490
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.050 (0.0750)	-0.145 (0.0753)	-0.136 (0.0753)
	90% CI (2-sided)		-0.173, 0.074	-0.270, -0.021	-0.260, -0.012
	P-value		0.5095	0.0547	0.0719

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.4
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	1.519 (0.6539)	1.411 (0.6623)	1.366 (0.6864)	1.288 (0.6991)
	Median	1.642	1.505	1.371	1.429
	Q1 - Q3	1.181 - 2.000	1.000 - 1.938	1.000 - 1.879	1.000 - 1.740
	Min - Max	0 - 2.67	0 - 2.60	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.4
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 2: All Available Data)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-0.777 (0.6425)	-0.905 (0.6659)	-0.982 (0.6290)	-1.004 (0.7272)
	Median	-0.586	-0.743	-0.952	-0.888
	Q1 - Q3	-1.054 - -0.296	-1.286 - -0.381	-1.404 - -0.417	-1.370 - -0.410
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02
	LS Mean (SE)	-0.828 (0.0922)	-0.954 (0.0911)	-1.027 (0.0927)	-1.065 (0.0935)
	90% CI (2-sided)	-0.980, -0.676	-1.104, -0.803	-1.180, -0.874	-1.219, -0.911
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.125 (0.1144)	-0.198 (0.1154)	-0.237 (0.1158)
	90% CI (2-sided)		-0.314, 0.064	-0.389, -0.008	-0.428, -0.046
	P-value		0.2744	0.0866	0.0420

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

All available data within a week were used.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.5

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 3: Different Formula of Mean Severity)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.314 (0.2064)	2.316 (0.2040)	2.347 (0.2124)	2.306 (0.2175)
	Median	2.288	2.249	2.342	2.300
	Q1 - Q3	2.132 - 2.487	2.169 - 2.500	2.218 - 2.488	2.093 - 2.470
	Min - Max	2.00 - 2.73	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.905 (0.3933)	1.877 (0.4106)	1.812 (0.4843)	1.773 (0.4150)
	Median	1.970	1.878	1.878	1.870
	Q1 - Q3	1.713 - 2.153	1.646 - 2.133	1.600 - 2.065	1.513 - 2.090
	Min - Max	0 - 2.67	0 - 2.88	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated based on the daily mean over 7 days prior to randomization. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of moderate VMS for 7 days x 2 + number of severe VMS for 7 days x 3) / (total number of moderate and severe VMS episodes over 7 days).

Post-baseline values were calculated based on the daily mean over 7 days during particular week. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of mild VMS over 7 days x 1 + number of moderate VMS over 7 days x 2 + number of severe VMS over 7 days x 3) / (total number of mild, moderate and severe VMS episodes over 7 days).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.5

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 3: Different Formula of Mean Severity)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.404 (0.3909)	-0.444 (0.3586)	-0.538 (0.4508)	-0.533 (0.4111)
	Median	-0.398	-0.420	-0.405	-0.424
	Q1 - Q3	-0.573 - -0.136	-0.634 - -0.205	-0.762 - -0.213	-0.778 - -0.248
	Min - Max	-2.50 - 0.08	-2.05 - 0.36	-2.11 - 0	-2.00 - 0
	LS Mean (SE)	-0.438 (0.0614)	-0.478 (0.0612)	-0.566 (0.0625)	-0.572 (0.0622)
	90% CI (2-sided)	-0.539, -0.337	-0.579, -0.377	-0.669, -0.463	-0.675, -0.469
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.040 (0.0681)	-0.128 (0.0686)	-0.134 (0.0683)
	90% CI (2-sided)		-0.152, 0.073	-0.242, -0.015	-0.247, -0.021
	P-value		0.5608	0.0622	0.0508

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated based on the daily mean over 7 days prior to randomization. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of moderate VMS for 7 days x 2 + number of severe VMS for 7 days x 3) / (total number of moderate and severe VMS episodes over 7 days).

Post-baseline values were calculated based on the daily mean over 7 days during particular week. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of mild VMS over 7 days x 1 + number of moderate VMS over 7 days x 2 + number of severe VMS over 7 days x 3) / (total number of mild, moderate and severe VMS episodes over 7 days).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.5

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 3: Different Formula of Mean Severity)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	1.581 (0.6223)	1.574 (0.5999)	1.443 (0.6405)	1.379 (0.6560)
	Median	1.709	1.603	1.425	1.529
	Q1 - Q3	1.225 - 2.029	1.259 - 2.000	1.128 - 1.926	1.037 - 1.974
	Min - Max	0 - 2.67	0 - 3.00	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated based on the daily mean over 7 days prior to randomization. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of moderate VMS for 7 days x 2 + number of severe VMS for 7 days x 3) / (total number of moderate and severe VMS episodes over 7 days).

Post-baseline values were calculated based on the daily mean over 7 days during particular week. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of mild VMS over 7 days x 1 + number of moderate VMS over 7 days x 2 + number of severe VMS over 7 days x 3) / (total number of mild, moderate and severe VMS episodes over 7 days).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.5

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 3: Different Formula of Mean Severity)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-0.715 (0.6149)	-0.743 (0.6063)	-0.905 (0.6019)	-0.917 (0.6772)
	Median	-0.543	-0.675	-0.856	-0.839
	Q1 - Q3	-0.981 - -0.282	-1.075 - -0.320	-1.232 - -0.413	-1.259 - -0.389
	Min - Max	-2.55 - 0.08	-2.61 - 0.80	-2.51 - 0	-2.64 - 0.01
	LS Mean (SE)	-0.764 (0.0854)	-0.789 (0.0843)	-0.932 (0.0859)	-0.975 (0.0866)
	90% CI (2-sided)	-0.905, -0.623	-0.928, -0.650	-1.074, -0.791	-1.118, -0.832
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.025 (0.1074)	-0.169 (0.1084)	-0.211 (0.1087)
	90% CI (2-sided)		-0.203, 0.152	-0.347, 0.010	-0.391, -0.032
	P-value		0.8128	0.1211	0.0531

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated based on the daily mean over 7 days prior to randomization. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of moderate VMS for 7 days x 2 + number of severe VMS for 7 days x 3) / (total number of moderate and severe VMS episodes over 7 days).

Post-baseline values were calculated based on the daily mean over 7 days during particular week. Daily mean severity over 7 days were calculated using a weighed mean method with the following formula: (number of mild VMS over 7 days x 1 + number of moderate VMS over 7 days x 2 + number of severe VMS over 7 days x 3) / (total number of mild, moderate and severe VMS episodes over 7 days).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.6

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 4: Multiple Imputation)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	n	67	69	67	68
	LS Mean (SE)	-5.196 (0.5452)	-6.009 (0.5387)	-6.184 (0.5500)	-6.502 (0.5520)
	90% CI (2-sided)	-6.093, -4.299	-6.895, -5.123	-7.088, -5.279	-7.410, -5.594
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.813 (0.6289)	-0.988 (0.6309)	-1.306 (0.6324)
	90% CI (2-sided)		-1.848, 0.221	-2.026, 0.050	-2.347, -0.266
	P-value		0.1961	0.1173	0.0388
Week 12	n	64	66	65	63
	LS Mean (SE)	-9.119 (0.4791)	-9.507 (0.4730)	-10.508 (0.4847)	-10.459 (0.4891)
	90% CI (2-sided)	-9.907, -8.331	-10.286, -8.729	-11.305, -9.710	-11.264, -9.654
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.389 (0.5121)	-1.389 (0.5150)	-1.340 (0.5187)
	90% CI (2-sided)		-1.231, 0.454	-2.236, -0.542	-2.193, -0.487
	P-value		0.4479	0.0070	0.0098

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing. Missing values (after handling of ICEs) were imputed by multiple imputation (MI) method.

Table 14.2.2.2.7

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 4: Multiple Imputation)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	n	67	69	67	68
	LS Mean (SE)	-0.457 (0.0677)	-0.503 (0.0668)	-0.601 (0.0688)	-0.593 (0.0686)
	90% CI (2-sided)	-0.568, -0.346	-0.613, -0.393	-0.714, -0.487	-0.706, -0.480
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.046 (0.0748)	-0.144 (0.0754)	-0.136 (0.0752)
	90% CI (2-sided)		-0.169, 0.077	-0.268, -0.020	-0.260, -0.012
	P-value		0.5399	0.0568	0.0702
Week 12	n	64	66	65	63
	LS Mean (SE)	-0.818 (0.0918)	-0.937 (0.0901)	-1.016 (0.0920)	-1.054 (0.0928)
	90% CI (2-sided)	-0.969, -0.667	-1.086, -0.789	-1.168, -0.865	-1.207, -0.902
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.120 (0.1143)	-0.199 (0.1153)	-0.236 (0.1154)
	90% CI (2-sided)		-0.308, 0.068	-0.388, -0.009	-0.426, -0.047
	P-value		0.2954	0.0847	0.0404

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing. Missing values (after handling of ICEs) were imputed by multiple imputation (MI) method.

Table 14.2.2.2.8

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 4)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4

PPS4

Analysis Week	Statistic	Placebo N = 66	GS1-144 30 mg QD N = 67	GS1-144 60 mg QD N = 66	GS1-144 30 mg BID N = 65
Baseline	Observed Value				
	n	66	67	66	65
	Mean (SD)	12.693 (2.5901)	12.893 (3.7366)	13.005 (4.4870)	12.857 (3.6882)
	Median	12.071	12.714	12.071	12.286
	Q1 - Q3	11.143 - 13.714	10.286 - 13.857	10.429 - 13.714	10.714 - 14.429
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 4	Observed Value				
	n	66	67	66	65
	Mean (SD)	7.529 (3.6408)	6.866 (3.9125)	6.705 (4.2797)	6.352 (4.2208)
	Median	8.143	6.143	6.357	6.143
	Q1 - Q3	5.429 - 9.857	4.000 - 9.714	3.571 - 9.286	3.000 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.8

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 4)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4

PPS4

Analysis Week	Statistic	Placebo N = 66	GS1-144 30 mg QD N = 67	GS1-144 60 mg QD N = 66	GS1-144 30 mg BID N = 65
Week 4	Change from Baseline				
	n	66	67	66	65
	Mean (SD)	-5.164 (4.0649)	-6.028 (4.6653)	-6.301 (4.2377)	-6.505 (3.9587)
	Median	-3.929	-5.000	-4.929	-6.286
	Q1 - Q3	-6.429 - -2.429	-9.286 - -2.429	-8.857 - -3.286	-8.571 - -3.286
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43
	LS Mean (SE)	-5.420 (0.6227)	-6.176 (0.6310)	-6.386 (0.6332)	-6.674 (0.6349)
	90% CI (2-sided)	-6.448, -4.393	-7.218, -5.135	-7.431, -5.341	-7.722, -5.626
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.756 (0.6422)	-0.965 (0.6448)	-1.254 (0.6470)
	90% CI (2-sided)		-1.816, 0.304	-2.030, 0.099	-2.322, -0.186
	P-value		0.2402	0.1356	0.0538

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.9

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 4)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4

PPS4

Analysis Week	Statistic	Placebo N = 66	GS1-144 30 mg QD N = 67	GS1-144 60 mg QD N = 66	GS1-144 30 mg BID N = 65
Baseline	Observed Value				
	n	66	67	66	65
	Mean (SD)	2.304 (0.2040)	2.312 (0.1997)	2.347 (0.2154)	2.298 (0.2212)
	Median	2.285	2.245	2.333	2.296
	Q1 - Q3	2.126 - 2.458	2.169 - 2.491	2.215 - 2.490	2.079 - 2.478
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	66	67	66	65
	Mean (SD)	1.879 (0.4267)	1.842 (0.4331)	1.783 (0.5352)	1.762 (0.4365)
	Median	1.929	1.878	1.894	1.869
	Q1 - Q3	1.714 - 2.124	1.617 - 2.128	1.596 - 2.062	1.524 - 2.108
	Min - Max	0 - 2.67	0 - 2.58	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.9

Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 4)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4

PPS4

Analysis Week	Statistic	Placebo N = 66	GS1-144 30 mg QD N = 67	GS1-144 60 mg QD N = 66	GS1-144 30 mg BID N = 65
Week 4	Change from Baseline				
	n	66	67	66	65
	Mean (SD)	-0.426 (0.4130)	-0.470 (0.3898)	-0.565 (0.4903)	-0.535 (0.4312)
	Median	-0.374	-0.419	-0.400	-0.422
	Q1 - Q3	-0.574 - -0.156	-0.636 - -0.199	-0.812 - -0.210	-0.764 - -0.250
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.00 - 0.03
	LS Mean (SE)	-0.485 (0.0684)	-0.529 (0.0691)	-0.616 (0.0696)	-0.597 (0.0697)
	90% CI (2-sided)	-0.597, -0.372	-0.643, -0.415	-0.731, -0.501	-0.712, -0.482
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.044 (0.0745)	-0.131 (0.0750)	-0.113 (0.0751)
	90% CI (2-sided)		-0.167, 0.079	-0.255, -0.008	-0.237, 0.011
	P-value		0.5542	0.0809	0.1346

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.10
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 12)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 12
PPS12

Analysis Week	Statistic	Placebo N = 63	GS1-144 30 mg QD N = 64	GS1-144 60 mg QD N = 65	GS1-144 30 mg BID N = 60
Baseline	Observed Value				
	n	63	64	65	60
	Mean (SD)	12.671 (2.5862)	12.962 (3.7706)	13.021 (4.5202)	12.816 (3.8045)
	Median	12.143	12.714	12.143	12.214
	Q1 - Q3	11.143 - 13.714	10.357 - 13.786	10.429 - 13.714	10.571 - 14.429
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 12	Observed Value				
	n	63	64	65	60
	Mean (SD)	3.655 (3.2991)	3.319 (3.6216)	2.272 (2.3579)	2.350 (2.6320)
	Median	2.857	2.071	1.667	1.643
	Q1 - Q3	1.000 - 5.714	0.214 - 5.786	0.143 - 3.429	0.143 - 3.929
	Min - Max	0 - 12.43	0 - 14.00	0 - 9.71	0 - 11.57

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.10
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 12)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 12
PPS12

Analysis Week	Statistic	Placebo N = 63	GS1-144 30 mg QD N = 64	GS1-144 60 mg QD N = 65	GS1-144 30 mg BID N = 60
Week 12	Change from Baseline				
	n	63	64	65	60
	Mean (SD)	-9.017 (4.1461)	-9.643 (4.7389)	-10.748 (5.1597)	-10.466 (4.6351)
	Median	-8.714	-9.857	-10.000	-10.714
	Q1 - Q3	-12.000 - -6.143	-12.929 - -6.714	-11.714 - -8.000	-12.286 - -7.643
	Min - Max	-21.71 - -0.43	-22.43 - 1.00	-31.71 - -1.98	-31.00 - 2.57
	LS Mean (SE)	-9.237 (0.5103)	-9.586 (0.5253)	-10.635 (0.5153)	-10.548 (0.5244)
	90% CI (2-sided)	-10.079, -8.395	-10.453, -8.719	-11.485, -9.784	-11.413, -9.683
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.350 (0.5384)	-1.398 (0.5360)	-1.311 (0.5465)
	90% CI (2-sided)		-1.238, 0.539	-2.283, -0.513	-2.214, -0.409
	P-value		0.5168	0.0097	0.0172

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.11
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 12)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 12
PPS12

Analysis Week	Statistic	Placebo N = 63	GS1-144 30 mg QD N = 64	GS1-144 60 mg QD N = 65	GS1-144 30 mg BID N = 60
Baseline	Observed Value				
	n	63	64	65	60
	Mean (SD)	2.292 (0.1978)	2.308 (0.1963)	2.348 (0.2171)	2.287 (0.2153)
	Median	2.275	2.244	2.335	2.270
	Q1 - Q3	2.124 - 2.456	2.178 - 2.481	2.215 - 2.490	2.055 - 2.465
	Min - Max	2.00 - 2.68	2.00 - 2.70	2.00 - 3.00	2.00 - 2.68
Week 12	Observed Value				
	n	63	64	65	60
	Mean (SD)	1.515 (0.6583)	1.414 (0.6490)	1.366 (0.6864)	1.305 (0.6878)
	Median	1.610	1.505	1.371	1.432
	Q1 - Q3	1.177 - 2.000	1.000 - 1.936	1.000 - 1.879	1.018 - 1.727
	Min - Max	0 - 2.67	0 - 2.60	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.11
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 5: PPS for Week 12)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 12
PPS12

Analysis Week	Statistic	Placebo N = 63	GS1-144 30 mg QD N = 64	GS1-144 60 mg QD N = 65	GS1-144 30 mg BID N = 60
Week 12	Change from Baseline				
	n	63	64	65	60
	Mean (SD)	-0.777 (0.6476)	-0.894 (0.6505)	-0.982 (0.6290)	-0.982 (0.7155)
	Median	-0.581	-0.743	-0.952	-0.873
	Q1 - Q3	-1.085 - -0.287	-1.284 - -0.416	-1.404 - -0.417	-1.326 - -0.399
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02
	LS Mean (SE)	-0.835 (0.0941)	-0.950 (0.0951)	-1.023 (0.0942)	-1.044 (0.0966)
	90% CI (2-sided)	-0.991, -0.680	-1.107, -0.793	-1.178, -0.868	-1.203, -0.884
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.115 (0.1166)	-0.187 (0.1166)	-0.208 (0.1184)
	90% CI (2-sided)		-0.307, 0.078	-0.380, 0.005	-0.404, -0.013
	P-value		0.3260	0.1092	0.0800

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.2.2.12
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 6: Tipping Point)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

	Placebo N = 69	GS1-144 30 mg QD N = 70			
Difference (GS1-144 v.s. Placebo)	Delta=1	Delta=3	Delta=5	Delta=7	Delta=9
Week 4					
LS Mean (SE)	-0.758 (0.6327)	-0.733 (0.6354)	-0.707 (0.6392)	-0.681 (0.6440)	-0.655 (0.6499)
90% CI (2-sided)	-1.799, 0.283	-1.778, 0.312	-1.759, 0.344	-1.741, 0.378	-1.724, 0.414
P-value	0.2309	0.2487	0.2684	0.2901	0.3135
Week 12					
LS Mean (SE)	-0.373 (0.5809)	-0.260 (0.5843)	-0.146 (0.5925)	-0.033 (0.6055)	0.082 (0.6229)
90% CI (2-sided)	-1.328, 0.583	-1.221, 0.701	-1.121, 0.828	-1.028, 0.963	-0.943, 1.106
P-value	0.5210	0.6566	0.8049	0.9571	0.8959

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

A tipping point analysis was applied to assess the sensitivity assuming missing not at random (MNAR).

Table 14.2.2.2.12
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 6: Tipping Point)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Placebo N = 69	GS1-144 60 mg QD N = 69				
Difference (GS1-144 v.s. Placebo)	Delta=1	Delta=3	Delta=5	Delta=7	Delta=9
Week 4					
LS Mean (SE)	-0.969 (0.6181)	-0.909 (0.6182)	-0.850 (0.6210)	-0.791 (0.6264)	-0.732 (0.6344)
90% CI (2-sided)	-1.985, 0.048	-1.926, 0.107	-1.872, 0.171	-1.821, 0.239	-1.775, 0.312
P-value	0.1171	0.1412	0.1709	0.2067	0.2489
Week 12					
LS Mean (SE)	-1.321 (0.4934)	-1.203 (0.5007)	-1.085 (0.5141)	-0.966 (0.5333)	-0.848 (0.5576)
90% CI (2-sided)	-2.133, -0.510	-2.027, -0.380	-1.930, -0.239	-1.844, -0.089	-1.765, 0.069
P-value	0.0074	0.0163	0.0349	0.0700	0.1283

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

A tipping point analysis was applied to assess the sensitivity assuming missing not at random (MNAR).

Table 14.2.2.2.12
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 6: Tipping Point)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Placebo N = 69	GS1-144 30 mg BID N = 68				
Difference (GS1-144 v.s. Placebo)	Delta=1	Delta=3	Delta=5	Delta=7	Delta=9
Week 4					
LS Mean (SE)	-1.337 (0.6260)	-1.338 (0.6258)	-1.339 (0.6256)	-1.340 (0.6255)	-1.341 (0.6255)
90% CI (2-sided)	-2.367, -0.307	-2.367, -0.309	-2.368, -0.310	-2.369, -0.311	-2.370, -0.312
P-value	0.0327	0.0325	0.0323	0.0322	0.0320
Week 12					
LS Mean (SE)	-1.267 (0.5148)	-1.122 (0.5232)	-0.977 (0.5392)	-0.832 (0.5619)	-0.687 (0.5906)
90% CI (2-sided)	-2.114, -0.420	-1.983, -0.261	-1.864, -0.090	-1.756, 0.092	-1.658, 0.285
P-value	0.0138	0.0320	0.0699	0.1387	0.2450

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

A tipping point analysis was applied to assess the sensitivity assuming missing not at random (MNAR).

Table 14.2.2.2.13
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 6: Tipping Point)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

	Placebo N = 69	GS1-144 30 mg QD N = 70			
Difference (GS1-144 v.s. Placebo)	Delta=0.1	Delta=0.3	Delta=0.5	Delta=0.7	Delta=0.9
Week 4					
LS Mean (SE)	-0.045 (0.0684)	-0.042 (0.0687)	-0.040 (0.0690)	-0.037 (0.0695)	-0.035 (0.0700)
90% CI (2-sided)	-0.158, 0.068	-0.155, 0.071	-0.153, 0.074	-0.151, 0.077	-0.150, 0.081
P-value	0.5108	0.5369	0.5641	0.5921	0.6208
Week 12					
LS Mean (SE)	-0.114 (0.1119)	-0.103 (0.1122)	-0.092 (0.1127)	-0.081 (0.1134)	-0.070 (0.1145)
90% CI (2-sided)	-0.299, 0.070	-0.288, 0.081	-0.277, 0.093	-0.268, 0.106	-0.258, 0.118
P-value	0.3068	0.3573	0.4137	0.4753	0.5417

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

A tipping point analysis was applied to assess the sensitivity assuming missing not at random (MNAR).

Table 14.2.2.2.13
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 6: Tipping Point)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Placebo N = 69	GS1-144 60 mg QD N = 69				
Difference (GS1-144 v.s. Placebo)	Delta=0.1	Delta=0.3	Delta=0.5	Delta=0.7	Delta=0.9
Week 4					
LS Mean (SE)	-0.144 (0.0774)	-0.138 (0.0773)	-0.132 (0.0774)	-0.126 (0.0777)	-0.120 (0.0782)
90% CI (2-sided)	-0.272, -0.017	-0.266, -0.011	-0.260, -0.005	-0.254, 0.001	-0.249, 0.008
P-value	0.0619	0.0732	0.0870	0.1037	0.1237
Week 12					
LS Mean (SE)	-0.206 (0.1107)	-0.195 (0.1106)	-0.183 (0.1108)	-0.171 (0.1114)	-0.159 (0.1122)
90% CI (2-sided)	-0.389, -0.024	-0.377, -0.013	-0.365, -0.001	-0.354, 0.012	-0.344, 0.025
P-value	0.0622	0.0784	0.0988	0.1241	0.1550

Data Source: Listing 16.2.6.1
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).
Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).
In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.
A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.
A tipping point analysis was applied to assess the sensitivity assuming missing not at random (MNAR).

Table 14.2.2.2.13
Primary Endpoint Analysis (Primary Estimand, Sensitivity Analysis 6: Tipping Point)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Placebo N = 69	GS1-144 30 mg BID N = 68				
Difference (GS1-144 v.s. Placebo)	Delta=0.1	Delta=0.3	Delta=0.5	Delta=0.7	Delta=0.9
Week 4					
LS Mean (SE)	-0.138 (0.0740)	-0.138 (0.0740)	-0.138 (0.0740)	-0.138 (0.0740)	-0.138 (0.0740)
90% CI (2-sided)	-0.260, -0.017	-0.260, -0.017	-0.260, -0.017	-0.260, -0.017	-0.260, -0.017
P-value	0.0616	0.0616	0.0616	0.0616	0.0616
Week 12					
LS Mean (SE)	-0.232 (0.1170)	-0.217 (0.1172)	-0.202 (0.1177)	-0.187 (0.1186)	-0.172 (0.1197)
90% CI (2-sided)	-0.424, -0.040	-0.410, -0.024	-0.396, -0.009	-0.382, 0.008	-0.369, 0.025
P-value	0.0473	0.0639	0.0858	0.1142	0.1501

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

A tipping point analysis was applied to assess the sensitivity assuming missing not at random (MNAR).

Table 14.2.2.3.1
Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	12.628 (2.5693)	12.957 (3.7763)	12.883 (4.4260)	12.979 (3.6833)
	Median	12.000	12.571	11.571	12.429
	Q1 - Q3	11.143 - 13.571	10.429 - 13.857	10.000 - 13.571	10.714 - 14.786
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 4	Observed Value				
	n	69	70	69	68
	Mean (SD)	7.575 (3.7260)	6.880 (3.9294)	6.815 (4.2291)	6.345 (4.2275)
	Median	8.143	6.143	6.429	6.214
	Q1 - Q3	5.429 - 10.000	4.000 - 9.714	3.714 - 9.714	2.857 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.1
Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	69	70	69	68
	Mean (SD)	-5.053 (4.0830)	-6.078 (4.7018)	-6.068 (4.2957)	-6.634 (3.9523)
	Median	-3.857	-5.071	-4.571	-6.429
	Q1 - Q3	-6.429 - -2.286	-9.286 - -2.429	-8.714 - -2.857	-8.857 - -3.357
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43
	LS Mean (SE)	-4.978 (0.5659)	-5.819 (0.5574)	-5.839 (0.5731)	-6.351 (0.5756)
	90% CI (2-sided)	-5.911, -4.044	-6.739, -4.900	-6.785, -4.894	-7.300, -5.401
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.842 (0.6332)	-0.862 (0.6354)	-1.373 (0.6379)
	90% CI (2-sided)		-1.887, 0.203	-1.910, 0.187	-2.426, -0.320
	P-value		0.1849	0.1762	0.0323

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.1
Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	69	70	69	68
	Mean (SD)	4.283 (4.0039)	3.796 (4.0436)	2.757 (3.0269)	3.134 (3.8659)
	Median	3.286	2.357	1.714	2.000
	Q1 - Q3	1.286 - 6.429	0.286 - 6.286	0.143 - 3.857	0.143 - 4.714
	Min - Max	0 - 16.86	0 - 14.86	0 - 12.00	0 - 15.86

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.1
Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	69	70	69	68
	Mean (SD)	-8.345 (4.6062)	-9.161 (5.0887)	-10.125 (5.6088)	-9.844 (5.2249)
	Median	-8.571	-9.643	-9.714	-10.214
	Q1 - Q3	-11.571 - -5.857	-12.857 - -5.857	-11.714 - -7.024	-12.357 - -7.202
	Min - Max	-21.71 - 0	-22.43 - 1.00	-31.71 - 0	-31.00 - 2.57
	LS Mean (SE)	-8.360 (0.5690)	-8.867 (0.5605)	-9.889 (0.5762)	-9.516 (0.5787)
	90% CI (2-sided)	-9.298, -7.421	-9.791, -7.942	-10.839, -8.938	-10.471, -8.561
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.507 (0.6386)	-1.529 (0.6408)	-1.156 (0.6434)
	90% CI (2-sided)		-1.561, 0.547	-2.587, -0.472	-2.218, -0.095
	P-value		0.4279	0.0177	0.0734

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.2
Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.313 (0.2072)	2.315 (0.2042)	2.345 (0.2127)	2.302 (0.2180)
	Median	2.287	2.249	2.335	2.296
	Q1 - Q3	2.131 - 2.474	2.169 - 2.498	2.215 - 2.484	2.092 - 2.471
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	69	70	69	68
	Mean (SD)	1.898 (0.4313)	1.845 (0.4309)	1.794 (0.5297)	1.744 (0.4669)
	Median	1.970	1.903	1.908	1.871
	Q1 - Q3	1.715 - 2.150	1.617 - 2.128	1.600 - 2.065	1.506 - 2.092
	Min - Max	0 - 2.71	0 - 2.58	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.2
Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	69	70	69	68
	Mean (SD)	-0.415 (0.4105)	-0.470 (0.3950)	-0.551 (0.4894)	-0.558 (0.4697)
	Median	-0.350	-0.417	-0.394	-0.424
	Q1 - Q3	-0.568 - -0.135	-0.636 - -0.199	-0.792 - -0.195	-0.766 - -0.255
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.23 - 0.03
	LS Mean (SE)	-0.442 (0.0671)	-0.496 (0.0661)	-0.570 (0.0681)	-0.589 (0.0683)
	90% CI (2-sided)	-0.553, -0.331	-0.605, -0.387	-0.683, -0.458	-0.701, -0.476
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.054 (0.0747)	-0.128 (0.0750)	-0.147 (0.0752)
	90% CI (2-sided)		-0.177, 0.070	-0.252, -0.005	-0.271, -0.022
	P-value		0.4725	0.0881	0.0523

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.2
Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)
Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	69	70	69	68
	Mean (SD)	1.592 (0.6849)	1.462 (0.6788)	1.421 (0.7026)	1.372 (0.7391)
	Median	1.710	1.557	1.409	1.488
	Q1 - Q3	1.205 - 2.032	1.000 - 2.000	1.048 - 2.000	1.018 - 1.979
	Min - Max	0 - 2.74	0 - 2.64	0 - 3.00	0 - 2.81

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.2

Primary Endpoint Analysis (Supplementary Estimand 1: Composite Strategy)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	69	70	69	68
	Mean (SD)	-0.721 (0.6508)	-0.853 (0.6800)	-0.925 (0.6525)	-0.930 (0.7477)
	Median	-0.541	-0.705	-0.888	-0.840
	Q1 - Q3	-0.959 - -0.273	-1.283 - -0.316	-1.335 - -0.390	-1.326 - -0.372
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02
	LS Mean (SE)	-0.747 (0.0920)	-0.878 (0.0909)	-0.945 (0.0928)	-0.960 (0.0932)
	90% CI (2-sided)	-0.899, -0.595	-1.028, -0.728	-1.098, -0.792	-1.113, -0.806
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.131 (0.1159)	-0.198 (0.1165)	-0.213 (0.1168)
	90% CI (2-sided)		-0.323, 0.060	-0.390, -0.006	-0.405, -0.020
	P-value		0.2586	0.0902	0.0698

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value.

Table 14.2.2.3.3
Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	12.628 (2.5693)	12.957 (3.7763)	12.883 (4.4260)	12.979 (3.6833)
	Median	12.000	12.571	11.571	12.429
	Q1 - Q3	11.143 - 13.571	10.429 - 13.857	10.000 - 13.571	10.714 - 14.786
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	7.436 (3.6916)	6.803 (3.9056)	6.711 (4.2475)	6.345 (4.2275)
	Median	8.143	6.143	6.429	6.214
	Q1 - Q3	5.429 - 9.857	4.000 - 9.571	3.571 - 9.286	2.857 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.3

Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-5.204 (4.0472)	-6.166 (4.6777)	-6.249 (4.2264)	-6.634 (3.9523)
	Median	-4.000	-5.143	-4.857	-6.429
	Q1 - Q3	-7.714 - -2.429	-9.286 - -2.571	-8.857 - -3.000	-8.857 - -3.357
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43
	LS Mean (SE)	-5.277 (0.5444)	-6.124 (0.5364)	-6.212 (0.5523)	-6.583 (0.5517)
	90% CI (2-sided)	-6.175, -4.379	-7.008, -5.239	-7.123, -5.302	-7.492, -5.673
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.847 (0.6270)	-0.935 (0.6316)	-1.306 (0.6310)
	90% CI (2-sided)		-1.882, 0.188	-1.978, 0.107	-2.347, -0.264
	P-value		0.1781	0.1398	0.0395

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.3
Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)
Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	65	67	65	63
	Mean (SD)	3.597 (3.2640)	3.320 (3.5885)	2.272 (2.3579)	2.324 (2.6140)
	Median	2.857	2.143	1.667	1.429
	Q1 - Q3	1.000 - 5.286	0.143 - 5.857	0.143 - 3.429	0.143 - 4.000
	Min - Max	0 - 12.43	0 - 14.00	0 - 9.71	0 - 11.57

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.3

Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	65	67	65	63
	Mean (SD)	-8.997 (4.0839)	-9.657 (4.6815)	-10.748 (5.1597)	-10.625 (4.5897)
	Median	-8.714	-9.857	-10.000	-10.714
	Q1 - Q3	-11.714 - -6.286	-13.000 - -6.714	-11.714 - -8.000	-12.571 - -7.714
	Min - Max	-21.71 - -0.43	-22.43 - 1.00	-31.71 - -1.98	-31.00 - 2.57
	LS Mean (SE)	-9.277 (0.4833)	-9.594 (0.4781)	-10.631 (0.4901)	-10.620 (0.4933)
	90% CI (2-sided)	-10.074, -8.479	-10.382, -8.805	-11.439, -9.822	-11.434, -9.806
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.317 (0.5176)	-1.354 (0.5222)	-1.344 (0.5257)
	90% CI (2-sided)		-1.171, 0.537	-2.216, -0.492	-2.211, -0.476
	P-value		0.5409	0.0101	0.0111

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.4

Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.313 (0.2072)	2.315 (0.2042)	2.345 (0.2127)	2.302 (0.2180)
	Median	2.287	2.249	2.335	2.296
	Q1 - Q3	2.131 - 2.474	2.169 - 2.498	2.215 - 2.484	2.092 - 2.471
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.880 (0.4237)	1.843 (0.4337)	1.781 (0.5313)	1.744 (0.4669)
	Median	1.931	1.878	1.879	1.871
	Q1 - Q3	1.714 - 2.124	1.617 - 2.128	1.596 - 2.062	1.506 - 2.092
	Min - Max	0 - 2.67	0 - 2.58	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.4

Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.428 (0.4101)	-0.477 (0.3937)	-0.568 (0.4871)	-0.558 (0.4697)
	Median	-0.398	-0.419	-0.405	-0.424
	Q1 - Q3	-0.574 - -0.156	-0.636 - -0.247	-0.812 - -0.210	-0.766 - -0.255
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.23 - 0.03
	LS Mean (SE)	-0.457 (0.0672)	-0.501 (0.0661)	-0.591 (0.0684)	-0.593 (0.0681)
	90% CI (2-sided)	-0.568, -0.346	-0.610, -0.392	-0.704, -0.478	-0.705, -0.481
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.044 (0.0746)	-0.134 (0.0753)	-0.136 (0.0751)
	90% CI (2-sided)		-0.167, 0.079	-0.258, -0.010	-0.260, -0.012
	P-value		0.5559	0.0762	0.0712

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.4

Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	65	67	65	63
	Mean (SD)	1.515 (0.6493)	1.424 (0.6650)	1.366 (0.6864)	1.288 (0.6991)
	Median	1.610	1.510	1.371	1.429
	Q1 - Q3	1.185 - 2.000	1.000 - 1.943	1.000 - 1.879	1.000 - 1.740
	Min - Max	0 - 2.67	0 - 2.60	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.4

Primary Endpoint Analysis (Supplementary Estimand 2: Treatment Policy Strategy)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	65	67	65	63
	Mean (SD)	-0.787 (0.6427)	-0.895 (0.6655)	-0.982 (0.6290)	-1.004 (0.7272)
	Median	-0.590	-0.721	-0.952	-0.888
	Q1 - Q3	-1.085 - -0.305	-1.286 - -0.318	-1.404 - -0.417	-1.370 - -0.410
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02
	LS Mean (SE)	-0.824 (0.0914)	-0.927 (0.0897)	-1.008 (0.0921)	-1.055 (0.0928)
	90% CI (2-sided)	-0.975, -0.673	-1.075, -0.779	-1.160, -0.856	-1.208, -0.902
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.103 (0.1142)	-0.184 (0.1155)	-0.231 (0.1159)
	90% CI (2-sided)		-0.291, 0.086	-0.375, 0.007	-0.422, -0.040
	P-value		0.3681	0.1122	0.0474

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

All ICEs were handled by treatment policy strategy, data after occurrence of ICEs (should be within washout period for ICE1) were used if available.

Table 14.2.2.3.5

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	12.628 (2.5693)	12.957 (3.7763)	12.883 (4.4260)	12.979 (3.6833)
	Median	12.000	12.571	11.571	12.429
	Q1 - Q3	11.143 - 13.571	10.429 - 13.857	10.000 - 13.571	10.714 - 14.786
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	7.436 (3.6916)	6.803 (3.9056)	6.711 (4.2475)	6.345 (4.2275)
	Median	8.143	6.143	6.429	6.214
	Q1 - Q3	5.429 - 9.857	4.000 - 9.571	3.571 - 9.286	2.857 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.3.5

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-5.204 (4.0472)	-6.166 (4.6777)	-6.249 (4.2264)	-6.634 (3.9523)
	Median	-4.000	-5.143	-4.857	-6.429
	Q1 - Q3	-7.714 - -2.429	-9.286 - -2.571	-8.857 - -3.000	-8.857 - -3.357
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43
	LS Mean (SE)	-5.281 (0.5496)	-6.123 (0.5486)	-6.216 (0.5578)	-6.586 (0.5572)
	90% CI (2-sided)	-6.187, -4.374	-7.028, -5.218	-7.136, -5.296	-7.505, -5.667
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.842 (0.6295)	-0.935 (0.6324)	-1.305 (0.6319)
	90% CI (2-sided)		-1.881, 0.197	-1.979, 0.109	-2.348, -0.263
	P-value		0.1819	0.1403	0.0398

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.3.5

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	3.620 (3.2846)	3.323 (3.6159)	2.272 (2.3579)	2.324 (2.6140)
	Median	2.857	2.071	1.667	1.429
	Q1 - Q3	1.000 - 5.500	0.143 - 5.857	0.143 - 3.429	0.143 - 4.000
	Min - Max	0 - 12.43	0 - 14.00	0 - 9.71	0 - 11.57

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.3.5

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-8.997 (4.1162)	-9.716 (4.6916)	-10.748 (5.1597)	-10.625 (4.5897)
	Median	-8.643	-10.000	-10.000	-10.714
	Q1 - Q3	-11.857 - -6.214	-13.000 - -6.714	-11.714 - -8.000	-12.571 - -7.714
	Min - Max	-21.71 - -0.43	-22.43 - 1.00	-31.71 - -1.98	-31.00 - 2.57
	LS Mean (SE)	-9.219 (0.4896)	-9.639 (0.4874)	-10.637 (0.4966)	-10.626 (0.4997)
	90% CI (2-sided)	-10.027, -8.411	-10.443, -8.834	-11.456, -9.818	-11.450, -9.801
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.420 (0.5205)	-1.418 (0.5239)	-1.407 (0.5274)
	90% CI (2-sided)		-1.279, 0.440	-2.283, -0.553	-2.277, -0.536
	P-value		0.4209	0.0072	0.0081

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.3.6

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.313 (0.2072)	2.315 (0.2042)	2.345 (0.2127)	2.302 (0.2180)
	Median	2.287	2.249	2.335	2.296
	Q1 - Q3	2.131 - 2.474	2.169 - 2.498	2.215 - 2.484	2.092 - 2.471
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.880 (0.4237)	1.843 (0.4337)	1.781 (0.5313)	1.744 (0.4669)
	Median	1.931	1.878	1.879	1.871
	Q1 - Q3	1.714 - 2.124	1.617 - 2.128	1.596 - 2.062	1.506 - 2.092
	Min - Max	0 - 2.67	0 - 2.58	0 - 3.00	0 - 2.45

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.3.6

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.428 (0.4101)	-0.477 (0.3937)	-0.568 (0.4871)	-0.558 (0.4697)
	Median	-0.398	-0.419	-0.405	-0.424
	Q1 - Q3	-0.574 - -0.156	-0.636 - -0.247	-0.812 - -0.210	-0.766 - -0.255
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.23 - 0.03
	LS Mean (SE)	-0.469 (0.0681)	-0.518 (0.0679)	-0.603 (0.0693)	-0.605 (0.0690)
	90% CI (2-sided)	-0.581, -0.356	-0.630, -0.406	-0.718, -0.489	-0.719, -0.491
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.049 (0.0747)	-0.135 (0.0753)	-0.136 (0.0750)
	90% CI (2-sided)		-0.173, 0.074	-0.259, -0.011	-0.260, -0.012
	P-value		0.5087	0.0744	0.0706

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.3.6

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	1.519 (0.6539)	1.411 (0.6623)	1.366 (0.6864)	1.288 (0.6991)
	Median	1.642	1.505	1.371	1.429
	Q1 - Q3	1.181 - 2.000	1.000 - 1.938	1.000 - 1.879	1.000 - 1.740
	Min - Max	0 - 2.67	0 - 2.60	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.3.6

Primary Endpoint Analysis (Supplementary Estimand 3)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-0.777 (0.6425)	-0.905 (0.6659)	-0.982 (0.6290)	-1.004 (0.7272)
	Median	-0.586	-0.743	-0.952	-0.888
	Q1 - Q3	-1.054 - -0.296	-1.286 - -0.381	-1.404 - -0.417	-1.370 - -0.410
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02
	LS Mean (SE)	-0.829 (0.0920)	-0.954 (0.0909)	-1.021 (0.0927)	-1.066 (0.0933)
	90% CI (2-sided)	-0.981, -0.677	-1.104, -0.804	-1.174, -0.868	-1.220, -0.912
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.125 (0.1144)	-0.192 (0.1154)	-0.237 (0.1158)
	90% CI (2-sided)		-0.314, 0.064	-0.382, -0.001	-0.428, -0.046
	P-value		0.2744	0.0980	0.0418

Data Source: Listing 16.2.6.1

LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A hypothetical strategy was used for ICE1 and ICE3, data after occurrence of ICEs (should be within washout period for ICE1) were considered as missing. A composite strategy was used for ICE2, data after occurrence of ICE2 were imputed with the baseline value.

Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Age (years) <55	n	34	29	39	35
		LS Mean (SE)	-6.224 (0.6575)	-6.180 (0.7119)	-7.185 (0.6139)	-7.361 (0.6480)
		90% CI (2-sided)	-7.313, -5.135	-7.359, -5.001	-8.202, -6.169	-8.434, -6.287
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.045 (0.9699)	-0.961 (0.9003)	-1.136 (0.9223)
		90% CI (2-sided)		-1.562, 1.651	-2.452, 0.530	-2.664, 0.391
		P-value		0.9635	0.2877	0.2201
	Age (years) >=55	n	33	40	28	33
		LS Mean (SE)	-4.317 (0.5838)	-6.074 (0.5404)	-5.001 (0.6392)	-5.699 (0.5963)
		90% CI (2-sided)	-5.284, -3.350	-6.969, -5.179	-6.059, -3.942	-6.687, -4.711
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-1.757 (0.7955)	-0.684 (0.8651)	-1.382 (0.8353)
		90% CI (2-sided)		-3.075, -0.439	-2.117, 0.749	-2.766, 0.001
		P-value		0.0289	0.4307	0.1003

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	BMI (kg/m^2) <28	n	63	65	64	65
		LS Mean (SE)	-5.147 (0.4518)	-6.175 (0.4495)	-6.122 (0.4505)	-6.452 (0.4495)
		90% CI (2-sided)	-5.893, -4.401	-6.917, -5.433	-6.865, -5.378	-7.194, -5.710
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-1.029 (0.6374)	-0.975 (0.6381)	-1.305 (0.6375)
		90% CI (2-sided)		-2.081, 0.023	-2.028, 0.078	-2.358, -0.253
		P-value		0.1077	0.1277	0.0416
	BMI (kg/m^2) >=28	n	4	4	3	3
		LS Mean (SE)	-7.410 (2.7199)	-5.293 (2.7251)	-8.092 (3.1427)	-9.323 (3.1414)
		90% CI (2-sided)	-12.396, -2.424	-10.288, -0.297	-13.853, -2.331	-15.082, -3.565
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		2.117 (3.8508)	-0.682 (4.1559)	-1.913 (4.1551)
		90% CI (2-sided)		-4.942, 9.176	-8.300, 6.936	-9.530, 5.703
		P-value		0.5958	0.8733	0.6561

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	BMI (kg/m^2) >=18.5 to <24	n	38	32	42	43
		LS Mean (SE)	-4.437 (0.5684)	-5.316 (0.6336)	-5.668 (0.5462)	-6.570 (0.5477)
		90% CI (2-sided)	-5.378, -3.497	-6.364, -4.267	-6.572, -4.764	-7.476, -5.663
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.878 (0.8508)	-1.231 (0.7882)	-2.132 (0.7898)
		90% CI (2-sided)		-2.286, 0.530	-2.535, 0.073	-3.439, -0.825
		P-value		0.3035	0.1204	0.0077
	BMI (kg/m^2) >=24 to <28	n	25	33	22	22
		LS Mean (SE)	-6.303 (0.7352)	-6.987 (0.6405)	-6.862 (0.7838)	-6.378 (0.7861)
		90% CI (2-sided)	-7.524, -5.082	-8.051, -5.923	-8.164, -5.561	-7.684, -5.072
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.684 (0.9780)	-0.559 (1.0776)	-0.075 (1.0722)
		90% CI (2-sided)		-2.308, 0.940	-2.349, 1.230	-1.855, 1.706
		P-value		0.4861	0.6050	0.9445

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	BMI (kg/m^2) >=28	n	4	4	3	3
		LS Mean (SE)	-7.410 (2.7199)	-5.293 (2.7251)	-8.092 (3.1427)	-9.323 (3.1414)
		90% CI (2-sided)	-12.396, -2.424	-10.288, -0.297	-13.853, -2.331	-15.082, -3.565
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		2.117 (3.8508)	-0.682 (4.1559)	-1.913 (4.1551)
		90% CI (2-sided)		-4.942, 9.176	-8.300, 6.936	-9.530, 5.703
		P-value		0.5958	0.8733	0.6561
	Smoking - Never/Former	n	67	69	65	66
		LS Mean (SE)	-5.290 (0.4486)	-6.131 (0.4465)	-6.238 (0.4575)	-6.620 (0.4565)
		90% CI (2-sided)	-6.030, -4.549	-6.868, -5.394	-6.993, -5.483	-7.374, -5.867
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.842 (0.6330)	-0.948 (0.6409)	-1.331 (0.6402)
		90% CI (2-sided)		-1.886, 0.203	-2.006, 0.109	-2.387, -0.274
		P-value		0.1848	0.1401	0.0386

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Baseline Moderate to Severe VMS Frequency - <=12	n	34	30	34	30
		LS Mean (SE)	-3.736 (0.5476)	-4.854 (0.5782)	-5.169 (0.5309)	-5.833 (0.5708)
		90% CI (2-sided)	-4.644, -2.829	-5.812, -3.896	-6.048, -4.289	-6.779, -4.888
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-1.118 (0.8122)	-1.432 (0.7682)	-2.097 (0.7931)
		90% CI (2-sided)		-2.463, 0.228	-2.705, -0.159	-3.411, -0.783
		P-value		0.1713	0.0646	0.0092
	Baseline Moderate to Severe VMS Frequency - >12	n	33	39	33	38
		LS Mean (SE)	-6.761 (0.7136)	-7.272 (0.6595)	-7.005 (0.7194)	-7.345 (0.6681)
		90% CI (2-sided)	-7.942, -5.579	-8.364, -6.180	-8.197, -5.814	-8.452, -6.239
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.512 (0.9725)	-0.245 (1.0176)	-0.585 (0.9769)
		90% CI (2-sided)		-2.122, 1.099	-1.930, 1.440	-2.202, 1.033
		P-value		0.5997	0.8103	0.5504

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Baseline Moderate to Severe VMS Frequency - <=10	n	6	13	17	12
		LS Mean (SE)	-3.486 (1.0874)	-4.272 (0.7463)	-4.883 (0.6393)	-4.207 (0.7689)
		90% CI (2-sided)	-5.313, -1.659	-5.526, -3.018	-5.957, -3.809	-5.499, -2.915
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.786 (1.3194)	-1.397 (1.2609)	-0.721 (1.3317)
		90% CI (2-sided)		-3.003, 1.431	-3.516, 0.721	-2.959, 1.517
		P-value		0.5546	0.2739	0.5910
	Baseline Moderate to Severe VMS Frequency - >10 to <=13	n	40	29	28	28
		LS Mean (SE)	-4.257 (0.5483)	-4.842 (0.6558)	-5.266 (0.6683)	-6.776 (0.6675)
		90% CI (2-sided)	-5.166, -3.349	-5.929, -3.755	-6.374, -4.158	-7.883, -5.670
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.585 (0.8551)	-1.009 (0.8640)	-2.519 (0.8641)
		90% CI (2-sided)		-2.002, 0.832	-2.441, 0.423	-3.951, -1.087
		P-value		0.4951	0.2454	0.0042

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Baseline Moderate to Severe VMS Frequency - >13	n	21	27	22	28
		LS Mean (SE)	-7.908 (0.9325)	-8.533 (0.8180)	-7.695 (0.9142)	-7.750 (0.8040)
		90% CI (2-sided)	-9.458, -6.359	-9.892, -7.174	-9.214, -6.176	-9.086, -6.415
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.625 (1.2411)	0.214 (1.3149)	0.158 (1.2284)
		90% CI (2-sided)		-2.686, 1.437	-1.971, 2.398	-1.883, 2.199
		P-value		0.6160	0.8712	0.8979
Week 12	Age (years) <55	n	33	28	37	32
		LS Mean (SE)	-9.794 (0.5043)	-9.889 (0.5404)	-11.046 (0.4698)	-10.806 (0.5084)
		90% CI (2-sided)	-10.630, -8.959	-10.784, -8.993	-11.825, -10.268	-11.649, -9.964
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.094 (0.7400)	-1.252 (0.6902)	-1.012 (0.7153)
		90% CI (2-sided)		-1.321, 1.132	-2.395, -0.109	-2.197, 0.173
		P-value		0.8986	0.0720	0.1595

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Age (years) >=55	n	31	38	28	31
		LS Mean (SE)	-8.609 (0.5454)	-9.426 (0.4967)	-10.211 (0.5872)	-10.352 (0.5526)
		90% CI (2-sided)	-9.513, -7.706	-10.249, -8.602	-11.185, -9.238	-11.267, -9.436
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.816 (0.7377)	-1.602 (0.8011)	-1.742 (0.7769)
		90% CI (2-sided)		-2.038, 0.406	-2.929, -0.275	-3.030, -0.455
		P-value		0.2707	0.0477	0.0266
	BMI (kg/m^2) <28	n	60	63	62	60
		LS Mean (SE)	-9.094 (0.3755)	-9.712 (0.3685)	-10.556 (0.3709)	-10.501 (0.3762)
		90% CI (2-sided)	-9.714, -8.474	-10.320, -9.103	-11.168, -9.943	-11.122, -9.879
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.618 (0.5262)	-1.462 (0.5280)	-1.407 (0.5317)
		90% CI (2-sided)		-1.486, 0.251	-2.334, -0.590	-2.285, -0.529
		P-value		0.2416	0.0061	0.0087

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	BMI (kg/m^2) >=28	n	4	3	3	3
		LS Mean (SE)	-11.375 (2.0780)	-8.573 (2.0837)	-12.004 (2.4010)	-13.042 (2.4000)
		90% CI (2-sided)	-15.185, -7.566	-12.392, -4.753	-16.406, -7.602	-17.442, -8.642
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		2.803 (2.9432)	-0.629 (3.1750)	-1.667 (3.1744)
		90% CI (2-sided)		-2.593, 8.198	-6.450, 5.192	-7.487, 4.153
		P-value		0.3658	0.8474	0.6122
	BMI (kg/m^2) >=18.5 to <24	n	37	32	41	40
		LS Mean (SE)	-8.769 (0.4650)	-9.898 (0.5095)	-10.038 (0.4447)	-10.171 (0.4515)
		90% CI (2-sided)	-9.539, -8.000	-10.742, -9.055	-10.774, -9.302	-10.919, -9.424
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-1.129 (0.6895)	-1.268 (0.6434)	-1.402 (0.6484)
		90% CI (2-sided)		-2.270, 0.013	-2.333, -0.203	-2.475, -0.329
		P-value		0.1038	0.0505	0.0322

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	BMI (kg/m^2) >=24 to <28	n	23	31	21	20
		LS Mean (SE)	-9.613 (0.6378)	-9.720 (0.5492)	-11.473 (0.6680)	-10.947 (0.6861)
		90% CI (2-sided)	-10.672, -8.553	-10.632, -8.808	-12.583, -10.364	-12.087, -9.808
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.108 (0.8449)	-1.861 (0.9266)	-1.335 (0.9325)
		90% CI (2-sided)		-1.511, 1.296	-3.400, -0.322	-2.883, 0.214
		P-value		0.8990	0.0474	0.1555
	BMI (kg/m^2) >=28	n	4	3	3	3
		LS Mean (SE)	-11.375 (2.0780)	-8.573 (2.0837)	-12.004 (2.4010)	-13.042 (2.4000)
		90% CI (2-sided)	-15.185, -7.566	-12.392, -4.753	-16.406, -7.602	-17.442, -8.642
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		2.803 (2.9432)	-0.629 (3.1750)	-1.667 (3.1744)
		90% CI (2-sided)		-2.593, 8.198	-6.450, 5.192	-7.487, 4.153
		P-value		0.3658	0.8474	0.6122

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Smoking - Never/Former	n	64	66	63	61
		LS Mean (SE)	-9.236 (0.3722)	-9.654 (0.3661)	-10.606 (0.3766)	-10.577 (0.3817)
		90% CI (2-sided)	-9.850, -8.621	-10.258, -9.050	-11.228, -9.984	-11.207, -9.947
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.418 (0.5222)	-1.370 (0.5297)	-1.341 (0.5333)
		90% CI (2-sided)		-1.280, 0.444	-2.245, -0.496	-2.222, -0.461
		P-value		0.4239	0.0102	0.0125
	Baseline Moderate to Severe VMS Frequency - <=12	n	32	28	32	29
		LS Mean (SE)	-6.552 (0.4660)	-7.737 (0.4917)	-8.585 (0.4543)	-8.378 (0.4842)
		90% CI (2-sided)	-7.324, -5.780	-8.552, -6.923	-9.337, -7.832	-9.181, -7.576
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-1.186 (0.6905)	-2.033 (0.6553)	-1.826 (0.6743)
		90% CI (2-sided)		-2.330, -0.041	-3.119, -0.947	-2.944, -0.709
		P-value		0.0885	0.0024	0.0077

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Baseline Moderate to Severe VMS Frequency - >12	n	32	38	33	34
		LS Mean (SE)	-11.661 (0.5850)	-11.455 (0.5301)	-12.388 (0.5774)	-12.644 (0.5582)
		90% CI (2-sided)	-12.630, -10.692	-12.333, -10.577	-13.344, -11.432	-13.569, -11.720
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.206 (0.7901)	-0.727 (0.8256)	-0.983 (0.8088)
		90% CI (2-sided)		-1.102, 1.515	-2.094, 0.641	-2.323, 0.357
		P-value		0.7942	0.3802	0.2263
	Baseline Moderate to Severe VMS Frequency - <=10	n	6	12	16	12
		LS Mean (SE)	-5.634 (1.1192)	-6.587 (0.7726)	-6.879 (0.6744)	-6.599 (0.7914)
		90% CI (2-sided)	-7.516, -3.752	-7.885, -5.288	-8.012, -5.746	-7.929, -5.268
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.952 (1.3605)	-1.245 (1.3062)	-0.964 (1.3707)
		90% CI (2-sided)		-3.240, 1.335	-3.441, 0.951	-3.269, 1.340
		P-value		0.4877	0.3459	0.4856

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.1

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Baseline Moderate to Severe VMS Frequency - >10 to <=13	n	38	28	27	25
		LS Mean (SE)	-7.792 (0.4730)	-8.046 (0.5600)	-9.758 (0.5672)	-9.702 (0.5846)
		90% CI (2-sided)	-8.576, -7.008	-8.975, -7.118	-10.699, -8.818	-10.670, -8.733
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.254 (0.7331)	-1.966 (0.7383)	-1.909 (0.7521)
		90% CI (2-sided)		-1.469, 0.961	-3.190, -0.742	-3.156, -0.663
		P-value		0.7297	0.0088	0.0124
	Baseline Moderate to Severe VMS Frequency - >13	n	20	26	22	26
		LS Mean (SE)	-13.064 (0.7174)	-13.082 (0.6171)	-13.523 (0.6884)	-13.823 (0.6218)
		90% CI (2-sided)	-14.257, -11.872	-14.108, -12.057	-14.667, -12.379	-14.856, -12.790
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.018 (0.9468)	-0.459 (1.0014)	-0.759 (0.9474)
		90% CI (2-sided)		-1.591, 1.556	-2.123, 1.206	-2.333, 0.816
		P-value		0.9850	0.6481	0.4252

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Age (years) <55	n	34	29	39	35
		LS Mean (SE)	-0.527 (0.0806)	-0.481 (0.0872)	-0.652 (0.0758)	-0.607 (0.0794)
		90% CI (2-sided)	-0.661, -0.394	-0.626, -0.337	-0.777, -0.526	-0.738, -0.475
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.046 (0.1186)	-0.124 (0.1110)	-0.079 (0.1130)
		90% CI (2-sided)		-0.150, 0.243	-0.308, 0.060	-0.266, 0.108
		P-value		0.6972	0.2654	0.4850
	Age (years) >=55	n	33	40	28	33
		LS Mean (SE)	-0.331 (0.0680)	-0.474 (0.0630)	-0.435 (0.0744)	-0.515 (0.0694)
		90% CI (2-sided)	-0.443, -0.218	-0.578, -0.370	-0.559, -0.312	-0.630, -0.400
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.143 (0.0927)	-0.105 (0.1008)	-0.184 (0.0972)
		90% CI (2-sided)		-0.297, 0.010	-0.272, 0.062	-0.345, -0.023
		P-value		0.1241	0.3000	0.0602

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	BMI (kg/m^2) <28	n	63	65	64	65
		LS Mean (SE)	-0.428 (0.0549)	-0.471 (0.0546)	-0.553 (0.0549)	-0.542 (0.0547)
		90% CI (2-sided)	-0.519, -0.337	-0.562, -0.381	-0.644, -0.463	-0.632, -0.451
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.044 (0.0775)	-0.126 (0.0777)	-0.114 (0.0775)
		90% CI (2-sided)		-0.172, 0.084	-0.254, 0.003	-0.242, 0.014
		P-value		0.5739	0.1073	0.1436
	BMI (kg/m^2) >=28	n	4	4	3	3
		LS Mean (SE)	-0.449 (0.1846)	-0.573 (0.1830)	-0.712 (0.2126)	-0.947 (0.2126)
		90% CI (2-sided)	-0.787, -0.111	-0.909, -0.238	-1.102, -0.323	-1.337, -0.558
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.124 (0.2593)	-0.264 (0.2836)	-0.499 (0.2837)
		90% CI (2-sided)		-0.600, 0.351	-0.783, 0.256	-1.019, 0.021
		P-value		0.6427	0.3768	0.1127

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	BMI (kg/m^2) >=18.5 to <24	n	38	32	42	43
		LS Mean (SE)	-0.408 (0.0700)	-0.473 (0.0775)	-0.484 (0.0675)	-0.595 (0.0669)
		90% CI (2-sided)	-0.524, -0.292	-0.602, -0.345	-0.596, -0.372	-0.706, -0.485
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.065 (0.1044)	-0.076 (0.0975)	-0.187 (0.0967)
		90% CI (2-sided)		-0.238, 0.108	-0.237, 0.086	-0.347, -0.027
		P-value		0.5332	0.4379	0.0547
	BMI (kg/m^2) >=24 to <28	n	25	33	22	22
		LS Mean (SE)	-0.482 (0.0851)	-0.475 (0.0740)	-0.662 (0.0906)	-0.427 (0.0909)
		90% CI (2-sided)	-0.623, -0.341	-0.598, -0.352	-0.813, -0.511	-0.578, -0.276
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.007 (0.1127)	-0.180 (0.1243)	0.055 (0.1248)
		90% CI (2-sided)		-0.180, 0.194	-0.386, 0.026	-0.153, 0.262
		P-value		0.9511	0.1509	0.6619

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	BMI (kg/m^2) >=28	n	4	4	3	3
		LS Mean (SE)	-0.449 (0.1846)	-0.573 (0.1830)	-0.712 (0.2126)	-0.947 (0.2126)
		90% CI (2-sided)	-0.787, -0.111	-0.909, -0.238	-1.102, -0.323	-1.337, -0.558
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.124 (0.2593)	-0.264 (0.2836)	-0.499 (0.2837)
		90% CI (2-sided)		-0.600, 0.351	-0.783, 0.256	-1.019, 0.021
		P-value		0.6427	0.3768	0.1127
	Smoking - Never/Former	n	67	69	65	66
		LS Mean (SE)	-0.428 (0.0534)	-0.477 (0.0531)	-0.560 (0.0546)	-0.566 (0.0543)
		90% CI (2-sided)	-0.516, -0.339	-0.565, -0.389	-0.650, -0.470	-0.656, -0.477
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.049 (0.0753)	-0.132 (0.0764)	-0.139 (0.0762)
		90% CI (2-sided)		-0.174, 0.075	-0.258, -0.006	-0.265, -0.013
		P-value		0.5118	0.0849	0.0694

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Baseline Moderate to Severe VMS Frequency - <=12	n	34	30	34	30
		LS Mean (SE)	-0.457 (0.0848)	-0.560 (0.0907)	-0.604 (0.0847)	-0.600 (0.0913)
		90% CI (2-sided)	-0.598, -0.317	-0.710, -0.409	-0.745, -0.464	-0.751, -0.448
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.102 (0.1245)	-0.147 (0.1194)	-0.143 (0.1254)
		90% CI (2-sided)		-0.309, 0.104	-0.345, 0.051	-0.350, 0.065
		P-value		0.4127	0.2203	0.2578
	Baseline Moderate to Severe VMS Frequency - >12	n	33	39	33	38
		LS Mean (SE)	-0.401 (0.0657)	-0.411 (0.0606)	-0.510 (0.0661)	-0.530 (0.0614)
		90% CI (2-sided)	-0.510, -0.292	-0.511, -0.311	-0.619, -0.400	-0.632, -0.428
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.010 (0.0896)	-0.109 (0.0936)	-0.129 (0.0901)
		90% CI (2-sided)		-0.158, 0.138	-0.264, 0.046	-0.278, 0.020
		P-value		0.9105	0.2465	0.1542

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Baseline Moderate to Severe VMS Frequency - <=10	n	6	13	17	12
		LS Mean (SE)	-0.487 (0.1716)	-0.506 (0.1175)	-0.697 (0.1009)	-0.551 (0.1214)
		90% CI (2-sided)	-0.775, -0.199	-0.703, -0.309	-0.866, -0.528	-0.755, -0.347
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.019 (0.2082)	-0.210 (0.1989)	-0.064 (0.2102)
		90% CI (2-sided)		-0.369, 0.331	-0.544, 0.124	-0.417, 0.289
		P-value		0.9278	0.2967	0.7620
	Baseline Moderate to Severe VMS Frequency - >10 to <=13	n	40	29	28	28
		LS Mean (SE)	-0.411 (0.0775)	-0.514 (0.0922)	-0.480 (0.0946)	-0.669 (0.0954)
		90% CI (2-sided)	-0.540, -0.283	-0.667, -0.362	-0.636, -0.323	-0.827, -0.511
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.103 (0.1206)	-0.068 (0.1217)	-0.257 (0.1238)
		90% CI (2-sided)		-0.303, 0.097	-0.270, 0.133	-0.463, -0.052
		P-value		0.3950	0.5762	0.0398

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Baseline Moderate to Severe VMS Frequency - >13	n	21	27	22	28
		LS Mean (SE)	-0.457 (0.0793)	-0.406 (0.0691)	-0.547 (0.0761)	-0.472 (0.0677)
		90% CI (2-sided)	-0.589, -0.325	-0.521, -0.291	-0.674, -0.421	-0.584, -0.359
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.051 (0.1063)	-0.090 (0.1101)	-0.015 (0.1050)
		90% CI (2-sided)		-0.125, 0.228	-0.273, 0.093	-0.189, 0.160
		P-value		0.6292	0.4156	0.8902
Week 12	Age (years) <55	n	33	28	37	32
		LS Mean (SE)	-0.817 (0.1157)	-0.971 (0.1243)	-1.047 (0.1091)	-1.054 (0.1164)
		90% CI (2-sided)	-1.009, -0.625	-1.177, -0.765	-1.228, -0.866	-1.247, -0.861
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.154 (0.1697)	-0.230 (0.1596)	-0.237 (0.1639)
		90% CI (2-sided)		-0.435, 0.128	-0.494, 0.034	-0.508, 0.035
		P-value		0.3671	0.1521	0.1507

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Age (years) >=55	n	31	38	28	31
		LS Mean (SE)	-0.767 (0.1171)	-0.866 (0.1065)	-0.884 (0.1254)	-0.991 (0.1184)
		90% CI (2-sided)	-0.961, -0.573	-1.042, -0.689	-1.092, -0.676	-1.187, -0.794
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.098 (0.1584)	-0.116 (0.1716)	-0.223 (0.1664)
		90% CI (2-sided)		-0.361, 0.164	-0.401, 0.168	-0.499, 0.053
		P-value		0.5356	0.4991	0.1824
	BMI (kg/m^2) <28	n	60	63	62	60
		LS Mean (SE)	-0.768 (0.0841)	-0.918 (0.0825)	-0.971 (0.0834)	-0.997 (0.0844)
		90% CI (2-sided)	-0.907, -0.629	-1.054, -0.782	-1.109, -0.833	-1.136, -0.858
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.150 (0.1179)	-0.203 (0.1186)	-0.229 (0.1190)
		90% CI (2-sided)		-0.344, 0.045	-0.399, -0.007	-0.425, -0.032
		P-value		0.2056	0.0883	0.0556

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	BMI (kg/m^2) >=28	n	4	3	3	3
		LS Mean (SE)	-1.101 (0.3804)	-0.863 (0.3828)	-1.134 (0.4380)	-1.531 (0.4382)
		90% CI (2-sided)	-1.799, -0.402	-1.565, -0.162	-1.939, -0.329	-2.336, -0.726
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.237 (0.5377)	-0.033 (0.5845)	-0.430 (0.5848)
		90% CI (2-sided)		-0.749, 1.224	-1.107, 1.040	-1.504, 0.644
		P-value		0.6695	0.9557	0.4809
	BMI (kg/m^2) >=18.5 to <24	n	37	32	41	40
		LS Mean (SE)	-0.835 (0.1085)	-0.952 (0.1179)	-0.828 (0.1042)	-1.012 (0.1043)
		90% CI (2-sided)	-1.015, -0.656	-1.147, -0.757	-1.000, -0.655	-1.185, -0.840
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.117 (0.1602)	0.008 (0.1510)	-0.177 (0.1503)
		90% CI (2-sided)		-0.382, 0.148	-0.242, 0.258	-0.426, 0.072
		P-value		0.4675	0.9596	0.2404

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	BMI (kg/m^2) >=24 to <28	n	23	31	21	20
		LS Mean (SE)	-0.699 (0.1281)	-0.894 (0.1100)	-1.202 (0.1342)	-0.958 (0.1380)
		90% CI (2-sided)	-0.912, -0.487	-1.077, -0.711	-1.425, -0.979	-1.188, -0.729
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.195 (0.1687)	-0.503 (0.1855)	-0.259 (0.1886)
		90% CI (2-sided)		-0.475, 0.085	-0.811, -0.195	-0.572, 0.054
		P-value		0.2511	0.0079	0.1726
	BMI (kg/m^2) >=28	n	4	3	3	3
		LS Mean (SE)	-1.101 (0.3804)	-0.863 (0.3828)	-1.134 (0.4380)	-1.531 (0.4382)
		90% CI (2-sided)	-1.799, -0.402	-1.565, -0.162	-1.939, -0.329	-2.336, -0.726
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.237 (0.5377)	-0.033 (0.5845)	-0.430 (0.5848)
		90% CI (2-sided)		-0.749, 1.224	-1.107, 1.040	-1.504, 0.644
		P-value		0.6695	0.9557	0.4809

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Smoking - Never/Former	n	64	66	63	61
		LS Mean (SE)	-0.789 (0.0817)	-0.913 (0.0803)	-0.972 (0.0829)	-1.000 (0.0837)
		90% CI (2-sided)	-0.924, -0.654	-1.046, -0.781	-1.109, -0.835	-1.138, -0.862
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.124 (0.1146)	-0.183 (0.1165)	-0.211 (0.1169)
		90% CI (2-sided)		-0.313, 0.065	-0.375, 0.009	-0.404, -0.018
		P-value		0.2791	0.1178	0.0725
	Baseline Moderate to Severe VMS Frequency - <=12	n	32	28	32	29
		LS Mean (SE)	-0.745 (0.1149)	-0.922 (0.1225)	-1.016 (0.1152)	-1.046 (0.1230)
		90% CI (2-sided)	-0.936, -0.555	-1.125, -0.719	-1.206, -0.825	-1.250, -0.842
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.176 (0.1682)	-0.270 (0.1622)	-0.301 (0.1692)
		90% CI (2-sided)		-0.455, 0.102	-0.539, -0.002	-0.581, -0.020
		P-value		0.2965	0.0981	0.0779

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

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Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Baseline Moderate to Severe VMS Frequency - >12	n	32	38	33	34
		LS Mean (SE)	-0.834 (0.1196)	-0.905 (0.1082)	-0.936 (0.1176)	-1.006 (0.1137)
		90% CI (2-sided)	-1.032, -0.636	-1.084, -0.726	-1.131, -0.741	-1.194, -0.818
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.071 (0.1617)	-0.102 (0.1687)	-0.172 (0.1651)
		90% CI (2-sided)		-0.339, 0.197	-0.381, 0.178	-0.445, 0.101
		P-value		0.6607	0.5471	0.2995
	Baseline Moderate to Severe VMS Frequency - <=10	n	6	12	16	12
		LS Mean (SE)	-0.631 (0.2307)	-0.918 (0.1594)	-0.904 (0.1396)	-0.933 (0.1631)
		90% CI (2-sided)	-1.019, -0.243	-1.185, -0.650	-1.138, -0.669	-1.207, -0.659
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.287 (0.2806)	-0.273 (0.2695)	-0.302 (0.2825)
		90% CI (2-sided)		-0.759, 0.185	-0.726, 0.180	-0.777, 0.173
		P-value		0.3123	0.3168	0.2905

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.2.4.2

Primary Endpoint Analysis (Primary Estimand, Subgroup Analysis)

Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12

FAS

Analysis Week	Subgroup	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Baseline Moderate to Severe VMS Frequency - >10 to <=13	n	38	28	27	25
		LS Mean (SE)	-0.770 (0.1080)	-0.931 (0.1272)	-0.981 (0.1302)	-1.171 (0.1352)
		90% CI (2-sided)	-0.949, -0.591	-1.142, -0.720	-1.197, -0.765	-1.395, -0.947
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.161 (0.1669)	-0.211 (0.1686)	-0.401 (0.1738)
		90% CI (2-sided)		-0.438, 0.116	-0.490, 0.069	-0.689, -0.113
		P-value		0.3365	0.2139	0.0228
	Baseline Moderate to Severe VMS Frequency - >13	n	20	26	22	26
		LS Mean (SE)	-0.863 (0.1566)	-0.875 (0.1341)	-0.999 (0.1471)	-0.963 (0.1340)
		90% CI (2-sided)	-1.124, -0.603	-1.098, -0.653	-1.244, -0.755	-1.185, -0.740
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.012 (0.2084)	-0.136 (0.2153)	-0.099 (0.2068)
		90% CI (2-sided)		-0.359, 0.334	-0.494, 0.222	-0.443, 0.245
		P-value		0.9533	0.5290	0.6325

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

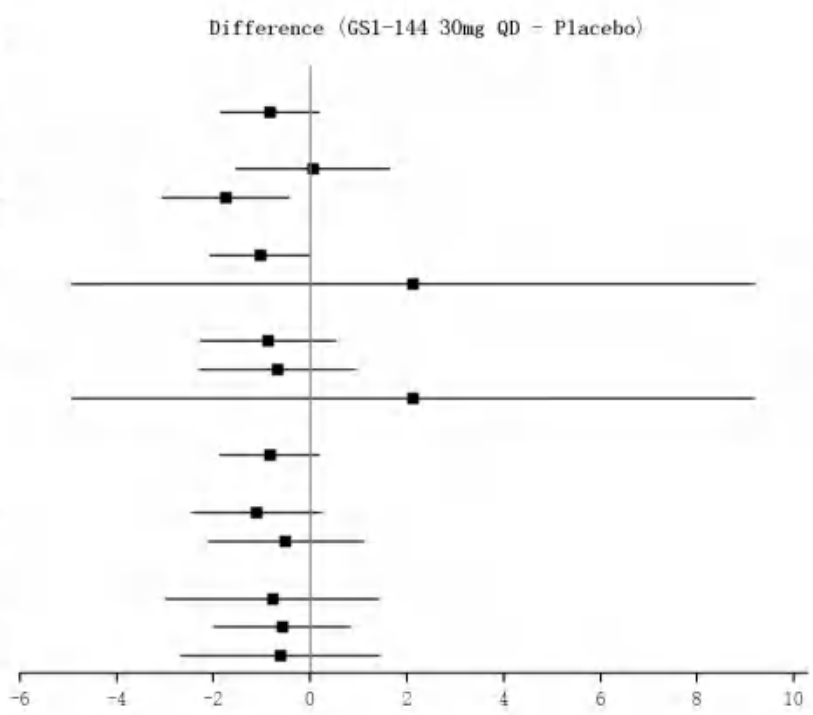
The subgroup analysis were performed with same baseline defination and ICEs rules defined for primary estimand, a similar MMRM model as primary analysis method (without stratification factor BMI group as factor) were be used for subgroup analysis.

The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.3
Forest Plot of Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 4
Treatment Group: GS1-144 30mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	69	67	-6.121 (0.4436)	-5.278 (0.4457)	-0.842 (-1.880, 0.196)
Age (years)					
<55	29	34	-6.180 (0.7119)	-6.224 (0.6575)	0.045 (-1.562, 1.651)
>=55	40	33	-6.074 (0.5404)	-4.317 (0.5838)	-1.757 (-3.075, -0.439)
BMI (kg/m²)					
<28	65	63	-6.175 (0.4495)	-5.147 (0.4518)	-1.029 (-2.081, 0.023)
>=28	4	4	-5.293 (2.7251)	-7.410 (2.7199)	2.117 (-4.942, 9.176)
BMI (kg/m²)					
>=18.5 to <24	32	38	-5.316 (0.6336)	-4.437 (0.5684)	-0.878 (-2.286, 0.530)
>=24 to <28	33	25	-6.987 (0.6405)	-6.303 (0.7352)	-0.684 (-2.308, 0.940)
>=28	4	4	-5.293 (2.7251)	-7.410 (2.7199)	2.117 (-4.942, 9.176)
Smoking					
Never/Former	69	67	-6.131 (0.4465)	-5.290 (0.4486)	-0.842 (-1.886, 0.203)
VMS Frequency					
<=12	30	34	-4.854 (0.5782)	-3.736 (0.5476)	-1.118 (-2.463, 0.228)
>12	39	33	-7.272 (0.6595)	-6.761 (0.7136)	-0.512 (-2.122, 1.099)
VMS Frequency					
<=10	13	6	-4.272 (0.7463)	-3.486 (1.0874)	-0.786 (-3.003, 1.431)
>10 to <=13	29	40	-4.842 (0.6558)	-4.257 (0.5483)	-0.585 (-2.002, 0.832)
>13	27	21	-8.533 (0.8180)	-7.908 (0.9325)	-0.625 (-2.686, 1.437)

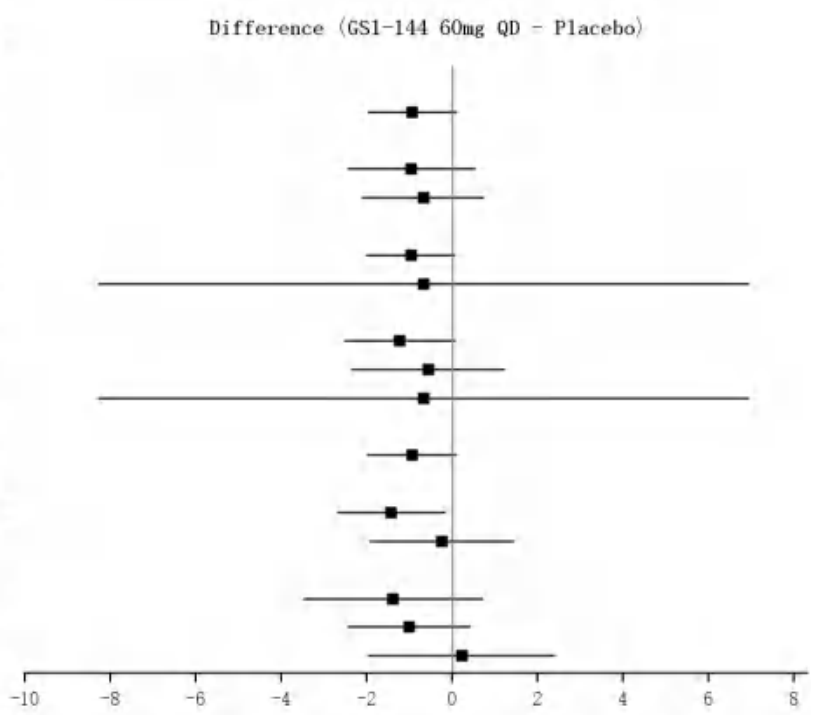


Data Source: Table 14.2.2.4.1
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Frequency means Baseline Moderate to Severe VMS Frequency.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.3
Forest Plot of Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 4
Treatment Group: GS1-144 60mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	67	67	-6.213 (0.4477)	-5.278 (0.4457)	-0.935 (-1.978, 0.108)
Age (years)					
<55	39	34	-7.185 (0.6139)	-6.224 (0.6575)	-0.961 (-2.452, 0.530)
>=55	28	33	-5.001 (0.6392)	-4.317 (0.5838)	-0.684 (-2.117, 0.749)
BMI (kg/m²)					
<28	64	63	-6.122 (0.4505)	-5.147 (0.4518)	-0.975 (-2.028, 0.078)
>=28	3	4	-8.092 (3.1427)	-7.410 (2.7199)	-0.682 (-8.300, 6.936)
BMI (kg/m²)					
>=18.5 to <24	42	38	-5.668 (0.5462)	-4.437 (0.5684)	-1.231 (-2.535, 0.073)
>=24 to <28	22	25	-6.862 (0.7838)	-6.303 (0.7352)	-0.559 (-2.349, 1.230)
>=28	3	4	-8.092 (3.1427)	-7.410 (2.7199)	-0.682 (-8.300, 6.936)
Smoking					
Never/Former	65	67	-6.238 (0.4575)	-5.290 (0.4486)	-0.948 (-2.006, 0.109)
VMS Frequency					
<=12	34	34	-5.169 (0.5309)	-3.736 (0.5476)	-1.432 (-2.705, -0.159)
>12	33	33	-7.005 (0.7194)	-6.761 (0.7136)	-0.245 (-1.930, 1.440)
VMS Frequency					
<=10	17	6	-4.883 (0.6393)	-3.486 (1.0874)	-1.397 (-3.516, 0.721)
>10 to <=13	28	40	-5.266 (0.6683)	-4.257 (0.5483)	-1.009 (-2.441, 0.423)
>13	22	21	-7.695 (0.9142)	-7.908 (0.9325)	0.214 (-1.971, 2.398)

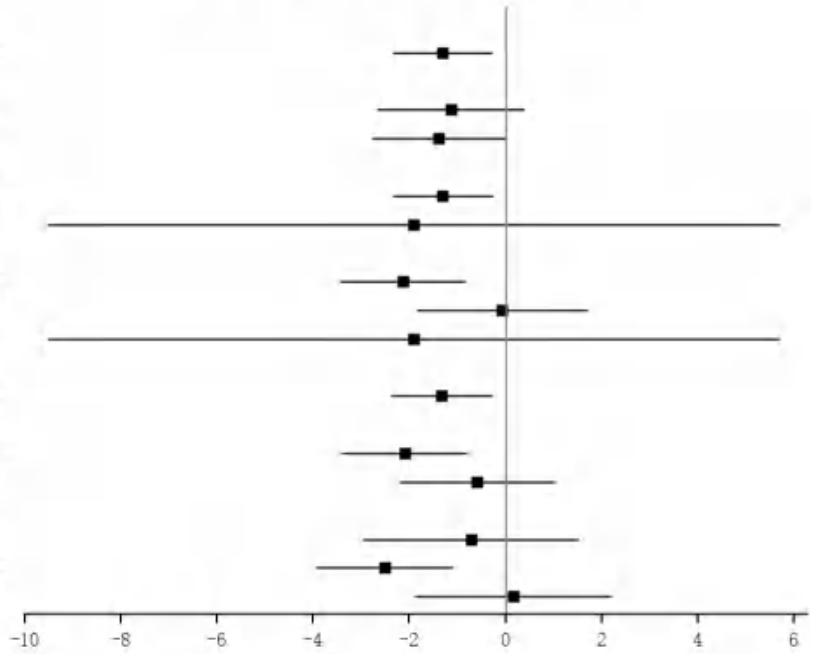


Data Source: Table 14.2.2.4.1
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Frequency means Baseline Moderate to Severe VMS Frequency.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.3
Forest Plot of Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 4
Treatment Group: GS1-144 30mg BID

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	68	67	-6.584 (0.4468)	-5.278 (0.4457)	-1.305 (-2.347, -0.264)
Age (years)					
<55	35	34	-7.361 (0.6480)	-6.224 (0.6575)	-1.136 (-2.664, 0.391)
>=55	33	33	-5.699 (0.5963)	-4.317 (0.5838)	-1.382 (-2.766, 0.001)
BMI (kg/m²)					
<28	65	63	-6.452 (0.4495)	-5.147 (0.4518)	-1.305 (-2.358, -0.253)
>=28	3	4	-9.323 (3.1414)	-7.410 (2.7199)	-1.913 (-9.530, 5.703)
BMI (kg/m²)					
>=18.5 to <24	43	38	-6.570 (0.5477)	-4.437 (0.5684)	-2.132 (-3.439, -0.825)
>=24 to <28	22	25	-6.378 (0.7861)	-6.303 (0.7352)	-0.075 (-1.855, 1.706)
>=28	3	4	-9.323 (3.1414)	-7.410 (2.7199)	-1.913 (-9.530, 5.703)
Smoking					
Never/Former	66	67	-6.620 (0.4565)	-5.290 (0.4486)	-1.331 (-2.387, -0.274)
VMS Frequency					
<=12	30	34	-5.833 (0.5708)	-3.736 (0.5476)	-2.097 (-3.411, -0.783)
>12	38	33	-7.345 (0.6681)	-6.761 (0.7136)	-0.585 (-2.202, 1.033)
VMS Frequency					
<=10	12	6	-4.207 (0.7689)	-3.486 (1.0874)	-0.721 (-2.959, 1.517)
>10 to <=13	28	40	-6.776 (0.6675)	-4.257 (0.5483)	-2.519 (-3.951, -1.087)
>13	28	21	-7.750 (0.8040)	-7.908 (0.9325)	0.158 (-1.883, 2.199)

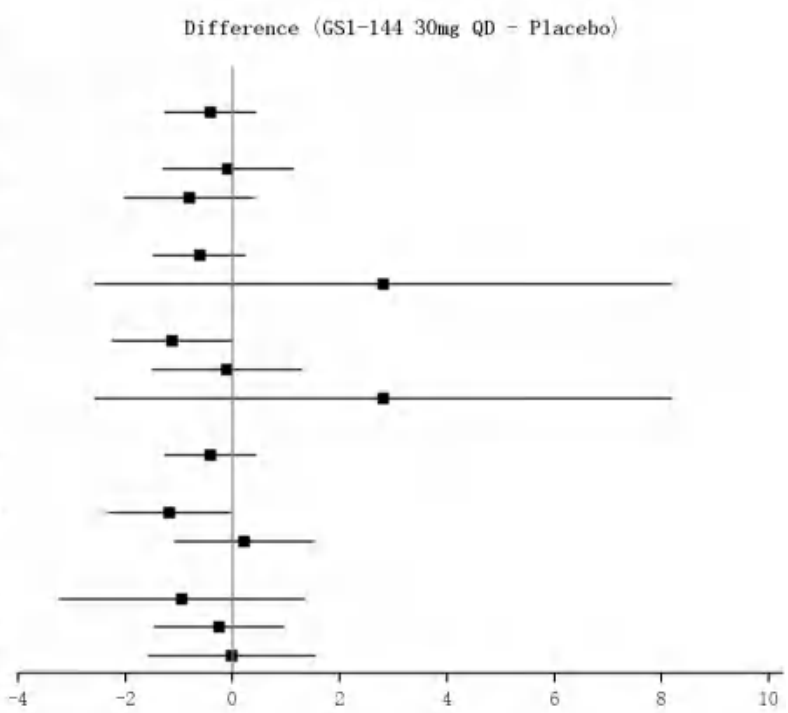


Data Source: Table 14.2.2.4.1
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Frequency means Baseline Moderate to Severe VMS Frequency.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.3
Forest Plot of Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 12
Treatment Group: GS1-144 30mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	66	64	-9.636 (0.3644)	-9.217 (0.3705)	-0.419 (-1.277, 0.439)
Age (years)					
<55	28	33	-9.889 (0.5404)	-9.794 (0.5043)	-0.094 (-1.321, 1.132)
>=55	38	31	-9.426 (0.4967)	-8.609 (0.5454)	-0.816 (-2.038, 0.406)
BMI (kg/m²)					
<28	63	60	-9.712 (0.3685)	-9.094 (0.3755)	-0.618 (-1.486, 0.251)
>=28	3	4	-8.573 (2.0837)	-11.375 (2.0780)	2.803 (-2.593, 8.198)
BMI (kg/m²)					
>=18.5 to <24	32	37	-9.898 (0.5095)	-8.769 (0.4650)	-1.129 (-2.270, 0.013)
>=24 to <28	31	23	-9.720 (0.5492)	-9.613 (0.6378)	-0.108 (-1.511, 1.296)
>=28	3	4	-8.573 (2.0837)	-11.375 (2.0780)	2.803 (-2.593, 8.198)
Smoking					
Never/Former	66	64	-9.654 (0.3661)	-9.236 (0.3722)	-0.418 (-1.280, 0.444)
VMS Frequency					
<=12	28	32	-7.737 (0.4917)	-6.552 (0.4660)	-1.186 (-2.330, -0.041)
>12	38	32	-11.455 (0.5301)	-11.661 (0.5850)	0.206 (-1.102, 1.515)
VMS Frequency					
<=10	12	6	-6.587 (0.7726)	-5.634 (1.1192)	-0.952 (-3.240, 1.335)
>10 to <=13	28	38	-8.046 (0.5600)	-7.792 (0.4730)	-0.254 (-1.469, 0.961)
>13	26	20	-13.082 (0.6171)	-13.064 (0.7174)	-0.018 (-1.591, 1.556)

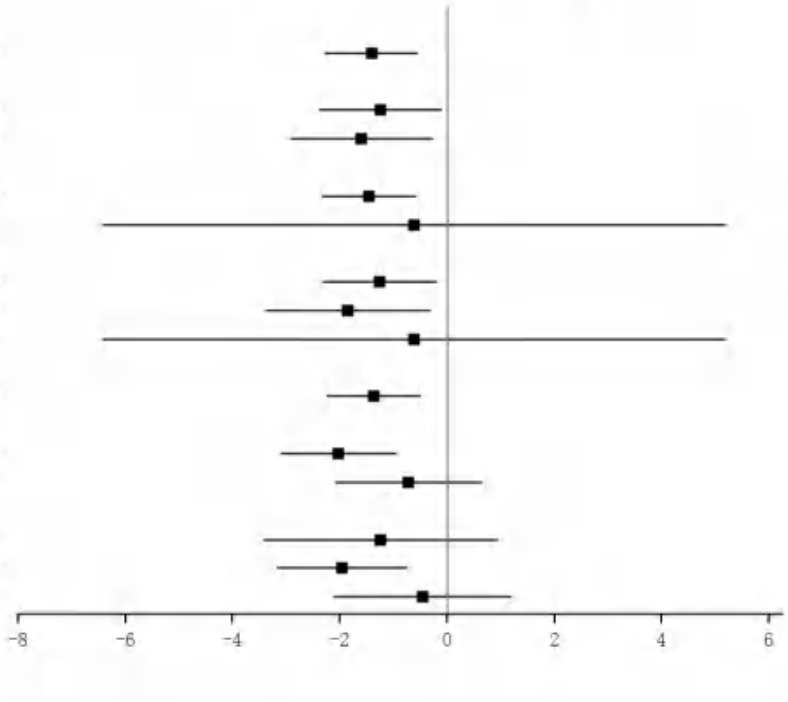


Data Source: Table 14.2.2.4.1
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Frequency means Baseline Moderate to Severe VMS Frequency.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.3
Forest Plot of Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 12
Treatment Group: GS1-144 60mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	65	64	-10.635 (0.3691)	-9.217 (0.3705)	-1.418 (-2.281, -0.554)
Age (years)					
<55	37	33	-11.046 (0.4698)	-9.794 (0.5043)	-1.252 (-2.395, -0.109)
>=55	28	31	-10.211 (0.5872)	-8.609 (0.5454)	-1.602 (-2.929, -0.275)
BMI (kg/m²)					
<28	62	60	-10.556 (0.3709)	-9.094 (0.3755)	-1.462 (-2.334, -0.590)
>=28	3	4	-12.004 (2.4010)	-11.375 (2.0780)	-0.629 (-6.450, 5.192)
BMI (kg/m²)					
>=18.5 to <24	41	37	-10.038 (0.4447)	-8.769 (0.4650)	-1.268 (-2.333, -0.203)
>=24 to <28	21	23	-11.473 (0.6680)	-9.613 (0.6378)	-1.861 (-3.400, -0.322)
>=28	3	4	-12.004 (2.4010)	-11.375 (2.0780)	-0.629 (-6.450, 5.192)
Smoking					
Never/Former	63	64	-10.606 (0.3766)	-9.236 (0.3722)	-1.370 (-2.245, -0.496)
VMS Frequency					
<=12	32	32	-8.585 (0.4543)	-6.552 (0.4660)	-2.033 (-3.119, -0.947)
>12	33	32	-12.388 (0.5774)	-11.661 (0.5850)	-0.727 (-2.094, 0.641)
VMS Frequency					
<=10	16	6	-6.879 (0.6744)	-5.634 (1.1192)	-1.245 (-3.441, 0.951)
>10 to <=13	27	38	-9.758 (0.5672)	-7.792 (0.4730)	-1.966 (-3.190, -0.742)
>13	22	20	-13.523 (0.6884)	-13.064 (0.7174)	-0.459 (-2.123, 1.206)

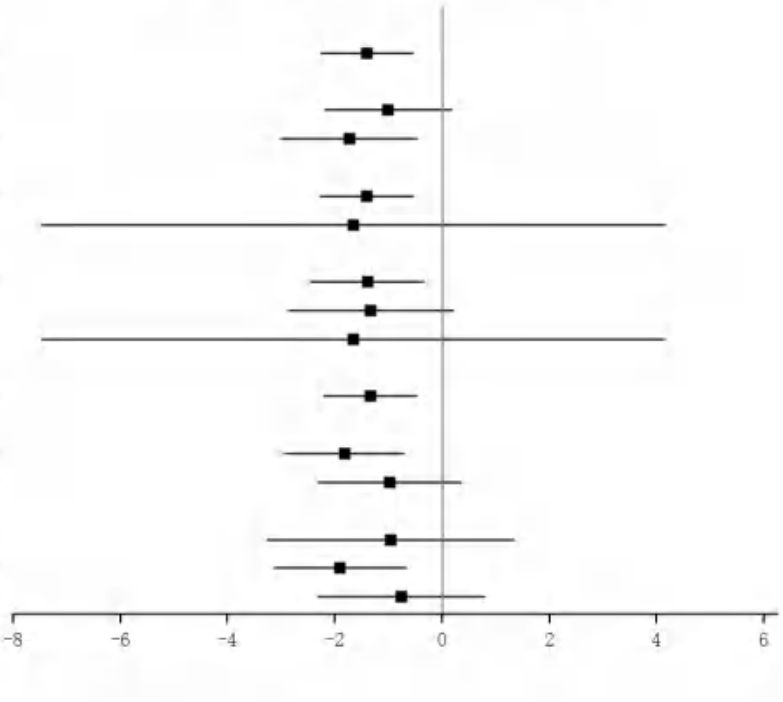


Data Source: Table 14.2.2.4.1
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Frequency means Baseline Moderate to Severe VMS Frequency.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.3
Forest Plot of Change from Baseline in the Frequency of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 12
Treatment Group: GS1-144 30mg BID

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	63	64	-10.623 (0.3740)	-9.217 (0.3705)	-1.407 (-2.276, -0.537)
Age (years)					
<55	32	33	-10.806 (0.5084)	-9.794 (0.5043)	-1.012 (-2.197, 0.173)
>=55	31	31	-10.352 (0.5526)	-8.609 (0.5454)	-1.742 (-3.030, -0.455)
BMI (kg/m²)					
<28	60	60	-10.501 (0.3762)	-9.094 (0.3755)	-1.407 (-2.285, -0.529)
>=28	3	4	-13.042 (2.4000)	-11.375 (2.0780)	-1.667 (-7.487, 4.153)
BMI (kg/m²)					
>=18.5 to <24	40	37	-10.171 (0.4515)	-8.769 (0.4650)	-1.402 (-2.475, -0.329)
>=24 to <28	20	23	-10.947 (0.6861)	-9.613 (0.6378)	-1.335 (-2.883, 0.214)
>=28	3	4	-13.042 (2.4000)	-11.375 (2.0780)	-1.667 (-7.487, 4.153)
Smoking					
Never/Former	61	64	-10.577 (0.3817)	-9.236 (0.3722)	-1.341 (-2.222, -0.461)
VMS Frequency					
<=12	29	32	-8.378 (0.4842)	-6.552 (0.4660)	-1.826 (-2.944, -0.709)
>12	34	32	-12.644 (0.5582)	-11.661 (0.5850)	-0.983 (-2.323, 0.357)
VMS Frequency					
<=10	12	6	-6.599 (0.7914)	-5.634 (1.1192)	-0.964 (-3.269, 1.340)
>10 to <=13	25	38	-9.702 (0.5846)	-7.792 (0.4730)	-1.909 (-3.156, -0.663)
>13	26	20	-13.823 (0.6218)	-13.064 (0.7174)	-0.759 (-2.333, 0.816)

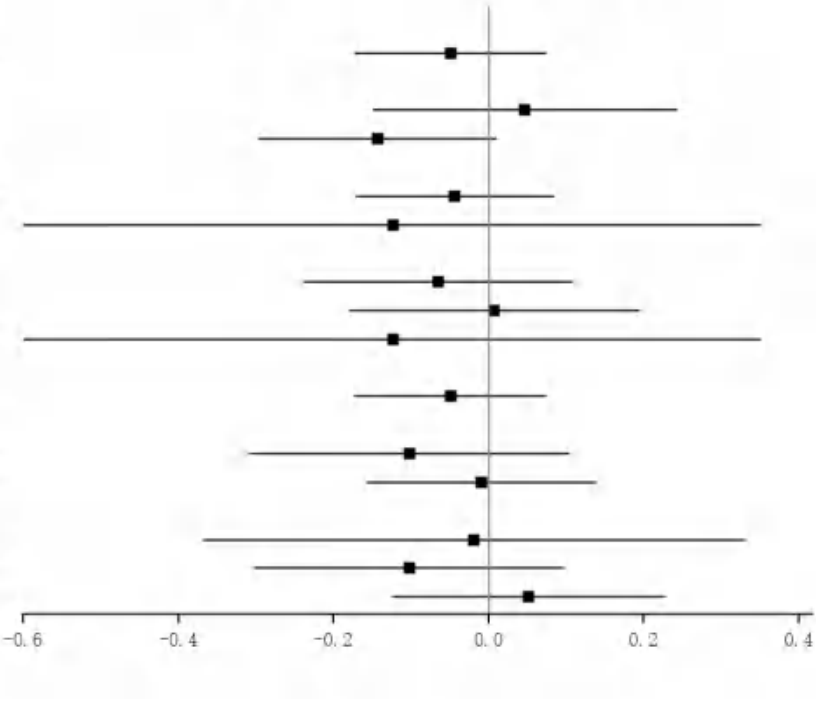


Data Source: Table 14.2.2.4.1
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Frequency means Baseline Moderate to Severe VMS Frequency.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.4
Forest Plot of Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 4
Treatment Group: GS1-144 30mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	69	67	-0.477 (0.0527)	-0.427 (0.0531)	-0.049 (-0.173, 0.074)
Age (years)					
<55	29	34	-0.481 (0.0872)	-0.527 (0.0806)	0.046 (-0.150, 0.243)
>=55	40	33	-0.474 (0.0630)	-0.331 (0.0680)	-0.143 (-0.297, 0.010)
BMI (kg/m²)					
<28	65	63	-0.471 (0.0546)	-0.428 (0.0549)	-0.044 (-0.172, 0.084)
>=28	4	4	-0.573 (0.1830)	-0.449 (0.1846)	-0.124 (-0.600, 0.351)
BMI (kg/m²)					
>=18.5 to <24	32	38	-0.473 (0.0775)	-0.408 (0.0700)	-0.065 (-0.238, 0.108)
>=24 to <28	33	25	-0.475 (0.0740)	-0.482 (0.0851)	0.007 (-0.180, 0.194)
>=28	4	4	-0.573 (0.1830)	-0.449 (0.1846)	-0.124 (-0.600, 0.351)
Smoking					
Never/Former	69	67	-0.477 (0.0531)	-0.428 (0.0534)	-0.049 (-0.174, 0.075)
VMS Frequency					
<=12	30	34	-0.560 (0.0907)	-0.457 (0.0848)	-0.102 (-0.309, 0.104)
>12	39	33	-0.411 (0.0606)	-0.401 (0.0657)	-0.010 (-0.158, 0.138)
VMS Frequency					
<=10	13	6	-0.506 (0.1175)	-0.487 (0.1716)	-0.019 (-0.369, 0.331)
>10 to <=13	29	40	-0.514 (0.0922)	-0.411 (0.0775)	-0.103 (-0.303, 0.097)
>13	27	21	-0.406 (0.0691)	-0.457 (0.0793)	0.051 (-0.125, 0.228)

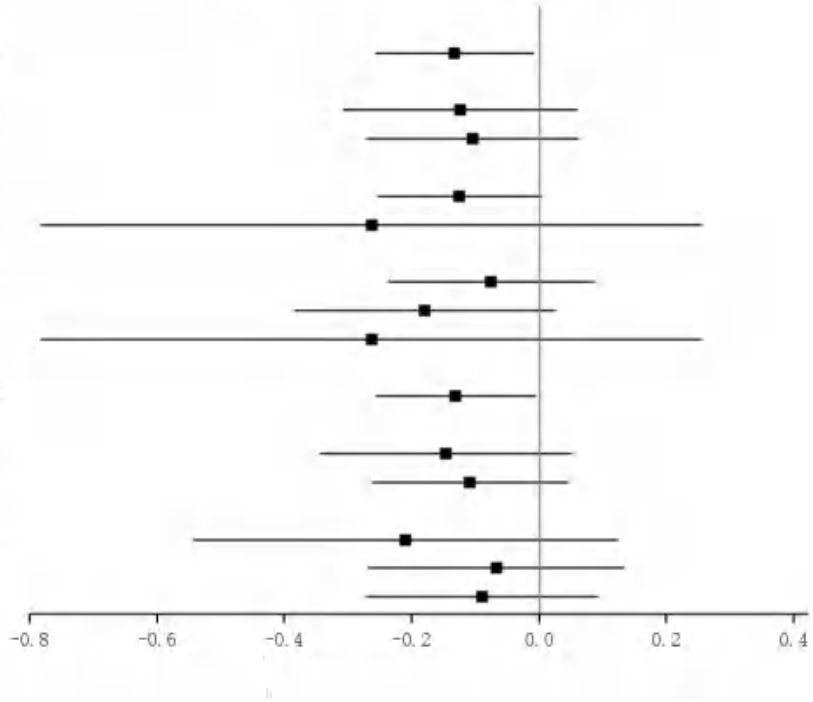


Data Source: Table 14.2.2.4.2
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Severity means Baseline Moderate to Severe VMS Severity.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.4
Forest Plot of Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 4
Treatment Group: GS1-144 60mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	67	67	-0.561 (0.0534)	-0.427 (0.0531)	-0.133 (-0.258, -0.009)
Age (years)					
<55	39	34	-0.652 (0.0758)	-0.527 (0.0806)	-0.124 (-0.308, 0.060)
>=55	28	33	-0.435 (0.0744)	-0.331 (0.0680)	-0.105 (-0.272, 0.062)
BMI (kg/m²)					
<28	64	63	-0.553 (0.0549)	-0.428 (0.0549)	-0.126 (-0.254, 0.003)
>=28	3	4	-0.712 (0.2126)	-0.449 (0.1846)	-0.264 (-0.783, 0.256)
BMI (kg/m²)					
>=18.5 to <24	42	38	-0.484 (0.0675)	-0.408 (0.0700)	-0.076 (-0.237, 0.086)
>=24 to <28	22	25	-0.662 (0.0906)	-0.482 (0.0851)	-0.180 (-0.386, 0.026)
>=28	3	4	-0.712 (0.2126)	-0.449 (0.1846)	-0.264 (-0.783, 0.256)
Smoking					
Never/Former	65	67	-0.560 (0.0546)	-0.428 (0.0534)	-0.132 (-0.258, -0.006)
VMS Frequency					
<=12	34	34	-0.604 (0.0847)	-0.457 (0.0848)	-0.147 (-0.345, 0.051)
>12	33	33	-0.510 (0.0661)	-0.401 (0.0657)	-0.109 (-0.264, 0.046)
VMS Frequency					
<=10	17	6	-0.697 (0.1009)	-0.487 (0.1716)	-0.210 (-0.544, 0.124)
>10 to <=13	28	40	-0.480 (0.0946)	-0.411 (0.0775)	-0.068 (-0.270, 0.133)
>13	22	21	-0.547 (0.0761)	-0.457 (0.0793)	-0.090 (-0.273, 0.093)

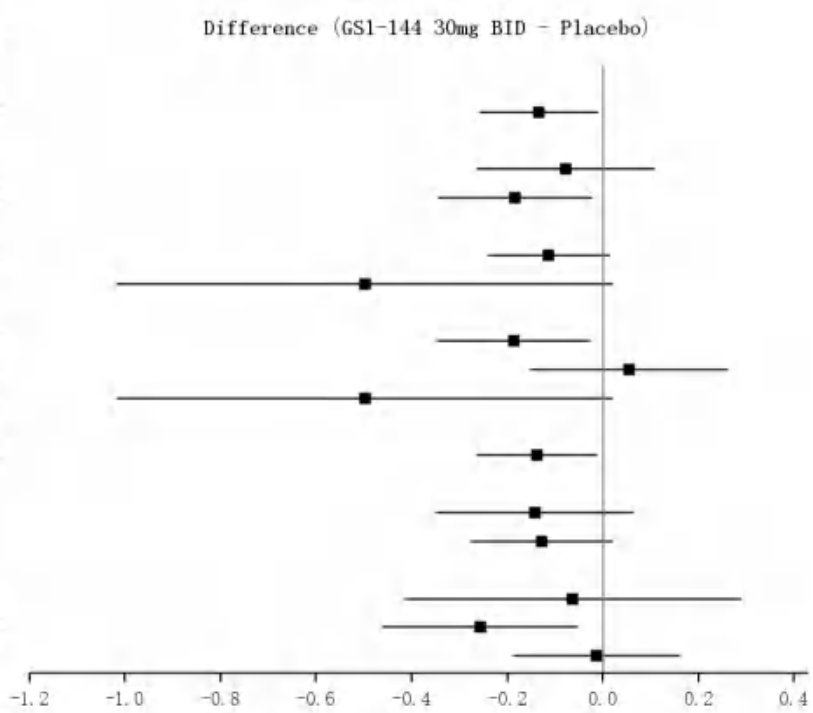


Data Source: Table 14.2.2.4.2
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Severity means Baseline Moderate to Severe VMS Severity.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.4
Forest Plot of Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 4
Treatment Group: GS1-144 30mg BID

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	68	67	-0.562 (0.0532)	-0.427 (0.0531)	-0.135 (-0.259, -0.011)
Age (years)					
<55	35	34	-0.607 (0.0794)	-0.527 (0.0806)	-0.079 (-0.266, 0.108)
>=55	33	33	-0.515 (0.0694)	-0.331 (0.0680)	-0.184 (-0.345, -0.023)
BMI (kg/m²)					
<28	65	63	-0.542 (0.0547)	-0.428 (0.0549)	-0.114 (-0.242, 0.014)
>=28	3	4	-0.947 (0.2126)	-0.449 (0.1846)	-0.499 (-1.019, 0.021)
BMI (kg/m²)					
>=18.5 to <24	43	38	-0.595 (0.0669)	-0.408 (0.0700)	-0.187 (-0.347, -0.027)
>=24 to <28	22	25	-0.427 (0.0909)	-0.482 (0.0851)	0.055 (-0.153, 0.262)
>=28	3	4	-0.947 (0.2126)	-0.449 (0.1846)	-0.499 (-1.019, 0.021)
Smoking					
Never/Former	66	67	-0.566 (0.0543)	-0.428 (0.0534)	-0.139 (-0.265, -0.013)
VMS Frequency					
<=12	30	34	-0.600 (0.0913)	-0.457 (0.0848)	-0.143 (-0.350, 0.065)
>12	38	33	-0.530 (0.0614)	-0.401 (0.0657)	-0.129 (-0.278, 0.020)
VMS Frequency					
<=10	12	6	-0.551 (0.1214)	-0.487 (0.1716)	-0.064 (-0.417, 0.289)
>10 to <=13	28	40	-0.669 (0.0954)	-0.411 (0.0775)	-0.257 (-0.463, -0.052)
>13	28	21	-0.472 (0.0677)	-0.457 (0.0793)	-0.015 (-0.189, 0.160)

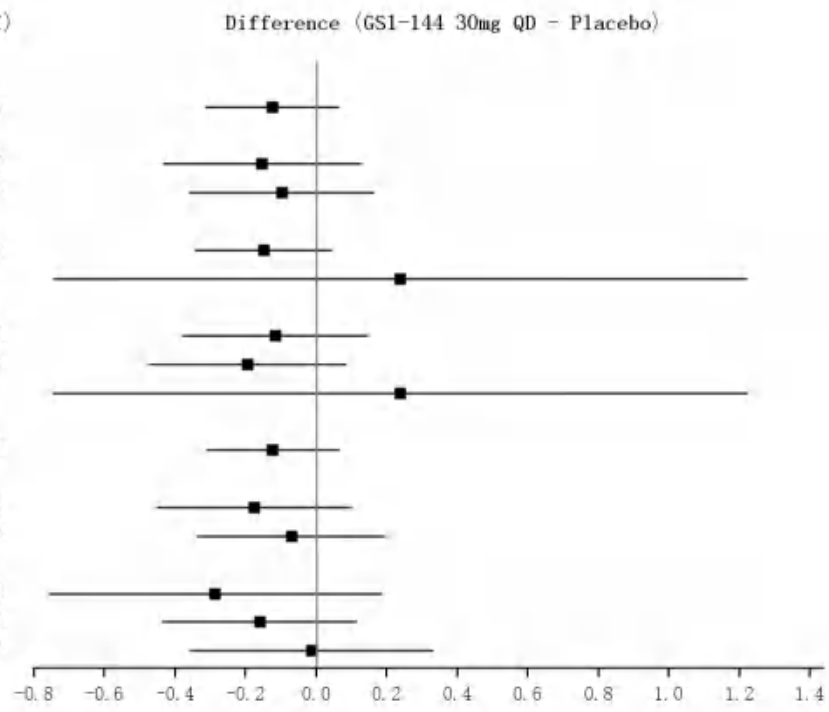


Data Source: Table 14.2.2.4.2
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Severity means Baseline Moderate to Severe VMS Severity.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.4
Forest Plot of Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 12
Treatment Group: GS1-144 30mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	66	64	-0.913 (0.0803)	-0.788 (0.0817)	-0.125 (-0.314, 0.064)
Age (years)					
<55	28	33	-0.971 (0.1243)	-0.817 (0.1157)	-0.154 (-0.435, 0.128)
>=55	38	31	-0.866 (0.1065)	-0.767 (0.1171)	-0.098 (-0.361, 0.164)
BMI (kg/m²)					
<28	63	60	-0.918 (0.0825)	-0.768 (0.0841)	-0.150 (-0.344, 0.045)
>=28	3	4	-0.863 (0.3828)	-1.101 (0.3804)	0.237 (-0.749, 1.224)
BMI (kg/m²)					
>=18.5 to <24	32	37	-0.952 (0.1179)	-0.835 (0.1085)	-0.117 (-0.382, 0.148)
>=24 to <28	31	23	-0.894 (0.1100)	-0.699 (0.1281)	-0.195 (-0.475, 0.085)
>=28	3	4	-0.863 (0.3828)	-1.101 (0.3804)	0.237 (-0.749, 1.224)
Smoking					
Never/Former	66	64	-0.913 (0.0803)	-0.789 (0.0817)	-0.124 (-0.313, 0.065)
VMS Frequency					
<=12	28	32	-0.922 (0.1225)	-0.745 (0.1149)	-0.176 (-0.455, 0.102)
>12	38	32	-0.905 (0.1082)	-0.834 (0.1196)	-0.071 (-0.339, 0.197)
VMS Frequency					
<=10	12	6	-0.918 (0.1594)	-0.631 (0.2307)	-0.287 (-0.759, 0.185)
>10 to <=13	28	38	-0.931 (0.1272)	-0.770 (0.1080)	-0.161 (-0.438, 0.116)
>13	26	20	-0.875 (0.1341)	-0.863 (0.1566)	-0.012 (-0.359, 0.334)

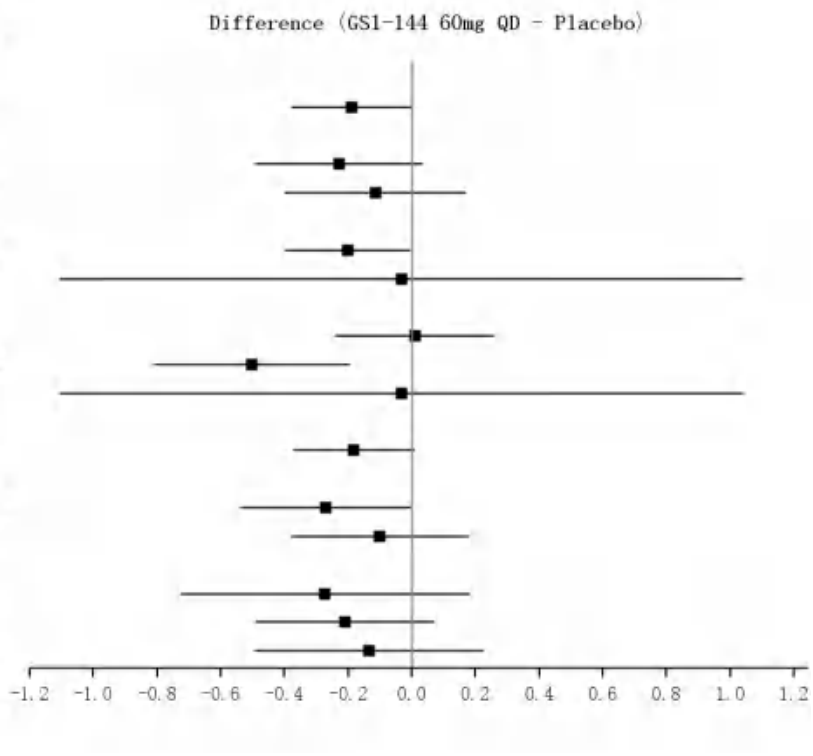


Data Source: Table 14.2.2.4.2
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Severity means Baseline Moderate to Severe VMS Severity.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.4
Forest Plot of Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 12
Treatment Group: GS1-144 60mg QD

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	65	64	-0.978 (0.0816)	-0.788 (0.0817)	-0.190 (-0.381, 0.001)
Age (years)					
<55	37	33	-1.047 (0.1091)	-0.817 (0.1157)	-0.230 (-0.494, 0.034)
>=55	28	31	-0.884 (0.1254)	-0.767 (0.1171)	-0.116 (-0.401, 0.168)
BMI (kg/m²)					
<28	62	60	-0.971 (0.0834)	-0.768 (0.0841)	-0.203 (-0.399, -0.007)
>=28	3	4	-1.134 (0.4380)	-1.101 (0.3804)	-0.033 (-1.107, 1.040)
BMI (kg/m²)					
>=18.5 to <24	41	37	-0.828 (0.1042)	-0.835 (0.1085)	0.008 (-0.242, 0.258)
>=24 to <28	21	23	-1.202 (0.1342)	-0.699 (0.1281)	-0.503 (-0.811, -0.195)
>=28	3	4	-1.134 (0.4380)	-1.101 (0.3804)	-0.033 (-1.107, 1.040)
Smoking					
Never/Former	63	64	-0.972 (0.0829)	-0.789 (0.0817)	-0.183 (-0.375, 0.009)
VMS Frequency					
<=12	32	32	-1.016 (0.1152)	-0.745 (0.1149)	-0.270 (-0.539, -0.002)
>12	33	32	-0.936 (0.1176)	-0.834 (0.1196)	-0.102 (-0.381, 0.178)
VMS Frequency					
<=10	16	6	-0.904 (0.1396)	-0.631 (0.2307)	-0.273 (-0.726, 0.180)
>10 to <=13	27	38	-0.981 (0.1302)	-0.770 (0.1080)	-0.211 (-0.490, 0.069)
>13	22	20	-0.999 (0.1471)	-0.863 (0.1566)	-0.136 (-0.494, 0.222)

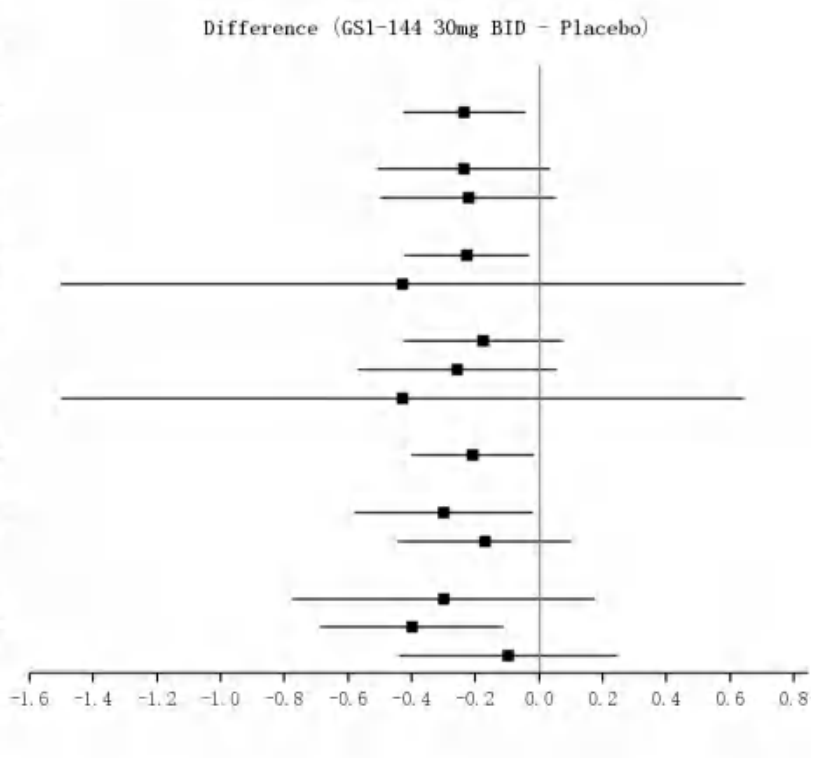


Data Source: Table 14.2.2.4.2
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Severity means Baseline Moderate to Severe VMS Severity.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Figure 14.2.2.4.4
Forest Plot of Change from Baseline in the Severity of Moderate to Severe VMS at Week 4 and Week 12
FAS

Week 12
Treatment Group: GS1-144 30mg BID

Subgroup	N GS	N PLA	LS Mean (SE) GS	LS Mean (SE) PLA	Difference (90% CI)
Overall	63	64	-1.023 (0.0824)	-0.788 (0.0817)	-0.236 (-0.427, -0.044)
Age (years)					
<55	32	33	-1.054 (0.1164)	-0.817 (0.1157)	-0.237 (-0.508, 0.035)
>=55	31	31	-0.991 (0.1184)	-0.767 (0.1171)	-0.223 (-0.499, 0.053)
BMI (kg/m²)					
<28	60	60	-0.997 (0.0844)	-0.768 (0.0841)	-0.229 (-0.425, -0.032)
>=28	3	4	-1.531 (0.4382)	-1.101 (0.3804)	-0.430 (-1.504, 0.644)
BMI (kg/m²)					
>=18.5 to <24	40	37	-1.012 (0.1043)	-0.835 (0.1085)	-0.177 (-0.426, 0.072)
>=24 to <28	20	23	-0.958 (0.1380)	-0.699 (0.1281)	-0.259 (-0.572, 0.054)
>=28	3	4	-1.531 (0.4382)	-1.101 (0.3804)	-0.430 (-1.504, 0.644)
Smoking					
Never/Former	61	64	-1.000 (0.0837)	-0.789 (0.0817)	-0.211 (-0.404, -0.018)
VMS Frequency					
<=12	29	32	-1.046 (0.1230)	-0.745 (0.1149)	-0.301 (-0.581, -0.020)
>12	34	32	-1.006 (0.1137)	-0.834 (0.1196)	-0.172 (-0.445, 0.101)
VMS Frequency					
<=10	12	6	-0.933 (0.1631)	-0.631 (0.2307)	-0.302 (-0.777, 0.173)
>10 to <=13	25	38	-1.171 (0.1352)	-0.770 (0.1080)	-0.401 (-0.689, -0.113)
>13	26	20	-0.963 (0.1340)	-0.863 (0.1566)	-0.099 (-0.443, 0.245)



Data Source: Table 14.2.2.4.2
GS = GS1-144; PLA = Placebo; LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
N = number of subjects in GS1-144 group or Placebo group.
VMS Severity means Baseline Moderate to Severe VMS Severity.
The "Current" subgroup for Smoking was not presented due to limited number of subjects (only 4 subjects in total).

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	12.628 (2.5693)	12.957 (3.7763)	12.883 (4.4260)	12.979 (3.6833)
	Median	12.000	12.571	11.571	12.429
	Q1 - Q3	11.143 - 13.571	10.429 - 13.857	10.000 - 13.571	10.714 - 14.786
	Min - Max	8.00 - 21.71	7.29 - 23.71	7.83 - 32.29	7.00 - 31.43
Week 1	Observed Value				
	n	69	70	69	68
	Mean (SD)	9.971 (3.0938)	9.656 (3.4136)	9.456 (4.6454)	9.334 (4.1951)
	Median	10.571	9.714	9.286	9.500
	Q1 - Q3	8.143 - 12.000	7.143 - 12.143	6.714 - 11.571	6.429 - 12.071
	Min - Max	1.86 - 16.57	2.86 - 17.00	0.14 - 26.86	0.29 - 20.71
	Change from Baseline				
	n	69	70	69	68
	Mean (SD)	-2.657 (3.0031)	-3.301 (3.3110)	-3.427 (3.3092)	-3.645 (3.4659)
	Median	-1.857	-2.357	-2.286	-2.714
	Q1 - Q3	-4.000 - -0.571	-5.238 - -0.857	-4.571 - -1.286	-5.214 - -1.000
	Min - Max	-12.71 - 2.86	-15.71 - 2.86	-12.14 - 1.71	-12.43 - 2.71

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 1	Percentage Change from Baseline				
	n	69	70	69	68
	Mean (SD)	-20.34 (22.658)	-24.27 (21.506)	-27.16 (25.265)	-27.99 (26.041)
	Median	-15.12	-18.17	-18.97	-23.41
	Q1 - Q3	-28.87 - -4.40	-38.60 - -6.94	-37.31 - -9.71	-39.25 - -8.79
	Min - Max	-83.5 - 26.3	-72.5 - 22.0	-98.6 - 9.9	-97.4 - 30.2
Week 2	Observed Value				
	n	69	69	68	68
	Mean (SD)	9.037 (3.3560)	8.234 (3.8621)	8.167 (4.4547)	8.281 (4.3409)
	Median	9.143	8.571	8.214	8.929
	Q1 - Q3	6.857 - 11.571	6.000 - 11.429	5.429 - 10.214	4.429 - 11.500
	Min - Max	0.57 - 16.43	0 - 16.43	0 - 22.57	0 - 20.43
	Change from Baseline				
	n	69	69	68	68
	Mean (SD)	-3.590 (3.5234)	-4.735 (3.9679)	-4.745 (3.8139)	-4.697 (3.7096)
	Median	-2.571	-4.000	-3.429	-3.714
	Q1 - Q3	-6.571 - -0.857	-7.714 - -1.857	-7.071 - -1.857	-6.714 - -1.917
	Min - Max	-16.57 - 1.29	-16.00 - 3.43	-15.86 - 1.14	-13.86 - 2.71

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 2	Percentage Change from Baseline				
	n	69	69	68	68
	Mean (SD)	-27.57 (25.667)	-35.72 (27.486)	-36.81 (26.697)	-36.52 (28.909)
	Median	-20.88	-28.81	-30.04	-30.03
	Q1 - Q3	-47.31 - -7.58	-51.20 - -14.29	-54.79 - -15.50	-54.41 - -15.55
	Min - Max	-94.9 - 11.5	-100.0 - 26.4	-100.0 - 6.6	-100.0 - 30.2
Week 3	Observed Value				
	n	67	69	67	68
	Mean (SD)	8.086 (3.6390)	7.323 (3.9867)	7.328 (4.5954)	7.019 (4.2955)
	Median	8.286	7.000	7.000	7.429
	Q1 - Q3	6.000 - 11.000	5.143 - 10.286	4.000 - 10.143	3.214 - 10.500
	Min - Max	0 - 13.86	0 - 18.00	0 - 19.71	0 - 17.71
	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-4.554 (3.9882)	-5.646 (4.5963)	-5.632 (4.1262)	-5.959 (3.8976)
	Median	-3.286	-4.571	-4.167	-5.286
	Q1 - Q3	-6.714 - -1.857	-8.857 - -2.000	-8.429 - -2.857	-9.143 - -3.000
	Min - Max	-20.71 - 0.43	-20.86 - 5.00	-16.71 - 0.71	-16.00 - 1.71

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	Percentage Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-35.11 (27.734)	-42.31 (29.959)	-43.71 (28.300)	-46.47 (29.265)
	Median	-27.78	-40.28	-37.36	-41.97
	Q1 - Q3	-50.00 - -17.05	-61.38 - -19.64	-60.29 - -25.93	-69.70 - -24.25
	Min - Max	-100.0 - 3.9	-100.0 - 38.5	-100.0 - 4.1	-100.0 - 19.0
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	7.436 (3.6916)	6.803 (3.9056)	6.711 (4.2475)	6.345 (4.2275)
	Median	8.143	6.143	6.429	6.214
	Q1 - Q3	5.429 - 9.857	4.000 - 9.571	3.571 - 9.286	2.857 - 9.857
	Min - Max	0 - 14.43	0 - 17.71	0 - 17.71	0 - 17.29
	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-5.204 (4.0472)	-6.166 (4.6777)	-6.249 (4.2264)	-6.634 (3.9523)
	Median	-4.000	-5.143	-4.857	-6.429
	Q1 - Q3	-7.714 - -2.429	-9.286 - -2.571	-8.857 - -3.000	-8.857 - -3.357
	Min - Max	-20.14 - 2.43	-20.00 - 4.71	-18.71 - 0.43	-16.43 - 2.43

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Percentage Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-40.39 (28.090)	-46.24 (29.688)	-48.19 (27.827)	-51.67 (29.712)
	Median	-30.70	-47.54	-42.47	-50.07
	Q1 - Q3	-55.67 - -18.99	-70.21 - -22.99	-68.13 - -28.57	-74.79 - -27.86
	Min - Max	-100.0 - 20.2	-100.0 - 36.3	-100.0 - 2.5	-100.0 - 27.0
Week 5	Observed Value				
	n	66	69	67	64
	Mean (SD)	6.496 (3.6061)	6.188 (3.8076)	5.814 (3.8197)	5.600 (3.8942)
	Median	7.286	5.429	5.571	6.071
	Q1 - Q3	4.429 - 9.286	4.000 - 8.857	3.429 - 8.000	1.857 - 9.071
	Min - Max	0 - 13.71	0 - 16.71	0 - 17.29	0 - 15.14
	Change from Baseline				
	n	66	69	67	64
	Mean (SD)	-6.080 (4.1174)	-6.781 (4.4449)	-7.146 (4.3003)	-7.395 (3.9085)
	Median	-5.143	-6.000	-5.714	-7.429
	Q1 - Q3	-8.143 - -3.143	-9.286 - -3.571	-9.429 - -4.286	-9.857 - -4.286
	Min - Max	-19.29 - 0.86	-18.29 - 3.71	-20.71 - -0.14	-16.71 - 0.86

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	Percentage Change from Baseline				
	n	66	69	67	64
	Mean (SD)	-47.34 (28.539)	-51.61 (28.115)	-54.97 (25.434)	-57.31 (27.449)
	Median	-44.56	-54.22	-52.85	-56.98
	Q1 - Q3	-65.98 - -23.68	-71.64 - -29.73	-73.53 - -36.67	-82.96 - -33.42
	Min - Max	-100.0 - 7.1	-100.0 - 28.6	-100.0 - -0.8	-100.0 - 9.5
Week 6	Observed Value				
	n	66	68	67	64
	Mean (SD)	5.982 (3.6211)	5.735 (3.7440)	5.222 (3.7645)	4.919 (3.7374)
	Median	6.571	5.071	4.429	4.714
	Q1 - Q3	3.571 - 8.143	3.214 - 7.714	2.857 - 7.000	1.643 - 8.143
	Min - Max	0 - 13.29	0 - 15.00	0 - 18.29	0 - 15.71
	Change from Baseline				
	n	66	68	67	64
	Mean (SD)	-6.595 (4.2063)	-7.269 (4.4770)	-7.738 (4.4271)	-8.077 (3.9213)
	Median	-6.000	-6.643	-6.857	-7.643
	Q1 - Q3	-9.286 - -3.571	-9.714 - -4.286	-10.000 - -5.143	-10.786 - -5.417
	Min - Max	-19.29 - 1.29	-19.71 - 2.00	-25.71 - -0.57	-17.14 - 2.86

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 6	Percentage Change from Baseline				
	n	66	68	67	64
	Mean (SD)	-51.37 (28.832)	-55.21 (28.015)	-59.52 (24.681)	-62.45 (27.435)
	Median	-48.54	-57.34	-58.21	-65.58
	Q1 - Q3	-76.83 - -32.53	-74.46 - -34.52	-76.52 - -43.36	-87.48 - -42.30
	Min - Max	-100.0 - 10.7	-100.0 - 15.4	-100.0 - -3.3	-100.0 - 31.7
Week 7	Observed Value				
	n	66	68	67	63
	Mean (SD)	5.444 (3.6914)	5.192 (3.6273)	4.655 (3.2332)	4.436 (3.7363)
	Median	4.929	4.500	4.000	4.000
	Q1 - Q3	2.286 - 7.714	2.571 - 7.286	2.286 - 6.857	1.000 - 7.714
	Min - Max	0 - 14.14	0 - 14.14	0 - 13.43	0 - 17.86
	Change from Baseline				
	n	66	68	67	63
	Mean (SD)	-7.132 (4.2805)	-7.813 (4.3603)	-8.306 (4.2695)	-8.513 (3.6965)
	Median	-6.500	-7.500	-7.571	-8.000
	Q1 - Q3	-10.143 - -4.000	-10.429 - -4.869	-10.000 - -5.571	-11.000 - -6.286
	Min - Max	-20.71 - 1.14	-19.43 - 1.14	-24.57 - -0.98	-17.14 - 3.00

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 7	Percentage Change from Baseline				
	n	66	68	67	63
	Mean (SD)	-55.84 (28.760)	-59.61 (26.871)	-63.88 (22.771)	-66.49 (26.661)
	Median	-55.79	-63.34	-63.79	-71.63
	Q1 - Q3	-84.21 - -33.33	-80.77 - -42.66	-80.82 - -47.92	-91.67 - -47.37
	Min - Max	-100.0 - 9.5	-100.0 - 8.8	-100.0 - -12.5	-100.0 - 33.3
Week 8	Observed Value				
	n	65	68	66	63
	Mean (SD)	5.298 (3.6912)	4.807 (3.7437)	3.982 (2.8936)	4.046 (3.7293)
	Median	5.286	4.000	3.143	3.714
	Q1 - Q3	2.429 - 7.714	1.857 - 7.286	2.143 - 6.143	0.714 - 6.857
	Min - Max	0 - 14.43	0 - 16.00	0 - 12.71	0 - 17.57
	Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-7.296 (4.2922)	-8.197 (4.5817)	-9.023 (4.2653)	-8.903 (3.7664)
	Median	-6.429	-8.643	-8.429	-8.857
	Q1 - Q3	-10.571 - -4.143	-10.929 - -4.643	-10.714 - -6.024	-11.429 - -6.286
	Min - Max	-20.57 - 1.14	-20.57 - 3.00	-24.43 - -1.69	-17.14 - 3.00

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 8	Percentage Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-57.09 (28.678)	-62.50 (28.550)	-69.10 (20.405)	-69.58 (27.075)
	Median	-52.11	-68.37	-72.07	-75.36
	Q1 - Q3	-83.16 - -36.67	-86.43 - -42.36	-83.33 - -55.68	-94.12 - -50.96
	Min - Max	-100.0 - 9.5	-100.0 - 23.1	-100.0 - -21.6	-100.0 - 33.3
Week 9	Observed Value				
	n	65	68	66	63
	Mean (SD)	4.742 (3.4722)	4.292 (3.5927)	3.451 (2.5601)	3.397 (3.1767)
	Median	4.857	3.286	3.000	2.571
	Q1 - Q3	2.143 - 6.714	1.286 - 6.714	1.143 - 5.000	0.286 - 5.714
	Min - Max	0 - 14.00	0 - 15.71	0 - 10.43	0 - 11.86
	Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-7.851 (4.1327)	-8.712 (4.5574)	-9.554 (4.7055)	-9.553 (4.2551)
	Median	-7.714	-8.786	-8.429	-9.143
	Q1 - Q3	-10.429 - -4.857	-11.357 - -5.429	-11.286 - -7.000	-11.857 - -6.714
	Min - Max	-21.14 - -0.43	-20.43 - 2.71	-25.71 - -2.00	-26.14 - 2.86

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	Percentage Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-61.55 (26.941)	-66.45 (27.550)	-72.41 (19.796)	-73.78 (26.193)
	Median	-61.29	-75.13	-73.96	-80.72
	Q1 - Q3	-82.47 - -43.75	-88.82 - -45.36	-89.09 - -58.68	-96.67 - -53.19
	Min - Max	-100.0 - -3.8	-100.0 - 20.9	-100.0 - -25.5	-100.0 - 31.7
Week 10	Observed Value				
	n	64	68	65	63
	Mean (SD)	4.340 (3.4350)	3.949 (3.5493)	3.000 (2.4629)	2.995 (2.9956)
	Median	4.143	2.857	2.714	1.857
	Q1 - Q3	1.714 - 6.714	1.286 - 6.357	0.857 - 4.571	0.286 - 5.286
	Min - Max	0 - 12.71	0 - 13.86	0 - 10.86	0 - 11.86
	Change from Baseline				
	n	64	68	65	63
	Mean (SD)	-8.261 (4.1796)	-9.056 (4.5730)	-10.021 (5.0049)	-9.954 (4.4748)
	Median	-8.357	-9.286	-9.000	-9.857
	Q1 - Q3	-11.071 - -5.071	-11.786 - -5.786	-11.190 - -7.000	-12.286 - -7.143
	Min - Max	-21.14 - 0	-22.00 - 0.57	-28.71 - -1.83	-29.86 - 2.86

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 10	Percentage Change from Baseline				
	n	64	68	65	63
	Mean (SD)	-64.72 (26.976)	-69.17 (27.170)	-75.67 (19.892)	-76.47 (25.617)
	Median	-67.16	-77.26	-78.13	-82.43
	Q1 - Q3	-85.93 - -45.76	-92.50 - -52.31	-91.43 - -62.07	-96.67 - -62.67
	Min - Max	-100.0 - 0	-100.0 - 4.4	-100.0 - -23.4	-100.0 - 31.7
Week 11	Observed Value				
	n	64	68	65	63
	Mean (SD)	3.928 (3.3361)	3.593 (3.5878)	2.622 (2.3587)	2.717 (2.9375)
	Median	3.143	2.429	2.000	1.571
	Q1 - Q3	1.214 - 6.357	1.000 - 6.000	0.714 - 3.857	0.286 - 4.429
	Min - Max	0 - 11.00	0 - 14.43	0 - 10.57	0 - 12.00
	Change from Baseline				
	n	64	68	65	63
	Mean (SD)	-8.688 (4.1666)	-9.411 (4.6458)	-10.399 (5.0602)	-10.233 (4.5911)
	Median	-8.571	-9.929	-9.143	-10.571
	Q1 - Q3	-11.429 - -5.786	-12.214 - -6.214	-11.429 - -7.714	-12.286 - -7.429
	Min - Max	-21.71 - -0.86	-21.86 - 1.43	-29.43 - -1.69	-30.57 - 3.00

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	Percentage Change from Baseline				
	n	64	68	65	63
	Mean (SD)	-67.99 (26.932)	-71.98 (27.412)	-78.61 (19.253)	-78.41 (24.990)
	Median	-75.70	-81.26	-84.62	-85.43
	Q1 - Q3	-90.68 - -47.82	-94.62 - -57.63	-94.12 - -67.03	-97.53 - -62.67
	Min - Max	-100.0 - -7.6	-100.0 - 11.0	-100.0 - -21.6	-100.0 - 33.3
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	3.620 (3.2846)	3.323 (3.6159)	2.272 (2.3579)	2.324 (2.6140)
	Median	2.857	2.071	1.667	1.429
	Q1 - Q3	1.000 - 5.500	0.143 - 5.857	0.143 - 3.429	0.143 - 4.000
	Min - Max	0 - 12.43	0 - 14.00	0 - 9.71	0 - 11.57
	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-8.997 (4.1162)	-9.716 (4.6916)	-10.748 (5.1597)	-10.625 (4.5897)
	Median	-8.643	-10.000	-10.000	-10.714
	Q1 - Q3	-11.857 - -6.214	-13.000 - -6.714	-11.714 - -8.000	-12.571 - -7.714
	Min - Max	-21.71 - -0.43	-22.43 - 1.00	-31.71 - -1.98	-31.00 - 2.57

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.1
Summary of Mean Daily Frequency of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Percentage Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-70.50 (26.369)	-74.20 (27.702)	-81.31 (19.389)	-81.11 (23.547)
	Median	-76.41	-83.03	-85.59	-89.80
	Q1 - Q3	-91.45 - -50.77	-98.51 - -55.74	-98.53 - -68.97	-98.70 - -66.67
	Min - Max	-100.0 - -3.6	-100.0 - 7.7	-100.0 - -25.2	-100.0 - 28.6

Data Source: Listing 16.2.6.1

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 1	n	69	70	69	68
	LS Mean (SE)	-2.699 (0.4664)	-3.233 (0.4593)	-3.381 (0.4726)	-3.567 (0.4746)
	90% CI (2-sided)	-3.469, -1.930	-3.991, -2.476	-4.161, -2.601	-4.350, -2.784
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.534 (0.5159)	-0.682 (0.5176)	-0.867 (0.5197)
	90% CI (2-sided)		-1.386, 0.317	-1.536, 0.173	-1.725, -0.010
	P-value		0.3013	0.1889	0.0963
Week 2	n	69	69	68	68
	LS Mean (SE)	-3.654 (0.5058)	-4.615 (0.4989)	-4.787 (0.5119)	-4.612 (0.5139)
	90% CI (2-sided)	-4.488, -2.820	-5.438, -3.793	-5.631, -3.943	-5.459, -3.764
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.962 (0.5852)	-1.133 (0.5873)	-0.958 (0.5892)
	90% CI (2-sided)		-1.927, 0.004	-2.102, -0.164	-1.930, 0.014
	P-value		0.1016	0.0548	0.1051

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	n	67	69	67	68
	LS Mean (SE)	-4.562 (0.5354)	-5.521 (0.5283)	-5.646 (0.5413)	-5.866 (0.5426)
	90% CI (2-sided)	-5.445, -3.679	-6.392, -4.649	-6.539, -4.753	-6.761, -4.971
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.959 (0.6352)	-1.084 (0.6378)	-1.304 (0.6391)
	90% CI (2-sided)		-2.007, 0.089	-2.137, -0.032	-2.359, -0.250
	P-value		0.1323	0.0902	0.0422
Week 4	n	67	69	67	68
	LS Mean (SE)	-5.232 (0.5327)	-6.039 (0.5259)	-6.248 (0.5387)	-6.535 (0.5394)
	90% CI (2-sided)	-6.110, -4.353	-6.906, -5.172	-7.136, -5.359	-7.425, -5.646
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.807 (0.6305)	-1.016 (0.6334)	-1.304 (0.6341)
	90% CI (2-sided)		-1.848, 0.233	-2.061, 0.030	-2.350, -0.257
	P-value		0.2014	0.1099	0.0408

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	n	66	69	67	64
	LS Mean (SE)	-6.217 (0.5159)	-6.656 (0.5092)	-7.123 (0.5217)	-7.265 (0.5231)
	90% CI (2-sided)	-7.068, -5.367	-7.496, -5.816	-7.983, -6.262	-8.127, -6.402
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.439 (0.6017)	-0.905 (0.6048)	-1.047 (0.6062)
	90% CI (2-sided)		-1.432, 0.554	-1.903, 0.093	-2.048, -0.047
	P-value		0.4666	0.1356	0.0852
Week 6	n	66	68	67	64
	LS Mean (SE)	-6.743 (0.5148)	-7.170 (0.5082)	-7.702 (0.5202)	-7.958 (0.5226)
	90% CI (2-sided)	-7.592, -5.894	-8.008, -6.332	-8.560, -6.844	-8.820, -7.096
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.427 (0.5996)	-0.959 (0.6027)	-1.215 (0.6050)
	90% CI (2-sided)		-1.416, 0.563	-1.954, 0.036	-2.213, -0.216
	P-value		0.4774	0.1128	0.0457

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 7	n	66	68	67	63
	LS Mean (SE)	-7.287 (0.5015)	-7.712 (0.4954)	-8.258 (0.5069)	-8.502 (0.5098)
	90% CI (2-sided)	-8.114, -6.460	-8.529, -6.895	-9.094, -7.422	-9.343, -7.662
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.425 (0.5768)	-0.971 (0.5798)	-1.215 (0.5826)
	90% CI (2-sided)		-1.377, 0.527	-1.928, -0.014	-2.177, -0.254
	P-value		0.4618	0.0951	0.0379
Week 8	n	65	68	66	63
	LS Mean (SE)	-7.458 (0.5008)	-8.090 (0.4946)	-8.912 (0.5061)	-8.897 (0.5092)
	90% CI (2-sided)	-8.284, -6.633	-8.906, -7.274	-9.747, -8.078	-9.737, -8.057
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.631 (0.5755)	-1.454 (0.5786)	-1.438 (0.5817)
	90% CI (2-sided)		-1.581, 0.318	-2.409, -0.499	-2.398, -0.478
	P-value		0.2735	0.0126	0.0140

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

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A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	n	65	68	66	63
	LS Mean (SE)	-8.049 (0.4835)	-8.583 (0.4775)	-9.425 (0.4888)	-9.540 (0.4923)
	90% CI (2-sided)	-8.847, -7.252	-9.371, -7.795	-10.231, -8.618	-10.352, -8.728
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.534 (0.5452)	-1.375 (0.5484)	-1.491 (0.5519)
	90% CI (2-sided)		-1.433, 0.366	-2.280, -0.470	-2.402, -0.580
	P-value		0.3285	0.0128	0.0074
Week 10	n	64	68	65	63
	LS Mean (SE)	-8.521 (0.4795)	-8.920 (0.4736)	-9.899 (0.4848)	-9.937 (0.4885)
	90% CI (2-sided)	-9.312, -7.730	-9.701, -8.139	-10.699, -9.099	-10.742, -9.131
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.399 (0.5380)	-1.378 (0.5414)	-1.416 (0.5451)
	90% CI (2-sided)		-1.287, 0.489	-2.272, -0.485	-2.315, -0.516
	P-value		0.4588	0.0115	0.0099

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	n	64	68	65	63
	LS Mean (SE)	-8.849 (0.4765)	-9.269 (0.4706)	-10.265 (0.4818)	-10.213 (0.4856)
	90% CI (2-sided)	-9.635, -8.063	-10.045, -8.493	-11.060, -9.470	-11.014, -9.412
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.420 (0.5325)	-1.416 (0.5361)	-1.364 (0.5400)
	90% CI (2-sided)		-1.299, 0.459	-2.301, -0.531	-2.255, -0.473
	P-value		0.4313	0.0088	0.0121
Week 12	n	64	66	65	63
	LS Mean (SE)	-9.166 (0.4688)	-9.573 (0.4637)	-10.606 (0.4742)	-10.604 (0.4780)
	90% CI (2-sided)	-9.939, -8.393	-10.338, -8.808	-11.388, -9.823	-11.393, -9.816
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.407 (0.5191)	-1.440 (0.5225)	-1.438 (0.5265)
	90% CI (2-sided)		-1.264, 0.450	-2.302, -0.577	-2.307, -0.569
	P-value		0.4335	0.0063	0.0067

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.3
Secondary Endpoint Analysis
Percentage Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 1	n	69	70	69	68
	LS Mean (SE)	-21.19 (3.699)	-24.99 (3.642)	-27.94 (3.750)	-28.75 (3.765)
	90% CI (2-sided)	-27.29, -15.09	-30.99, -18.98	-34.13, -21.76	-34.96, -22.54
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-3.80 (4.066)	-6.76 (4.080)	-7.56 (4.096)
	90% CI (2-sided)		-10.51, 2.91	-13.49, -0.02	-14.32, -0.80
	P-value		0.3510	0.0989	0.0661
Week 2	n	69	69	68	68
	LS Mean (SE)	-28.40 (4.039)	-36.10 (3.983)	-38.50 (4.088)	-37.28 (4.104)
	90% CI (2-sided)	-35.06, -21.74	-42.67, -29.54	-45.24, -31.75	-44.05, -30.52
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-7.70 (4.666)	-10.09 (4.682)	-8.88 (4.698)
	90% CI (2-sided)		-15.40, 0.00	-17.82, -2.36	-16.63, -1.13
	P-value		0.1000	0.0320	0.0598

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.3
Secondary Endpoint Analysis
Percentage Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	n	67	69	67	68
	LS Mean (SE)	-35.39 (4.194)	-42.72 (4.138)	-45.34 (4.242)	-47.22 (4.252)
	90% CI (2-sided)	-42.31, -28.47	-49.54, -35.89	-52.34, -38.35	-54.24, -40.21
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-7.33 (4.929)	-9.95 (4.949)	-11.83 (4.959)
	90% CI (2-sided)		-15.46, 0.81	-18.12, -1.79	-20.02, -3.65
	P-value		0.1383	0.0453	0.0177
Week 4	n	67	69	67	68
	LS Mean (SE)	-40.72 (4.196)	-46.67 (4.142)	-49.72 (4.245)	-52.42 (4.250)
	90% CI (2-sided)	-47.64, -33.80	-53.50, -39.84	-56.72, -42.72	-59.43, -45.41
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-5.94 (4.932)	-9.00 (4.954)	-11.69 (4.960)
	90% CI (2-sided)		-14.08, 2.20	-17.17, -0.82	-19.88, -3.51
	P-value		0.2291	0.0705	0.0191

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.3
Secondary Endpoint Analysis
Percentage Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	n	66	69	67	64
	LS Mean (SE)	-48.09 (4.057)	-52.09 (4.004)	-56.35 (4.104)	-57.87 (4.114)
	90% CI (2-sided)	-54.78, -41.39	-58.70, -45.49	-63.12, -49.59	-64.66, -51.09
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-4.01 (4.691)	-8.27 (4.715)	-9.79 (4.726)
	90% CI (2-sided)		-11.75, 3.74	-16.05, -0.49	-17.59, -1.99
	P-value		0.3937	0.0806	0.0393
Week 6	n	66	68	67	64
	LS Mean (SE)	-52.14 (4.050)	-56.16 (3.998)	-60.80 (4.095)	-63.11 (4.111)
	90% CI (2-sided)	-58.82, -45.46	-62.75, -49.56	-67.56, -54.05	-69.89, -56.33
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-4.02 (4.678)	-8.67 (4.702)	-10.97 (4.718)
	90% CI (2-sided)		-11.74, 3.70	-16.43, -0.91	-18.76, -3.18
	P-value		0.3907	0.0664	0.0208

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.3
Secondary Endpoint Analysis
Percentage Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 7	n	66	68	67	63
	LS Mean (SE)	-56.57 (3.964)	-60.56 (3.916)	-65.09 (4.008)	-67.67 (4.029)
	90% CI (2-sided)	-63.11, -50.03	-67.02, -54.10	-71.70, -58.48	-74.32, -61.03
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-3.99 (4.529)	-8.52 (4.553)	-11.10 (4.573)
	90% CI (2-sided)		-11.46, 3.49	-16.04, -1.01	-18.65, -3.55
	P-value		0.3794	0.0623	0.0159
Week 8	n	65	68	66	63
	LS Mean (SE)	-57.92 (3.966)	-63.44 (3.917)	-70.00 (4.009)	-70.81 (4.032)
	90% CI (2-sided)	-64.46, -51.38	-69.90, -56.98	-76.62, -63.39	-77.46, -64.16
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-5.51 (4.531)	-12.08 (4.555)	-12.88 (4.579)
	90% CI (2-sided)		-12.99, 1.97	-19.60, -4.56	-20.44, -5.32
	P-value		0.2247	0.0085	0.0053

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.3
Secondary Endpoint Analysis
Percentage Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	n	65	68	66	63
	LS Mean (SE)	-62.48 (3.857)	-67.31 (3.811)	-73.22 (3.901)	-75.03 (3.926)
	90% CI (2-sided)	-68.84, -56.12	-73.59, -61.02	-79.65, -66.79	-81.50, -68.55
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-4.83 (4.341)	-10.74 (4.365)	-12.55 (4.392)
	90% CI (2-sided)		-11.99, 2.34	-17.94, -3.53	-19.79, -5.30
	P-value		0.2670	0.0145	0.0046
Week 10	n	64	68	65	63
	LS Mean (SE)	-66.10 (3.835)	-70.01 (3.788)	-76.74 (3.879)	-77.69 (3.906)
	90% CI (2-sided)	-72.43, -59.78	-76.26, -63.77	-83.13, -70.34	-84.14, -71.25
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-3.91 (4.301)	-10.64 (4.327)	-11.59 (4.355)
	90% CI (2-sided)		-11.01, 3.19	-17.78, -3.49	-18.78, -4.40
	P-value		0.3638	0.0146	0.0082

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.3
Secondary Endpoint Analysis
Percentage Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	n	64	68	65	63
	LS Mean (SE)	-68.53 (3.815)	-72.80 (3.768)	-79.63 (3.859)	-79.62 (3.888)
	90% CI (2-sided)	-74.83, -62.24	-79.01, -66.58	-85.99, -73.26	-86.03, -73.21
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-4.26 (4.264)	-11.09 (4.292)	-11.09 (4.322)
	90% CI (2-sided)		-11.30, 2.78	-18.18, -4.01	-18.22, -3.95
	P-value		0.3183	0.0103	0.0109
Week 12	n	64	66	65	63
	LS Mean (SE)	-71.08 (3.771)	-75.16 (3.728)	-82.28 (3.814)	-82.33 (3.844)
	90% CI (2-sided)	-77.30, -64.86	-81.31, -69.01	-88.57, -75.99	-88.67, -75.99
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-4.08 (4.186)	-11.20 (4.213)	-11.25 (4.244)
	90% CI (2-sided)		-10.99, 2.83	-18.15, -4.24	-18.26, -4.25
	P-value		0.3308	0.0083	0.0085

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

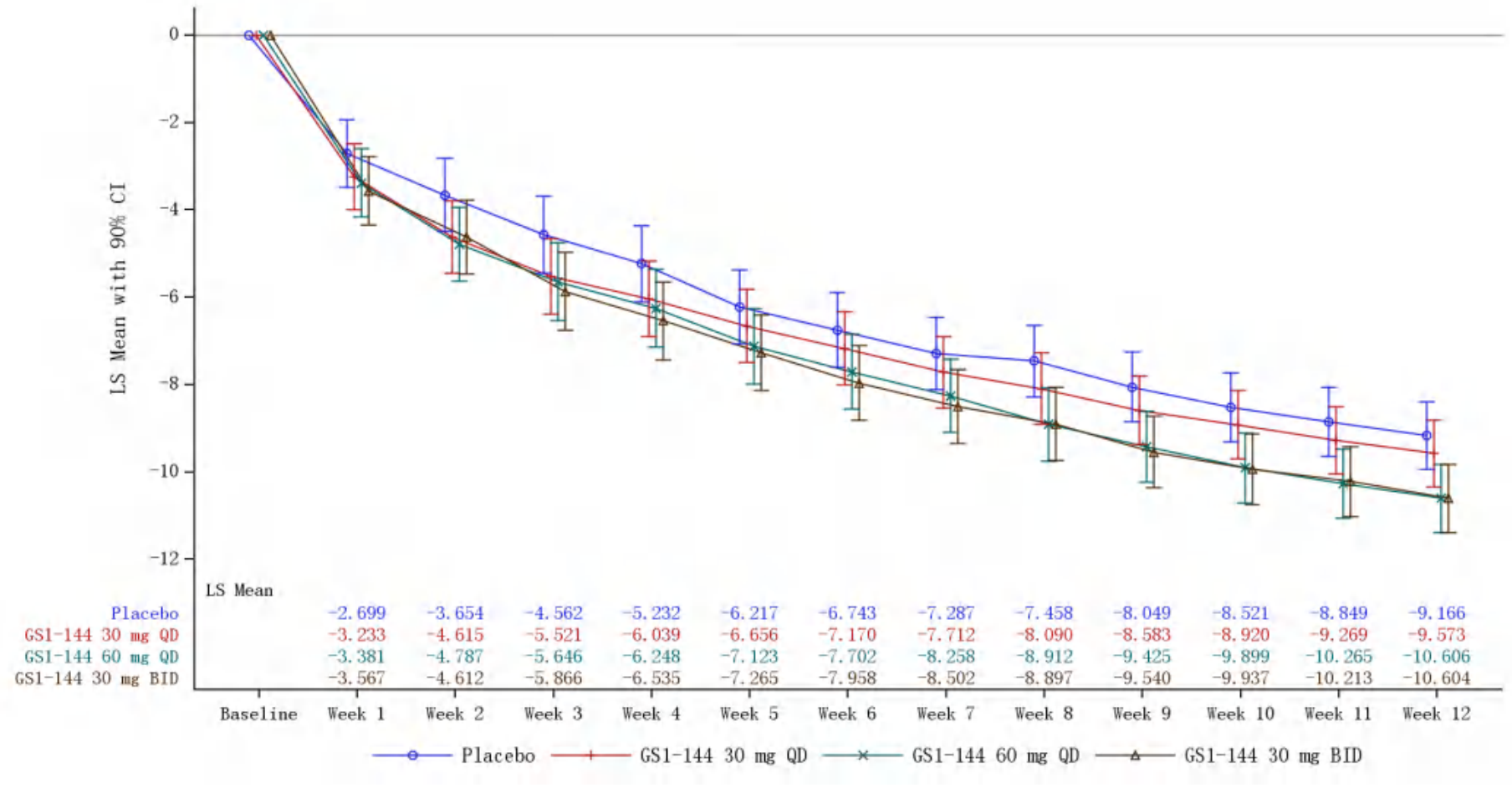
Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

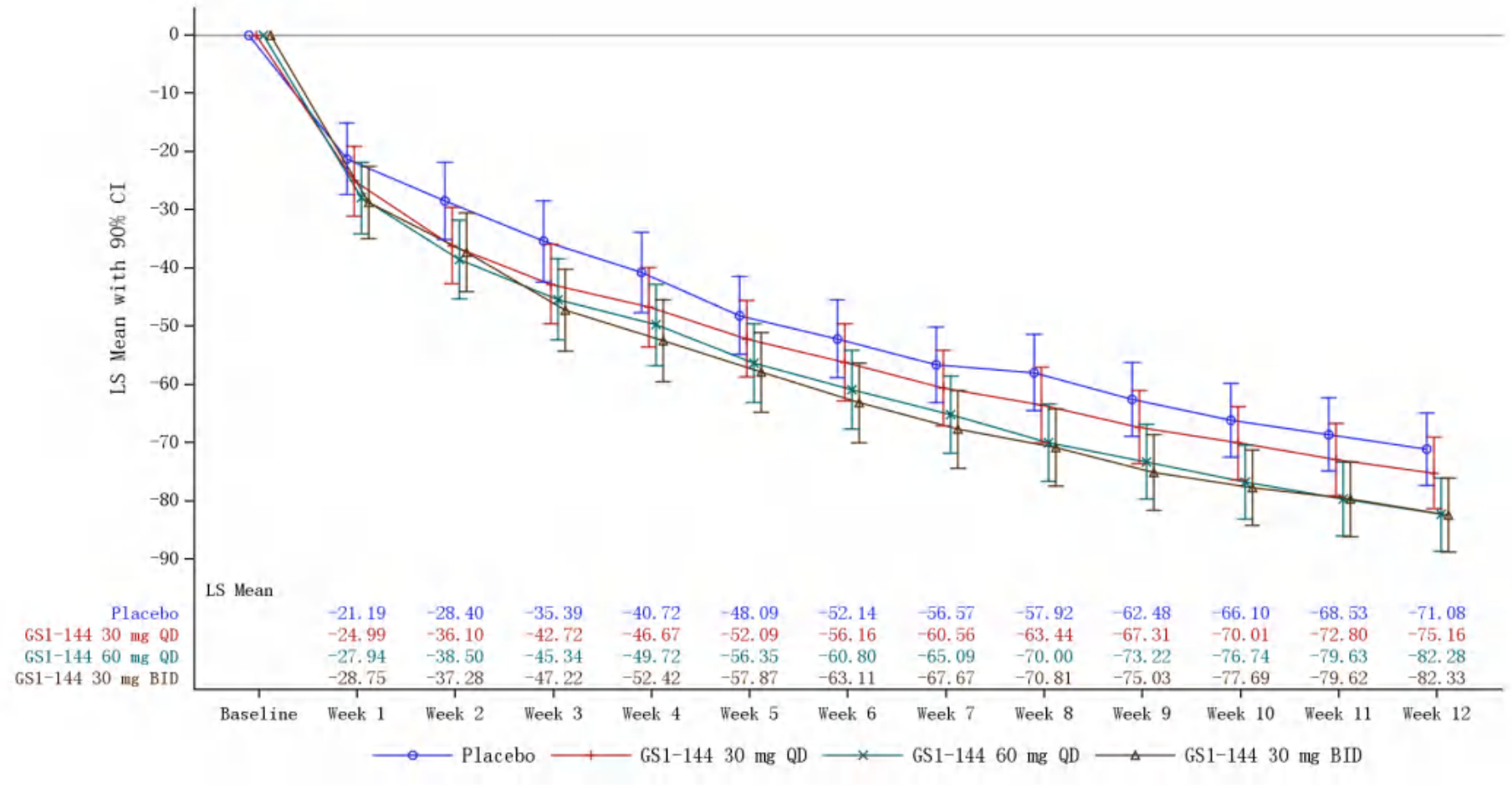
A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Figure 14.2.3.1.4
Line Plot of Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS



Data Source: Table 14.2.3.1.2
LS = Least Squares; CI = Confidence Interval.

Figure 14.2.3.1.5
Line Plot of Percentage Change from Baseline Over Time in the Frequency of Moderate to Severe VMS
FAS



Data Source: Table 14.2.3.1.3
LS = Least Squares; CI = Confidence Interval.

Table 14.2.3.1.6
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Mild to Severe VMS
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 1	n	69	70	69	68
	LS Mean (SE)	-2.434 (0.4884)	-2.828 (0.4800)	-3.133 (0.4959)	-3.255 (0.4995)
	90% CI (2-sided)	-3.240, -1.628	-3.620, -2.036	-3.952, -2.315	-4.079, -2.431
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.394 (0.5126)	-0.700 (0.5144)	-0.821 (0.5170)
	90% CI (2-sided)		-1.240, 0.452	-1.549, 0.149	-1.675, 0.032
	P-value		0.4428	0.1749	0.1133
Week 2	n	69	69	68	68
	LS Mean (SE)	-3.397 (0.5376)	-4.163 (0.5293)	-4.490 (0.5449)	-4.190 (0.5485)
	90% CI (2-sided)	-4.284, -2.510	-5.036, -3.290	-5.388, -3.591	-5.095, -3.285
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.766 (0.6028)	-1.093 (0.6050)	-0.793 (0.6076)
	90% CI (2-sided)		-1.761, 0.229	-2.091, -0.094	-1.796, 0.210
	P-value		0.2049	0.0720	0.1929

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.6
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Mild to Severe VMS
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	n	67	69	67	68
	LS Mean (SE)	-4.437 (0.5949)	-5.033 (0.5860)	-5.412 (0.6015)	-5.462 (0.6045)
	90% CI (2-sided)	-5.418, -3.455	-6.000, -4.067	-6.404, -4.420	-6.459, -4.465
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.597 (0.7011)	-0.975 (0.7041)	-1.025 (0.7062)
	90% CI (2-sided)		-1.754, 0.560	-2.137, 0.187	-2.191, 0.140
	P-value		0.3953	0.1671	0.1477
Week 4	n	67	69	67	68
	LS Mean (SE)	-5.084 (0.6000)	-5.579 (0.5913)	-6.008 (0.6066)	-6.144 (0.6090)
	90% CI (2-sided)	-6.074, -4.095	-6.554, -4.604	-7.008, -5.007	-7.149, -5.140
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.495 (0.7095)	-0.923 (0.7128)	-1.060 (0.7144)
	90% CI (2-sided)		-1.666, 0.677	-2.100, 0.253	-2.239, 0.119
	P-value		0.4864	0.1964	0.1391

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.6
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Mild to Severe VMS
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	n	66	69	67	64
	LS Mean (SE)	-5.853 (0.5915)	-6.145 (0.5828)	-6.963 (0.5978)	-6.935 (0.6013)
	90% CI (2-sided)	-6.828, -4.877	-7.106, -5.184	-7.949, -5.977	-7.927, -5.944
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.292 (0.6947)	-1.110 (0.6984)	-1.082 (0.7009)
	90% CI (2-sided)		-1.438, 0.855	-2.263, 0.042	-2.239, 0.074
	P-value		0.6749	0.1131	0.1237
Week 6	n	66	68	67	64
	LS Mean (SE)	-6.460 (0.5882)	-6.819 (0.5796)	-7.568 (0.5942)	-7.772 (0.5986)
	90% CI (2-sided)	-7.430, -5.490	-7.775, -5.863	-8.548, -6.588	-8.760, -6.785
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.358 (0.6889)	-1.108 (0.6925)	-1.312 (0.6960)
	90% CI (2-sided)		-1.495, 0.779	-2.251, 0.035	-2.461, -0.163
	P-value		0.6034	0.1109	0.0605

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.6
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Mild to Severe VMS
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 7	n	66	68	67	63
	LS Mean (SE)	-7.177 (0.5810)	-7.337 (0.5730)	-8.142 (0.5870)	-8.507 (0.5919)
	90% CI (2-sided)	-8.135, -6.219	-8.282, -6.392	-9.110, -7.174	-9.483, -7.531
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.160 (0.6769)	-0.965 (0.6804)	-1.330 (0.6844)
	90% CI (2-sided)		-1.277, 0.957	-2.088, 0.158	-2.459, -0.200
	P-value		0.8133	0.1574	0.0531
Week 8	n	65	68	66	63
	LS Mean (SE)	-7.474 (0.5862)	-7.693 (0.5779)	-8.801 (0.5919)	-8.929 (0.5972)
	90% CI (2-sided)	-8.441, -6.508	-8.646, -6.740	-9.777, -7.825	-9.913, -7.944
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.219 (0.6854)	-1.326 (0.6891)	-1.454 (0.6934)
	90% CI (2-sided)		-1.350, 0.912	-2.464, -0.189	-2.599, -0.310
	P-value		0.7496	0.0553	0.0369

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.6
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Mild to Severe VMS
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	n	65	68	66	63
	LS Mean (SE)	-7.944 (0.5732)	-8.241 (0.5648)	-9.403 (0.5789)	-9.712 (0.5847)
	90% CI (2-sided)	-8.890, -6.999	-9.173, -7.310	-10.358, -8.449	-10.676, -8.747
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.297 (0.6631)	-1.459 (0.6668)	-1.767 (0.6717)
	90% CI (2-sided)		-1.392, 0.797	-2.560, -0.358	-2.876, -0.659
	P-value		0.6546	0.0296	0.0090
Week 10	n	64	68	65	63
	LS Mean (SE)	-8.420 (0.5719)	-8.651 (0.5633)	-9.908 (0.5773)	-10.133 (0.5835)
	90% CI (2-sided)	-9.363, -7.477	-9.580, -7.722	-10.860, -8.956	-11.095, -9.171
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.231 (0.6604)	-1.488 (0.6644)	-1.713 (0.6695)
	90% CI (2-sided)		-1.321, 0.859	-2.584, -0.391	-2.818, -0.608
	P-value		0.7267	0.0260	0.0111

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.1.6
Secondary Endpoint Analysis
Change from Baseline Over Time in the Frequency of Mild to Severe VMS
FAS, Adhoc

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	n	64	68	65	63
	LS Mean (SE)	-8.804 (0.5727)	-9.110 (0.5640)	-10.432 (0.5780)	-10.528 (0.5846)
	90% CI (2-sided)	-9.749, -7.860	-10.040, -8.180	-11.385, -9.479	-11.493, -9.564
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.306 (0.6616)	-1.628 (0.6659)	-1.724 (0.6714)
	90% CI (2-sided)		-1.398, 0.786	-2.727, -0.529	-2.832, -0.616
	P-value		0.6443	0.0152	0.0108
Week 12	n	64	66	65	63
	LS Mean (SE)	-9.119 (0.5680)	-9.634 (0.5597)	-10.847 (0.5733)	-10.920 (0.5801)
	90% CI (2-sided)	-10.055, -8.182	-10.557, -8.711	-11.792, -9.901	-11.877, -9.963
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.515 (0.6537)	-1.728 (0.6579)	-1.802 (0.6636)
	90% CI (2-sided)		-1.594, 0.564	-2.814, -0.642	-2.897, -0.706
	P-value		0.4315	0.0091	0.0071

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.

The p-values were nominal.

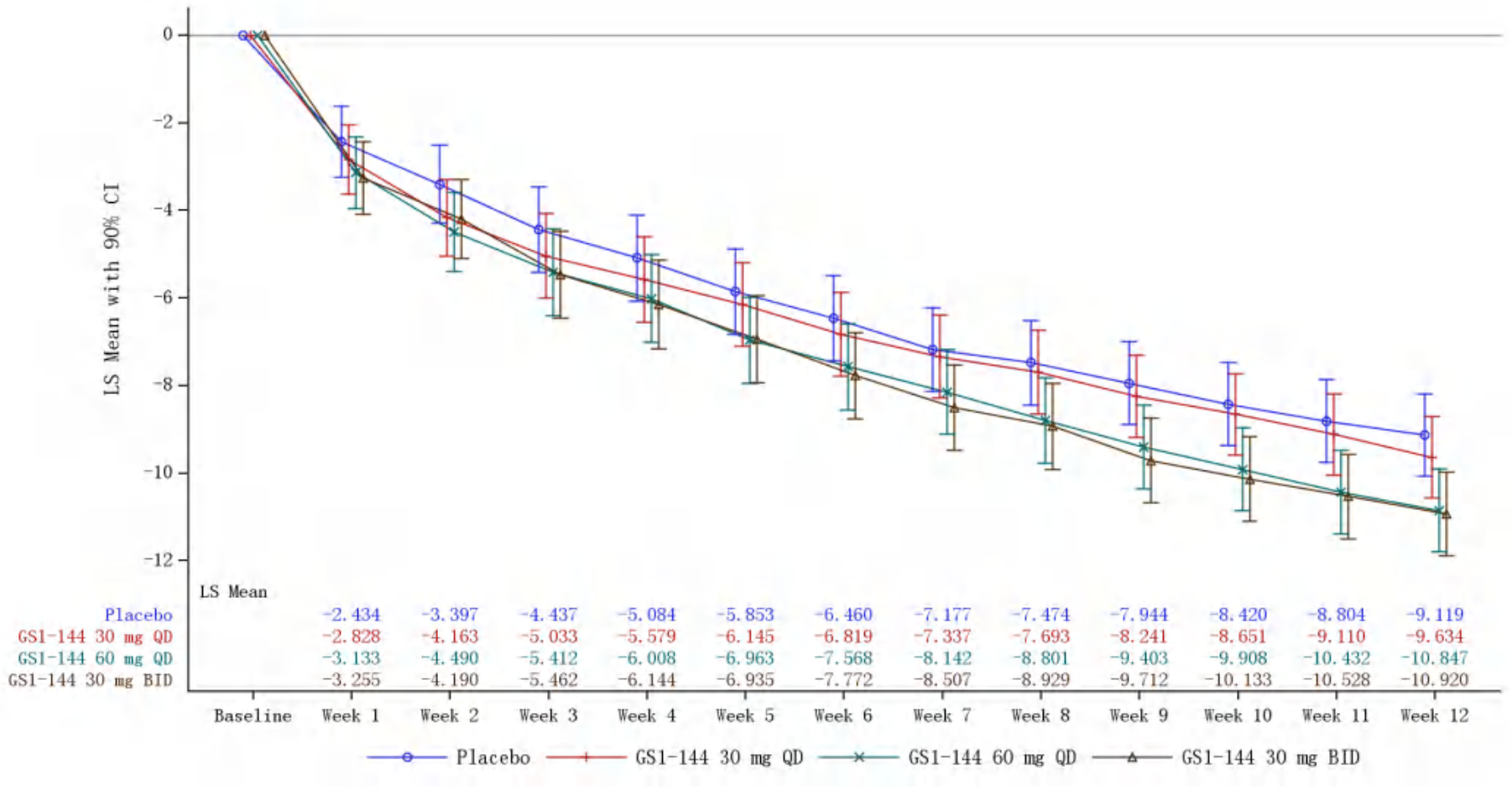
Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of mild to severe VMS during the 7 days prior to randomization) / (total number of available days with data).Post-baseline values were aggregated to a mean daily frequency as (total number of mild to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Figure 14.2.3.1.7
Line Plot of Change from Baseline Over Time in the Frequency of Mild to Severe VMS
FAS, Adhoc



Data Source: Table 14.2.3.1.6
LS = Least Squares; CI = Confidence Interval.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.313 (0.2072)	2.315 (0.2042)	2.345 (0.2127)	2.302 (0.2180)
	Median	2.287	2.249	2.335	2.296
	Q1 - Q3	2.131 - 2.474	2.169 - 2.498	2.215 - 2.484	2.092 - 2.471
	Min - Max	2.00 - 2.74	2.00 - 2.70	2.00 - 3.00	2.00 - 2.81
Week 1	Observed Value				
	n	69	70	69	68
	Mean (SD)	2.012 (0.2562)	2.033 (0.2865)	1.999 (0.3550)	1.941 (0.3567)
	Median	2.000	2.062	2.052	1.955
	Q1 - Q3	1.884 - 2.214	1.820 - 2.198	1.828 - 2.232	1.765 - 2.167
	Min - Max	1.25 - 2.58	1.41 - 2.73	0.62 - 3.00	0.43 - 2.64
	Change from Baseline				
	n	69	70	69	68
	Mean (SD)	-0.301 (0.2455)	-0.282 (0.2243)	-0.347 (0.3081)	-0.361 (0.3136)
	Median	-0.304	-0.275	-0.275	-0.339
	Q1 - Q3	-0.466 - -0.104	-0.433 - -0.092	-0.448 - -0.126	-0.512 - -0.136
	Min - Max	-0.99 - 0.08	-1.02 - 0.24	-1.49 - 0.09	-1.57 - 0.35

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 2	Observed Value				
	n	69	69	68	68
	Mean (SD)	1.976 (0.3292)	1.947 (0.3903)	1.921 (0.4079)	1.856 (0.4477)
	Median	1.970	1.986	1.961	1.896
	Q1 - Q3	1.790 - 2.200	1.741 - 2.166	1.726 - 2.123	1.701 - 2.162
	Min - Max	0.86 - 2.62	0.29 - 2.57	0 - 3.00	0 - 2.52
	Change from Baseline				
	n	69	69	68	68
	Mean (SD)	-0.337 (0.3048)	-0.372 (0.3305)	-0.428 (0.3739)	-0.446 (0.3997)
	Median	-0.299	-0.310	-0.317	-0.393
	Q1 - Q3	-0.483 - -0.087	-0.510 - -0.164	-0.576 - -0.155	-0.601 - -0.142
	Min - Max	-1.25 - 0.09	-1.76 - 0.36	-2.11 - 0	-2.00 - 0.13
Week 3	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.904 (0.4321)	1.859 (0.4358)	1.830 (0.5002)	1.799 (0.4293)
	Median	2.000	1.931	1.908	1.888
	Q1 - Q3	1.727 - 2.150	1.714 - 2.152	1.578 - 2.092	1.526 - 2.125
	Min - Max	0 - 2.61	0 - 2.52	0 - 3.00	0 - 2.36

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.404 (0.4236)	-0.460 (0.3920)	-0.518 (0.4516)	-0.503 (0.4185)
	Median	-0.373	-0.376	-0.384	-0.429
	Q1 - Q3	-0.536 - -0.118	-0.592 - -0.220	-0.808 - -0.185	-0.719 - -0.197
	Min - Max	-2.07 - 0.10	-2.05 - 0.31	-2.11 - 0	-2.00 - 0.03
Week 4	Observed Value				
	n	67	69	67	68
	Mean (SD)	1.880 (0.4237)	1.843 (0.4337)	1.781 (0.5313)	1.744 (0.4669)
	Median	1.931	1.878	1.879	1.871
	Q1 - Q3	1.714 - 2.124	1.617 - 2.128	1.596 - 2.062	1.506 - 2.092
	Min - Max	0 - 2.67	0 - 2.58	0 - 3.00	0 - 2.45
	Change from Baseline				
	n	67	69	67	68
	Mean (SD)	-0.428 (0.4101)	-0.477 (0.3937)	-0.568 (0.4871)	-0.558 (0.4697)
	Median	-0.398	-0.419	-0.405	-0.424
	Q1 - Q3	-0.574 - -0.156	-0.636 - -0.247	-0.812 - -0.210	-0.766 - -0.255
	Min - Max	-2.50 - 0.08	-2.05 - 0.38	-2.11 - 0	-2.23 - 0.03

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	Observed Value				
	n	66	69	67	64
	Mean (SD)	1.807 (0.4892)	1.795 (0.4468)	1.755 (0.4950)	1.702 (0.4792)
	Median	1.879	1.852	1.844	1.774
	Q1 - Q3	1.615 - 2.110	1.566 - 2.119	1.525 - 2.000	1.416 - 2.000
	Min - Max	0 - 2.67	0 - 2.55	0 - 3.00	0 - 2.44
	Change from Baseline				
	n	66	69	67	64
	Mean (SD)	-0.499 (0.4533)	-0.525 (0.4219)	-0.594 (0.4505)	-0.598 (0.4876)
	Median	-0.408	-0.451	-0.444	-0.525
	Q1 - Q3	-0.625 - -0.265	-0.732 - -0.270	-0.910 - -0.248	-0.823 - -0.235
	Min - Max	-2.50 - 0.05	-2.21 - 0.29	-2.00 - 0	-2.23 - 0.07
Week 6	Observed Value				
	n	66	68	67	64
	Mean (SD)	1.787 (0.4983)	1.761 (0.4651)	1.728 (0.5209)	1.649 (0.5201)
	Median	1.897	1.839	1.753	1.756
	Q1 - Q3	1.569 - 2.091	1.555 - 2.073	1.518 - 2.011	1.354 - 2.000
	Min - Max	0 - 2.71	0 - 2.57	0 - 3.00	0 - 2.61

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 6	Change from Baseline				
	n	66	68	67	64
	Mean (SD)	-0.519 (0.4585)	-0.563 (0.4435)	-0.620 (0.4714)	-0.651 (0.5345)
	Median	-0.449	-0.503	-0.455	-0.537
	Q1 - Q3	-0.681 - -0.203	-0.731 - -0.261	-0.886 - -0.286	-0.955 - -0.276
	Min - Max	-2.50 - 0.09	-2.07 - 0.38	-2.11 - 0.05	-2.30 - 0.06
Week 7	Observed Value				
	n	66	68	67	63
	Mean (SD)	1.747 (0.4912)	1.729 (0.4957)	1.690 (0.5353)	1.603 (0.5643)
	Median	1.828	1.810	1.785	1.692
	Q1 - Q3	1.516 - 2.092	1.498 - 2.048	1.449 - 2.000	1.271 - 2.000
	Min - Max	0 - 2.68	0 - 2.71	0 - 3.00	0 - 2.53
	Change from Baseline				
	n	66	68	67	63
	Mean (SD)	-0.559 (0.4529)	-0.595 (0.4719)	-0.658 (0.4901)	-0.689 (0.5831)
	Median	-0.493	-0.539	-0.508	-0.500
	Q1 - Q3	-0.683 - -0.281	-0.790 - -0.270	-0.921 - -0.329	-0.942 - -0.255
	Min - Max	-2.50 - 0.06	-2.20 - 0.29	-2.11 - 0.07	-2.44 - 0.04

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 8	Observed Value				
	n	65	68	66	63
	Mean (SD)	1.741 (0.5159)	1.685 (0.4652)	1.612 (0.5817)	1.527 (0.6003)
	Median	1.820	1.733	1.678	1.650
	Q1 - Q3	1.488 - 2.044	1.427 - 2.000	1.400 - 2.000	1.238 - 1.964
	Min - Max	0 - 2.67	0 - 2.56	0 - 3.00	0 - 2.53
	Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-0.562 (0.4770)	-0.638 (0.4495)	-0.736 (0.5369)	-0.765 (0.6180)
	Median	-0.511	-0.552	-0.656	-0.600
	Q1 - Q3	-0.690 - -0.243	-0.926 - -0.280	-0.956 - -0.330	-1.006 - -0.279
	Min - Max	-2.50 - 0.13	-2.05 - 0.45	-2.30 - 0	-2.44 - 0.02
Week 9	Observed Value				
	n	65	68	66	63
	Mean (SD)	1.694 (0.5183)	1.650 (0.4629)	1.566 (0.5939)	1.465 (0.6317)
	Median	1.766	1.681	1.603	1.531
	Q1 - Q3	1.429 - 2.000	1.441 - 1.995	1.305 - 2.000	1.095 - 1.932
	Min - Max	0 - 2.64	0 - 2.55	0 - 3.00	0 - 2.47

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-0.608 (0.4869)	-0.673 (0.4416)	-0.782 (0.5533)	-0.827 (0.6501)
	Median	-0.489	-0.582	-0.714	-0.714
	Q1 - Q3	-0.760 - -0.287	-0.951 - -0.383	-1.039 - -0.384	-1.135 - -0.301
	Min - Max	-2.50 - 0.05	-2.05 - 0.32	-2.51 - 0	-2.64 - 0.04
Week 10	Observed Value				
	n	64	68	65	63
	Mean (SD)	1.600 (0.5645)	1.586 (0.5536)	1.489 (0.6494)	1.427 (0.6323)
	Median	1.734	1.650	1.498	1.452
	Q1 - Q3	1.275 - 2.000	1.318 - 2.000	1.193 - 1.989	1.000 - 1.929
	Min - Max	0 - 2.69	0 - 2.60	0 - 3.00	0 - 2.45
	Change from Baseline				
	n	64	68	65	63
	Mean (SD)	-0.703 (0.5385)	-0.737 (0.5484)	-0.859 (0.5973)	-0.865 (0.6524)
	Median	-0.558	-0.613	-0.780	-0.857
	Q1 - Q3	-0.927 - -0.342	-1.047 - -0.299	-1.215 - -0.395	-1.214 - -0.328
	Min - Max	-2.50 - 0.08	-2.42 - 0.37	-2.51 - 0	-2.48 - 0.03

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	Observed Value				
	n	64	68	65	63
	Mean (SD)	1.562 (0.6015)	1.478 (0.6349)	1.463 (0.6541)	1.377 (0.6332)
	Median	1.696	1.551	1.476	1.452
	Q1 - Q3	1.201 - 2.000	1.139 - 1.949	1.195 - 1.948	1.000 - 1.873
	Min - Max	0 - 2.61	0 - 2.59	0 - 3.00	0 - 2.48
	Change from Baseline				
	n	64	68	65	63
	Mean (SD)	-0.734 (0.5850)	-0.845 (0.6300)	-0.885 (0.6094)	-0.915 (0.6584)
	Median	-0.540	-0.702	-0.841	-0.893
	Q1 - Q3	-0.963 - -0.314	-1.152 - -0.327	-1.145 - -0.378	-1.264 - -0.354
	Min - Max	-2.50 - 0.04	-2.47 - 0.41	-2.51 - 0	-2.48 - 0.09
Week 12	Observed Value				
	n	64	66	65	63
	Mean (SD)	1.519 (0.6539)	1.411 (0.6623)	1.366 (0.6864)	1.288 (0.6991)
	Median	1.642	1.505	1.371	1.429
	Q1 - Q3	1.181 - 2.000	1.000 - 1.938	1.000 - 1.879	1.000 - 1.740
	Min - Max	0 - 2.67	0 - 2.60	0 - 3.00	0 - 2.52

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.1
Summary of Mean Daily Severity of Moderate to Severe VMS Over Time
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 12	Change from Baseline				
	n	64	66	65	63
	Mean (SD)	-0.777 (0.6425)	-0.905 (0.6659)	-0.982 (0.6290)	-1.004 (0.7272)
	Median	-0.586	-0.743	-0.952	-0.888
	Q1 - Q3	-1.054 - -0.296	-1.286 - -0.381	-1.404 - -0.417	-1.370 - -0.410
	Min - Max	-2.55 - 0.08	-2.61 - 0.46	-2.51 - 0	-2.64 - 0.02

Data Source: Listing 16.2.6.1

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Severity of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 1	n	69	70	69	68
	LS Mean (SE)	-0.367 (0.0449)	-0.345 (0.0441)	-0.407 (0.0457)	-0.431 (0.0457)
	90% CI (2-sided)	-0.441, -0.293	-0.417, -0.272	-0.482, -0.332	-0.506, -0.355
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		0.022 (0.0460)	-0.040 (0.0462)	-0.064 (0.0463)
	90% CI (2-sided)		-0.054, 0.098	-0.117, 0.036	-0.141, 0.012
	P-value		0.6322	0.3829	0.1664
Week 2	n	69	69	68	68
	LS Mean (SE)	-0.402 (0.0528)	-0.431 (0.0519)	-0.500 (0.0535)	-0.514 (0.0536)
	90% CI (2-sided)	-0.489, -0.315	-0.516, -0.345	-0.588, -0.412	-0.603, -0.426
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.028 (0.0604)	-0.098 (0.0607)	-0.112 (0.0608)
	90% CI (2-sided)		-0.128, 0.072	-0.198, 0.002	-0.212, -0.011
	P-value		0.6411	0.1085	0.0671

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval. The p-values were nominal.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Severity of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	n	67	69	67	68
	LS Mean (SE)	-0.467 (0.0595)	-0.518 (0.0586)	-0.589 (0.0602)	-0.572 (0.0601)
	90% CI (2-sided)	-0.565, -0.369	-0.615, -0.422	-0.688, -0.489	-0.671, -0.473
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.051 (0.0717)	-0.122 (0.0722)	-0.105 (0.0721)
	90% CI (2-sided)		-0.170, 0.067	-0.241, -0.002	-0.224, 0.014
	P-value		0.4745	0.0933	0.1468
Week 4	n	67	69	67	68
	LS Mean (SE)	-0.491 (0.0614)	-0.535 (0.0605)	-0.637 (0.0621)	-0.628 (0.0620)
	90% CI (2-sided)	-0.592, -0.390	-0.635, -0.436	-0.739, -0.534	-0.730, -0.526
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.044 (0.0748)	-0.146 (0.0754)	-0.137 (0.0752)
	90% CI (2-sided)		-0.168, 0.079	-0.270, -0.021	-0.261, -0.013
	P-value		0.5563	0.0543	0.0696

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval. The p-values were nominal.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Severity of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	n	66	69	67	64
	LS Mean (SE)	-0.564 (0.0626)	-0.584 (0.0616)	-0.662 (0.0632)	-0.662 (0.0633)
	90% CI (2-sided)	-0.667, -0.461	-0.685, -0.482	-0.766, -0.558	-0.766, -0.557
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.020 (0.0766)	-0.098 (0.0772)	-0.098 (0.0772)
	90% CI (2-sided)		-0.146, 0.107	-0.226, 0.029	-0.225, 0.030
	P-value		0.7980	0.2048	0.2074
Week 6	n	66	68	67	64
	LS Mean (SE)	-0.584 (0.0652)	-0.626 (0.0642)	-0.690 (0.0658)	-0.714 (0.0659)
	90% CI (2-sided)	-0.692, -0.476	-0.732, -0.520	-0.798, -0.581	-0.822, -0.605
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.042 (0.0808)	-0.105 (0.0814)	-0.130 (0.0815)
	90% CI (2-sided)		-0.175, 0.092	-0.240, 0.029	-0.264, 0.005
	P-value		0.6055	0.1963	0.1123

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval. The p-values were nominal.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Severity of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 7	n	66	68	67	63
	LS Mean (SE)	-0.624 (0.0680)	-0.658 (0.0669)	-0.725 (0.0685)	-0.769 (0.0687)
	90% CI (2-sided)	-0.736, -0.512	-0.769, -0.548	-0.838, -0.612	-0.883, -0.656
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.035 (0.0852)	-0.101 (0.0858)	-0.145 (0.0859)
	90% CI (2-sided)		-0.175, 0.106	-0.243, 0.041	-0.287, -0.003
	P-value		0.6849	0.2401	0.0920
Week 8	n	65	68	66	63
	LS Mean (SE)	-0.630 (0.0704)	-0.701 (0.0692)	-0.806 (0.0709)	-0.847 (0.0712)
	90% CI (2-sided)	-0.746, -0.514	-0.815, -0.587	-0.922, -0.689	-0.964, -0.729
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.071 (0.0889)	-0.176 (0.0896)	-0.217 (0.0898)
	90% CI (2-sided)		-0.218, 0.075	-0.324, -0.028	-0.365, -0.068
	P-value		0.4231	0.0509	0.0165

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval. The p-values were nominal.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Severity of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	n	65	68	66	63
	LS Mean (SE)	-0.677 (0.0721)	-0.736 (0.0709)	-0.848 (0.0726)	-0.910 (0.0731)
	90% CI (2-sided)	-0.796, -0.558	-0.853, -0.619	-0.968, -0.728	-1.031, -0.790
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.059 (0.0916)	-0.171 (0.0924)	-0.233 (0.0927)
	90% CI (2-sided)		-0.210, 0.092	-0.324, -0.019	-0.386, -0.080
	P-value		0.5194	0.0652	0.0124
Week 10	n	64	68	65	63
	LS Mean (SE)	-0.772 (0.0777)	-0.800 (0.0762)	-0.934 (0.0781)	-0.948 (0.0787)
	90% CI (2-sided)	-0.900, -0.643	-0.926, -0.675	-1.062, -0.805	-1.078, -0.818
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.029 (0.1001)	-0.162 (0.1010)	-0.176 (0.1014)
	90% CI (2-sided)		-0.194, 0.136	-0.329, 0.005	-0.344, -0.009
	P-value		0.7730	0.1096	0.0830

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval. The p-values were nominal.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Table 14.2.3.2.2
Secondary Endpoint Analysis
Change from Baseline Over Time in the Severity of Moderate to Severe VMS
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	n	64	68	65	63
	LS Mean (SE)	-0.806 (0.0819)	-0.908 (0.0803)	-0.957 (0.0822)	-1.000 (0.0829)
	90% CI (2-sided)	-0.941, -0.671	-1.040, -0.775	-1.092, -0.821	-1.137, -0.863
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.102 (0.1063)	-0.151 (0.1073)	-0.194 (0.1078)
	90% CI (2-sided)		-0.277, 0.074	-0.328, 0.027	-0.372, -0.016
	P-value		0.3401	0.1617	0.0732
Week 12	n	64	66	65	63
	LS Mean (SE)	-0.850 (0.0871)	-0.968 (0.0855)	-1.053 (0.0874)	-1.089 (0.0883)
	90% CI (2-sided)	-0.994, -0.706	-1.109, -0.827	-1.197, -0.909	-1.235, -0.944
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.118 (0.1143)	-0.203 (0.1153)	-0.239 (0.1158)
	90% CI (2-sided)		-0.307, 0.070	-0.394, -0.013	-0.431, -0.048
	P-value		0.3013	0.0793	0.0397

Data Source: Listing 16.2.6.1

n = number of subjects at specific week. LS = Least Squares; SE = Standard Errors; CI = Confidence Interval. The p-values were nominal.

Baseline values were calculated by averaging the mean daily severity of the available days during the 7 days prior to randomization. Daily severity was calculated using a weighed mean method with the following formula: (number of moderate VMS x 2 + number of severe VMS x 3) / (total number of moderate and severe VMS episodes that day).

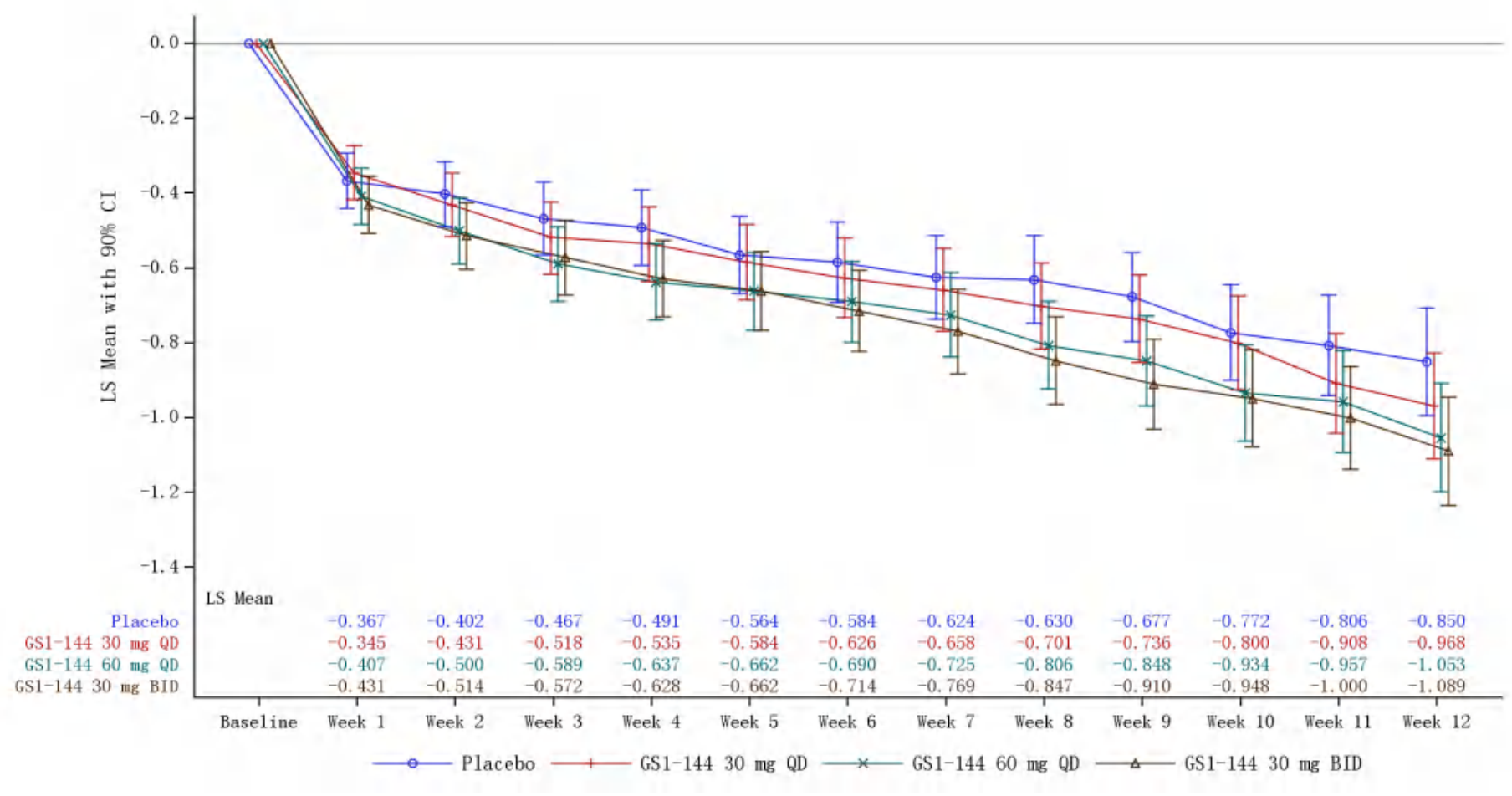
Post-baseline values were calculated by averaging the mean daily severity of the available days during particular week. Daily severity was calculated using a weighed mean method with the following formula: (number of mild VMS x 1 + number of moderate VMS x 2 + number of severe VMS x 3) / (total number of mild, moderate and severe VMS episodes that day).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) model, with treatment group, stratification factor BMI and week as factors, and baseline measurement as covariate, as well as treatment by week interaction and baseline measurement by week interaction.

A composite strategy was used for ICE1 and ICE2, data after occurrence of ICEs (should be within washout period for ICE1) were imputed with the baseline value. A hypothetical strategy was used for ICE3, data after occurrence of ICE3 were considered as missing.

Figure 14.2.3.2.3
Line Plot of Change from Baseline Over Time in the Severity of Moderate to Severe VMS
FAS



Data Source: Table 14.2.3.2.2
LS = Least Squares; CI = Confidence Interval.

Table 14.2.3.3.1

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS >= 50%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 1	n (%)	9 (13.0)	9 (12.9)	12 (17.4)	13 (19.1)
	90% CI (2-sided)*	7.0, 21.7	6.9, 21.4	10.4, 26.6	11.7, 28.7
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-0.3	4.3	6.3
	90% CI (2-sided)		-9.7, 9.0	-5.7, 14.4	-4.0, 16.5
	P-value**		0.9555	0.4816	0.3215
Week 2	n (%)	16 (23.2)	19 (27.1)	21 (30.4)	20 (29.4)
	90% CI (2-sided)*	15.1, 33.1	18.6, 37.2	21.4, 40.8	20.4, 39.8
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		4.2	7.3	6.3
	90% CI (2-sided)		-7.9, 16.2	-5.3, 19.8	-6.3, 18.8
	P-value**		0.5731	0.3384	0.4089

Data Source: Listing 16.2.6.1

n = number of subjects with >=50% decrease from baseline; CI = Confidence Interval. Subject with a percentage change <=-50% was considered to have a >=50% decrease from baseline.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.1
Secondary Endpoint Analysis
Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS >= 50%
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	n (%)	18 (26.1)	27 (38.6)	23 (33.3)	28 (41.2)
	90% CI (2-sided)*	17.6, 36.2	28.8, 49.1	24.0, 43.8	31.1, 51.9
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		12.3	7.5	15.2
	90% CI (2-sided)		-0.6, 25.3	-5.3, 20.2	2.1, 28.4
	P-value**		0.1229	0.3412	0.0609
Week 4	n (%)	22 (31.9)	30 (42.9)	25 (36.2)	34 (50.0)
	90% CI (2-sided)*	22.7, 42.3	32.8, 53.4	26.6, 46.8	39.4, 60.6
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		10.9	4.7	18.4
	90% CI (2-sided)		-2.6, 24.3	-8.5, 17.9	4.8, 31.9
	P-value**		0.1883	0.5606	0.0296

Data Source: Listing 16.2.6.1

n = number of subjects with >=50% decrease from baseline; CI = Confidence Interval. Subject with a percentage change <=-50% was considered to have a >=50% decrease from baseline.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.1
Secondary Endpoint Analysis
Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS >= 50%
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	n (%)	27 (39.1)	37 (52.9)	40 (58.0)	38 (55.9)
	90% CI (2-sided)*	29.3, 49.7	42.4, 63.1	47.4, 68.1	45.2, 66.2
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		13.6	19.0	16.9
	90% CI (2-sided)		-0.2, 27.4	5.3, 32.7	3.1, 30.7
	P-value**		0.1101	0.0267	0.0491
Week 6	n (%)	32 (46.4)	39 (55.7)	45 (65.2)	43 (63.2)
	90% CI (2-sided)*	36.1, 56.9	45.2, 65.9	54.7, 74.7	52.6, 73.0
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		9.3	18.9	16.9
	90% CI (2-sided)		-4.6, 23.2	5.2, 32.5	3.1, 30.7
	P-value**		0.2775	0.0268	0.0486

Data Source: Listing 16.2.6.1

n = number of subjects with >=50% decrease from baseline; CI = Confidence Interval. Subject with a percentage change <=-50% was considered to have a >=50% decrease from baseline.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.1
Secondary Endpoint Analysis
Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS >= 50%
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 7	n (%)	35 (50.7)	48 (68.6)	50 (72.5)	46 (67.6)
	90% CI (2-sided)*	40.2, 61.2	58.3, 77.7	62.3, 81.2	57.1, 77.0
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		17.9	21.7	16.9
	90% CI (2-sided)		4.5, 31.4	8.4, 35.0	3.3, 30.5
	P-value**		0.0326	0.0094	0.0459
Week 8	n (%)	36 (52.2)	46 (65.7)	55 (79.7)	49 (72.1)
	90% CI (2-sided)*	41.6, 62.6	55.3, 75.1	70.1, 87.3	61.8, 80.9
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		13.6	27.7	20.0
	90% CI (2-sided)		0.0, 27.2	15.0, 40.3	6.7, 33.4
	P-value**		0.1058	0.0007	0.0164

Data Source: Listing 16.2.6.1

n = number of subjects with >=50% decrease from baseline; CI = Confidence Interval. Subject with a percentage change <=-50% was considered to have a >=50% decrease from baseline.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.1

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS >= 50%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	n (%)	43 (62.3)	48 (68.6)	58 (84.1)	49 (72.1)
	90% CI (2-sided)*	51.7, 72.1	58.3, 77.7	75.0, 90.8	61.8, 80.9
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		6.2	22.0	10.0
	90% CI (2-sided)		-7.0, 19.5	10.0, 33.9	-3.0, 23.1
	P-value**		0.4428	0.0038	0.2130
Week 10	n (%)	43 (62.3)	53 (75.7)	58 (84.1)	53 (77.9)
	90% CI (2-sided)*	51.7, 72.1	65.8, 83.9	75.0, 90.8	68.1, 85.9
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		13.4	22.0	15.9
	90% CI (2-sided)		0.6, 26.2	10.0, 33.9	3.3, 28.5
	P-value**		0.0891	0.0038	0.0434

Data Source: Listing 16.2.6.1

n = number of subjects with >=50% decrease from baseline; CI = Confidence Interval. Subject with a percentage change <=-50% was considered to have a >=50% decrease from baseline.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.1

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS >= 50%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	n (%)	49 (71.0)	53 (75.7)	60 (87.0)	56 (82.4)
	90% CI (2-sided)*	60.7, 79.9	65.8, 83.9	78.3, 93.0	73.0, 89.5
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		4.6	16.3	11.7
	90% CI (2-sided)		-7.8, 17.0	5.2, 27.4	0.0, 23.4
	P-value**		0.5389	0.0186	0.1047
Week 12	n (%)	50 (72.5)	55 (78.6)	60 (87.0)	59 (86.8)
	90% CI (2-sided)*	62.3, 81.2	68.9, 86.3	78.3, 93.0	78.0, 92.9
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		6.4	14.6	14.4
	90% CI (2-sided)		-5.6, 18.4	3.5, 25.7	3.3, 25.5
	P-value**		0.3809	0.0342	0.0379

Data Source: Listing 16.2.6.1

n = number of subjects with >=50% decrease from baseline; CI = Confidence Interval. Subject with a percentage change <=-50% was considered to have a >=50% decrease from baseline.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.2

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS = 100%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 1	n (%)	0	0	0	0
	90% CI (2-sided)*	0, 4.2	0, 4.2	0, 4.2	0, 4.3
Week 2	n (%)	0	1 (1.4)	1 (1.4)	2 (2.9)
	90% CI (2-sided)*	0, 4.2	0.1, 6.6	0.1, 6.7	0.5, 9.0
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		1.4	1.4	2.9
	90% CI (2-sided)		-0.9, 3.8	-0.9, 3.8	-0.4, 6.3
	P-value**		0.3173	0.3210	0.1557

Data Source: Listing 16.2.6.1

n = number of subjects with 100% decrease from baseline; CI = Confidence Interval. Subject had 100% decrease from baseline if frequency of moderate to severe VMS at specific Week = 0.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.2

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS = 100%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 3	n (%)	2 (2.9)	1 (1.4)	1 (1.4)	1 (1.5)
	90% CI (2-sided)*	0.5, 8.8	0.1, 6.6	0.1, 6.7	0.1, 6.8
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-1.4	-1.5	-1.5
	90% CI (2-sided)		-5.5, 2.6	-5.6, 2.6	-5.6, 2.6
	P-value**		0.5606	0.5517	0.5606
Week 4	n (%)	1 (1.4)	1 (1.4)	3 (4.3)	2 (2.9)
	90% CI (2-sided)*	0.1, 6.7	0.1, 6.6	1.2, 10.9	0.5, 9.0
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		0	2.9	1.5
	90% CI (2-sided)		-3.3, 3.3	-1.8, 7.5	-2.7, 5.6
	P-value**		1.0000	0.3191	0.5606

Data Source: Listing 16.2.6.1

n = number of subjects with 100% decrease from baseline; CI = Confidence Interval. Subject had 100% decrease from baseline if frequency of moderate to severe VMS at specific Week = 0.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.2
Secondary Endpoint Analysis
Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS = 100%
FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 5	n (%)	3 (4.3)	1 (1.4)	2 (2.9)	3 (4.4)
	90% CI (2-sided)*	1.2, 10.9	0.1, 6.6	0.5, 8.8	1.2, 11.0
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-2.9	-1.5	0
	90% CI (2-sided)		-7.5, 1.8	-6.7, 3.7	-5.8, 5.8
	P-value**		0.3116	0.6372	1.0000
Week 6	n (%)	5 (7.2)	4 (5.7)	2 (2.9)	5 (7.4)
	90% CI (2-sided)*	2.9, 14.6	2.0, 12.6	0.5, 8.8	2.9, 14.8
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-1.6	-4.2	0.2
	90% CI (2-sided)		-8.5, 5.3	-10.3, 1.9	-7.1, 7.5
	P-value**		0.7040	0.2638	0.9629

Data Source: Listing 16.2.6.1

n = number of subjects with 100% decrease from baseline; CI = Confidence Interval. Subject had 100% decrease from baseline if frequency of moderate to severe VMS at specific Week = 0.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.2

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS = 100%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 7	n (%)	5 (7.2)	3 (4.3)	4 (5.8)	7 (10.3)
	90% CI (2-sided)*	2.9, 14.6	1.2, 10.7	2.0, 12.8	4.9, 18.5
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-3.0	-1.3	3.3
	90% CI (2-sided)		-9.6, 3.5	-8.2, 5.6	-4.5, 11.2
	P-value**		0.4457	0.7535	0.4894
Week 8	n (%)	4 (5.8)	3 (4.3)	5 (7.2)	8 (11.8)
	90% CI (2-sided)*	2.0, 12.8	1.2, 10.7	2.9, 14.6	6.0, 20.2
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-1.6	1.6	6.1
	90% CI (2-sided)		-7.8, 4.6	-5.3, 8.5	-1.9, 14.0
	P-value**		0.6690	0.7114	0.2142

Data Source: Listing 16.2.6.1

n = number of subjects with 100% decrease from baseline; CI = Confidence Interval. Subject had 100% decrease from baseline if frequency of moderate to severe VMS at specific Week = 0.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.2

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS = 100%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 9	n (%)	6 (8.7)	4 (5.7)	4 (5.8)	11 (16.2)
	90% CI (2-sided)*	3.9, 16.4	2.0, 12.6	2.0, 12.8	9.3, 25.4
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-3.0	-2.6	7.7
	90% CI (2-sided)		-10.3, 4.2	-9.7, 4.6	-1.4, 16.9
	P-value**		0.4918	0.5584	0.1724
Week 10	n (%)	8 (11.6)	6 (8.6)	8 (11.6)	12 (17.6)
	90% CI (2-sided)*	5.9, 19.9	3.8, 16.2	5.9, 19.9	10.5, 27.0
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		-3.0	0.3	6.1
	90% CI (2-sided)		-11.5, 5.4	-8.6, 9.2	-3.9, 16.0
	P-value**		0.5548	0.9622	0.3196

Data Source: Listing 16.2.6.1

n = number of subjects with 100% decrease from baseline; CI = Confidence Interval. Subject had 100% decrease from baseline if frequency of moderate to severe VMS at specific Week = 0.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.3.3.2

Secondary Endpoint Analysis

Proportion of Decrease from Baseline Over Time in the Frequency of Moderate to Severe VMS = 100%

FAS

Analysis Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 11	n (%)	10 (14.5)	12 (17.1)	7 (10.1)	11 (16.2)
	90% CI (2-sided)*	8.1, 23.3	10.2, 26.3	4.9, 18.2	9.3, 25.4
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		2.6	-3.9	1.9
	90% CI (2-sided)		-7.8, 12.9	-12.9, 5.1	-8.3, 12.1
	P-value**		0.6817	0.4827	0.7617
Week 12	n (%)	12 (17.4)	14 (20.0)	14 (20.3)	15 (22.1)
	90% CI (2-sided)*	10.4, 26.6	12.5, 29.5	12.7, 29.9	14.1, 31.9
	Difference (GS1-144 v.s. Placebo)				
	Adjusted Risk Difference		2.6	3.1	4.8
	90% CI (2-sided)		-8.3, 13.4	-7.9, 14.0	-6.4, 16.0
	P-value**		0.7011	0.6494	0.4834

Data Source: Listing 16.2.6.1

n = number of subjects with 100% decrease from baseline; CI = Confidence Interval. Subject had 100% decrease from baseline if frequency of moderate to severe VMS at specific Week = 0.

Baseline values were calculated by aggregating all available days during the 7 days prior to randomization to a mean daily frequency as (total number of moderate to severe VMS during the 7 days prior to randomization) / (total number of available days with data). Post-baseline values were aggregated to a mean daily frequency as (total number of moderate to severe VMS during that week) / (total number of available days with data during that week).

In case data of VMS were missing for more than 2 days within a week, the value for that particular week were set to missing.

The common stratified (stratification factor BMI) Cochran-Mantel-Haenszel (CMH) and 90% CI were calculated.

* CI was calculated using exact clopper-pearson method.

** The p-values were nominal.

ICE1 and ICE2 were handled by composite strategy, data after occurrence of ICEs (should be within washout period for ICE1) were considered as non-responder; ICE3 was handled by treatment policy strategy, data after ICE occurrence were used if available. Subjects with missing values (after handling of ICEs) were considered as non-responder.

Table 14.2.4.1.1
Exploratory Endpoint Analysis 1 - MMRM Analysis of PGIC
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D29	Observed Value				
	n	68	69	67	67
	Mean (SD)	2.5 (0.82)	2.5 (0.88)	2.3 (0.86)	2.3 (0.76)
	Median	3.0	3.0	2.0	2.0
	Q1 - Q3	2.0 - 3.0	2.0 - 3.0	2.0 - 3.0	2.0 - 3.0
	Min - Max	1 - 4	1 - 5	1 - 4	1 - 4
	LS Mean (SE)	2.263 (0.1347)	2.329 (0.1343)	2.145 (0.1372)	2.100 (0.1372)
	90% CI (2-sided)	2.041, 2.486	2.107, 2.551	1.918, 2.371	1.874, 2.326
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		0.065 (0.1409)	-0.119 (0.1419)	-0.164 (0.1419)
	90% CI (2-sided)		-0.167, 0.298	-0.353, 0.116	-0.398, 0.071
	P-value		0.6424	0.4036	0.2504

Data Source: Listing 16.2.6.4
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, as well as treatment by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.1.1
Exploratory Endpoint Analysis 1 - MMRM Analysis of PGIC
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D57	Observed Value				
	n	65	68	66	63
	Mean (SD)	2.3 (1.01)	2.3 (0.89)	2.0 (0.76)	2.2 (0.91)
	Median	2.0	2.0	2.0	2.0
	Q1 - Q3	1.0 - 3.0	2.0 - 3.0	1.0 - 2.0	2.0 - 3.0
	Min - Max	1 - 4	1 - 4	1 - 4	1 - 4
	LS Mean (SE)	2.088 (0.1429)	2.112 (0.1416)	1.768 (0.1446)	2.000 (0.1459)
	90% CI (2-sided)	1.852, 2.324	1.878, 2.345	1.530, 2.007	1.759, 2.241
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		0.023 (0.1555)	-0.320 (0.1567)	-0.088 (0.1581)
	90% CI (2-sided)		-0.233, 0.280	-0.579, -0.061	-0.349, 0.172
	P-value		0.8800	0.0422	0.5762

Data Source: Listing 16.2.6.4
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, as well as treatment by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.1.1
Exploratory Endpoint Analysis 1 - MMRM Analysis of PGIC
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D85	Observed Value				
	n	64	67	65	63
	Mean (SD)	2.1 (1.10)	2.1 (0.90)	1.8 (0.81)	2.0 (0.99)
	Median	2.0	2.0	2.0	2.0
	Q1 - Q3	1.0 - 3.0	1.0 - 3.0	1.0 - 2.0	1.0 - 2.0
	Min - Max	1 - 4	1 - 4	1 - 4	1 - 4
	LS Mean (SE)	1.873 (0.1486)	1.919 (0.1473)	1.642 (0.1501)	1.761 (0.1513)
	90% CI (2-sided)	1.627, 2.118	1.676, 2.162	1.395, 1.890	1.512, 2.011
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		0.047 (0.1656)	-0.230 (0.1668)	-0.111 (0.1681)
	90% CI (2-sided)		-0.226, 0.320	-0.506, 0.045	-0.389, 0.166
	P-value		0.7774	0.1688	0.5091

Data Source: Listing 16.2.6.4
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, as well as treatment by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.1.2
Exploratory Endpoint Analysis 1 - Proportion of PGIC
FAS

Visit	Category	Placebo N = 69 n(%)	GS1-144 30 mg QD N = 70 n(%)	GS1-144 60 mg QD N = 69 n(%)	GS1-144 30 mg BID N = 68 n(%)
D29	Number of subjects (%)	68 (100)	69 (100)	67 (100)	67 (100)
	1 - Very Much Improved	9 (13.2)	9 (13.0)	13 (19.4)	10 (14.9)
	2 - Much Improved	24 (35.3)	23 (33.3)	22 (32.8)	29 (43.3)
	3 - Minimally Improved	30 (44.1)	30 (43.5)	28 (41.8)	26 (38.8)
	4 - No Change	5 (7.4)	6 (8.7)	4 (6.0)	2 (3.0)
	5 - Minimally Worse	0	1 (1.4)	0	0
D57	Number of subjects (%)	65 (100)	68 (100)	66 (100)	63 (100)
	1 - Very Much Improved	17 (26.2)	14 (20.6)	19 (28.8)	15 (23.8)
	2 - Much Improved	21 (32.3)	24 (35.3)	31 (47.0)	27 (42.9)
	3 - Minimally Improved	18 (27.7)	25 (36.8)	15 (22.7)	15 (23.8)
	4 - No Change	9 (13.8)	5 (7.4)	1 (1.5)	6 (9.5)
D85	Number of subjects (%)	64 (100)	67 (100)	65 (100)	63 (100)
	1 - Very Much Improved	27 (42.2)	19 (28.4)	25 (38.5)	25 (39.7)
	2 - Much Improved	14 (21.9)	24 (35.8)	27 (41.5)	23 (36.5)
	3 - Minimally Improved	14 (21.9)	20 (29.9)	11 (16.9)	8 (12.7)
	4 - No Change	9 (14.1)	4 (6.0)	2 (3.1)	7 (11.1)

Data Source: Listing 16.2.6.4
Percentages were based on number of subjects at specific visit.

Table 14.2.4.2.1
Exploratory Endpoint Analysis 2 - MMRM Analysis of PGIS
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	3.0 (1.03)	3.4 (0.76)	3.3 (0.80)	3.0 (1.03)
	Median	3.0	3.0	3.0	3.0
	Q1 - Q3	3.0 - 4.0	3.0 - 4.0	3.0 - 4.0	2.5 - 4.0
	Min - Max	1 - 5	1 - 5	1 - 5	1 - 5
D29	Observed Value				
	n	68	69	67	67
	Mean (SD)	2.4 (0.77)	2.5 (0.68)	2.3 (0.81)	2.2 (0.79)
	Median	2.0	3.0	2.0	2.0
	Q1 - Q3	2.0 - 3.0	2.0 - 3.0	2.0 - 3.0	2.0 - 3.0
	Min - Max	1 - 4	1 - 4	1 - 4	1 - 4

Data Source: Listing 16.2.6.5
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.2.1
Exploratory Endpoint Analysis 2 - MMRM Analysis of PGIS
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D29	Change from Baseline				
	n	68	69	67	67
	Mean (SD)	-0.7 (0.78)	-0.9 (0.77)	-0.9 (0.93)	-0.8 (0.78)
	Median	-1.0	-1.0	-1.0	-1.0
	Q1 - Q3	-1.0 - 0.0	-1.0 - 0.0	-2.0 - 0.0	-1.0 - 0.0
	Min - Max	-3 - 1	-3 - 1	-4 - 1	-3 - 1
	LS Mean (SE)	-0.870 (0.0993)	-0.903 (0.0998)	-0.992 (0.1014)	-1.018 (0.1010)
	90% CI (2-sided)	-1.034, -0.706	-1.067, -0.738	-1.159, -0.825	-1.184, -0.851
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.033 (0.1104)	-0.122 (0.1107)	-0.148 (0.1102)
	90% CI (2-sided)		-0.215, 0.149	-0.305, 0.061	-0.330, 0.034
	P-value		0.7659	0.2707	0.1808

Data Source: Listing 16.2.6.5
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.2.1
Exploratory Endpoint Analysis 2 - MMRM Analysis of PGIS
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D57	Observed Value				
	n	65	68	66	63
	Mean (SD)	2.0 (0.66)	2.3 (0.61)	2.0 (0.69)	2.0 (0.70)
	Median	2.0	2.0	2.0	2.0
	Q1 - Q3	2.0 - 2.0	2.0 - 3.0	2.0 - 3.0	2.0 - 2.0
	Min - Max	1 - 3	1 - 4	1 - 3	1 - 4
	Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-1.0 (0.77)	-1.1 (0.92)	-1.2 (0.87)	-1.0 (0.87)
	Median	-1.0	-1.0	-1.0	-1.0
	Q1 - Q3	-1.0 - 0.0	-2.0 - -0.5	-2.0 - -1.0	-2.0 - -1.0
	Min - Max	-3 - 0	-4 - 1	-3 - 1	-4 - 1
	LS Mean (SE)	-1.192 (0.0959)	-1.092 (0.0958)	-1.271 (0.0974)	-1.260 (0.0979)
	90% CI (2-sided)	-1.350, -1.034	-1.250, -0.934	-1.432, -1.111	-1.422, -1.099
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		0.099 (0.1038)	-0.079 (0.1041)	-0.068 (0.1045)
	90% CI (2-sided)		-0.072, 0.271	-0.251, 0.092	-0.241, 0.104
	P-value		0.3390	0.4463	0.5143

Data Source: Listing 16.2.6.5
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.2.1
Exploratory Endpoint Analysis 2 - MMRM Analysis of PGIS
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D85	Observed Value				
	n	64	67	65	63
	Mean (SD)	1.8 (0.66)	2.1 (0.62)	1.8 (0.69)	1.9 (0.65)
	Median	2.0	2.0	2.0	2.0
	Q1 - Q3	1.0 - 2.0	2.0 - 2.0	1.0 - 2.0	1.0 - 2.0
	Min - Max	1 - 3	1 - 4	1 - 3	1 - 4
	Change from Baseline				
	n	64	67	65	63
	Mean (SD)	-1.2 (0.99)	-1.2 (0.90)	-1.4 (0.98)	-1.2 (0.92)
	Median	-1.0	-1.0	-2.0	-1.0
	Q1 - Q3	-2.0 - -1.0	-2.0 - -1.0	-2.0 - -1.0	-2.0 - -1.0
	Min - Max	-4 - 1	-4 - 1	-4 - 0	-4 - 1
	LS Mean (SE)	-1.476 (0.0991)	-1.217 (0.0991)	-1.508 (0.1003)	-1.383 (0.1008)
	90% CI (2-sided)	-1.640, -1.313	-1.380, -1.053	-1.674, -1.343	-1.549, -1.217
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		0.260 (0.1095)	-0.032 (0.1098)	0.093 (0.1101)
	90% CI (2-sided)		0.079, 0.440	-0.213, 0.149	-0.088, 0.275
	P-value		0.0185	0.7713	0.3968

Data Source: Listing 16.2.6.5
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.2.2
Exploratory Endpoint Analysis 2 - Proportion of PGIS
FAS

Visit	Category	Placebo N = 69 n(%)	GS1-144 30 mg QD N = 70 n(%)	GS1-144 60 mg QD N = 69 n(%)	GS1-144 30 mg BID N = 68 n(%)
Baseline	Number of subjects (%)	69 (100)	70 (100)	69 (100)	68 (100)
	1 - None	8 (11.6)	1 (1.4)	1 (1.4)	7 (10.3)
	2 - Mild	7 (10.1)	5 (7.1)	8 (11.6)	10 (14.7)
	3 - Moderate	33 (47.8)	35 (50.0)	36 (52.2)	27 (39.7)
	4 - Severe	17 (24.6)	25 (35.7)	20 (29.0)	21 (30.9)
	5 - Very Severe	4 (5.8)	4 (5.7)	4 (5.8)	3 (4.4)
D29	Number of subjects (%)	68 (100)	69 (100)	67 (100)	67 (100)
	1 - None	10 (14.7)	5 (7.2)	12 (17.9)	14 (20.9)
	2 - Mild	26 (38.2)	28 (40.6)	22 (32.8)	26 (38.8)
	3 - Moderate	30 (44.1)	34 (49.3)	31 (46.3)	26 (38.8)
	4 - Severe	2 (2.9)	2 (2.9)	2 (3.0)	1 (1.5)
D57	Number of subjects (%)	65 (100)	68 (100)	66 (100)	63 (100)
	1 - None	13 (20.0)	4 (5.9)	14 (21.2)	14 (22.2)
	2 - Mild	37 (56.9)	44 (64.7)	35 (53.0)	36 (57.1)
	3 - Moderate	15 (23.1)	18 (26.5)	17 (25.8)	12 (19.0)
	4 - Severe	0	2 (2.9)	0	1 (1.6)
D85	Number of subjects (%)	64 (100)	67 (100)	65 (100)	63 (100)
	1 - None	23 (35.9)	8 (11.9)	23 (35.4)	16 (25.4)
	2 - Mild	33 (51.6)	44 (65.7)	32 (49.2)	39 (61.9)
	3 - Moderate	8 (12.5)	14 (20.9)	10 (15.4)	7 (11.1)
	4 - Severe	0	1 (1.5)	0	1 (1.6)

Data Source: Listing 16.2.6.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on number of subjects at specific visit.

Table 14.2.4.2.3
Exploratory Endpoint Analysis 2 - Shift of PGIS by Visit
FAS

Visit	Treatment Group	Post-Baseline	Baseline None n (%)	Baseline Mild n (%)	Baseline Moderate n (%)	Baseline Severe n (%)	Baseline Very Severe n (%)	Baseline Total n (%)
D29	Placebo (N=69)	None	7 (10.3)	2 (2.9)	1 (1.5)	0	0	10 (14.7)
		Mild	1 (1.5)	3 (4.4)	18 (26.5)	3 (4.4)	1 (1.5)	26 (38.2)
		Moderate	0	2 (2.9)	13 (19.1)	12 (17.6)	3 (4.4)	30 (44.1)
		Severe	0	0	0	2 (2.9)	0	2 (2.9)
		Very Severe	0	0	0	0	0	0
		Total	8 (11.8)	7 (10.3)	32 (47.1)	17 (25.0)	4 (5.9)	68 (100)
	GS1-144 30 mg QD (N=70)	None	1 (1.4)	2 (2.9)	2 (2.9)	0	0	5 (7.2)
		Mild	0	2 (2.9)	17 (24.6)	8 (11.6)	1 (1.4)	28 (40.6)
		Moderate	0	1 (1.4)	15 (21.7)	15 (21.7)	3 (4.3)	34 (49.3)
		Severe	0	0	0	2 (2.9)	0	2 (2.9)
		Very Severe	0	0	0	0	0	0
		Total	1 (1.4)	5 (7.2)	34 (49.3)	25 (36.2)	4 (5.8)	69 (100)
	GS1-144 60 mg QD (N=69)	None	1 (1.5)	3 (4.5)	7 (10.4)	0	1 (1.5)	12 (17.9)
		Mild	0	4 (6.0)	10 (14.9)	7 (10.4)	1 (1.5)	22 (32.8)
		Moderate	0	1 (1.5)	17 (25.4)	11 (16.4)	2 (3.0)	31 (46.3)
		Severe	0	0	0	2 (3.0)	0	2 (3.0)
		Very Severe	0	0	0	0	0	0
		Total	1 (1.5)	8 (11.9)	34 (50.7)	20 (29.9)	4 (6.0)	67 (100)

Data Source: Listing 16.2.6.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.2.4.2.3
Exploratory Endpoint Analysis 2 - Shift of PGIS by Visit
FAS

Visit	Treatment Group	Post-Baseline	Baseline None n (%)	Baseline Mild n (%)	Baseline Moderate n (%)	Baseline Severe n (%)	Baseline Very Severe n (%)	Baseline Total n (%)
D29	GS1-144 30 mg BID (N=68)	None	6 (9.0)	6 (9.0)	1 (1.5)	1 (1.5)	0	14 (20.9)
		Mild	1 (1.5)	3 (4.5)	17 (25.4)	4 (6.0)	1 (1.5)	26 (38.8)
		Moderate	0	1 (1.5)	9 (13.4)	14 (20.9)	2 (3.0)	26 (38.8)
		Severe	0	0	0	1 (1.5)	0	1 (1.5)
		Very Severe	0	0	0	0	0	0
		Total	7 (10.4)	10 (14.9)	27 (40.3)	20 (29.9)	3 (4.5)	67 (100)
D57	Placebo (N=69)	None	8 (12.3)	2 (3.1)	3 (4.6)	0	0	13 (20.0)
		Mild	0	5 (7.7)	22 (33.8)	8 (12.3)	2 (3.1)	37 (56.9)
		Moderate	0	0	5 (7.7)	9 (13.8)	1 (1.5)	15 (23.1)
		Severe	0	0	0	0	0	0
		Very Severe	0	0	0	0	0	0
		Total	8 (12.3)	7 (10.8)	30 (46.2)	17 (26.2)	3 (4.6)	65 (100)
	GS1-144 30 mg QD (N=70)	None	1 (1.5)	1 (1.5)	1 (1.5)	0	1 (1.5)	4 (5.9)
		Mild	0	3 (4.4)	23 (33.8)	15 (22.1)	3 (4.4)	44 (64.7)
		Moderate	0	1 (1.5)	10 (14.7)	7 (10.3)	0	18 (26.5)
		Severe	0	0	0	2 (2.9)	0	2 (2.9)
		Very Severe	0	0	0	0	0	0
		Total	1 (1.5)	5 (7.4)	34 (50.0)	24 (35.3)	4 (5.9)	68 (100)

Data Source: Listing 16.2.6.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.2.4.2.3
Exploratory Endpoint Analysis 2 - Shift of PGIS by Visit
FAS

Visit	Treatment Group	Post-Baseline	Baseline None n (%)	Baseline Mild n (%)	Baseline Moderate n (%)	Baseline Severe n (%)	Baseline Very Severe n (%)	Baseline Total n (%)
D57	GS1-144 60 mg QD (N=69)	None	1 (1.5)	4 (6.1)	7 (10.6)	2 (3.0)	0	14 (21.2)
		Mild	0	3 (4.5)	19 (28.8)	11 (16.7)	2 (3.0)	35 (53.0)
		Moderate	0	1 (1.5)	8 (12.1)	6 (9.1)	2 (3.0)	17 (25.8)
		Severe	0	0	0	0	0	0
		Very Severe	0	0	0	0	0	0
		Total	1 (1.5)	8 (12.1)	34 (51.5)	19 (28.8)	4 (6.1)	66 (100)
	GS1-144 30 mg BID (N=68)	None	5 (7.9)	4 (6.3)	3 (4.8)	1 (1.6)	1 (1.6)	14 (22.2)
		Mild	1 (1.6)	4 (6.3)	22 (34.9)	9 (14.3)	0	36 (57.1)
		Moderate	0	1 (1.6)	2 (3.2)	7 (11.1)	2 (3.2)	12 (19.0)
		Severe	0	0	0	1 (1.6)	0	1 (1.6)
		Very Severe	0	0	0	0	0	0
		Total	6 (9.5)	9 (14.3)	27 (42.9)	18 (28.6)	3 (4.8)	63 (100)
D85	Placebo (N=69)	None	8 (12.5)	3 (4.7)	8 (12.5)	3 (4.7)	1 (1.6)	23 (35.9)
		Mild	0	3 (4.7)	18 (28.1)	10 (15.6)	2 (3.1)	33 (51.6)
		Moderate	0	1 (1.6)	3 (4.7)	4 (6.3)	0	8 (12.5)
		Severe	0	0	0	0	0	0
		Very Severe	0	0	0	0	0	0
		Total	8 (12.5)	7 (10.9)	29 (45.3)	17 (26.6)	3 (4.7)	64 (100)

Data Source: Listing 16.2.6.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.2.4.2.3
Exploratory Endpoint Analysis 2 - Shift of PGIS by Visit
FAS

Visit	Treatment Group	Post-Baseline	Baseline None n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Very Severe n (%)	Total n (%)
D85	GS1-144 30 mg QD (N=70)	None	1 (1.5)	2 (3.0)	2 (3.0)	2 (3.0)	1 (1.5)	8 (11.9)
		Mild	0	2 (3.0)	25 (37.3)	15 (22.4)	2 (3.0)	44 (65.7)
		Moderate	0	1 (1.5)	7 (10.4)	6 (9.0)	0	14 (20.9)
		Severe	0	0	0	1 (1.5)	0	1 (1.5)
		Very Severe	0	0	0	0	0	0
		Total	1 (1.5)	5 (7.5)	34 (50.7)	24 (35.8)	3 (4.5)	67 (100)
	GS1-144 60 mg QD (N=69)	None	1 (1.5)	3 (4.6)	13 (20.0)	5 (7.7)	1 (1.5)	23 (35.4)
		Mild	0	5 (7.7)	14 (21.5)	11 (16.9)	2 (3.1)	32 (49.2)
		Moderate	0	0	7 (10.8)	2 (3.1)	1 (1.5)	10 (15.4)
		Severe	0	0	0	0	0	0
		Very Severe	0	0	0	0	0	0
		Total	1 (1.5)	8 (12.3)	34 (52.3)	18 (27.7)	4 (6.2)	65 (100)
	GS1-144 30 mg BID (N=68)	None	5 (7.9)	4 (6.3)	4 (6.3)	2 (3.2)	1 (1.6)	16 (25.4)
		Mild	1 (1.6)	5 (7.9)	21 (33.3)	11 (17.5)	1 (1.6)	39 (61.9)
		Moderate	0	0	2 (3.2)	4 (6.3)	1 (1.6)	7 (11.1)
		Severe	0	0	0	1 (1.6)	0	1 (1.6)
		Very Severe	0	0	0	0	0	0
		Total	6 (9.5)	9 (14.3)	27 (42.9)	18 (28.6)	3 (4.8)	63 (100)

Data Source: Listing 16.2.6.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.2.4.3.1
Exploratory Endpoint Analysis 3 - MMRM Analysis of Modified Kupperman Index Total Score
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Baseline	Observed Value				
	n	69	70	69	68
	Mean (SD)	27.3 (9.69)	27.3 (8.40)	26.8 (9.05)	24.9 (8.02)
	Median	27.0	27.0	26.0	24.0
	Q1 - Q3	19.0 - 34.0	21.0 - 32.0	20.0 - 32.0	19.0 - 30.5
	Min - Max	9 - 53	13 - 52	12 - 53	9 - 45
D29	Observed Value				
	n	68	69	67	67
	Mean (SD)	18.3 (7.41)	17.7 (6.93)	17.9 (7.61)	17.2 (7.11)
	Median	17.0	16.0	17.0	17.0
	Q1 - Q3	13.0 - 22.5	13.0 - 22.0	12.0 - 23.0	12.0 - 23.0
	Min - Max	6 - 36	5 - 40	2 - 38	6 - 34

Data Source: Listing 16.2.6.6.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.3.1
Exploratory Endpoint Analysis 3 - MMRM Analysis of Modified Kupperman Index Total Score
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D29	Change from Baseline				
	n	68	69	67	67
	Mean (SD)	-9.0 (7.31)	-9.6 (7.31)	-8.8 (8.24)	-7.7 (5.88)
	Median	-8.0	-8.0	-8.0	-7.0
	Q1 - Q3	-12.0 - -4.0	-13.0 - -4.0	-13.0 - -4.0	-11.0 - -3.0
	Min - Max	-32 - 8	-39 - 3	-34 - 11	-26 - 6
	LS Mean (SE)	-9.354 (0.9292)	-9.960 (0.9263)	-9.502 (0.9452)	-9.264 (0.9459)
	90% CI (2-sided)	-10.887, -7.821	-11.488, -8.432	-11.062, -7.942	-10.824, -7.703
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.606 (0.9799)	-0.148 (0.9876)	0.091 (0.9917)
	90% CI (2-sided)		-2.223, 1.012	-1.778, 1.482	-1.546, 1.727
	P-value		0.5370	0.8810	0.9273

Data Source: Listing 16.2.6.6.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.3.1
Exploratory Endpoint Analysis 3 - MMRM Analysis of Modified Kupperman Index Total Score
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D57	Observed Value				
	n	65	68	66	63
	Mean (SD)	15.9 (6.79)	15.6 (6.87)	14.7 (6.75)	14.6 (7.61)
	Median	15.0	14.0	13.0	14.0
	Q1 - Q3	11.0 - 20.0	10.0 - 20.0	10.0 - 19.0	8.0 - 21.0
	Min - Max	0 - 33	4 - 31	4 - 30	1 - 30
	Change from Baseline				
	n	65	68	66	63
	Mean (SD)	-11.0 (6.98)	-11.7 (7.51)	-11.6 (7.03)	-10.4 (7.04)
	Median	-10.0	-11.0	-11.0	-9.0
	Q1 - Q3	-16.0 - -6.0	-16.0 - -6.0	-16.0 - -6.0	-15.0 - -6.0
	Min - Max	-28 - 4	-40 - 5	-33 - 1	-32 - 4
	LS Mean (SE)	-11.473 (0.9200)	-12.115 (0.9138)	-12.501 (0.9326)	-12.047 (0.9392)
	90% CI (2-sided)	-12.991, -9.955	-13.623, -10.607	-14.040, -10.962	-13.597, -10.498
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.642 (0.9609)	-1.028 (0.9683)	-0.574 (0.9780)
	90% CI (2-sided)		-2.228, 0.944	-2.627, 0.570	-2.189, 1.040
	P-value		0.5045	0.2893	0.5574

Data Source: Listing 16.2.6.6.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.3.1
Exploratory Endpoint Analysis 3 - MMRM Analysis of Modified Kupperman Index Total Score
FAS

Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
D85	Observed Value				
	n	64	67	65	63
	Mean (SD)	13.0 (6.90)	12.9 (6.50)	11.6 (6.94)	12.5 (7.32)
	Median	11.5	12.0	10.0	11.0
	Q1 - Q3	8.0 - 17.0	8.0 - 17.0	8.0 - 15.0	6.0 - 19.0
	Min - Max	0 - 30	2 - 27	0 - 35	0 - 30
	Change from Baseline				
	n	64	67	65	63
	Mean (SD)	-14.0 (9.18)	-14.2 (8.38)	-14.6 (8.37)	-12.5 (7.57)
	Median	-12.0	-16.0	-13.0	-10.0
	Q1 - Q3	-18.5 - -7.0	-19.0 - -7.0	-21.0 - -8.0	-18.0 - -7.0
	Min - Max	-41 - 2	-44 - 3	-38 - 1	-31 - 5
	LS Mean (SE)	-14.311 (0.9825)	-14.646 (0.9752)	-15.563 (0.9924)	-14.289 (1.0018)
	90% CI (2-sided)	-15.932, -12.690	-16.255, -13.038	-17.200, -13.926	-15.942, -12.636
	Difference (GS1-144 v.s. Placebo)				
	LS Mean (SE)		-0.335 (1.0748)	-1.252 (1.0833)	0.022 (1.0950)
	90% CI (2-sided)		-2.110, 1.439	-3.040, 0.536	-1.786, 1.829
	P-value		0.7552	0.2488	0.9842

Data Source: Listing 16.2.6.6.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.3.2
Exploratory Endpoint Analysis 3 - Proportion of Modified Kupperman Index Total Score
FAS

Visit	Category	Placebo N = 69 n(%)	GS1-144 30 mg QD N = 70 n(%)	GS1-144 60 mg QD N = 69 n(%)	GS1-144 30 mg BID N = 68 n(%)
Baseline	Number of subjects (%)	69 (100)	70 (100)	69 (100)	68 (100)
	Normal	0	0	0	0
	Mild	6 (8.7)	3 (4.3)	6 (8.7)	9 (13.2)
	Moderate	37 (53.6)	46 (65.7)	42 (60.9)	42 (61.8)
	Severe	26 (37.7)	21 (30.0)	21 (30.4)	17 (25.0)
D29	Number of subjects (%)	68 (100)	69 (100)	67 (100)	67 (100)
	Normal	0	1 (1.4)	2 (3.0)	0
	Mild	27 (39.7)	33 (47.8)	27 (40.3)	32 (47.8)
	Moderate	35 (51.5)	33 (47.8)	34 (50.7)	32 (47.8)
	Severe	6 (8.8)	2 (2.9)	4 (6.0)	3 (4.5)
D57	Number of subjects (%)	65 (100)	68 (100)	66 (100)	63 (100)
	Normal	1 (1.5)	2 (2.9)	3 (4.5)	9 (14.3)
	Mild	33 (50.8)	34 (50.0)	38 (57.6)	29 (46.0)
	Moderate	30 (46.2)	30 (44.1)	25 (37.9)	25 (39.7)
	Severe	1 (1.5)	2 (2.9)	0	0
D85	Number of subjects (%)	64 (100)	67 (100)	65 (100)	63 (100)
	Normal	5 (7.8)	10 (14.9)	12 (18.5)	11 (17.5)
	Mild	39 (60.9)	38 (56.7)	38 (58.5)	32 (50.8)
	Moderate	20 (31.3)	19 (28.4)	14 (21.5)	20 (31.7)
	Severe	0	0	1 (1.5)	0

Data Source: Listing 16.2.6.6.2
Normal = total score of < 6, Mild = total score 6 - 15, Moderate = total score 16 - 30, and Severe = total score > 30.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on number of subjects at specific visit.

Table 14.2.4.3.3
Exploratory Endpoint Analysis 3 - Shift of Modified Kupperman Index Total Score by Visit
FAS

Visit	Treatment Group	Post-Baseline	Baseline				
			Normal n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Total n (%)
D29	Placebo (N=69)	Normal	0	0	0	0	0
		Mild	0	6 (8.8)	18 (26.5)	3 (4.4)	27 (39.7)
		Moderate	0	0	18 (26.5)	17 (25.0)	35 (51.5)
		Severe	0	0	0	6 (8.8)	6 (8.8)
		Total	0	6 (8.8)	36 (52.9)	26 (38.2)	68 (100)
	GS1-144 30 mg QD (N=70)	Normal	0	0	1 (1.4)	0	1 (1.4)
		Mild	0	3 (4.3)	28 (40.6)	2 (2.9)	33 (47.8)
		Moderate	0	0	16 (23.2)	17 (24.6)	33 (47.8)
		Severe	0	0	0	2 (2.9)	2 (2.9)
		Total	0	3 (4.3)	45 (65.2)	21 (30.4)	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	0	0	2 (3.0)	0	2 (3.0)
		Mild	0	6 (9.0)	18 (26.9)	3 (4.5)	27 (40.3)
		Moderate	0	0	19 (28.4)	15 (22.4)	34 (50.7)
		Severe	0	0	2 (3.0)	2 (3.0)	4 (6.0)
		Total	0	6 (9.0)	41 (61.2)	20 (29.9)	67 (100)
	GS1-144 30 mg BID (N=68)	Normal	0	0	0	0	0
		Mild	0	9 (13.4)	21 (31.3)	2 (3.0)	32 (47.8)
		Moderate	0	0	20 (29.9)	12 (17.9)	32 (47.8)
		Severe	0	0	0	3 (4.5)	3 (4.5)
		Total	0	9 (13.4)	41 (61.2)	17 (25.4)	67 (100)

Data Source: Listing 16.2.6.6.2
Normal = total score of < 6, Mild = total score 6 - 15, Moderate = total score 16 -30, and Severe = total score > 30.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.2.4.3.3
Exploratory Endpoint Analysis 3 - Shift of Modified Kupperman Index Total Score by Visit
FAS

Visit	Treatment Group	Post-Baseline	Baseline				
			Normal n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Total n (%)
D57	Placebo (N=69)	Normal	0	0	1 (1.5)	0	1 (1.5)
		Mild	0	6 (9.2)	20 (30.8)	7 (10.8)	33 (50.8)
		Moderate	0	0	14 (21.5)	16 (24.6)	30 (46.2)
		Severe	0	0	0	1 (1.5)	1 (1.5)
		Total	0	6 (9.2)	35 (53.8)	24 (36.9)	65 (100)
	GS1-144 30 mg QD (N=70)	Normal	0	0	2 (2.9)	0	2 (2.9)
		Mild	0	3 (4.4)	27 (39.7)	4 (5.9)	34 (50.0)
		Moderate	0	0	15 (22.1)	15 (22.1)	30 (44.1)
		Severe	0	0	0	2 (2.9)	2 (2.9)
		Total	0	3 (4.4)	44 (64.7)	21 (30.9)	68 (100)
	GS1-144 60 mg QD (N=69)	Normal	0	0	2 (3.0)	1 (1.5)	3 (4.5)
		Mild	0	6 (9.1)	28 (42.4)	4 (6.1)	38 (57.6)
		Moderate	0	0	11 (16.7)	14 (21.2)	25 (37.9)
		Severe	0	0	0	0	0
		Total	0	6 (9.1)	41 (62.1)	19 (28.8)	66 (100)
	GS1-144 30 mg BID (N=68)	Normal	0	2 (3.2)	6 (9.5)	1 (1.6)	9 (14.3)
		Mild	0	6 (9.5)	21 (33.3)	2 (3.2)	29 (46.0)
		Moderate	0	0	13 (20.6)	12 (19.0)	25 (39.7)
		Severe	0	0	0	0	0
		Total	0	8 (12.7)	40 (63.5)	15 (23.8)	63 (100)

Data Source: Listing 16.2.6.6.2
Normal = total score of < 6, Mild = total score 6 - 15, Moderate = total score 16 -30, and Severe = total score > 30.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.2.4.3.3
Exploratory Endpoint Analysis 3 - Shift of Modified Kupperman Index Total Score by Visit
FAS

Visit	Treatment Group	Post-Baseline	Baseline				
			Normal n (%)	Mild n (%)	Moderate n (%)	Severe n (%)	Total n (%)
D85	Placebo (N=69)	Normal	0	0	3 (4.7)	2 (3.1)	5 (7.8)
		Mild	0	6 (9.4)	22 (34.4)	11 (17.2)	39 (60.9)
		Moderate	0	0	9 (14.1)	11 (17.2)	20 (31.3)
		Severe	0	0	0	0	0
		Total	0	6 (9.4)	34 (53.1)	24 (37.5)	64 (100)
	GS1-144 30 mg QD (N=70)	Normal	0	1 (1.5)	9 (13.4)	0	10 (14.9)
		Mild	0	2 (3.0)	27 (40.3)	9 (13.4)	38 (56.7)
		Moderate	0	0	8 (11.9)	11 (16.4)	19 (28.4)
		Severe	0	0	0	0	0
		Total	0	3 (4.5)	44 (65.7)	20 (29.9)	67 (100)
	GS1-144 60 mg QD (N=69)	Normal	0	1 (1.5)	10 (15.4)	1 (1.5)	12 (18.5)
		Mild	0	5 (7.7)	25 (38.5)	8 (12.3)	38 (58.5)
		Moderate	0	0	6 (9.2)	8 (12.3)	14 (21.5)
		Severe	0	0	0	1 (1.5)	1 (1.5)
		Total	0	6 (9.2)	41 (63.1)	18 (27.7)	65 (100)
	GS1-144 30 mg BID (N=68)	Normal	0	3 (4.8)	7 (11.1)	1 (1.6)	11 (17.5)
		Mild	0	5 (7.9)	22 (34.9)	5 (7.9)	32 (50.8)
		Moderate	0	0	11 (17.5)	9 (14.3)	20 (31.7)
		Severe	0	0	0	0	0
		Total	0	8 (12.7)	40 (63.5)	15 (23.8)	63 (100)

Data Source: Listing 16.2.6.6.2
Normal = total score of < 6, Mild = total score 6 - 15, Moderate = total score 16 -30, and Severe = total score > 30.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Vasomotor	Baseline	Observed Value				
		n	69	70	69	68
		Mean (SD)	6.043 (0.9834)	6.200 (1.0532)	5.918 (1.1707)	6.015 (0.9401)
		Median	6.000	6.333	6.000	6.000
		Q1 - Q3	5.333 - 6.667	5.333 - 7.000	5.333 - 6.667	5.333 - 6.667
		Min - Max	3.00 - 8.00	3.33 - 8.00	1.00 - 8.00	3.67 - 8.00
	D29	Observed Value				
		n	68	69	67	67
		Mean (SD)	4.480 (1.2818)	4.435 (1.3628)	4.313 (1.3570)	4.149 (1.1896)
		Median	4.667	4.333	4.667	4.333
		Q1 - Q3	3.667 - 5.333	3.667 - 5.000	3.333 - 5.333	3.333 - 5.000
		Min - Max	1.33 - 7.67	1.00 - 7.67	1.00 - 7.33	1.33 - 6.67

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Vasomotor	D29	Change from Baseline				
		n	68	69	67	67
		Mean (SD)	-1.574 (1.3455)	-1.783 (1.2958)	-1.592 (1.3790)	-1.876 (1.1675)
		Median	-1.333	-2.000	-1.333	-1.667
		Q1 - Q3	-2.333 - -0.667	-2.667 - -0.667	-2.333 - -1.000	-2.667 - -1.000
		Min - Max	-5.33 - 1.00	-5.00 - 1.00	-6.33 - 1.67	-5.33 - 0.00
		LS Mean (SE)	-1.855 (0.1908)	-1.985 (0.1911)	-1.956 (0.1940)	-2.181 (0.1941)
		90% CI (2-sided)	-2.170, -1.541	-2.301, -1.670	-2.276, -1.636	-2.501, -1.861
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.130 (0.2028)	-0.100 (0.2043)	-0.325 (0.2041)
		90% CI (2-sided)		-0.465, 0.205	-0.437, 0.237	-0.662, 0.011
		P-value		0.5226	0.6246	0.1120

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Vasomotor	D57	Observed Value				
		n	65	68	66	63
		Mean (SD)	3.656 (1.3163)	3.922 (1.4026)	3.672 (0.9723)	3.455 (1.1521)
		Median	3.667	3.833	3.833	3.333
		Q1 - Q3	3.000 - 4.667	3.000 - 4.833	3.000 - 4.333	3.000 - 4.000
		Min - Max	1.00 - 7.00	1.00 - 8.00	1.00 - 6.00	1.00 - 6.00
		Change from Baseline				
		n	65	68	66	63
		Mean (SD)	-2.385 (1.3414)	-2.289 (1.4749)	-2.212 (1.1689)	-2.561 (1.2498)
		Median	-2.000	-2.333	-2.000	-2.667
		Q1 - Q3	-3.333 - -1.667	-3.333 - -1.333	-3.000 - -1.333	-3.333 - -1.667
		Min - Max	-5.33 - 0.33	-5.00 - 1.00	-4.67 - 0.67	-6.33 - 0.00
		LS Mean (SE)	-2.654 (0.1882)	-2.489 (0.1878)	-2.621 (0.1906)	-2.882 (0.1920)
		90% CI (2-sided)	-2.965, -2.344	-2.799, -2.180	-2.935, -2.306	-3.199, -2.565
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.165 (0.1975)	0.034 (0.1989)	-0.228 (0.2000)
		90% CI (2-sided)		-0.161, 0.491	-0.295, 0.362	-0.558, 0.102
		P-value		0.4044	0.8662	0.2555

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Vasomotor	D85	Observed Value				
		n	64	67	65	63
		Mean (SD)	3.125 (1.3327)	3.144 (1.4428)	2.964 (1.1609)	3.127 (1.1445)
		Median	3.000	3.000	3.000	3.000
		Q1 - Q3	2.000 - 4.333	2.000 - 4.000	2.333 - 3.667	2.333 - 4.000
		Min - Max	1.00 - 7.00	1.00 - 6.67	1.00 - 6.00	1.00 - 5.67
		Change from Baseline				
		n	64	67	65	63
		Mean (SD)	-2.922 (1.5162)	-3.050 (1.5883)	-2.933 (1.3658)	-2.889 (1.2269)
		Median	-2.833	-3.000	-3.000	-3.000
		Q1 - Q3	-4.000 - -1.833	-4.333 - -1.667	-3.667 - -2.000	-3.667 - -2.000
		Min - Max	-6.33 - 0.00	-5.67 - 0.33	-7.00 - 0.00	-6.33 - 0.00
		LS Mean (SE)	-3.183 (0.1974)	-3.257 (0.1970)	-3.349 (0.1994)	-3.210 (0.2011)
		90% CI (2-sided)	-3.508, -2.857	-3.582, -2.932	-3.678, -3.020	-3.541, -2.878
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.074 (0.2143)	-0.167 (0.2159)	-0.027 (0.2173)
		90% CI (2-sided)		-0.428, 0.279	-0.523, 0.190	-0.386, 0.332
		P-value		0.7289	0.4408	0.9010

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Psychosocial	Baseline	Observed Value				
		n	69	70	69	68
		Mean (SD)	3.675 (1.8793)	3.769 (1.8071)	3.551 (1.6342)	3.439 (1.6294)
		Median	3.143	3.786	3.429	3.286
		Q1 - Q3	2.143 - 5.286	2.143 - 5.143	2.143 - 4.857	1.929 - 4.714
		Min - Max	1.00 - 7.71	1.14 - 7.71	1.00 - 6.57	1.00 - 7.14
	D29	Observed Value				
		n	68	69	67	67
		Mean (SD)	2.975 (1.5984)	2.870 (1.5158)	2.642 (1.3980)	2.751 (1.2698)
		Median	2.786	2.857	2.286	2.714
		Q1 - Q3	1.571 - 4.143	1.429 - 3.857	1.571 - 3.429	1.714 - 3.571
		Min - Max	1.00 - 7.29	1.00 - 7.29	1.00 - 6.14	1.00 - 6.14

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Psychosocial	D29	Change from Baseline				
		n	68	69	67	67
		Mean (SD)	-0.718 (1.0722)	-0.905 (1.3398)	-0.900 (1.2168)	-0.719 (1.0156)
		Median	-0.429	-0.714	-0.571	-0.429
		Q1 - Q3	-1.143 - 0.000	-1.571 - -0.143	-1.714 - 0.000	-1.143 - -0.143
		Min - Max	-5.29 - 0.71	-4.14 - 4.71	-4.86 - 2.00	-5.71 - 0.71
		LS Mean (SE)	-0.713 (0.1518)	-0.869 (0.1513)	-0.953 (0.1544)	-0.799 (0.1545)
		90% CI (2-sided)	-0.963, -0.463	-1.118, -0.619	-1.207, -0.698	-1.054, -0.544
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.156 (0.1654)	-0.240 (0.1667)	-0.086 (0.1668)
		90% CI (2-sided)		-0.429, 0.117	-0.515, 0.035	-0.361, 0.189
		P-value		0.3474	0.1517	0.6072

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Psychosocial	D57	Observed Value				
		n	65	68	66	63
		Mean (SD)	2.343 (1.1279)	2.479 (1.2333)	2.136 (0.9344)	2.474 (1.1743)
		Median	2.143	2.357	1.929	2.429
		Q1 - Q3	1.571 - 3.000	1.286 - 3.357	1.286 - 2.714	1.571 - 3.429
		Min - Max	1.00 - 5.14	1.00 - 5.71	1.00 - 5.14	1.00 - 5.14
		Change from Baseline				
		n	65	68	66	63
		Mean (SD)	-1.273 (1.4762)	-1.279 (1.3991)	-1.361 (1.2942)	-1.007 (1.2183)
		Median	-0.857	-1.000	-1.000	-0.571
		Q1 - Q3	-2.000 - -0.143	-2.214 - -0.286	-2.143 - -0.286	-1.571 - -0.286
		Min - Max	-5.57 - 0.86	-4.29 - 2.43	-4.86 - 0.29	-5.71 - 0.86
		LS Mean (SE)	-1.276 (0.1445)	-1.220 (0.1435)	-1.479 (0.1466)	-1.115 (0.1476)
		90% CI (2-sided)	-1.515, -1.038	-1.456, -0.983	-1.721, -1.237	-1.359, -0.871
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.057 (0.1516)	-0.203 (0.1528)	0.161 (0.1538)
		90% CI (2-sided)		-0.194, 0.307	-0.455, 0.049	-0.093, 0.415
		P-value		0.7086	0.1852	0.2955

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Psychosocial	D85	Observed Value				
		n	64	67	65	63
		Mean (SD)	2.118 (1.0961)	2.066 (1.0053)	1.996 (0.9823)	2.288 (1.1118)
		Median	1.857	1.714	1.857	1.857
		Q1 - Q3	1.143 - 2.857	1.286 - 2.571	1.286 - 2.429	1.286 - 3.143
		Min - Max	1.00 - 5.43	1.00 - 5.00	1.00 - 5.43	1.00 - 4.86
		Change from Baseline				
		n	64	67	65	63
		Mean (SD)	-1.520 (1.6674)	-1.665 (1.5156)	-1.492 (1.3446)	-1.193 (1.3174)
		Median	-1.071	-1.286	-1.286	-1.000
		Q1 - Q3	-2.500 - -0.286	-2.857 - -0.571	-2.571 - -0.286	-1.857 - -0.286
		Min - Max	-6.71 - 0.57	-5.43 - 1.29	-4.57 - 0.57	-5.71 - 0.57
		LS Mean (SE)	-1.507 (0.1455)	-1.614 (0.1447)	-1.617 (0.1474)	-1.308 (0.1485)
		90% CI (2-sided)	-1.747, -1.267	-1.853, -1.376	-1.860, -1.374	-1.554, -1.063
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.108 (0.1533)	-0.110 (0.1545)	0.198 (0.1558)
		90% CI (2-sided)		-0.361, 0.146	-0.365, 0.145	-0.059, 0.456
		P-value		0.4837	0.4767	0.2039

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Physical	Baseline	Observed Value				
		n	69	70	69	68
		Mean (SD)	3.251 (1.4516)	3.211 (1.2727)	3.121 (1.2960)	2.994 (1.3511)
		Median	3.000	2.875	2.938	2.781
		Q1 - Q3	2.000 - 4.250	2.250 - 4.125	2.063 - 4.000	2.000 - 3.813
		Min - Max	1.00 - 6.50	1.25 - 6.44	1.13 - 6.19	1.00 - 6.94
	D29	Observed Value				
		n	68	69	67	67
		Mean (SD)	2.624 (1.2476)	2.456 (0.9887)	2.391 (0.8978)	2.445 (1.0976)
		Median	2.313	2.313	2.250	2.250
		Q1 - Q3	1.594 - 3.313	1.625 - 3.125	1.688 - 3.000	1.688 - 3.125
		Min - Max	1.00 - 6.75	1.00 - 5.25	1.00 - 5.38	1.00 - 5.69

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Physical	D29	Change from Baseline				
		n	68	69	67	67
		Mean (SD)	-0.636 (0.9857)	-0.760 (0.9512)	-0.726 (0.8677)	-0.564 (0.7344)
		Median	-0.438	-0.500	-0.563	-0.438
		Q1 - Q3	-1.188 - -0.063	-1.125 - -0.188	-1.125 - -0.250	-0.938 - -0.063
		Min - Max	-4.69 - 1.81	-3.19 - 2.50	-3.31 - 1.69	-2.69 - 0.94
		LS Mean (SE)	-0.647 (0.1119)	-0.789 (0.1114)	-0.797 (0.1137)	-0.679 (0.1137)
		90% CI (2-sided)	-0.831, -0.462	-0.973, -0.605	-0.984, -0.609	-0.866, -0.491
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.142 (0.1202)	-0.150 (0.1212)	-0.032 (0.1213)
		90% CI (2-sided)		-0.340, 0.056	-0.350, 0.050	-0.232, 0.168
		P-value		0.2381	0.2175	0.7929

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Physical	D57	Observed Value				
		n	65	68	66	63
		Mean (SD)	2.211 (0.9408)	2.238 (0.8640)	2.085 (0.7606)	2.234 (0.9231)
		Median	2.063	2.219	2.031	2.125
		Q1 - Q3	1.438 - 2.625	1.531 - 2.719	1.438 - 2.563	1.375 - 2.875
		Min - Max	1.00 - 4.81	1.00 - 5.13	1.00 - 4.31	1.00 - 4.44
		Change from Baseline				
		n	65	68	66	63
		Mean (SD)	-0.999 (1.1134)	-0.975 (1.0299)	-0.993 (0.8884)	-0.802 (0.9258)
		Median	-0.688	-0.625	-0.719	-0.563
		Q1 - Q3	-1.688 - -0.188	-1.594 - -0.313	-1.750 - -0.313	-1.313 - -0.188
		Min - Max	-5.06 - 0.50	-3.94 - 0.69	-3.38 - 0.50	-3.44 - 1.44
		LS Mean (SE)	-1.003 (0.1080)	-1.001 (0.1071)	-1.102 (0.1094)	-0.911 (0.1102)
		90% CI (2-sided)	-1.182, -0.825	-1.178, -0.825	-1.283, -0.922	-1.093, -0.729
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.002 (0.1127)	-0.099 (0.1136)	0.093 (0.1146)
		90% CI (2-sided)		-0.184, 0.188	-0.286, 0.089	-0.097, 0.282
		P-value		0.9863	0.3846	0.4203

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Physical	D85	Observed Value				
		n	64	67	65	63
		Mean (SD)	2.063 (0.8653)	2.032 (0.9258)	1.978 (0.8204)	2.157 (0.9982)
		Median	1.844	1.750	1.938	1.938
		Q1 - Q3	1.375 - 2.688	1.313 - 2.500	1.313 - 2.375	1.313 - 2.750
		Min - Max	1.00 - 4.44	1.00 - 5.06	1.00 - 4.94	1.00 - 5.06
		Change from Baseline				
		n	64	67	65	63
		Mean (SD)	-1.167 (1.2308)	-1.183 (1.1949)	-1.102 (0.9852)	-0.879 (0.8671)
		Median	-0.813	-1.000	-0.813	-0.750
		Q1 - Q3	-2.063 - -0.313	-2.188 - -0.313	-1.625 - -0.313	-1.313 - -0.250
		Min - Max	-5.19 - 0.75	-5.31 - 1.06	-4.13 - 0.63	-3.50 - 1.25
		LS Mean (SE)	-1.157 (0.1154)	-1.204 (0.1144)	-1.199 (0.1165)	-0.994 (0.1175)
		90% CI (2-sided)	-1.347, -0.967	-1.393, -1.016	-1.391, -1.007	-1.187, -0.800
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.047 (0.1261)	-0.042 (0.1272)	0.163 (0.1283)
		90% CI (2-sided)		-0.256, 0.161	-0.252, 0.168	-0.048, 0.375
		P-value		0.7079	0.7434	0.2036

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Sexual	Baseline	Observed Value				
		n	69	70	69	68
		Mean (SD)	3.952 (2.3181)	4.076 (2.1007)	3.541 (1.9132)	3.525 (2.1727)
		Median	3.333	3.667	3.333	3.167
		Q1 - Q3	2.000 - 6.000	2.667 - 5.667	2.000 - 5.000	1.667 - 5.333
		Min - Max	1.00 - 8.00	1.00 - 8.00	1.00 - 8.00	1.00 - 8.00
	D29	Observed Value				
		n	68	69	67	67
		Mean (SD)	3.221 (2.2010)	3.019 (1.8488)	2.920 (1.6269)	3.124 (1.9226)
		Median	2.333	2.333	2.333	3.000
		Q1 - Q3	1.333 - 4.333	1.667 - 4.333	1.667 - 4.000	1.333 - 4.667
		Min - Max	1.00 - 8.00	1.00 - 8.00	1.00 - 7.00	1.00 - 8.00

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Sexual	D29	Change from Baseline				
		n	68	69	67	67
		Mean (SD)	-0.755 (1.3624)	-1.053 (1.2778)	-0.607 (1.3925)	-0.438 (1.0286)
		Median	0.000	-0.667	0.000	0.000
		Q1 - Q3	-1.333 - 0.000	-2.000 - 0.000	-1.000 - 0.000	-1.000 - 0.000
		Min - Max	-5.00 - 2.00	-4.00 - 2.67	-7.00 - 1.67	-3.00 - 3.33
		LS Mean (SE)	-0.580 (0.1892)	-0.851 (0.1888)	-0.553 (0.1928)	-0.374 (0.1927)
		90% CI (2-sided)	-0.893, -0.268	-1.163, -0.540	-0.871, -0.235	-0.692, -0.056
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.271 (0.1930)	0.027 (0.1950)	0.206 (0.1949)
		90% CI (2-sided)		-0.590, 0.048	-0.295, 0.349	-0.116, 0.528
		P-value		0.1615	0.8889	0.2913

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Sexual	D57	Observed Value				
		n	65	68	66	63
		Mean (SD)	2.615 (1.7866)	2.775 (1.7586)	2.601 (1.6058)	2.984 (1.9068)
		Median	2.000	2.167	2.333	2.667
		Q1 - Q3	1.000 - 3.333	1.167 - 3.833	1.000 - 3.667	1.000 - 4.000
		Min - Max	1.00 - 8.00	1.00 - 8.00	1.00 - 7.00	1.00 - 8.00
		Change from Baseline				
		n	65	68	66	63
		Mean (SD)	-1.272 (1.7459)	-1.309 (1.6353)	-0.929 (1.6325)	-0.667 (1.4066)
		Median	-0.667	-1.000	-0.667	0.000
		Q1 - Q3	-2.667 - 0.000	-2.333 - 0.000	-1.667 - 0.000	-1.000 - 0.000
		Min - Max	-6.33 - 2.33	-6.33 - 2.33	-6.67 - 4.33	-4.67 - 3.33
		LS Mean (SE)	-1.080 (0.2071)	-1.074 (0.2055)	-0.920 (0.2096)	-0.599 (0.2112)
		90% CI (2-sided)	-1.421, -0.738	-1.413, -0.735	-1.266, -0.575	-0.947, -0.250
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.005 (0.2259)	0.159 (0.2280)	0.481 (0.2295)
		90% CI (2-sided)		-0.367, 0.378	-0.217, 0.536	0.102, 0.860
		P-value		0.9810	0.4853	0.0370

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Sexual	D85	Observed Value				
		n	64	67	65	63
		Mean (SD)	2.458 (1.6908)	2.532 (1.7466)	2.559 (1.6616)	2.915 (1.7980)
		Median	2.000	2.000	2.333	2.333
		Q1 - Q3	1.000 - 3.000	1.000 - 3.333	1.000 - 3.333	1.000 - 4.333
		Min - Max	1.00 - 7.33	1.00 - 8.00	1.00 - 7.67	1.00 - 7.33
		Change from Baseline				
		n	64	67	65	63
		Mean (SD)	-1.458 (1.7872)	-1.557 (1.9231)	-0.964 (1.6998)	-0.735 (1.4220)
		Median	-1.333	-1.333	-0.667	-0.333
		Q1 - Q3	-2.500 - 0.000	-2.667 - 0.000	-1.667 - 0.000	-1.333 - 0.000
		Min - Max	-6.33 - 1.00	-6.33 - 2.33	-7.00 - 4.00	-4.67 - 4.00
		LS Mean (SE)	-1.242 (0.2113)	-1.296 (0.2098)	-0.959 (0.2137)	-0.676 (0.2152)
		90% CI (2-sided)	-1.590, -0.893	-1.642, -0.950	-1.311, -0.606	-1.031, -0.320
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.054 (0.2335)	0.283 (0.2357)	0.566 (0.2370)
		90% CI (2-sided)		-0.440, 0.331	-0.106, 0.672	0.175, 0.957
		P-value		0.8158	0.2305	0.0176

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Total	Baseline	Observed Value				
		n	69	70	69	68
		Mean (SD)	4.230 (1.4477)	4.314 (1.2700)	4.033 (1.1885)	3.993 (1.2683)
		Median	4.058	4.151	3.889	3.896
		Q1 - Q3	3.127 - 5.313	3.358 - 5.191	3.150 - 5.096	2.985 - 5.156
		Min - Max	1.87 - 7.39	2.28 - 7.04	1.94 - 6.53	1.77 - 7.08
	D29	Observed Value				
		n	68	69	67	67
		Mean (SD)	3.325 (1.3455)	3.195 (1.1325)	3.067 (1.0420)	3.117 (1.1474)
		Median	3.041	3.013	2.836	3.032
		Q1 - Q3	2.279 - 4.231	2.365 - 3.903	2.347 - 3.609	2.100 - 4.092
		Min - Max	1.48 - 7.43	1.25 - 6.86	1.20 - 6.12	1.13 - 6.37

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Total	D29	Change from Baseline				
		n	68	69	67	67
		Mean (SD)	-0.921 (0.8957)	-1.125 (0.9157)	-0.956 (0.8291)	-0.899 (0.7017)
		Median	-0.715	-1.015	-0.783	-0.824
		Q1 - Q3	-1.417 - -0.359	-1.670 - -0.613	-1.435 - -0.365	-1.227 - -0.410
		Min - Max	-4.41 - 0.64	-3.20 - 1.36	-3.29 - 1.01	-3.18 - 0.87
		LS Mean (SE)	-0.958 (0.1222)	-1.140 (0.1220)	-1.063 (0.1244)	-1.008 (0.1244)
		90% CI (2-sided)	-1.160, -0.756	-1.341, -0.939	-1.268, -0.857	-1.213, -0.802
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.182 (0.1273)	-0.105 (0.1285)	-0.050 (0.1285)
		90% CI (2-sided)		-0.392, 0.028	-0.317, 0.107	-0.262, 0.162
		P-value		0.1537	0.4155	0.6995

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Total	D57	Observed Value				
		n	65	68	66	63
		Mean (SD)	2.706 (1.0341)	2.853 (1.0574)	2.624 (0.8620)	2.787 (1.0407)
		Median	2.548	2.785	2.510	2.661
		Q1 - Q3	1.865 - 3.401	1.954 - 3.458	2.006 - 3.052	1.867 - 3.553
		Min - Max	1.00 - 5.28	1.45 - 5.53	1.12 - 5.54	1.08 - 4.94
		Change from Baseline				
		n	65	68	66	63
		Mean (SD)	-1.482 (1.1182)	-1.463 (1.0453)	-1.374 (0.9257)	-1.259 (0.8837)
		Median	-1.379	-1.297	-1.123	-1.124
		Q1 - Q3	-2.045 - -0.622	-2.119 - -0.831	-1.919 - -0.670	-1.964 - -0.629
		Min - Max	-5.33 - 0.51	-4.04 - 0.94	-3.73 - 0.04	-3.58 - 1.24
		LS Mean (SE)	-1.509 (0.1251)	-1.457 (0.1243)	-1.535 (0.1268)	-1.378 (0.1276)
		90% CI (2-sided)	-1.716, -1.303	-1.662, -1.252	-1.744, -1.326	-1.588, -1.167
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		0.052 (0.1324)	-0.026 (0.1336)	0.131 (0.1345)
		90% CI (2-sided)		-0.167, 0.271	-0.246, 0.195	-0.091, 0.353
		P-value		0.6943	0.8466	0.3297

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.4
Exploratory Endpoint Analysis 4 - MMRM Analysis of MENQOL Score
FAS

Domain	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Total	D85	Observed Value				
		n	64	67	65	63
		Mean (SD)	2.441 (0.9583)	2.444 (1.0223)	2.374 (0.9550)	2.622 (1.0524)
		Median	2.251	2.101	2.260	2.385
		Q1 - Q3	1.739 - 2.971	1.768 - 2.920	1.687 - 2.820	1.801 - 3.320
		Min - Max	1.00 - 5.14	1.10 - 5.29	1.00 - 6.01	1.08 - 4.94
		Change from Baseline				
		n	64	67	65	63
		Mean (SD)	-1.767 (1.2614)	-1.864 (1.2242)	-1.623 (1.0231)	-1.424 (0.9042)
		Median	-1.715	-1.740	-1.525	-1.264
		Q1 - Q3	-2.645 - -0.775	-2.609 - -1.083	-2.282 - -0.842	-1.896 - -0.896
		Min - Max	-6.14 - 0.10	-5.35 - 0.57	-4.15 - -0.10	-3.88 - 1.42
		LS Mean (SE)	-1.776 (0.1316)	-1.852 (0.1307)	-1.787 (0.1330)	-1.550 (0.1341)
		90% CI (2-sided)	-1.993, -1.559	-2.068, -1.636	-2.006, -1.567	-1.772, -1.329
		Difference (GS1-144 v.s. Placebo)				
		LS Mean (SE)		-0.076 (0.1442)	-0.011 (0.1454)	0.226 (0.1465)
		90% CI (2-sided)		-0.314, 0.162	-0.251, 0.229	-0.016, 0.467
		P-value		0.5982	0.9401	0.1250

Data Source: Listing 16.2.6.7.2
LS = Least Squares; SE = Standard Errors; CI = Confidence Interval.
The p-values were nominal.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Treatment comparisons were performed using a mixed-effect model for repeated measures (MMRM) incorporating post-baseline data collected up to D85, with treatment group, stratification factor BMI and visit as factors, and baseline measurement as covariate, as well as treatment by visit interaction and baseline measurement by visit interaction.
Observed data were used and missing values were not imputed.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Follicle Stimulating Hormone (IU/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	66.076 (24.6143)	66.776 (25.4683)	68.945 (25.8618)	71.243 (20.3987)	68.966 (24.0149)	68.244 (24.1536)
		Median	64.360	65.550	68.730	70.560	68.160	66.295
		Q1 - Q3	48.850 - 76.190	52.690 - 79.810	50.720 - 82.490	58.920 - 83.885	53.580 - 82.070	52.850 - 81.810
		Min - Max	11.44 - 140.04	4.52 - 144.69	25.66 - 150.00	25.82 - 139.39	4.52 - 150.00	4.52 - 150.00
	D15	Observed Value						
		n	69	70	67	68	205	274
		Mean (SD)	65.425 (26.6619)	68.772 (26.4183)	68.980 (26.0007)	70.254 (19.2315)	69.331 (24.0142)	68.348 (24.7159)
		Median	61.840	65.425	66.730	67.570	66.730	65.445
		Q1 - Q3	49.670 - 76.660	52.010 - 78.390	50.910 - 86.220	57.615 - 82.720	53.340 - 82.610	52.630 - 81.820
		Min - Max	9.02 - 138.75	5.25 - 150.00	15.65 - 150.00	27.37 - 138.85	5.25 - 150.00	5.25 - 150.00
	D15	Change from Baseline						
		n	69	70	67	68	205	274
		Mean (SD)	-0.651 (10.5932)	1.995 (10.7737)	-0.117 (8.6794)	-0.989 (9.3916)	0.315 (9.7055)	0.072 (9.9256)
		Median	-0.180	1.625	1.390	0.400	0.930	0.570
		Q1 - Q3	-3.220 - 4.370	-2.280 - 4.870	-3.630 - 5.080	-4.555 - 3.150	-3.630 - 4.070	-3.440 - 4.240
		Min - Max	-41.42 - 24.92	-42.10 - 44.00	-28.65 - 20.64	-49.87 - 17.23	-49.87 - 44.00	-49.87 - 44.00

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Follicle Stimulating Hormone (IU/L)	D29	Observed Value						
		n	66	69	67	67	203	269
		Mean (SD)	63.233 (24.0373)	66.068 (26.4361)	67.589 (25.7852)	66.095 (20.7032)	66.579 (24.3526)	65.758 (24.2738)
		Median	60.695	66.350	66.370	65.050	66.230	64.860
		Q1 - Q3	45.060 - 79.870	50.070 - 77.040	49.920 - 84.120	52.210 - 78.270	50.770 - 79.520	50.070 - 79.520
		Min - Max	6.69 - 117.17	6.83 - 143.16	12.57 - 150.00	11.08 - 143.73	6.83 - 150.00	6.69 - 150.00
	D29	Change from Baseline						
		n	66	69	67	67	203	269
		Mean (SD)	-1.905 (10.2285)	-0.682 (9.5640)	-1.610 (13.4629)	-5.037 (15.7284)	-2.425 (13.2046)	-2.298 (12.5238)
		Median	-1.015	-0.260	-0.520	-1.670	-0.520	-0.800
		Q1 - Q3	-4.630 - 1.810	-3.040 - 2.260	-4.970 - 3.770	-10.830 - 3.270	-5.850 - 3.270	-5.220 - 2.760
		Min - Max	-38.39 - 32.61	-36.81 - 19.78	-64.33 - 38.15	-68.35 - 20.12	-68.35 - 38.15	-68.35 - 38.15
	D43	Observed Value						
		n	65	69	67	64	200	265
		Mean (SD)	62.228 (25.5492)	65.025 (26.3713)	66.166 (24.9045)	64.657 (20.4821)	65.289 (24.0118)	64.538 (24.3843)
		Median	60.490	64.010	61.300	63.220	62.720	61.280
		Q1 - Q3	47.350 - 76.370	51.210 - 77.790	48.750 - 80.130	54.175 - 78.380	51.120 - 79.580	49.950 - 78.400
		Min - Max	5.89 - 128.61	7.28 - 148.75	24.76 - 150.00	12.59 - 116.06	7.28 - 150.00	5.89 - 150.00

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Follicle Stimulating Hormone (IU/L)	D43	Change from Baseline						
		n	65	69	67	64	200	265
		Mean (SD)	-2.912 (10.4508)	-1.725 (9.6868)	-3.033 (12.5998)	-6.305 (12.2702)	-3.629 (11.6645)	-3.453 (11.3637)
		Median	-3.240	-1.040	-2.270	-4.810	-2.170	-2.600
		Q1 - Q3	-6.630 - 1.190	-4.610 - 2.430	-7.520 - 2.450	-12.445 - 1.880	-7.635 - 2.290	-7.430 - 2.150
		Min - Max	-35.58 - 24.34	-52.28 - 29.32	-49.02 - 47.57	-50.85 - 26.04	-52.28 - 47.57	-52.28 - 47.57
	D57	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	61.876 (25.1190)	64.189 (23.6221)	64.660 (24.2233)	66.466 (19.0095)	65.077 (22.3642)	64.280 (23.0728)
		Median	58.420	62.190	61.070	65.300	63.250	61.070
		Q1 - Q3	48.180 - 80.000	48.865 - 72.250	45.810 - 84.410	53.600 - 79.290	49.700 - 78.410	49.070 - 78.500
		Min - Max	14.76 - 136.14	11.66 - 141.92	24.66 - 150.00	12.00 - 127.16	11.66 - 150.00	11.66 - 150.00
	D57	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-3.683 (12.7768)	-2.633 (10.4538)	-4.893 (11.1017)	-5.083 (11.6707)	-4.170 (11.0712)	-4.049 (11.4960)
		Median	-3.970	-2.100	-3.330	-4.530	-3.085	-3.280
		Q1 - Q3	-9.610 - -0.050	-8.095 - 1.230	-9.630 - 0.970	-9.050 - 2.460	-8.940 - 1.390	-9.400 - 1.050
		Min - Max	-45.03 - 40.11	-26.79 - 42.96	-47.85 - 35.60	-51.44 - 30.24	-51.44 - 42.96	-51.44 - 42.96

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Follicle Stimulating Hormone (IU/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	63.060 (24.0361)	61.643 (26.3527)	65.801 (25.8529)	66.027 (20.9739)	64.431 (24.5357)	64.090 (24.3734)
		Median	57.650	59.700	60.250	64.820	60.910	60.250
		Q1 - Q3	45.630 - 78.850	46.305 - 71.300	45.660 - 84.530	51.300 - 79.090	48.375 - 77.975	47.670 - 78.850
		Min - Max	22.84 - 139.12	13.13 - 150.00	24.64 - 150.00	10.19 - 122.26	10.19 - 150.00	10.19 - 150.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-2.500 (12.6735)	-5.179 (12.2599)	-3.532 (11.8136)	-5.522 (12.1728)	-4.743 (12.0545)	-4.184 (12.2256)
		Median	-3.920	-4.750	-3.390	-5.210	-4.145	-4.090
		Q1 - Q3	-7.450 - -0.260	-9.100 - 0.490	-6.610 - 0.720	-9.230 - 1.320	-8.420 - 0.790	-8.140 - 0.390
		Min - Max	-31.41 - 43.09	-55.00 - 24.84	-49.42 - 46.93	-47.00 - 23.56	-55.00 - 46.93	-55.00 - 46.93
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	63.459 (21.4299)	62.603 (24.3785)	64.882 (26.0032)	67.305 (19.2928)	64.870 (23.4403)	64.521 (22.9273)
		Median	60.430	61.020	63.965	65.480	64.450	63.420
		Q1 - Q3	48.510 - 78.820	47.620 - 75.260	45.250 - 82.910	53.670 - 77.560	48.750 - 77.360	48.710 - 77.390
		Min - Max	21.05 - 110.01	9.04 - 142.89	16.87 - 150.00	19.75 - 128.96	9.04 - 150.00	9.04 - 150.00

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Follicle Stimulating Hormone (IU/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-2.132 (13.9150)	-4.259 (11.5273)	-4.846 (9.4600)	-3.799 (11.8299)	-4.311 (10.9259)	-3.773 (11.7444)
		Median	-3.620	-4.100	-3.255	-3.435	-3.720	-3.720
		Q1 - Q3	-7.535 - 0.350	-8.460 - 0.470	-8.360 - -0.400	-8.070 - 0.480	-8.360 - 0.220	-8.320 - 0.220
		Min - Max	-45.51 - 47.69	-39.02 - 45.70	-37.59 - 14.93	-43.43 - 30.39	-43.43 - 45.70	-45.51 - 47.69
Testosterone (ng/dL)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	19.9 (6.26)	19.8 (5.85)	22.5 (7.16)	18.9 (5.56)	20.4 (6.39)	20.3 (6.35)
		Median	19.0	19.0	21.0	17.0	19.0	19.0
		Q1 - Q3	15.0 - 24.0	16.0 - 22.0	17.0 - 28.0	15.0 - 21.0	16.0 - 24.0	16.0 - 24.0
		Min - Max	3 - 38	13 - 41	11 - 46	10 - 43	10 - 46	3 - 46
	D15	Observed Value						
		n	69	70	67	68	205	274
		Mean (SD)	21.0 (6.08)	21.0 (5.83)	22.6 (8.02)	19.9 (5.80)	21.2 (6.68)	21.1 (6.52)
		Median	20.0	20.0	22.0	18.5	20.0	20.0
		Q1 - Q3	16.0 - 25.0	16.0 - 25.0	16.0 - 27.0	15.5 - 24.0	16.0 - 25.0	16.0 - 25.0
		Min - Max	2 - 35	11 - 36	10 - 51	12 - 41	10 - 51	2 - 51

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Testosterone (ng/dL)	D15	Change from Baseline						
		n	69	70	67	68	205	274
		Mean (SD)	1.2 (4.35)	1.1 (4.20)	0.3 (5.28)	1.0 (4.16)	0.8 (4.56)	0.9 (4.50)
		Median	1.0	1.5	-1.0	1.0	1.0	1.0
		Q1 - Q3	-1.0 - 4.0	-1.0 - 3.0	-3.0 - 4.0	-2.0 - 3.0	-2.0 - 3.0	-2.0 - 4.0
		Min - Max	-10 - 11	-6 - 14	-12 - 15	-9 - 12	-12 - 15	-12 - 15
	D29	Observed Value						
		n	66	69	67	67	203	269
		Mean (SD)	22.0 (6.18)	22.6 (6.32)	22.1 (7.31)	21.0 (6.81)	21.9 (6.82)	21.9 (6.65)
		Median	21.0	21.0	22.0	19.0	21.0	21.0
		Q1 - Q3	17.0 - 26.0	18.0 - 25.0	17.0 - 26.0	16.0 - 25.0	17.0 - 25.0	17.0 - 25.0
		Min - Max	8 - 39	12 - 43	11 - 53	13 - 49	11 - 53	8 - 53
	D29	Change from Baseline						
		n	66	69	67	67	203	269
		Mean (SD)	2.0 (5.13)	2.7 (5.04)	-0.1 (4.86)	2.1 (4.20)	1.6 (4.85)	1.7 (4.92)
		Median	2.0	2.0	0	2.0	2.0	2.0
		Q1 - Q3	-2.0 - 5.0	0 - 4.0	-3.0 - 3.0	0 - 4.0	-1.0 - 4.0	-1.0 - 4.0
		Min - Max	-8 - 14	-8 - 23	-15 - 11	-8 - 15	-15 - 23	-15 - 23

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Testosterone (ng/dL)	D43	Observed Value						
		n	65	69	67	64	200	265
		Mean (SD)	22.9 (6.92)	22.3 (6.78)	24.1 (7.93)	22.3 (8.75)	22.9 (7.85)	22.9 (7.62)
		Median	22.0	22.0	22.0	20.0	21.0	22.0
		Q1 - Q3	18.0 - 27.0	18.0 - 25.0	18.0 - 27.0	16.0 - 28.0	17.0 - 27.0	17.0 - 27.0
		Min - Max	11 - 45	5 - 45	14 - 57	13 - 68	5 - 68	5 - 68
	D43	Change from Baseline						
		n	65	69	67	64	200	265
		Mean (SD)	2.7 (5.19)	2.5 (5.42)	1.9 (5.30)	3.3 (5.33)	2.6 (5.36)	2.6 (5.31)
		Median	3.0	3.0	2.0	3.0	2.0	3.0
		Q1 - Q3	-1.0 - 6.0	-1.0 - 7.0	-2.0 - 5.0	0 - 5.5	-1.0 - 6.0	-1.0 - 6.0
		Min - Max	-9 - 19	-12 - 14	-9 - 21	-7 - 25	-12 - 25	-12 - 25
	D57	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	23.1 (5.83)	21.4 (6.11)	23.7 (8.33)	22.1 (7.94)	22.4 (7.52)	22.6 (7.13)
		Median	23.0	20.0	23.0	20.0	21.0	21.0
		Q1 - Q3	19.0 - 27.0	17.0 - 25.0	18.0 - 28.0	16.0 - 28.0	17.0 - 26.0	17.0 - 26.0
		Min - Max	13 - 39	4 - 40	11 - 62	13 - 52	4 - 62	4 - 62

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Testosterone (ng/dL)	D57	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	3.0 (5.73)	1.7 (6.00)	1.8 (5.19)	3.2 (5.11)	2.2 (5.47)	2.4 (5.54)
		Median	2.0	1.5	1.0	2.0	1.0	2.0
		Q1 - Q3	0 - 6.0	-1.0 - 4.0	-1.0 - 5.0	0 - 6.0	-1.0 - 5.0	-1.0 - 5.0
		Min - Max	-10 - 21	-15 - 23	-8 - 16	-7 - 20	-15 - 23	-15 - 23
	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	22.0 (6.23)	23.6 (7.93)	25.0 (8.42)	22.3 (6.87)	23.6 (7.82)	23.2 (7.48)
		Median	21.0	22.0	24.0	20.0	22.0	21.0
		Q1 - Q3	17.0 - 26.0	17.0 - 26.5	18.0 - 31.0	17.0 - 29.0	17.0 - 29.0	17.0 - 28.0
		Min - Max	13 - 39	12 - 47	13 - 51	13 - 45	12 - 51	12 - 51
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	2.0 (4.99)	3.9 (5.96)	3.2 (6.00)	3.3 (4.30)	3.5 (5.48)	3.1 (5.39)
		Median	2.0	3.0	2.0	3.0	3.0	2.0
		Q1 - Q3	0 - 4.0	0 - 6.5	-1.0 - 7.0	0 - 6.0	0 - 6.0	0 - 6.0
		Min - Max	-14 - 14	-7 - 21	-7 - 24	-5 - 16	-7 - 24	-14 - 24

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Testosterone (ng/dL)	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	25.0 (9.80)	24.0 (7.48)	23.9 (8.18)	21.7 (6.93)	23.2 (7.59)	23.7 (8.21)
		Median	24.5	23.0	22.0	19.0	22.0	22.0
		Q1 - Q3	18.5 - 28.5	19.0 - 28.0	18.0 - 29.0	16.0 - 27.0	18.0 - 28.0	18.0 - 28.0
		Min - Max	8 - 73	13 - 50	12 - 58	13 - 49	12 - 58	8 - 73
	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	5.0 (9.34)	4.1 (5.05)	1.9 (5.69)	2.8 (3.91)	2.9 (5.02)	3.4 (6.40)
		Median	4.0	4.0	1.0	2.0	3.0	3.0
		Q1 - Q3	1.0 - 8.5	0 - 7.0	-1.0 - 5.0	0 - 6.0	0 - 6.0	0 - 7.0
		Min - Max	-11 - 58	-7 - 15	-15 - 20	-6 - 11	-15 - 20	-15 - 58
Sex Hormone Binding Globulin (nmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	46.646 (18.7796)	48.147 (29.1600)	47.029 (23.0285)	44.180 (19.2013)	46.471 (24.1365)	46.515 (22.8825)
		Median	45.920	43.410	44.220	41.170	43.660	44.110
		Q1 - Q3	31.170 - 54.490	30.690 - 57.500	30.150 - 56.710	28.770 - 56.470	30.150 - 57.310	30.220 - 57.255
		Min - Max	14.80 - 112.50	10.89 - 214.07	10.85 - 139.18	14.36 - 92.36	10.85 - 214.07	10.85 - 214.07

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sex Hormone Binding Globulin (nmol/L)	D15	Observed Value						
		n	69	70	67	68	205	274
		Mean (SD)	46.908 (20.0288)	49.908 (31.0361)	49.664 (23.6044)	45.511 (19.3922)	48.370 (25.1725)	48.002 (23.9546)
		Median	45.610	43.460	44.930	42.580	43.060	44.230
		Q1 - Q3	31.710 - 57.390	30.750 - 62.860	32.000 - 62.530	30.285 - 61.720	30.750 - 61.880	30.750 - 61.100
		Min - Max	12.92 - 118.98	11.18 - 232.80	11.55 - 131.73	17.12 - 103.81	11.18 - 232.80	11.18 - 232.80
	D15	Change from Baseline						
		n	69	70	67	68	205	274
		Mean (SD)	0.262 (10.2153)	1.761 (9.8826)	2.093 (6.7972)	1.331 (5.4194)	1.727 (7.5976)	1.358 (8.3386)
		Median	0.670	0.095	1.820	0.735	0.800	0.715
		Q1 - Q3	-3.300 - 4.120	-2.980 - 3.450	-2.220 - 5.370	-1.390 - 3.940	-2.020 - 4.370	-2.410 - 4.330
		Min - Max	-59.10 - 23.93	-13.31 - 60.58	-14.80 - 19.72	-11.36 - 15.87	-14.80 - 60.58	-59.10 - 60.58
	D29	Observed Value						
		n	66	69	67	67	203	269
		Mean (SD)	49.411 (19.6870)	49.204 (31.1237)	47.800 (22.3680)	45.284 (19.5523)	47.447 (24.8419)	47.929 (23.6614)
		Median	48.665	43.130	43.660	43.000	43.130	44.070
		Q1 - Q3	34.080 - 62.780	33.550 - 54.480	31.330 - 59.980	29.930 - 56.040	31.160 - 59.350	32.430 - 59.980
		Min - Max	14.30 - 99.83	9.70 - 240.47	11.09 - 130.85	15.01 - 95.79	9.70 - 240.47	9.70 - 240.47

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sex Hormone Binding Globulin (nmol/L)	D29	Change from Baseline						
		n	66	69	67	67	203	269
		Mean (SD)	2.581 (9.1624)	0.678 (7.9311)	0.857 (6.4496)	0.978 (5.5870)	0.836 (6.7067)	1.264 (7.4047)
		Median	2.245	1.060	0.890	0.090	0.820	1.070
		Q1 - Q3	-3.100 - 7.470	-3.100 - 4.610	-2.740 - 4.410	-3.160 - 3.760	-2.830 - 4.110	-2.900 - 5.160
		Min - Max	-24.06 - 26.88	-21.25 - 26.40	-19.62 - 17.05	-8.64 - 21.84	-21.25 - 26.40	-24.06 - 26.88
	D43	Observed Value						
		n	65	69	67	64	200	265
		Mean (SD)	49.844 (22.1668)	50.660 (32.6293)	46.937 (20.7779)	46.778 (23.7308)	48.171 (26.2404)	48.581 (25.2719)
		Median	46.700	43.840	42.580	44.085	43.125	44.400
		Q1 - Q3	33.470 - 60.900	32.480 - 59.710	30.530 - 62.190	27.935 - 57.155	30.610 - 59.190	30.900 - 59.710
		Min - Max	11.84 - 103.04	12.04 - 248.90	10.88 - 116.09	16.49 - 126.82	10.88 - 248.90	10.88 - 248.90
	D43	Change from Baseline						
		n	65	69	67	64	200	265
		Mean (SD)	3.049 (13.0459)	2.134 (9.2898)	-0.006 (7.3570)	2.783 (10.4006)	1.625 (9.1160)	1.974 (10.2117)
		Median	1.800	1.440	0.340	1.935	1.410	1.440
		Q1 - Q3	-3.820 - 7.350	-3.090 - 6.250	-3.490 - 4.510	-3.495 - 7.580	-3.295 - 4.990	-3.510 - 5.890
		Min - Max	-26.39 - 67.00	-21.25 - 34.83	-23.09 - 18.36	-30.12 - 40.49	-30.12 - 40.49	-30.12 - 67.00

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sex Hormone Binding Globulin (nmol/L)	D57	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	48.097 (20.0155)	49.260 (31.6465)	46.222 (22.5907)	46.427 (22.9171)	47.342 (26.0875)	47.530 (24.6808)
		Median	46.240	45.870	42.600	41.460	42.980	44.650
		Q1 - Q3	32.640 - 61.660	30.400 - 57.410	29.910 - 56.900	26.270 - 58.400	30.090 - 57.315	30.120 - 57.880
		Min - Max	16.61 - 99.92	11.32 - 235.96	9.68 - 110.83	17.95 - 146.53	9.68 - 235.96	9.68 - 235.96
	D57	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.203 (10.8846)	0.716 (10.1482)	-0.430 (8.4500)	1.961 (10.8668)	0.736 (9.8642)	0.852 (10.1085)
		Median	0.580	0.120	-0.490	0.900	-0.005	0.240
		Q1 - Q3	-3.280 - 5.460	-4.125 - 5.545	-2.030 - 2.450	-3.160 - 5.820	-3.260 - 4.185	-3.280 - 4.740
		Min - Max	-42.71 - 29.48	-29.42 - 40.99	-32.46 - 18.14	-23.41 - 60.20	-32.46 - 60.20	-42.71 - 60.20
	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	47.439 (20.1342)	48.424 (32.8589)	47.134 (24.5416)	43.863 (19.0198)	46.530 (26.2172)	46.757 (24.8082)
		Median	44.740	43.490	44.830	40.280	43.490	44.000
		Q1 - Q3	33.500 - 60.530	30.230 - 55.005	27.030 - 55.950	26.730 - 60.660	28.640 - 57.045	30.270 - 58.940
		Min - Max	15.49 - 102.09	11.37 - 244.80	9.70 - 141.78	16.06 - 82.61	9.70 - 244.80	9.70 - 244.80

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sex Hormone Binding Globulin (nmol/L)	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.545 (9.4209)	-0.120 (12.9785)	0.281 (7.8986)	-0.603 (7.2351)	-0.142 (9.7531)	0.029 (9.6580)
		Median	0.320	-1.540	-0.480	-0.380	-0.695	-0.480
		Q1 - Q3	-5.410 - 6.290	-7.200 - 5.110	-5.160 - 4.810	-5.050 - 4.000	-5.825 - 4.230	-5.600 - 4.480
		Min - Max	-20.31 - 22.25	-32.41 - 44.80	-16.60 - 25.79	-22.79 - 18.39	-32.41 - 44.80	-32.41 - 44.80
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	46.690 (20.2548)	50.810 (32.3506)	47.355 (22.6431)	42.630 (17.6254)	47.040 (25.2323)	46.953 (24.0611)
		Median	45.610	41.300	44.440	39.890	41.880	43.820
		Q1 - Q3	33.195 - 54.820	32.580 - 60.280	30.400 - 60.730	27.780 - 55.750	30.820 - 58.930	30.820 - 57.950
		Min - Max	13.92 - 122.69	13.45 - 250.00	9.93 - 132.36	14.01 - 82.58	9.93 - 250.00	9.93 - 250.00
	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.507 (10.4397)	1.704 (10.9235)	0.686 (8.0275)	-1.213 (7.2048)	0.432 (8.9416)	0.200 (9.3218)
		Median	-1.325	0.200	0.585	-0.860	-0.230	-0.420
		Q1 - Q3	-5.965 - 5.315	-6.230 - 6.750	-4.510 - 5.470	-4.100 - 2.170	-5.090 - 5.260	-5.480 - 5.260
		Min - Max	-19.73 - 37.63	-17.93 - 38.55	-17.83 - 19.91	-27.10 - 12.80	-27.10 - 38.55	-27.10 - 38.55

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estrone (pmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	77.22 (79.364)	72.89 (43.022)	74.24 (47.100)	62.26 (58.382)	69.85 (49.894)	71.69 (58.588)
		Median	60.80	62.55	64.50	50.80	59.30	59.95
		Q1 - Q3	47.30 - 83.00	48.30 - 78.90	49.50 - 82.70	43.35 - 68.90	46.10 - 77.00	46.50 - 77.85
		Min - Max	6.7 - 660.7	29.8 - 268.0	28.7 - 305.4	18.7 - 510.1	18.7 - 510.1	6.7 - 660.7
	D15	Observed Value						
		n	69	70	67	68	205	274
		Mean (SD)	78.16 (59.916)	72.68 (38.084)	67.58 (32.819)	62.17 (33.616)	67.53 (35.055)	70.21 (42.823)
		Median	63.70	63.50	61.00	53.20	61.00	61.20
		Q1 - Q3	51.80 - 79.80	50.40 - 87.30	45.70 - 83.00	42.45 - 72.25	45.70 - 79.50	46.70 - 79.80
		Min - Max	4.1 - 398.4	13.7 - 198.8	24.5 - 252.8	23.4 - 271.1	13.7 - 271.1	4.1 - 398.4
	D15	Change from Baseline						
		n	69	70	67	68	205	274
		Mean (SD)	0.93 (70.138)	-0.21 (41.487)	-6.24 (34.422)	-0.09 (60.764)	-2.14 (46.758)	-1.36 (53.487)
		Median	2.80	0.10	-0.70	2.45	0.60	1.70
		Q1 - Q3	-7.10 - 9.80	-6.40 - 12.20	-7.70 - 7.70	-11.50 - 12.90	-7.60 - 11.90	-7.30 - 10.60
		Min - Max	-479.1 - 212.0	-237.5 - 140.0	-212.8 - 39.4	-425.8 - 218.3	-425.8 - 218.3	-479.1 - 218.3

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estrone (pmol/L)	D29	Observed Value						
		n	66	69	67	67	203	269
		Mean (SD)	80.25 (60.453)	84.19 (80.494)	67.74 (36.339)	70.10 (45.165)	74.11 (57.729)	75.62 (58.355)
		Median	68.30	62.60	60.80	56.50	62.20	62.50
		Q1 - Q3	49.40 - 88.20	52.00 - 82.30	49.30 - 77.40	43.30 - 77.10	48.80 - 79.20	48.90 - 79.50
		Min - Max	17.9 - 405.5	15.0 - 602.0	23.0 - 277.4	22.4 - 292.3	15.0 - 602.0	15.0 - 602.0
	D29	Change from Baseline						
		n	66	69	67	67	203	269
		Mean (SD)	2.46 (54.827)	11.65 (51.624)	-2.83 (42.083)	7.65 (69.363)	5.55 (55.545)	4.79 (55.283)
		Median	2.00	4.40	-1.90	2.80	1.80	1.80
		Q1 - Q3	-10.30 - 10.20	-5.20 - 15.30	-12.10 - 6.50	-4.30 - 15.50	-7.90 - 13.60	-7.90 - 11.90
		Min - Max	-255.2 - 208.4	-121.2 - 371.4	-178.7 - 195.4	-435.1 - 242.9	-435.1 - 371.4	-435.1 - 371.4
	D43	Observed Value						
		n	64	69	67	63	199	263
		Mean (SD)	76.64 (73.690)	67.60 (29.749)	70.23 (46.440)	84.72 (128.931)	73.90 (79.270)	74.57 (77.820)
		Median	61.00	63.20	64.40	56.80	61.80	61.20
		Q1 - Q3	51.40 - 80.10	46.20 - 78.90	48.10 - 77.40	41.80 - 78.00	45.30 - 78.00	46.20 - 78.60
		Min - Max	29.6 - 603.5	7.4 - 154.3	23.3 - 393.1	26.5 - 853.5	7.4 - 853.5	7.4 - 853.5

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estrone (pmol/L)	D43	Change from Baseline						
		n	64	69	67	63	199	263
		Mean (SD)	-2.04 (92.555)	-4.94 (37.947)	-0.34 (40.323)	21.79 (104.413)	5.07 (67.706)	3.34 (74.387)
		Median	0	0.70	-0.10	4.20	1.30	1.00
		Q1 - Q3	-7.80 - 13.30	-8.90 - 7.90	-10.40 - 10.30	-6.30 - 13.50	-8.90 - 11.50	-8.30 - 11.70
		Min - Max	-495.0 - 473.4	-194.7 - 108.3	-199.7 - 211.2	-23.4 - 804.1	-199.7 - 804.1	-495.0 - 804.1
	D57	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	80.17 (70.564)	63.00 (29.432)	66.41 (38.136)	58.14 (25.216)	62.57 (31.439)	66.95 (45.002)
		Median	64.40	58.25	61.80	52.10	57.70	58.70
		Q1 - Q3	48.60 - 77.90	43.25 - 75.75	47.00 - 73.80	40.40 - 69.80	43.45 - 74.60	44.60 - 74.90
		Min - Max	27.5 - 461.9	8.0 - 184.0	25.7 - 317.8	26.3 - 163.9	8.0 - 317.8	8.0 - 461.9
	D57	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.76 (105.612)	-9.60 (40.829)	-0.62 (38.687)	-4.85 (60.934)	-5.10 (47.521)	-3.39 (66.694)
		Median	-1.10	-1.45	-1.80	-1.10	-1.50	-1.50
		Q1 - Q3	-10.40 - 9.60	-13.70 - 5.50	-11.20 - 7.60	-9.30 - 10.50	-11.15 - 8.40	-11.10 - 9.20
		Min - Max	-602.6 - 331.8	-214.8 - 63.5	-115.4 - 247.7	-454.6 - 114.5	-454.6 - 247.7	-602.6 - 331.8

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estrone (pmol/L)	D71	Observed Value						
		n	64	68	64	63	195	259
		Mean (SD)	63.35 (21.072)	94.92 (120.647)	69.92 (43.873)	61.35 (34.326)	75.87 (78.968)	72.78 (69.475)
		Median	59.15	61.55	61.95	52.20	58.60	59.00
		Q1 - Q3	48.95 - 77.45	48.05 - 86.60	45.40 - 79.30	40.60 - 77.60	43.20 - 79.90	45.40 - 79.60
		Min - Max	23.5 - 122.7	24.7 - 749.8	22.6 - 319.5	21.9 - 217.0	21.9 - 749.8	21.9 - 749.8
	D71	Change from Baseline						
		n	64	68	64	63	195	259
		Mean (SD)	-15.36 (78.241)	22.33 (112.601)	3.21 (26.894)	-1.64 (67.618)	8.31 (78.642)	2.46 (79.056)
		Median	-1.90	2.95	-1.10	1.30	1.00	0.80
		Q1 - Q3	-11.00 - 8.40	-7.50 - 15.35	-9.40 - 9.25	-7.50 - 9.60	-8.00 - 10.50	-8.90 - 10.10
		Min - Max	-573.9 - 48.1	-164.0 - 661.4	-43.0 - 137.6	-483.4 - 150.7	-483.4 - 661.4	-573.9 - 661.4
	D85	Observed Value						
		n	63	67	65	62	194	257
		Mean (SD)	76.17 (60.054)	89.58 (121.350)	67.99 (41.440)	56.71 (20.420)	71.84 (76.973)	72.90 (73.101)
		Median	62.00	63.30	57.30	51.45	57.60	58.80
		Q1 - Q3	50.10 - 88.90	49.80 - 89.70	43.10 - 84.80	41.70 - 67.50	43.10 - 79.10	44.80 - 81.10
		Min - Max	28.9 - 480.0	29.0 - 996.8	22.3 - 312.1	24.1 - 116.1	22.3 - 996.8	22.3 - 996.8

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estrone (pmol/L)	D85	Change from Baseline						
		n	63	67	65	62	194	257
		Mean (SD)	-2.96 (99.238)	17.09 (95.394)	0.71 (35.826)	-6.68 (62.874)	4.01 (69.905)	2.30 (77.963)
		Median	1.80	3.00	-2.30	0.10	0.70	1.20
		Q1 - Q3	-5.70 - 12.90	-4.20 - 16.00	-13.30 - 4.50	-6.80 - 8.90	-8.50 - 12.00	-7.40 - 12.00
		Min - Max	-602.9 - 429.7	-176.1 - 728.8	-68.8 - 253.5	-482.3 - 27.6	-482.3 - 728.8	-602.9 - 728.8
Estradiol (pg/mL)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	29.6 (37.38)	27.8 (25.51)	29.3 (22.27)	26.8 (34.25)	28.0 (27.65)	28.4 (30.31)
		Median	23.0	22.5	23.0	22.0	23.0	23.0
		Q1 - Q3	15.0 - 28.0	17.0 - 29.0	19.0 - 30.0	16.0 - 28.0	17.0 - 29.0	17.0 - 29.0
		Min - Max	10 - 308	10 - 164	10 - 131	10 - 299	10 - 299	10 - 308
	D15	Observed Value						
		n	69	70	67	68	205	274
		Mean (SD)	28.4 (29.40)	24.7 (12.59)	26.1 (15.58)	25.3 (15.28)	25.3 (14.46)	26.1 (19.32)
		Median	20.0	22.0	23.0	22.0	22.0	22.0
		Q1 - Q3	17.0 - 28.0	17.0 - 29.0	19.0 - 29.0	19.0 - 27.5	18.0 - 28.0	18.0 - 28.0
		Min - Max	10 - 183	10 - 96	10 - 126	10 - 122	10 - 126	10 - 183

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estradiol (pg/mL)	D15	Change from Baseline						
		n	69	70	67	68	205	274
		Mean (SD)	-1.2 (31.05)	-3.1 (25.26)	-3.5 (18.16)	-1.5 (35.68)	-2.7 (27.23)	-2.3 (28.19)
		Median	-1.0	-1.0	-1.0	0	0	0
		Q1 - Q3	-8.0 - 6.0	-6.0 - 6.0	-8.0 - 5.0	-6.0 - 5.0	-6.0 - 5.0	-6.0 - 5.0
		Min - Max	-199 - 95	-141 - 63	-89 - 22	-257 - 112	-257 - 112	-257 - 112
	D29	Observed Value						
		n	66	69	67	67	203	269
		Mean (SD)	30.1 (38.76)	33.3 (48.23)	26.0 (25.86)	30.1 (32.85)	29.8 (36.92)	29.9 (37.31)
		Median	22.0	25.0	22.0	23.0	23.0	22.0
		Q1 - Q3	16.0 - 29.0	19.0 - 29.0	18.0 - 26.0	16.0 - 29.0	18.0 - 28.0	17.0 - 28.0
		Min - Max	10 - 288	10 - 368	10 - 218	10 - 197	10 - 368	10 - 368
	D29	Change from Baseline						
		n	66	69	67	67	203	269
		Mean (SD)	0.2 (19.58)	5.6 (30.61)	-2.3 (26.83)	3.4 (47.41)	2.3 (36.00)	1.7 (32.72)
		Median	-1.0	3.0	-3.0	-1.0	-1.0	-1.0
		Q1 - Q3	-9.0 - 8.0	-8.0 - 9.0	-8.0 - 3.0	-7.0 - 10.0	-8.0 - 7.0	-8.0 - 7.0
		Min - Max	-54 - 72	-57 - 204	-96 - 148	-259 - 181	-259 - 204	-259 - 204

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estradiol (pg/mL)	D43	Observed Value						
		n	65	69	67	64	200	265
		Mean (SD)	29.6 (54.40)	22.2 (11.93)	26.4 (25.62)	38.2 (91.83)	28.7 (54.60)	29.0 (54.45)
		Median	22.0	20.0	22.0	21.0	21.0	21.0
		Q1 - Q3	16.0 - 27.0	17.0 - 23.0	17.0 - 27.0	17.5 - 26.5	17.0 - 26.0	17.0 - 26.0
		Min - Max	10 - 442	10 - 85	10 - 215	10 - 614	10 - 614	10 - 614
	D43	Change from Baseline						
		n	65	69	67	64	200	265
		Mean (SD)	-0.6 (60.54)	-5.5 (22.82)	-1.8 (24.43)	11.5 (77.78)	1.2 (48.41)	0.7 (51.53)
		Median	-1.0	-2.0	-3.0	0	-2.0	-2.0
		Q1 - Q3	-8.0 - 6.0	-10.0 - 3.0	-8.0 - 6.0	-8.0 - 6.0	-9.0 - 5.0	-8.0 - 5.0
		Min - Max	-269 - 367	-102 - 65	-108 - 109	-21 - 598	-108 - 598	-269 - 598
	D57	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	26.8 (36.85)	21.8 (7.30)	24.0 (19.54)	21.0 (14.11)	22.3 (14.44)	23.4 (22.24)
		Median	20.0	21.5	20.0	19.0	20.0	20.0
		Q1 - Q3	16.0 - 24.0	16.5 - 25.0	17.0 - 25.0	15.0 - 23.0	16.0 - 25.0	16.0 - 24.0
		Min - Max	10 - 273	10 - 53	10 - 163	10 - 116	10 - 163	10 - 273

Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estradiol (pg/mL)	D57	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-3.2 (49.64)	-6.0 (25.53)	-2.7 (23.54)	-5.6 (38.56)	-4.8 (29.67)	-4.4 (35.60)
		Median	-4.0	-2.5	-3.0	-5.0	-3.0	-3.0
		Q1 - Q3	-10.0 - 6.0	-8.5 - 5.0	-10.0 - 4.0	-9.0 - 2.0	-9.0 - 4.0	-9.0 - 5.0
		Min - Max	-287 - 198	-141 - 27	-82 - 129	-280 - 100	-280 - 129	-287 - 198
	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	19.5 (7.99)	31.1 (46.81)	23.2 (20.01)	22.0 (19.54)	25.6 (31.97)	24.1 (28.10)
		Median	19.0	19.5	19.0	17.0	18.0	18.0
		Q1 - Q3	14.0 - 24.0	15.5 - 27.0	15.0 - 23.0	14.0 - 25.0	15.0 - 25.0	15.0 - 25.0
		Min - Max	10 - 53	10 - 288	10 - 150	10 - 144	10 - 288	10 - 288
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-10.5 (36.66)	3.3 (46.22)	-3.6 (14.95)	-4.6 (40.39)	-1.5 (36.58)	-3.7 (36.74)
		Median	-4.0	-1.0	-6.0	-4.0	-4.0	-4.0
		Q1 - Q3	-12.0 - 3.0	-10.5 - 6.0	-11.0 - 3.0	-9.0 - 2.0	-10.0 - 3.0	-10.0 - 3.0
		Min - Max	-271 - 30	-147 - 277	-33 - 46	-283 - 112	-283 - 277	-283 - 277

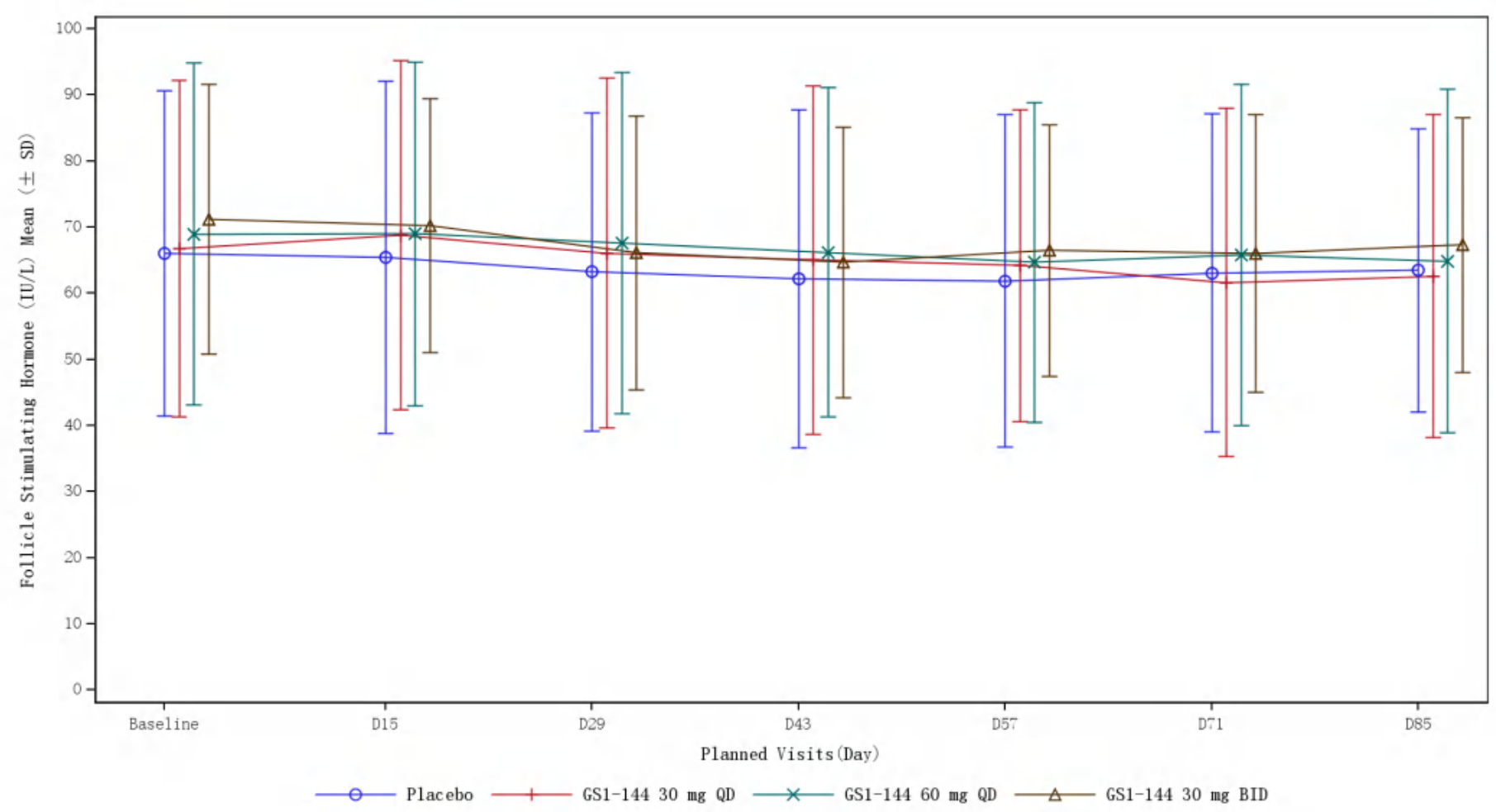
Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.5
Exploratory Endpoint Analysis 5 - Summary of Sex Hormones (Other Than LH)
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Estradiol (pg/mL)	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	22.3 (17.89)	31.0 (79.72)	21.2 (20.26)	17.6 (8.12)	23.4 (48.51)	23.2 (42.98)
		Median	17.0	18.0	16.5	16.0	17.0	17.0
		Q1 - Q3	13.0 - 24.0	11.0 - 24.0	10.0 - 25.0	10.0 - 21.0	10.0 - 23.0	11.0 - 23.0
		Min - Max	10 - 108	10 - 653	10 - 153	10 - 53	10 - 653	10 - 653
	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-7.9 (42.16)	3.2 (65.88)	-5.5 (20.82)	-9.1 (35.37)	-3.6 (45.19)	-4.7 (44.42)
		Median	-5.5	-5.0	-7.5	-5.0	-6.0	-6.0
		Q1 - Q3	-12.0 - 2.0	-12.0 - 6.0	-15.0 - 0	-11.0 - 1.0	-12.0 - 2.0	-12.0 - 2.0
		Min - Max	-289 - 93	-154 - 497	-60 - 135	-275 - 25	-275 - 497	-289 - 497

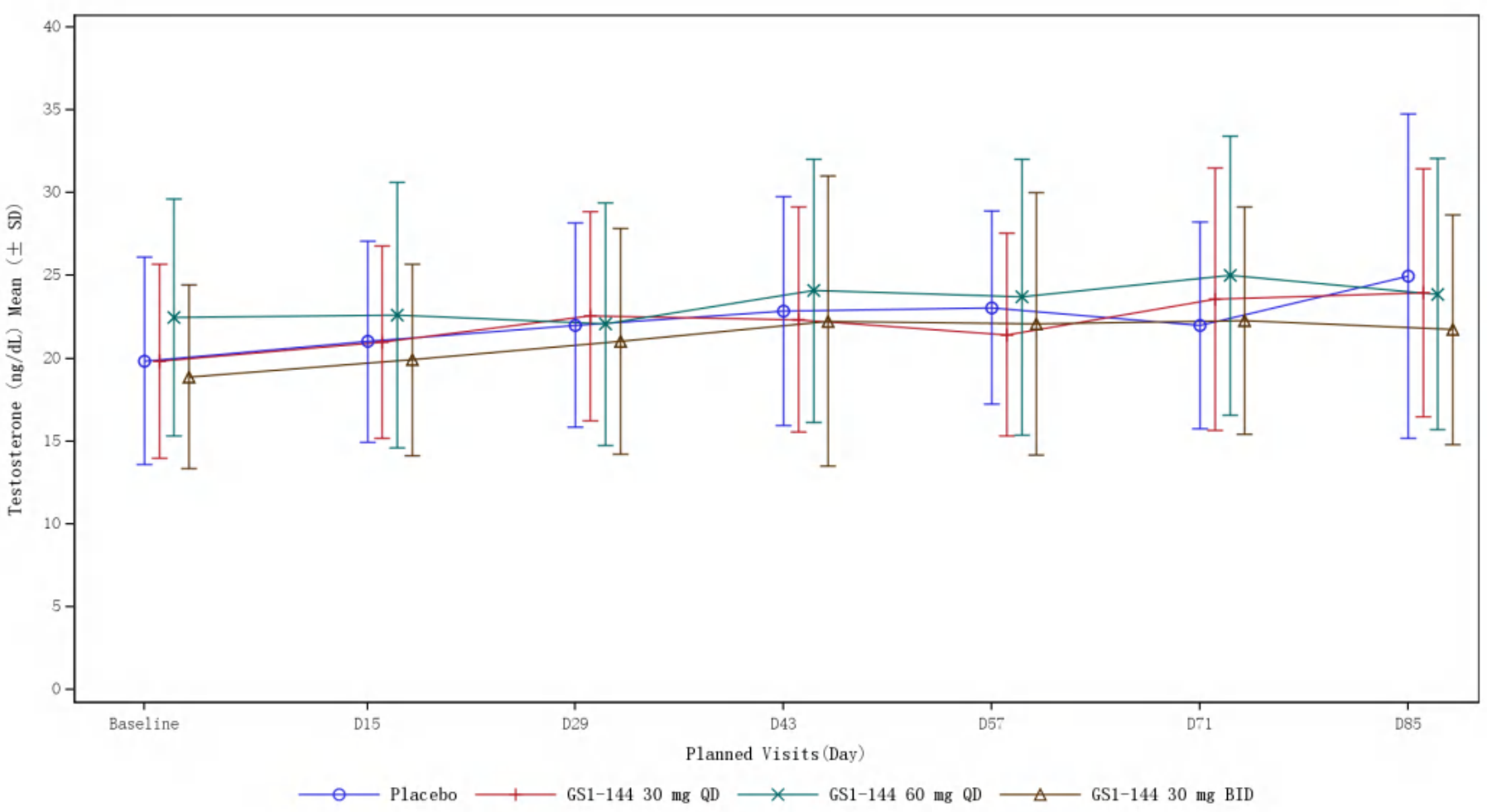
Data Source: Listing 16.2.6.8
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Figure 14.2.4.6
Exploratory Endpoint Analysis 5 - Line Plot of Observed Value Over Time of Sex Hormones (Other Than LH)
FAS



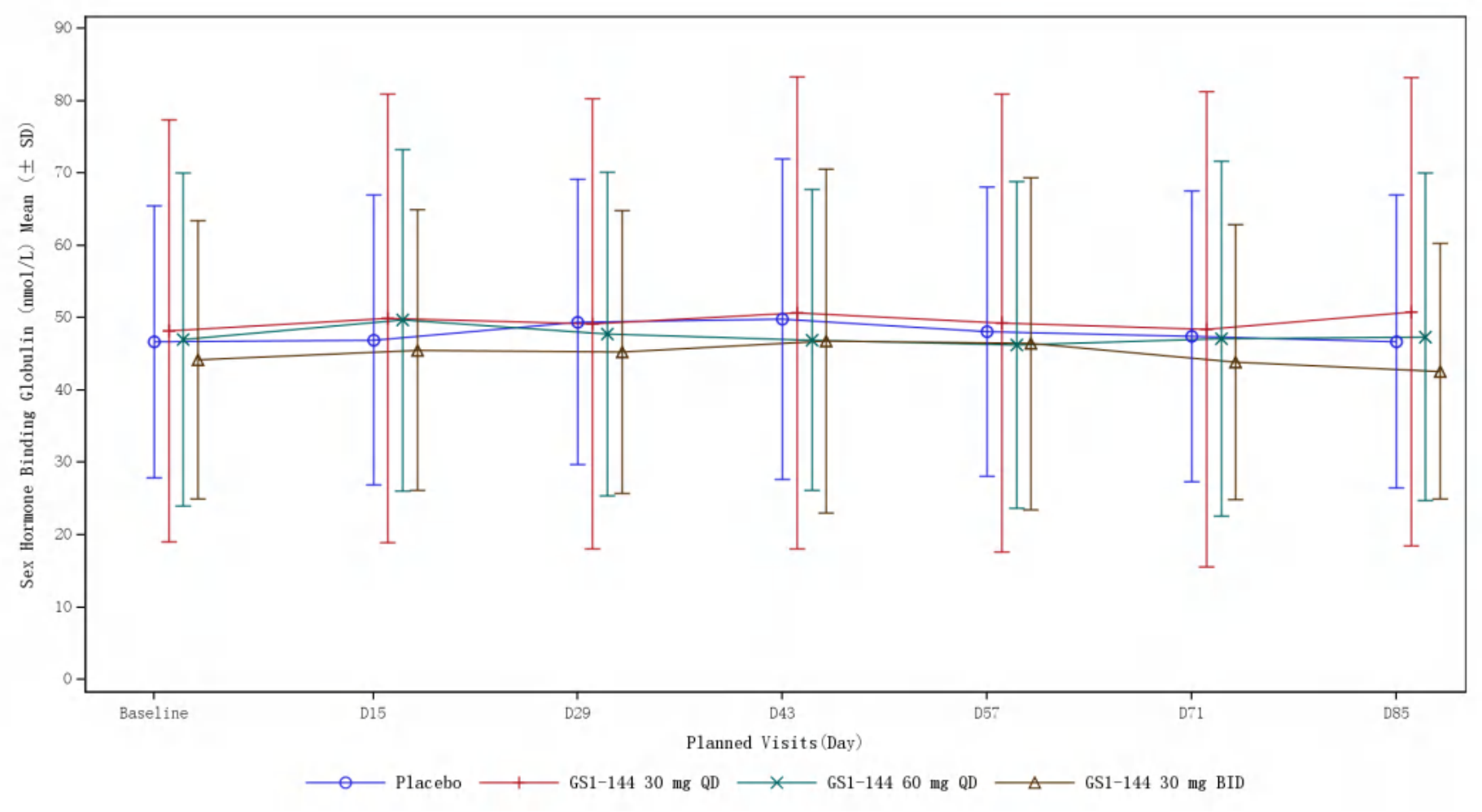
Data Source: Table 14.2.4.5

Figure 14.2.4.6
Exploratory Endpoint Analysis 5 - Line Plot of Observed Value Over Time of Sex Hormones (Other Than LH)
FAS



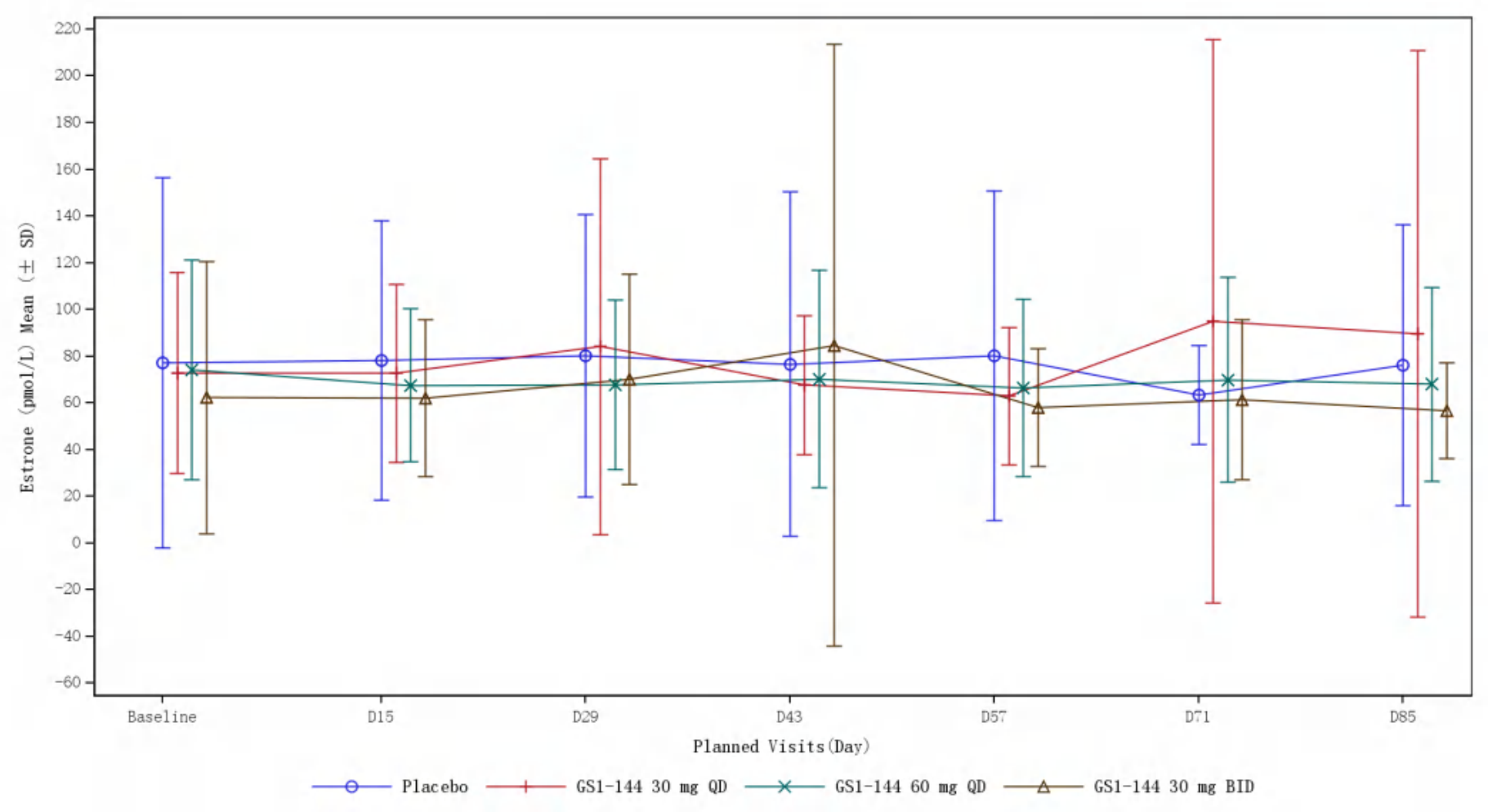
Data Source: Table 14.2.4.5

Figure 14.2.4.6
Exploratory Endpoint Analysis 5 - Line Plot of Observed Value Over Time of Sex Hormones (Other Than LH)
FAS



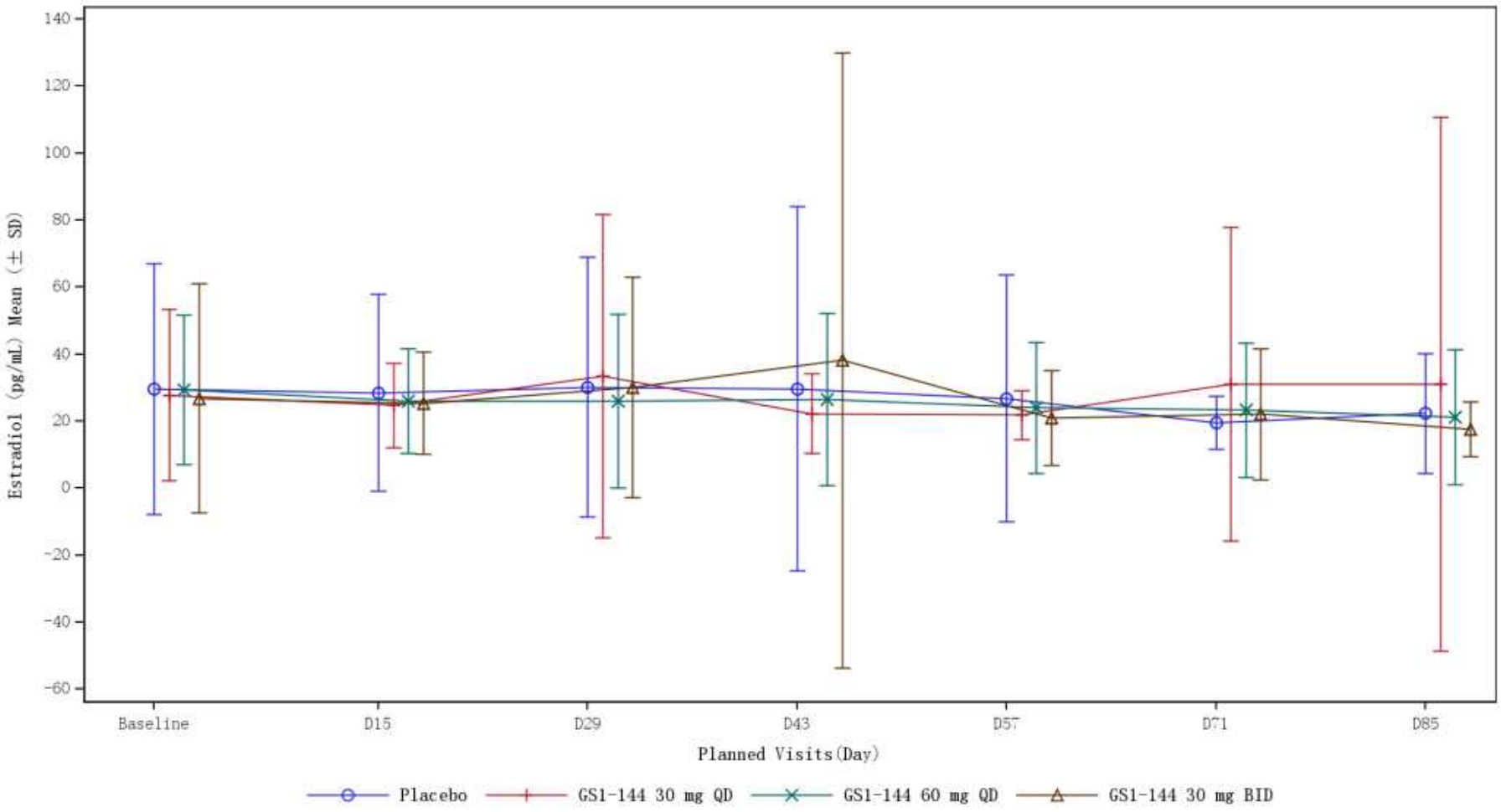
Data Source: Table 14.2.4.5

Figure 14.2.4.6
Exploratory Endpoint Analysis 5 - Line Plot of Observed Value Over Time of Sex Hormones (Other Than LH)
FAS



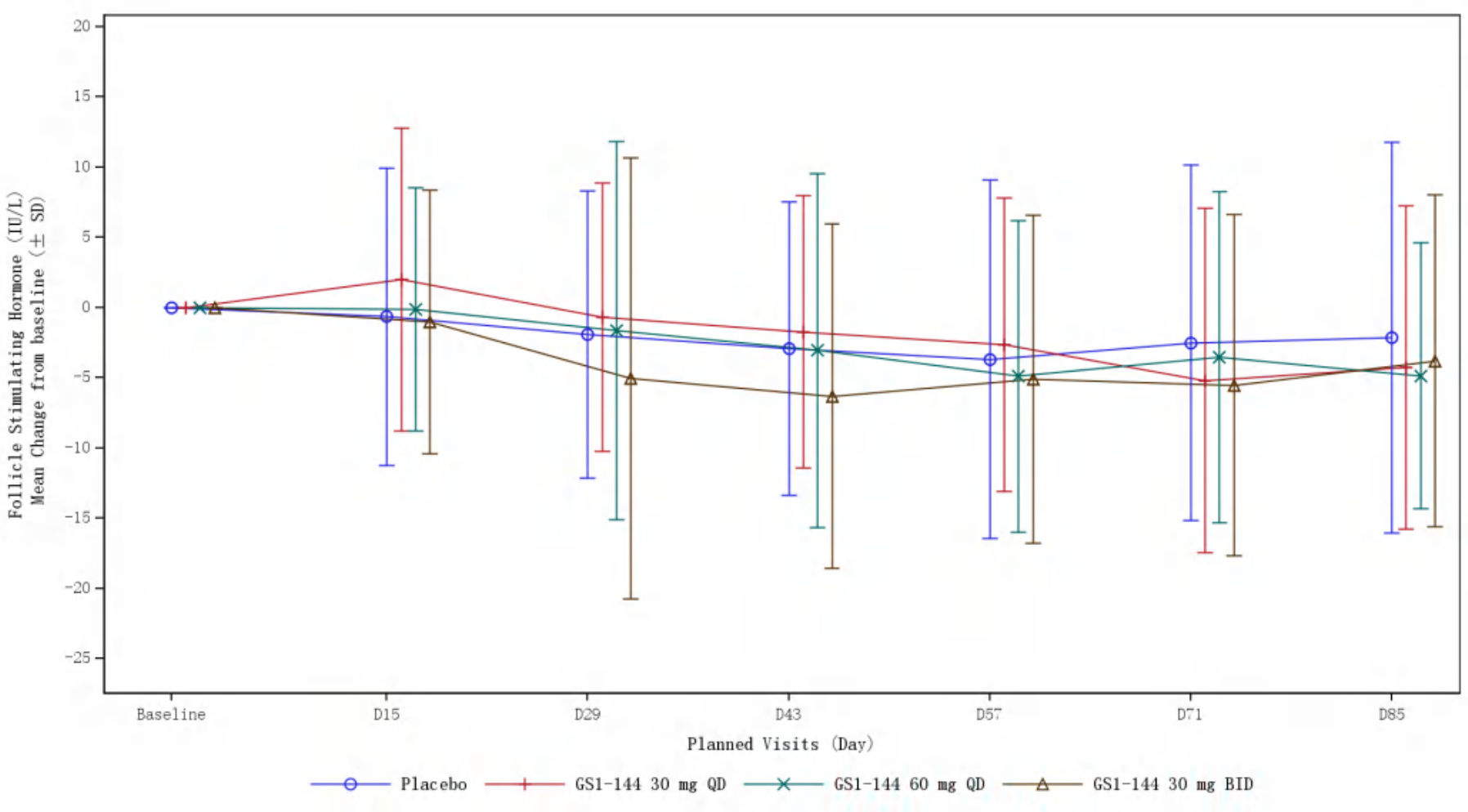
Data Source: Table 14.2.4.5

Figure 14.2.4.6
Exploratory Endpoint Analysis 5 - Line Plot of Observed Value Over Time of Sex Hormones (Other Than LH)
FAS



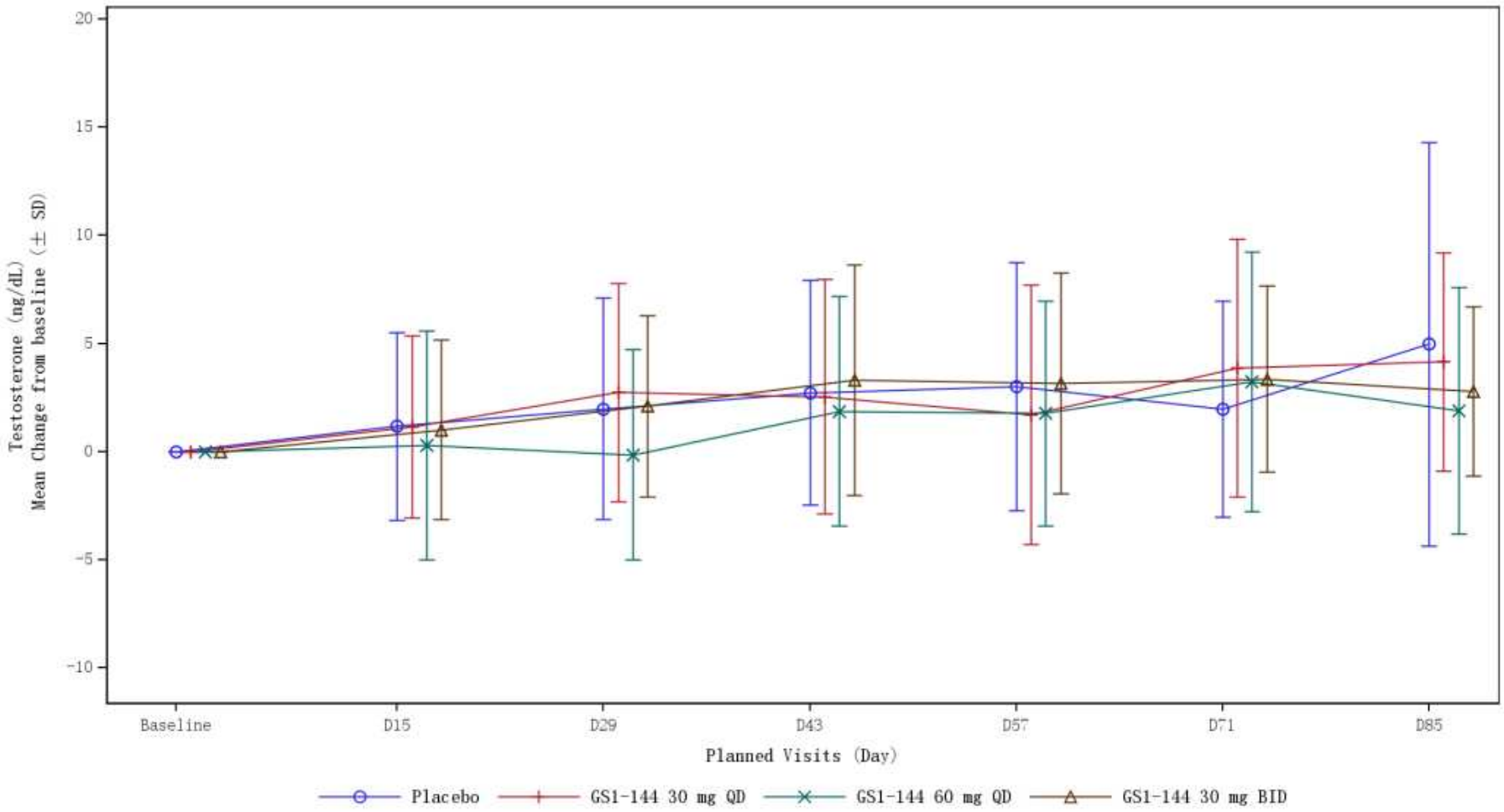
Data Source: Table 14.2.4.5

Figure 14.2.4.7
Exploratory Endpoint Analysis 5 - Line Plot of Change from Baseline Over Time of Sex Hormones (Other Than LH)
FAS



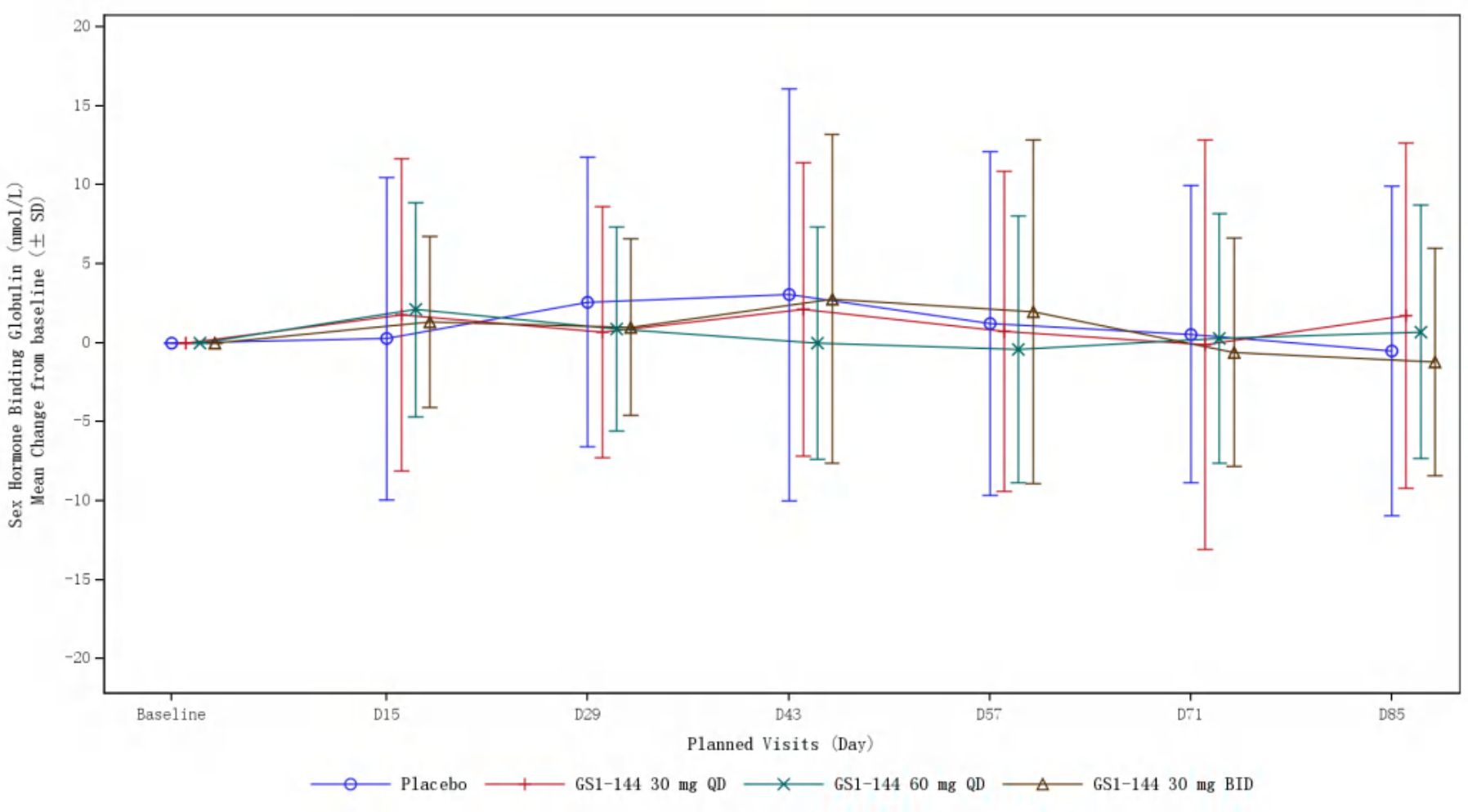
Data Source: Table 14.2.4.5

Figure 14.2.4.7
Exploratory Endpoint Analysis 5 - Line Plot of Change from Baseline Over Time of Sex Hormones (Other Than LH)
FAS



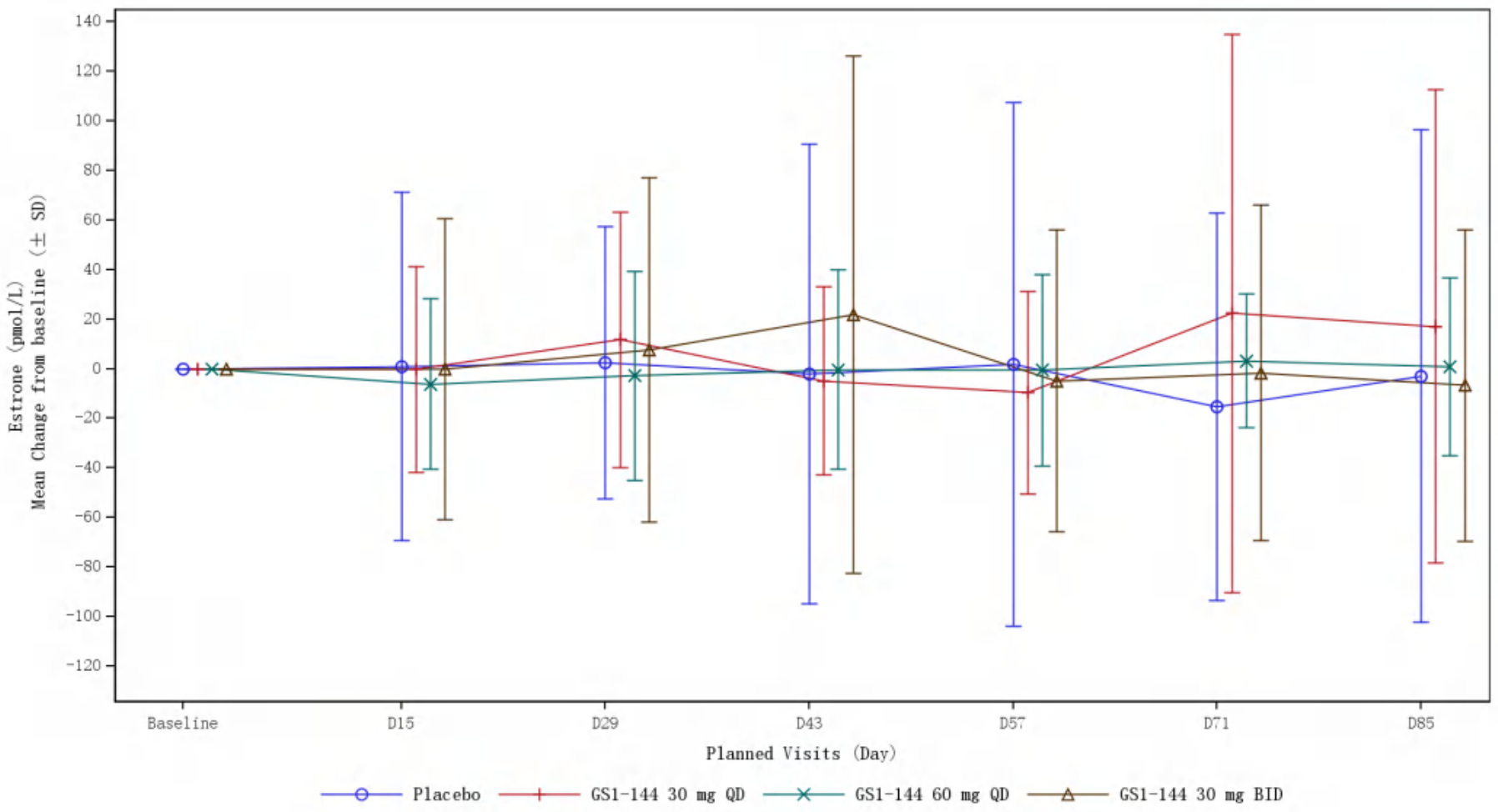
Data Source: Table 14.2.4.5

Figure 14.2.4.7
Exploratory Endpoint Analysis 5 - Line Plot of Change from Baseline Over Time of Sex Hormones (Other Than LH)
FAS



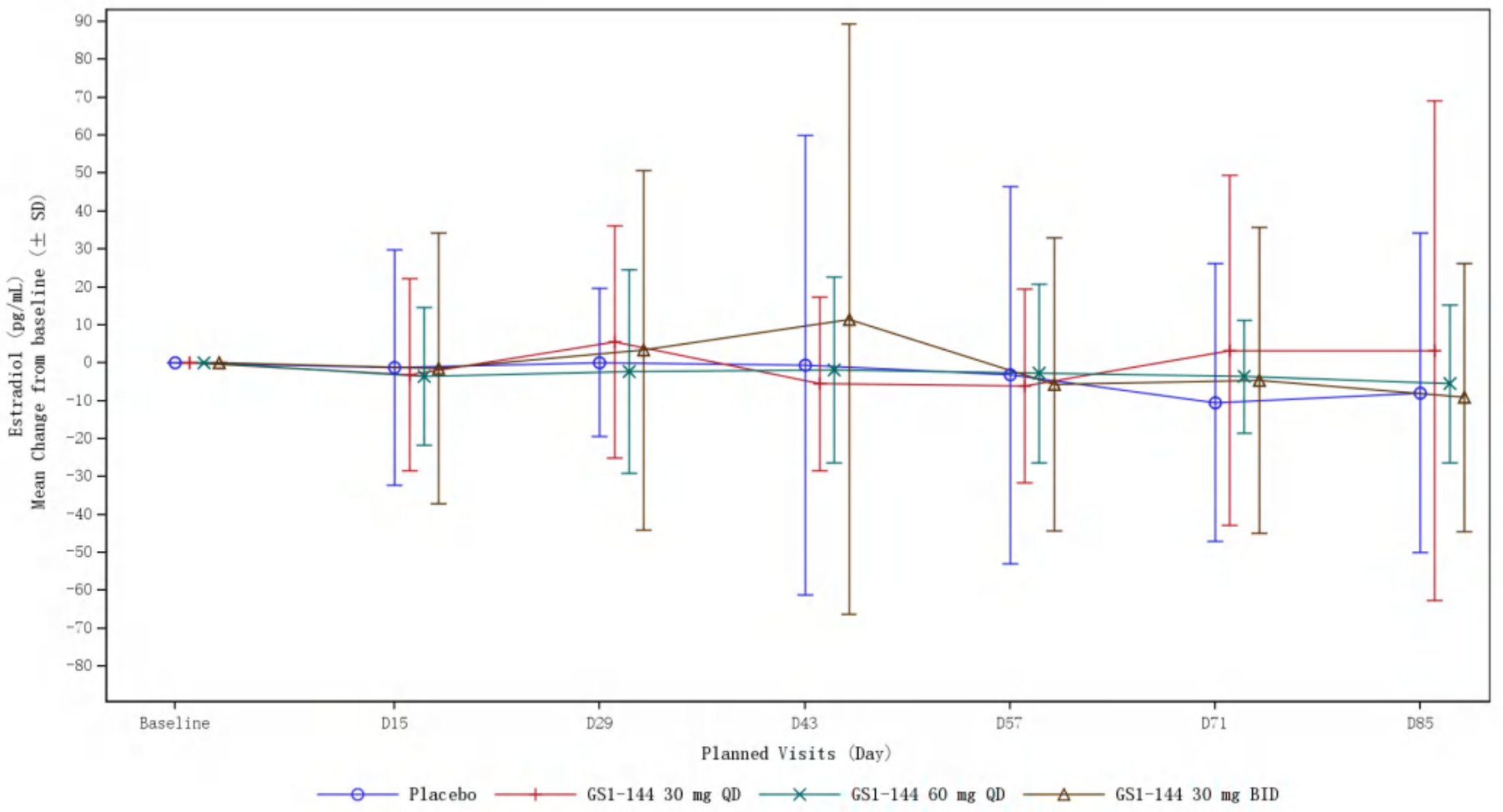
Data Source: Table 14.2.4.5

Figure 14.2.4.7
Exploratory Endpoint Analysis 5 - Line Plot of Change from Baseline Over Time of Sex Hormones (Other Than LH)
FAS



Data Source: Table 14.2.4.5

Figure 14.2.4.7
Exploratory Endpoint Analysis 5 - Line Plot of Change from Baseline Over Time of Sex Hormones (Other Than LH)
FAS



Data Source: Table 14.2.4.5

Table 14.2.4.8
Exploratory Endpoint Analysis 6 - Summary of Bone Turnover Marker
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Bone Specific Alkaline Phosphatase (ug/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	18.056 (6.5107)	18.137 (6.0290)	17.761 (5.0153)	17.320 (4.8822)	17.744 (5.3238)	17.822 (5.6330)
		Median	16.940	17.390	17.520	16.505	17.060	17.055
		Q1 - Q3	13.780 - 20.960	14.260 - 20.700	13.930 - 20.440	13.830 - 19.990	13.930 - 20.440	13.890 - 20.695
		Min - Max	9.44 - 46.17	6.20 - 36.10	8.64 - 30.94	7.37 - 31.27	6.20 - 36.10	6.20 - 46.17
	D85	Observed Value						
		n	64	67	65	62	194	258
		Mean (SD)	15.563 (4.8083)	16.508 (6.4001)	15.294 (4.4657)	14.557 (3.9818)	15.478 (5.1267)	15.499 (5.0405)
		Median	15.050	15.360	14.720	14.140	14.535	14.655
		Q1 - Q3	12.260 - 17.815	12.210 - 18.690	12.730 - 17.820	11.890 - 17.260	12.150 - 17.580	12.150 - 17.600
		Min - Max	5.18 - 32.86	6.81 - 40.00	7.50 - 31.73	7.44 - 26.43	6.81 - 40.00	5.18 - 40.00
	D85	Change from Baseline						
		n	64	67	65	62	194	258
		Mean (SD)	-2.597 (3.7612)	-1.567 (3.1861)	-2.441 (3.2684)	-2.597 (2.4592)	-2.189 (3.0223)	-2.290 (3.2185)
		Median	-2.145	-1.720	-1.980	-2.575	-1.945	-1.955
		Q1 - Q3	-4.310 - -0.690	-2.980 - -0.050	-4.140 - -0.250	-4.120 - -0.970	-3.950 - -0.480	-4.100 - -0.620
		Min - Max	-14.38 - 8.12	-8.31 - 10.88	-12.31 - 4.81	-10.15 - 2.29	-12.31 - 10.88	-14.38 - 10.88

Data Source: Listing 16.2.6.9
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.8
Exploratory Endpoint Analysis 6 - Summary of Bone Turnover Marker
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Procollagen 1 N-Terminal Propeptide (ng/mL)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	71.644 (28.2726)	67.494 (22.6775)	68.615 (22.2784)	71.001 (22.7317)	69.020 (22.5010)	69.676 (24.0461)
		Median	67.500	65.610	69.370	67.665	66.770	66.795
		Q1 - Q3	50.140 - 80.690	53.040 - 77.260	58.330 - 79.560	55.380 - 81.010	55.660 - 79.560	53.825 - 79.810
		Min - Max	15.59 - 155.30	24.86 - 141.30	10.52 - 149.10	35.79 - 136.80	10.52 - 149.10	10.52 - 155.30
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	74.106 (29.8166)	68.642 (24.3145)	68.356 (23.0726)	68.267 (18.3673)	68.426 (22.0362)	69.830 (24.2538)
		Median	67.205	65.930	63.655	67.370	65.960	66.590
		Q1 - Q3	52.690 - 86.550	52.270 - 80.300	54.260 - 74.210	57.990 - 76.440	54.260 - 77.390	53.790 - 79.870
		Min - Max	27.42 - 167.20	12.96 - 139.70	19.10 - 145.70	34.01 - 119.30	12.96 - 145.70	12.96 - 167.20
	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	1.800 (16.2255)	0.937 (14.4662)	0.356 (15.4904)	-1.931 (14.5027)	-0.171 (14.8066)	0.316 (15.1612)
		Median	0.500	1.840	-0.060	-1.665	-0.300	0
		Q1 - Q3	-9.880 - 10.115	-9.560 - 9.060	-10.520 - 9.420	-9.670 - 5.870	-10.450 - 8.580	-10.380 - 8.580
		Min - Max	-30.27 - 44.82	-28.80 - 42.42	-30.49 - 62.13	-42.30 - 31.70	-42.30 - 62.13	-42.30 - 62.13

Data Source: Listing 16.2.6.9
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.2.4.8
Exploratory Endpoint Analysis 6 - Summary of Bone Turnover Marker
FAS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Type I Collagen C-Telopeptides (ng/mL)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.6813 (0.40309)	0.6042 (0.27615)	0.6490 (0.34132)	0.6331 (0.33945)	0.6286 (0.31910)	0.6418 (0.34201)
		Median	0.6140	0.5470	0.6080	0.5435	0.5680	0.5895
		Q1 - Q3	0.3920 - 0.8540	0.3770 - 0.8010	0.4330 - 0.7720	0.4220 - 0.7655	0.4120 - 0.7830	0.4090 - 0.7985
		Min - Max	0.043 - 2.490	0.079 - 1.623	0.043 - 1.700	0.105 - 1.836	0.043 - 1.836	0.043 - 2.490
	D85	Observed Value						
		n	64	67	65	62	194	258
		Mean (SD)	0.7805 (0.35995)	0.7230 (0.37923)	0.7003 (0.25309)	0.7524 (0.34140)	0.7248 (0.32819)	0.7386 (0.33650)
		Median	0.6680	0.6490	0.6690	0.7120	0.6910	0.6725
		Q1 - Q3	0.5285 - 0.9900	0.4470 - 0.9820	0.4980 - 0.8630	0.4830 - 0.9260	0.4860 - 0.8920	0.4970 - 0.9220
		Min - Max	0.255 - 2.190	0.043 - 2.045	0.314 - 1.444	0.173 - 1.626	0.043 - 2.045	0.043 - 2.190
	D85	Change from Baseline						
		n	64	67	65	62	194	258
		Mean (SD)	0.1195 (0.28740)	0.1220 (0.33595)	0.0575 (0.29674)	0.1269 (0.36853)	0.1020 (0.33426)	0.1063 (0.32282)
		Median	0.1545	0.0600	0.0650	0.1165	0.0775	0.0830
		Q1 - Q3	-0.1015 - 0.3315	-0.1060 - 0.3170	-0.1350 - 0.2490	-0.0720 - 0.3570	-0.1060 - 0.2970	-0.1040 - 0.3080
		Min - Max	-0.488 - 0.667	-0.539 - 1.159	-0.763 - 0.804	-0.904 - 1.138	-0.904 - 1.159	-0.904 - 1.159

Data Source: Listing 16.2.6.9
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.1.1.1
Overview of Treatment-Emergent Adverse Events
SS

	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Treatment-Emergent Adverse Events (TEAEs)	43 (62.3) 119	48 (68.6) 126	48 (69.6) 121	44 (64.7) 104	140 (67.6) 351	183 (66.3) 470
Serious Adverse Events (SAEs)	1 (1.4) 1	1 (1.4) 1	0	2 (2.9) 2	3 (1.4) 3	4 (1.4) 4
Leading to drug interruption	5 (7.2) 13	1 (1.4) 2	3 (4.3) 6	2 (2.9) 4	6 (2.9) 12	11 (4.0) 25
Leading to drug withdrawal	2 (2.9) 3	2 (2.9) 2	0	1 (1.5) 1	3 (1.4) 3	5 (1.8) 6
Maximum Severity						
Mild	32 (46.4)	40 (57.1)	38 (55.1)	33 (48.5)	111 (53.6)	143 (51.8)
Moderate	11 (15.9)	8 (11.4)	10 (14.5)	10 (14.7)	28 (13.5)	39 (14.1)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Treatment-Related Adverse Events (TRAEs)	23 (33.3) 56	24 (34.3) 53	24 (34.8) 51	21 (30.9) 41	69 (33.3) 145	92 (33.3) 201
Serious Adverse Events (SAEs)	0	0	0	0	0	0
Leading to drug interruption	2 (2.9) 4	1 (1.4) 2	3 (4.3) 4	0	4 (1.9) 6	6 (2.2) 10
Leading to drug withdrawal	1 (1.4) 1	1 (1.4) 1	0	0	1 (0.5) 1	2 (0.7) 2
Maximum Severity						
Mild	20 (29.0)	21 (30.0)	21 (30.4)	20 (29.4)	62 (30.0)	82 (29.7)
Moderate	3 (4.3)	3 (4.3)	3 (4.3)	1 (1.5)	7 (3.4)	10 (3.6)
Severe	0	0	0	0	0	0
Procedure-Related TEAEs	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with specific TEAEs; E = event.
Any AEs occurring at or after the initial administration of study intervention or that are a consequence of a preexisting condition that has worsened after first study intervention is considered to be treatment emergent adverse events (TEAEs).
TEAEs with missing relationship to study treatment were regarded as Related to study treatment.

Table 14.3.1.1.2
Overview of TEAE of Special Interest – Hepatotoxic Events
SS

	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
TEAE of Special Interest (AESIs)	5 (7.2) 8	3 (4.3) 6	8 (11.6) 12	3 (4.4) 5	14 (6.8) 23	19 (6.9) 31
Serious Adverse Events (SAEs)	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Leading to drug interruption	0	0	0	1 (1.5) 2	1 (0.5) 2	1 (0.4) 2
Leading to drug withdrawal	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Maximum Severity						
Mild	3 (4.3)	2 (2.9)	7 (10.1)	2 (2.9)	11 (5.3)	14 (5.1)
Moderate	2 (2.9)	1 (1.4)	1 (1.4)	0	2 (1.0)	4 (1.4)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Treatment-Related AESIs	4 (5.8) 7	3 (4.3) 6	6 (8.7) 9	2 (2.9) 3	11 (5.3) 18	15 (5.4) 25
Serious Adverse Events (SAEs)	0	0	0	0	0	0
Leading to drug interruption	0	0	0	0	0	0
Leading to drug withdrawal	0	0	0	0	0	0
Maximum Severity						
Mild	3 (4.3)	2 (2.9)	5 (7.2)	2 (2.9)	9 (4.3)	12 (4.3)
Moderate	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4

n (%) = number and percentage of subjects with specific TEAEs; E = event.

Any AEs occurring at or after the initial administration of study intervention or that are a consequence of a preexisting condition that has worsened after first study intervention is considered to be treatment emergent adverse events (TEAEs).

TEAEs with missing relationship to study treatment were regarded as Related to study treatment.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
TEAEs	43 (62.3) 119	48 (68.6) 126	48 (69.6) 121	44 (64.7) 104	140 (67.6) 351	183 (66.3) 470
Investigations	23 (33.3) 61	25 (35.7) 54	19 (27.5) 42	17 (25.0) 30	61 (29.5) 126	84 (30.4) 187
Blood parathyroid hormone increased	10 (14.5) 12	10 (14.3) 14	7 (10.1) 8	5 (7.4) 8	22 (10.6) 30	32 (11.6) 42
Blood thyroid stimulating hormone increased	7 (10.1) 10	5 (7.1) 8	3 (4.3) 3	1 (1.5) 1	9 (4.3) 12	16 (5.8) 22
White blood cell count decreased	5 (7.2) 8	3 (4.3) 4	2 (2.9) 2	2 (2.9) 2	7 (3.4) 8	12 (4.3) 16
Neutrophil count decreased	4 (5.8) 6	1 (1.4) 2	2 (2.9) 3	0	3 (1.4) 5	7 (2.5) 11
White blood cells urine positive	1 (1.4) 1	3 (4.3) 4	2 (2.9) 2	1 (1.5) 1	6 (2.9) 7	7 (2.5) 8
Alanine aminotransferase increased	2 (2.9) 2	1 (1.4) 1	3 (4.3) 3	0	4 (1.9) 4	6 (2.2) 6
Gamma-glutamyltransferase increased	2 (2.9) 2	0	2 (2.9) 2	2 (2.9) 2	4 (1.9) 4	6 (2.2) 6
Urinary occult blood positive	2 (2.9) 2	2 (2.9) 2	1 (1.4) 1	1 (1.5) 1	4 (1.9) 4	6 (2.2) 6
Aspartate aminotransferase increased	2 (2.9) 2	1 (1.4) 1	2 (2.9) 2	0	3 (1.4) 3	5 (1.8) 5
Blood glucose increased	1 (1.4) 1	2 (2.9) 3	0	1 (1.5) 1	3 (1.4) 4	4 (1.4) 5
Blood creatine phosphokinase increased	0	1 (1.4) 1	1 (1.4) 1	1 (1.5) 1	3 (1.4) 3	3 (1.1) 3
Blood lactate dehydrogenase increased	1 (1.4) 1	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	3 (1.1) 3
Electrocardiogram T wave abnormal	2 (2.9) 3	1 (1.4) 1	0	0	1 (0.5) 1	3 (1.1) 4
Low density lipoprotein increased	0	1 (1.4) 1	1 (1.4) 1	1 (1.5) 1	3 (1.4) 3	3 (1.1) 3
Ultrasound uterus abnormal	0	1 (1.4) 1	2 (2.9) 2	0	3 (1.4) 3	3 (1.1) 3
Bacterial test positive	1 (1.4) 1	1 (1.4) 2	0	0	1 (0.5) 2	2 (0.7) 3
Blood fibrinogen decreased	0	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	2 (0.7) 2
Blood fibrinogen increased	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Investigations (con'd)						
Blood thyroid stimulating hormone decreased	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Fibrin D dimer increased	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Hepatic enzyme increased	0	1 (1.4) 3	0	1 (1.5) 2	2 (1.0) 5	2 (0.7) 5
Alpha hydroxybutyrate dehydrogenase increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Bile acids increased	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Blood bilirubin increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Blood cholesterol increased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Blood creatinine increased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Blood glucose abnormal	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Blood pressure increased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Bone density decreased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Electrocardiogram Q wave abnormal	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Electrocardiogram QT prolonged	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Electrocardiogram ST segment elevation	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Electrocardiogram U-wave abnormality	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Electrocardiogram abnormal	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Electrocardiogram high voltage	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Fibrin degradation products increased	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Haematocrit decreased	1 (1.4) 1	0	0	0	0	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Investigations (con'd)						
Haemoglobin decreased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Lipids increased	0	0	0	1 (1.5) 2	1 (0.5) 2	1 (0.4) 2
Lymphocyte count decreased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Neutrophil count increased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Prealbumin decreased	1 (1.4) 2	0	0	0	0	1 (0.4) 2
Protein urine present	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Red blood cells urine positive	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Thyroxine free decreased	1 (1.4) 2	0	0	0	0	1 (0.4) 2
Transaminases increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Infections and infestations	17 (24.6) 18	15 (21.4) 20	15 (21.7) 17	14 (20.6) 18	44 (21.3) 55	61 (22.1) 73
Upper respiratory tract infection	7 (10.1) 7	6 (8.6) 6	9 (13.0) 9	6 (8.8) 6	21 (10.1) 21	28 (10.1) 28
Urinary tract infection	5 (7.2) 5	5 (7.1) 5	5 (7.2) 6	4 (5.9) 5	14 (6.8) 16	19 (6.9) 21
Gastroenteritis	1 (1.4) 1	1 (1.4) 1	0	1 (1.5) 1	2 (1.0) 2	3 (1.1) 3
Nasopharyngitis	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	3 (1.1) 3
Bronchitis	1 (1.4) 1	1 (1.4) 1	0	0	1 (0.5) 1	2 (0.7) 2
Influenza	0	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	2 (0.7) 2
Pneumonia	0	1 (1.4) 1	0	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Vaginal infection	0	2 (2.9) 3	0	0	2 (1.0) 3	2 (0.7) 3
Bacterial vaginosis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Conjunctivitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Gastroenteritis viral	1 (1.4) 1	0	0	0	0	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Infections and infestations (con'd)						
Laryngopharyngitis	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Oral herpes	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Pericoronitis	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Pharyngitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Rhinitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Vulvitis	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Metabolism and nutrition disorders	8 (11.6) 10	15 (21.4) 25	10 (14.5) 15	11 (16.2) 15	36 (17.4) 55	44 (15.9) 65
Hypercholesterolaemia	5 (7.2) 6	3 (4.3) 3	4 (5.8) 4	6 (8.8) 6	13 (6.3) 13	18 (6.5) 19
Hyperlipidaemia	1 (1.4) 1	6 (8.6) 13	3 (4.3) 3	3 (4.4) 4	12 (5.8) 20	13 (4.7) 21
Hyperuricaemia	1 (1.4) 1	3 (4.3) 3	4 (5.8) 5	1 (1.5) 1	8 (3.9) 9	9 (3.3) 10
Hypertriglyceridaemia	2 (2.9) 2	2 (2.9) 3	2 (2.9) 2	2 (2.9) 2	6 (2.9) 7	8 (2.9) 9
Vitamin D deficiency	0	3 (4.3) 3	1 (1.4) 1	0	4 (1.9) 4	4 (1.4) 4
Hyperglycaemia	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Impaired fasting glucose	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Gastrointestinal disorders	4 (5.8) 4	5 (7.1) 5	11 (15.9) 13	10 (14.7) 13	26 (12.6) 31	30 (10.9) 35
Abdominal discomfort	0	2 (2.9) 2	0	1 (1.5) 1	3 (1.4) 3	3 (1.1) 3
Abdominal distension	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	3 (1.1) 3
Abdominal pain	1 (1.4) 1	0	2 (2.9) 3	0	2 (1.0) 3	3 (1.1) 4
Abdominal pain upper	0	0	1 (1.4) 1	2 (2.9) 2	3 (1.4) 3	3 (1.1) 3
Constipation	0	0	0	3 (4.4) 3	3 (1.4) 3	3 (1.1) 3
Dry mouth	0	1 (1.4) 1	1 (1.4) 1	1 (1.5) 1	3 (1.4) 3	3 (1.1) 3
Mouth ulceration	0	0	2 (2.9) 2	1 (1.5) 1	3 (1.4) 3	3 (1.1) 3
Dental abfraction	1 (1.4) 1	0	0	1 (1.5) 1	1 (0.5) 1	2 (0.7) 2
Diarrhoea	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Chronic gastritis	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Dental caries	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Gastric polyps	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Gastritis	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Gastrointestinal disorder	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Gingival pain	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Nausea	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Stomatitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Toothache	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Reproductive system and breast disorders	4 (5.8) 4	8 (11.4) 8	8 (11.6) 9	5 (7.4) 7	21 (10.1) 24	25 (9.1) 28
Breast mass	2 (2.9) 2	3 (4.3) 3	2 (2.9) 2	4 (5.9) 4	9 (4.3) 9	11 (4.0) 11
Endometrial thickening	1 (1.4) 1	2 (2.9) 2	4 (5.8) 4	0	6 (2.9) 6	7 (2.5) 7
Vaginal haemorrhage	0	2 (2.9) 2	0	0	2 (1.0) 2	2 (0.7) 2
Adenomyosis	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Atrophic vulvovaginitis	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Breast cyst	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Breast tenderness	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Cervical polyp	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hydrosalpinx	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Vulval ulceration	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Vulvar squamous cell hyperplasia	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Nervous system disorders	4 (5.8) 4	1 (1.4) 1	5 (7.2) 6	2 (2.9) 2	8 (3.9) 9	12 (4.3) 13
Headache	2 (2.9) 2	1 (1.4) 1	2 (2.9) 2	2 (2.9) 2	5 (2.4) 5	7 (2.5) 7
Dizziness	2 (2.9) 2	0	0	0	0	2 (0.7) 2
Formication	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Hypoaesthesia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Migraine	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Syncope	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Respiratory, thoracic and mediastinal disorders	2 (2.9) 3	3 (4.3) 4	4 (5.8) 4	0	7 (3.4) 8	9 (3.3) 11
Oropharyngeal pain	1 (1.4) 1	1 (1.4) 1	3 (4.3) 3	0	4 (1.9) 4	5 (1.8) 5
Cough	2 (2.9) 2	1 (1.4) 1	0	0	1 (0.5) 1	3 (1.1) 3
Nasal obstruction	0	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	2 (0.7) 2
Productive cough	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Cardiac disorders	2 (2.9) 2	1 (1.4) 2	4 (5.8) 4	1 (1.5) 1	6 (2.9) 7	8 (2.9) 9
Palpitations	2 (2.9) 2	0	1 (1.4) 1	0	1 (0.5) 1	3 (1.1) 3
Ventricular extrasystoles	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Arrhythmia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Sinus bradycardia	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Supraventricular extrasystoles	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Supraventricular tachycardia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Musculoskeletal and connective tissue disorders	3 (4.3) 3	1 (1.4) 1	1 (1.4) 1	3 (4.4) 5	5 (2.4) 7	8 (2.9) 10
Arthralgia	1 (1.4) 1	0	0	1 (1.5) 1	1 (0.5) 1	2 (0.7) 2
Pain in extremity	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Axillary mass	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Back pain	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Gouty arthritis	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Limb discomfort	0	0	0	1 (1.5) 2	1 (0.5) 2	1 (0.4) 2
Tenosynovitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Skin and subcutaneous tissue disorders	2 (2.9) 2	0	2 (2.9) 2	3 (4.4) 3	5 (2.4) 5	7 (2.5) 7
Dermatitis allergic	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Pruritus	0	0	0	2 (2.9) 2	2 (1.0) 2	2 (0.7) 2
Eczema	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Papule	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Urticaria	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hepatobiliary disorders	2 (2.9) 2	1 (1.4) 1	2 (2.9) 3	1 (1.5) 1	4 (1.9) 5	6 (2.2) 7
Hepatic function abnormal	2 (2.9) 2	1 (1.4) 1	2 (2.9) 3	1 (1.5) 1	4 (1.9) 5	6 (2.2) 7

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
General disorders and administration site conditions	2 (2.9) 3	0	2 (2.9) 2	1 (1.5) 1	3 (1.4) 3	5 (1.8) 6
Chest pain	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Pyrexia	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Asthenia	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Chest discomfort	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Blood and lymphatic system disorders	1 (1.4) 1	2 (2.9) 2	1 (1.4) 1	0	3 (1.4) 3	4 (1.4) 4
Anaemia	1 (1.4) 1	1 (1.4) 1	0	0	1 (0.5) 1	2 (0.7) 2
Lymphadenopathy	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Neutropenia	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Eye disorders	1 (1.4) 1	1 (1.4) 1	0	1 (1.5) 1	2 (1.0) 2	3 (1.1) 3
Blepharitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Dry eye	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Eyelid oedema	1 (1.4) 1	0	0	0	0	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
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Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (1.4) 1	2 (2.9) 2	3 (1.4) 3	3 (1.1) 3
Leiomyoma	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Ovarian cancer	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Uterine leiomyoma	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Vascular disorders	0	1 (1.4) 1	0	2 (2.9) 2	3 (1.4) 3	3 (1.1) 3
Hypertension	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Phlebitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Venous thrombosis limb	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Endocrine disorders	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Hyperthyroidism	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hypothyroidism	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Injury, poisoning and procedural complications	0	1 (1.4) 1	0	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Ligament sprain	0	1 (1.4) 1	0	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Psychiatric disorders	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Insomnia	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.1
TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Renal and urinary disorders	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Pollakiuria	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.2
Treatment-Emergent SAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Treatment-Emergent SAEs	1 (1.4) 1	1 (1.4) 1	0	2 (2.9) 2	3 (1.4) 3	4 (1.4) 4
Hepatobiliary disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hepatic function abnormal	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Infections and infestations	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Pneumonia	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Ovarian cancer	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Reproductive system and breast disorders	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Hydrosalpinx	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.2
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.3
TEAEs Leading to Drug Interruption by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
TEAEs Leading to Drug Interruption	5 (7.2) 13	1 (1.4) 2	3 (4.3) 6	2 (2.9) 4	6 (2.9) 12	11 (4.0) 25
Investigations	2 (2.9) 3	1 (1.4) 2	1 (1.4) 1	1 (1.5) 1	3 (1.4) 4	5 (1.8) 7
Blood fibrinogen increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Blood parathyroid hormone increased	0	1 (1.4) 2	0	0	1 (0.5) 2	1 (0.4) 2
Electrocardiogram QT prolonged	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Gamma-glutamyltransferase increased	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Neutrophil count decreased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
White blood cell count decreased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Cardiac disorders	1 (1.4) 1	0	2 (2.9) 2	0	2 (1.0) 2	3 (1.1) 3
Palpitations	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Supraventricular tachycardia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Infections and infestations	2 (2.9) 2	0	0	1 (1.5) 1	1 (0.5) 1	3 (1.1) 3
Gastroenteritis	1 (1.4) 1	0	0	1 (1.5) 1	1 (0.5) 1	2 (0.7) 2
Gastroenteritis viral	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Gastrointestinal disorders	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Abdominal pain upper	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Nausea	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.5
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.3
TEAEs Leading to Drug Interruption by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
General disorders and administration site conditions	2 (2.9) 3	0	0	0	0	2 (0.7) 3
Asthenia	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Chest pain	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Pyrexia	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Musculoskeletal and connective tissue disorders	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Arthralgia	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Pain in extremity	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Nervous system disorders	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Headache	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hypoaesthesia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Blood and lymphatic system disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Anaemia	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hepatobiliary disorders	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Hepatic function abnormal	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.5
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.3
TEAEs Leading to Drug Interruption by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Respiratory, thoracic and mediastinal disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Oropharyngeal pain	1 (1.4) 1	0	0	0	0	1 (0.4) 1

Data Source: Listing 16.2.7.5
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.2.4
TEAEs Leading to Drug Withdrawal by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
TEAEs Leading to Drug Withdrawal	2 (2.9) 3	2 (2.9) 2	0	1 (1.5) 1	3 (1.4) 3	5 (1.8) 6
Investigations	1 (1.4) 1	1 (1.4) 1	0	0	1 (0.5) 1	2 (0.7) 2
Blood parathyroid hormone increased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Blood pressure increased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hepatobiliary disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hepatic function abnormal	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Infections and infestations	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Pneumonia	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Musculoskeletal and connective tissue disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Gouty arthritis	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Ovarian cancer	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.6
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TEAEs	43 (62.3)	48 (68.6)	48 (69.6)	44 (64.7)	140 (67.6)	183 (66.3)
Mild	32 (46.4)	40 (57.1)	38 (55.1)	33 (48.5)	111 (53.6)	143 (51.8)
Moderate	11 (15.9)	8 (11.4)	10 (14.5)	10 (14.7)	28 (13.5)	39 (14.1)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Investigations	23 (33.3)	25 (35.7)	19 (27.5)	17 (25.0)	61 (29.5)	84 (30.4)
Mild	21 (30.4)	24 (34.3)	17 (24.6)	16 (23.5)	57 (27.5)	78 (28.3)
Moderate	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	6 (2.2)
Severe	0	0	0	0	0	0
Blood parathyroid hormone increased	10 (14.5)	10 (14.3)	7 (10.1)	5 (7.4)	22 (10.6)	32 (11.6)
Mild	10 (14.5)	10 (14.3)	7 (10.1)	5 (7.4)	22 (10.6)	32 (11.6)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood thyroid stimulating hormone increased	7 (10.1)	5 (7.1)	3 (4.3)	1 (1.5)	9 (4.3)	16 (5.8)
Mild	7 (10.1)	5 (7.1)	3 (4.3)	1 (1.5)	9 (4.3)	16 (5.8)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
White blood cell count decreased	5 (7.2)	3 (4.3)	2 (2.9)	2 (2.9)	7 (3.4)	12 (4.3)
Mild	5 (7.2)	2 (2.9)	2 (2.9)	2 (2.9)	6 (2.9)	11 (4.0)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Neutrophil count decreased	4 (5.8)	1 (1.4)	2 (2.9)	0	3 (1.4)	7 (2.5)
Mild	4 (5.8)	0	2 (2.9)	0	2 (1.0)	6 (2.2)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
White blood cells urine positive	1 (1.4)	3 (4.3)	2 (2.9)	1 (1.5)	6 (2.9)	7 (2.5)
Mild	1 (1.4)	3 (4.3)	2 (2.9)	1 (1.5)	6 (2.9)	7 (2.5)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Alanine aminotransferase increased	2 (2.9)	1 (1.4)	3 (4.3)	0	4 (1.9)	6 (2.2)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Gamma-glutamyltransferase increased	2 (2.9)	0	2 (2.9)	2 (2.9)	4 (1.9)	6 (2.2)
Mild	1 (1.4)	0	2 (2.9)	1 (1.5)	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Urinary occult blood positive	2 (2.9)	2 (2.9)	1 (1.4)	1 (1.5)	4 (1.9)	6 (2.2)
Mild	2 (2.9)	2 (2.9)	1 (1.4)	1 (1.5)	4 (1.9)	6 (2.2)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Aspartate aminotransferase increased	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Blood glucose increased	1 (1.4)	2 (2.9)	0	1 (1.5)	3 (1.4)	4 (1.4)
Mild	1 (1.4)	2 (2.9)	0	1 (1.5)	3 (1.4)	4 (1.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood creatine phosphokinase increased	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood lactate dehydrogenase increased	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram T wave abnormal	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Mild	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Low density lipoprotein increased	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Ultrasound uterus abnormal	0	1 (1.4)	2 (2.9)	0	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	2 (2.9)	0	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Bacterial test positive	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood fibrinogen decreased	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood fibrinogen increased	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Blood thyroid stimulating hormone decreased	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Fibrin D dimer increased	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hepatic enzyme increased	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Alpha hydroxybutyrate dehydrogenase increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Bile acids increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Blood bilirubin increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood cholesterol increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood creatinine increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood glucose abnormal	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood pressure increased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Bone density decreased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram Q wave abnormal	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram QT prolonged	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram ST segment elevation	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram U-wave abnormality	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Electrocardiogram abnormal	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram high voltage	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Fibrin degradation products increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Haematocrit decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Haemoglobin decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Lipids increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Lymphocyte count decreased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Neutrophil count increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Prealbumin decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Protein urine present	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Red blood cells urine positive	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Thyroxine free decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Transaminases increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Infections and infestations	17 (24.6)	15 (21.4)	15 (21.7)	14 (20.6)	44 (21.3)	61 (22.1)
Mild	11 (15.9)	12 (17.1)	11 (15.9)	12 (17.6)	35 (16.9)	46 (16.7)
Moderate	6 (8.7)	3 (4.3)	4 (5.8)	2 (2.9)	9 (4.3)	15 (5.4)
Severe	0	0	0	0	0	0
Upper respiratory tract infection	7 (10.1)	6 (8.6)	9 (13.0)	6 (8.8)	21 (10.1)	28 (10.1)
Mild	4 (5.8)	5 (7.1)	7 (10.1)	4 (5.9)	16 (7.7)	20 (7.2)
Moderate	3 (4.3)	1 (1.4)	2 (2.9)	2 (2.9)	5 (2.4)	8 (2.9)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Urinary tract infection	5 (7.2)	5 (7.1)	5 (7.2)	4 (5.9)	14 (6.8)	19 (6.9)
Mild	5 (7.2)	5 (7.1)	4 (5.8)	4 (5.9)	13 (6.3)	18 (6.5)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Gastroenteritis	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Nasopharyngitis	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Mild	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Bronchitis	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Influenza	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Mild	0	0	0	0	0	0
Moderate	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Pneumonia	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Vaginal infection	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Bacterial vaginosis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Conjunctivitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastroenteritis viral	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Laryngopharyngitis	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Oral herpes	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Pericoronitis	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Pharyngitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Rhinitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Vulvitis	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Metabolism and nutrition disorders	8 (11.6)	15 (21.4)	10 (14.5)	11 (16.2)	36 (17.4)	44 (15.9)
Mild	8 (11.6)	15 (21.4)	9 (13.0)	11 (16.2)	35 (16.9)	43 (15.6)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Hypercholesterolaemia	5 (7.2)	3 (4.3)	4 (5.8)	6 (8.8)	13 (6.3)	18 (6.5)
Mild	5 (7.2)	3 (4.3)	4 (5.8)	6 (8.8)	13 (6.3)	18 (6.5)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hyperlipidaemia	1 (1.4)	6 (8.6)	3 (4.3)	3 (4.4)	12 (5.8)	13 (4.7)
Mild	1 (1.4)	6 (8.6)	2 (2.9)	3 (4.4)	11 (5.3)	12 (4.3)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Hyperuricaemia	1 (1.4)	3 (4.3)	4 (5.8)	1 (1.5)	8 (3.9)	9 (3.3)
Mild	1 (1.4)	3 (4.3)	4 (5.8)	1 (1.5)	8 (3.9)	9 (3.3)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Hypertriglyceridaemia	2 (2.9)	2 (2.9)	2 (2.9)	2 (2.9)	6 (2.9)	8 (2.9)
Mild	2 (2.9)	2 (2.9)	2 (2.9)	2 (2.9)	6 (2.9)	8 (2.9)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Vitamin D deficiency	0	3 (4.3)	1 (1.4)	0	4 (1.9)	4 (1.4)
Mild	0	3 (4.3)	1 (1.4)	0	4 (1.9)	4 (1.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hyperglycaemia	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Impaired fasting glucose	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastrointestinal disorders	4 (5.8)	5 (7.1)	11 (15.9)	10 (14.7)	26 (12.6)	30 (10.9)
Mild	3 (4.3)	4 (5.7)	10 (14.5)	6 (8.8)	20 (9.7)	23 (8.3)
Moderate	1 (1.4)	1 (1.4)	1 (1.4)	4 (5.9)	6 (2.9)	7 (2.5)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Abdominal discomfort	0	2 (2.9)	0	1 (1.5)	3 (1.4)	3 (1.1)
Mild	0	2 (2.9)	0	1 (1.5)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Abdominal distension	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Abdominal pain	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Abdominal pain upper	0	0	1 (1.4)	2 (2.9)	3 (1.4)	3 (1.1)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Constipation	0	0	0	3 (4.4)	3 (1.4)	3 (1.1)
Mild	0	0	0	2 (2.9)	2 (1.0)	2 (0.7)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Dry mouth	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Mouth ulceration	0	0	2 (2.9)	1 (1.5)	3 (1.4)	3 (1.1)
Mild	0	0	2 (2.9)	1 (1.5)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Dental abfraction	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Diarrhoea	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Chronic gastritis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Dental caries	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastric polyps	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastritis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastrointestinal disorder	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Gingival pain	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Nausea	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Stomatitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Toothache	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Reproductive system and breast disorders	4 (5.8)	8 (11.4)	8 (11.6)	5 (7.4)	21 (10.1)	25 (9.1)
Mild	4 (5.8)	7 (10.0)	7 (10.1)	4 (5.9)	18 (8.7)	22 (8.0)
Moderate	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Severe	0	0	0	0	0	0
Breast mass	2 (2.9)	3 (4.3)	2 (2.9)	4 (5.9)	9 (4.3)	11 (4.0)
Mild	2 (2.9)	2 (2.9)	2 (2.9)	4 (5.9)	8 (3.9)	10 (3.6)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Endometrial thickening	1 (1.4)	2 (2.9)	4 (5.8)	0	6 (2.9)	7 (2.5)
Mild	1 (1.4)	2 (2.9)	3 (4.3)	0	5 (2.4)	6 (2.2)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Vaginal haemorrhage	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Mild	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Adenomyosis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Atrophic vulvovaginitis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Breast cyst	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Breast tenderness	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Cervical polyp	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hydrosalpinx	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Vulval ulceration	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Vulvar squamous cell hyperplasia	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Nervous system disorders	4 (5.8)	1 (1.4)	5 (7.2)	2 (2.9)	8 (3.9)	12 (4.3)
Mild	3 (4.3)	1 (1.4)	5 (7.2)	2 (2.9)	8 (3.9)	11 (4.0)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Headache	2 (2.9)	1 (1.4)	2 (2.9)	2 (2.9)	5 (2.4)	7 (2.5)
Mild	2 (2.9)	1 (1.4)	2 (2.9)	2 (2.9)	5 (2.4)	7 (2.5)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Dizziness	2 (2.9)	0	0	0	0	2 (0.7)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Formication	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hypoaesthesia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Migraine	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Syncope	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	2 (2.9)	3 (4.3)	4 (5.8)	0	7 (3.4)	9 (3.3)
Mild	2 (2.9)	3 (4.3)	4 (5.8)	0	7 (3.4)	9 (3.3)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Oropharyngeal pain	1 (1.4)	1 (1.4)	3 (4.3)	0	4 (1.9)	5 (1.8)
Mild	1 (1.4)	1 (1.4)	3 (4.3)	0	4 (1.9)	5 (1.8)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Cough	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Mild	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Nasal obstruction	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Productive cough	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Cardiac disorders	2 (2.9)	1 (1.4)	4 (5.8)	1 (1.5)	6 (2.9)	8 (2.9)
Mild	1 (1.4)	1 (1.4)	4 (5.8)	1 (1.5)	6 (2.9)	7 (2.5)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Palpitations	2 (2.9)	0	1 (1.4)	0	1 (0.5)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Ventricular extrasystoles	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Arrhythmia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Sinus bradycardia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Supraventricular extrasystoles	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Supraventricular tachycardia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	3 (4.3)	1 (1.4)	1 (1.4)	3 (4.4)	5 (2.4)	8 (2.9)
Mild	2 (2.9)	1 (1.4)	1 (1.4)	3 (4.4)	5 (2.4)	7 (2.5)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Arthralgia	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Pain in extremity	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Axillary mass	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Back pain	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gouty arthritis	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Limb discomfort	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Tenosynovitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (2.9)	0	2 (2.9)	3 (4.4)	5 (2.4)	7 (2.5)
Mild	2 (2.9)	0	2 (2.9)	2 (2.9)	4 (1.9)	6 (2.2)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Dermatitis allergic	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Pruritus	0	0	0	2 (2.9)	2 (1.0)	2 (0.7)
Mild	0	0	0	2 (2.9)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Eczema	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Papule	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Urticaria	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hepatobiliary disorders	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	6 (2.2)
Mild	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Moderate	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Hepatic function abnormal	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	6 (2.2)
Mild	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Moderate	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
General disorders and administration site conditions	2 (2.9)	0	2 (2.9)	1 (1.5)	3 (1.4)	5 (1.8)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	2 (2.9)	0	1 (1.4)	0	1 (0.5)	3 (1.1)
Severe	0	0	0	0	0	0
Chest pain	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Pyrexia	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Asthenia	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Chest discomfort	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Blood and lymphatic system disorders	1 (1.4)	2 (2.9)	1 (1.4)	0	3 (1.4)	4 (1.4)
Mild	1 (1.4)	2 (2.9)	1 (1.4)	0	3 (1.4)	4 (1.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Anaemia	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Lymphadenopathy	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Neutropenia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Eye disorders	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
Mild	1 (1.4)	1 (1.4)	0	1 (1.5)	2 (1.0)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Blepharitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Dry eye	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Eyelid oedema	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (1.4)	2 (2.9)	3 (1.4)	3 (1.1)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Leiomyoma	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Ovarian cancer	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Uterine leiomyoma	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Vascular disorders	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Severe	0	0	0	0	0	0
Hypertension	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Phlebitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Venous thrombosis limb	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Endocrine disorders	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hyperthyroidism	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hypothyroidism	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Injury, poisoning and procedural complications	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.1
TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Ligament sprain	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Psychiatric disorders	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Insomnia	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Renal and urinary disorders	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Pollakiuria	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.2
Severe TEAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Severe TEAEs	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Hepatobiliary disorders	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Hepatic function abnormal	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.3
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.3.3
Treatment-Emergent SAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Treatment-Emergent SAEs	1 (1.4)	1 (1.4)	0	2 (2.9)	3 (1.4)	4 (1.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	1 (1.4)	0	2 (2.9)	3 (1.4)	4 (1.4)
Severe	0	0	0	0	0	0
Hepatobiliary disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatic function abnormal	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Infections and infestations	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Pneumonia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.2
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.3
Treatment-Emergent SAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Ovarian cancer	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Reproductive system and breast disorders	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Hydrosalpinx	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.2
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.4
TEAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TEAEs Leading to Drug Interruption	5 (7.2)	1 (1.4)	3 (4.3)	2 (2.9)	6 (2.9)	11 (4.0)
Mild	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	6 (2.2)
Moderate	3 (4.3)	0	1 (1.4)	0	1 (0.5)	4 (1.4)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Investigations	2 (2.9)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	5 (1.8)
Mild	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Moderate	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Severe	0	0	0	0	0	0
Blood fibrinogen increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Blood parathyroid hormone increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram QT prolonged	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.4
TEAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Gamma-glutamyltransferase increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Neutrophil count decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
White blood cell count decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Cardiac disorders	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Mild	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Palpitations	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.4
TEAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Supraventricular tachycardia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Infections and infestations	2 (2.9)	0	0	1 (1.5)	1 (0.5)	3 (1.1)
Mild	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Gastroenteritis viral	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastrointestinal disorders	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.4
TEAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Abdominal pain upper	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Nausea	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
General disorders and administration site conditions	2 (2.9)	0	0	0	0	2 (0.7)
Mild	0	0	0	0	0	0
Moderate	2 (2.9)	0	0	0	0	2 (0.7)
Severe	0	0	0	0	0	0
Asthenia	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Chest pain	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.4
TEAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Pyrexia	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Arthralgia	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Pain in extremity	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Nervous system disorders	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.4
TEAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Headache	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hypoaesthesia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood and lymphatic system disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Anaemia	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hepatobiliary disorders	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	0	0	0
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.4
TEAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Hepatic function abnormal	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	0	0	0
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Respiratory, thoracic and mediastinal disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Oropharyngeal pain	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.5
TEAEs Leading to Drug Withdrawal by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TEAEs Leading to Drug Withdrawal	2 (2.9)	2 (2.9)	0	1 (1.5)	3 (1.4)	5 (1.8)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	2 (2.9)	1 (1.4)	0	1 (1.5)	2 (1.0)	4 (1.4)
Severe	0	0	0	0	0	0
Investigations	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Blood parathyroid hormone increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood pressure increased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatobiliary disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.6
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.5
TEAEs Leading to Drug Withdrawal by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Hepatic function abnormal	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Infections and infestations	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Pneumonia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Gouty arthritis	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.6
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.3.5
TEAEs Leading to Drug Withdrawal by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Ovarian cancer	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.6
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.4.1
TRAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
TRAEs	23 (33.3) 56	24 (34.3) 53	24 (34.8) 51	21 (30.9) 41	69 (33.3) 145	92 (33.3) 201
Investigations	20 (29.0) 50	19 (27.1) 38	16 (23.2) 32	11 (16.2) 20	46 (22.2) 90	66 (23.9) 140
Blood parathyroid hormone increased	10 (14.5) 12	10 (14.3) 14	7 (10.1) 8	4 (5.9) 5	21 (10.1) 27	31 (11.2) 39
Blood thyroid stimulating hormone increased	7 (10.1) 10	5 (7.1) 7	1 (1.4) 1	0	6 (2.9) 8	13 (4.7) 18
White blood cell count decreased	3 (4.3) 6	1 (1.4) 2	1 (1.4) 1	2 (2.9) 2	4 (1.9) 5	7 (2.5) 11
Alanine aminotransferase increased	2 (2.9) 2	1 (1.4) 1	3 (4.3) 3	0	4 (1.9) 4	6 (2.2) 6
Aspartate aminotransferase increased	2 (2.9) 2	1 (1.4) 1	2 (2.9) 2	0	3 (1.4) 3	5 (1.8) 5
Gamma-glutamyltransferase increased	2 (2.9) 2	0	2 (2.9) 2	1 (1.5) 1	3 (1.4) 3	5 (1.8) 5
Neutrophil count decreased	2 (2.9) 4	1 (1.4) 2	1 (1.4) 2	0	2 (1.0) 4	4 (1.4) 8
Urinary occult blood positive	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	1 (1.5) 1	3 (1.4) 3	4 (1.4) 4
White blood cells urine positive	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	1 (1.5) 1	3 (1.4) 3	4 (1.4) 4
Blood lactate dehydrogenase increased	1 (1.4) 1	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	3 (1.1) 3
Bacterial test positive	1 (1.4) 1	1 (1.4) 1	0	0	1 (0.5) 1	2 (0.7) 2
Blood creatine phosphokinase increased	0	1 (1.4) 1	0	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Blood fibrinogen decreased	0	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	2 (0.7) 2
Blood fibrinogen increased	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Electrocardiogram T wave abnormal	2 (2.9) 3	0	0	0	0	2 (0.7) 3
Fibrin D dimer increased	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Hepatic enzyme increased	0	1 (1.4) 3	0	1 (1.5) 2	2 (1.0) 5	2 (0.7) 5
Ultrasound uterus abnormal	0	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	2 (0.7) 2

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.1
TRAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Investigations (con'd)						
Alpha hydroxybutyrate dehydrogenase increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Bile acids increased	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Blood cholesterol increased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Blood glucose increased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Blood pressure increased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Blood thyroid stimulating hormone decreased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Electrocardiogram QT prolonged	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Electrocardiogram ST segment elevation	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Electrocardiogram U-wave abnormality	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Electrocardiogram high voltage	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Fibrin degradation products increased	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Lymphocyte count decreased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Protein urine present	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Red blood cells urine positive	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Thyroxine free decreased	1 (1.4) 2	0	0	0	0	1 (0.4) 2
Transaminases increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.1
TRAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Reproductive system and breast disorders	1 (1.4) 1	3 (4.3) 3	5 (7.2) 6	3 (4.4) 4	11 (5.3) 13	12 (4.3) 14
Breast mass	0	3 (4.3) 3	2 (2.9) 2	3 (4.4) 3	8 (3.9) 8	8 (2.9) 8
Endometrial thickening	0	0	2 (2.9) 2	0	2 (1.0) 2	2 (0.7) 2
Adenomyosis	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Breast cyst	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Breast tenderness	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Cervical polyp	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Gastrointestinal disorders	1 (1.4) 1	3 (4.3) 3	4 (5.8) 4	3 (4.4) 4	10 (4.8) 11	11 (4.0) 12
Dry mouth	0	1 (1.4) 1	1 (1.4) 1	1 (1.5) 1	3 (1.4) 3	3 (1.1) 3
Abdominal discomfort	0	2 (2.9) 2	0	0	2 (1.0) 2	2 (0.7) 2
Abdominal distension	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Constipation	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Diarrhoea	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Gastrointestinal disorder	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Gingival pain	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Nausea	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Stomatitis	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.1
TRAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Cardiac disorders	0	1 (1.4) 2	3 (4.3) 3	1 (1.5) 1	5 (2.4) 6	5 (1.8) 6
Ventricular extrasystoles	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Palpitations	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Sinus bradycardia	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Supraventricular extrasystoles	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Supraventricular tachycardia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Metabolism and nutrition disorders	0	2 (2.9) 3	1 (1.4) 2	2 (2.9) 3	5 (2.4) 8	5 (1.8) 8
Hyperlipidaemia	0	1 (1.4) 2	0	1 (1.5) 2	2 (1.0) 4	2 (0.7) 4
Hypertriglyceridaemia	0	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	2 (0.7) 2
Hypercholesterolaemia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Impaired fasting glucose	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Hepatobiliary disorders	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	3 (1.1) 3
Hepatic function abnormal	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	3 (1.1) 3
Infections and infestations	0	1 (1.4) 1	0	2 (2.9) 2	3 (1.4) 3	3 (1.1) 3
Urinary tract infection	0	1 (1.4) 1	0	2 (2.9) 2	3 (1.4) 3	3 (1.1) 3
Nervous system disorders	0	1 (1.4) 1	0	2 (2.9) 2	3 (1.4) 3	3 (1.1) 3
Headache	0	1 (1.4) 1	0	2 (2.9) 2	3 (1.4) 3	3 (1.1) 3

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.1
TRAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Endocrine disorders	1 (1.4) 1	0	1 (1.4) 1	0	1 (0.5) 1	2 (0.7) 2
Hyperthyroidism	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hypothyroidism	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Musculoskeletal and connective tissue disorders	0	1 (1.4) 1	0	1 (1.5) 2	2 (1.0) 3	2 (0.7) 3
Axillary mass	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Limb discomfort	0	0	0	1 (1.5) 2	1 (0.5) 2	1 (0.4) 2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (1.4) 1	1 (1.5) 1	2 (1.0) 2	2 (0.7) 2
Leiomyoma	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Uterine leiomyoma	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Blood and lymphatic system disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Anaemia	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Eye disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Eyelid oedema	1 (1.4) 1	0	0	0	0	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.1
TRAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
General disorders and administration site conditions	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Chest discomfort	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Oropharyngeal pain	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Skin and subcutaneous tissue disorders	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1
Pruritus	0	0	0	1 (1.5) 1	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.1
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.2
Treatment-Related SAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E

No data to be reported

Data Source: Listing 16.2.7.2
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.3
TRAEs Leading to Drug Interruption by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
TRAEs Leading to Drug Interruption	2 (2.9) 4	1 (1.4) 2	3 (4.3) 4	0	4 (1.9) 6	6 (2.2) 10
Investigations	2 (2.9) 3	1 (1.4) 2	1 (1.4) 1	0	2 (1.0) 3	4 (1.4) 6
Blood fibrinogen increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Blood parathyroid hormone increased	0	1 (1.4) 2	0	0	1 (0.5) 2	1 (0.4) 2
Electrocardiogram QT prolonged	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Neutrophil count decreased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
White blood cell count decreased	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Cardiac disorders	0	0	2 (2.9) 2	0	2 (1.0) 2	2 (0.7) 2
Palpitations	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Supraventricular tachycardia	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Blood and lymphatic system disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Anaemia	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Gastrointestinal disorders	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Nausea	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1

Data Source: Listing 16.2.7.5
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.4.4
TRAEs Leading to Drug Withdrawal by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
TRAEs Leading to Drug Withdrawal	1 (1.4) 1	1 (1.4) 1	0	0	1 (0.5) 1	2 (0.7) 2
Investigations	1 (1.4) 1	1 (1.4) 1	0	0	1 (0.5) 1	2 (0.7) 2
Blood parathyroid hormone increased	0	1 (1.4) 1	0	0	1 (0.5) 1	1 (0.4) 1
Blood pressure increased	1 (1.4) 1	0	0	0	0	1 (0.4) 1

Data Source: Listing 16.2.7.6
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TRAEs	23 (33.3)	24 (34.3)	24 (34.8)	21 (30.9)	69 (33.3)	92 (33.3)
Mild	20 (29.0)	21 (30.0)	21 (30.4)	20 (29.4)	62 (30.0)	82 (29.7)
Moderate	3 (4.3)	3 (4.3)	3 (4.3)	1 (1.5)	7 (3.4)	10 (3.6)
Severe	0	0	0	0	0	0
Investigations	20 (29.0)	19 (27.1)	16 (23.2)	11 (16.2)	46 (22.2)	66 (23.9)
Mild	18 (26.1)	18 (25.7)	14 (20.3)	11 (16.2)	43 (20.8)	61 (22.1)
Moderate	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
Severe	0	0	0	0	0	0
Blood parathyroid hormone increased	10 (14.5)	10 (14.3)	7 (10.1)	4 (5.9)	21 (10.1)	31 (11.2)
Mild	10 (14.5)	10 (14.3)	7 (10.1)	4 (5.9)	21 (10.1)	31 (11.2)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood thyroid stimulating hormone increased	7 (10.1)	5 (7.1)	1 (1.4)	0	6 (2.9)	13 (4.7)
Mild	7 (10.1)	5 (7.1)	1 (1.4)	0	6 (2.9)	13 (4.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
White blood cell count decreased	3 (4.3)	1 (1.4)	1 (1.4)	2 (2.9)	4 (1.9)	7 (2.5)
Mild	3 (4.3)	0	1 (1.4)	2 (2.9)	3 (1.4)	6 (2.2)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Alanine aminotransferase increased	2 (2.9)	1 (1.4)	3 (4.3)	0	4 (1.9)	6 (2.2)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Aspartate aminotransferase increased	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Gamma-glutamyltransferase increased	2 (2.9)	0	2 (2.9)	1 (1.5)	3 (1.4)	5 (1.8)
Mild	1 (1.4)	0	2 (2.9)	1 (1.5)	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Neutrophil count decreased	2 (2.9)	1 (1.4)	1 (1.4)	0	2 (1.0)	4 (1.4)
Mild	2 (2.9)	0	1 (1.4)	0	1 (0.5)	3 (1.1)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Urinary occult blood positive	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
Mild	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
White blood cells urine positive	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
Mild	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	4 (1.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood lactate dehydrogenase increased	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Bacterial test positive	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood creatine phosphokinase increased	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood fibrinogen decreased	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Blood fibrinogen increased	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Electrocardiogram T wave abnormal	2 (2.9)	0	0	0	0	2 (0.7)
Mild	2 (2.9)	0	0	0	0	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Fibrin D dimer increased	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hepatic enzyme increased	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Ultrasound uterus abnormal	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Alpha hydroxybutyrate dehydrogenase increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Bile acids increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood cholesterol increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood glucose increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood pressure increased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Blood thyroid stimulating hormone decreased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram QT prolonged	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram ST segment elevation	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram U-wave abnormality	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram high voltage	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Fibrin degradation products increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Lymphocyte count decreased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Protein urine present	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Red blood cells urine positive	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Thyroxine free decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Transaminases increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Reproductive system and breast disorders	1 (1.4)	3 (4.3)	5 (7.2)	3 (4.4)	11 (5.3)	12 (4.3)
Mild	1 (1.4)	2 (2.9)	4 (5.8)	3 (4.4)	9 (4.3)	10 (3.6)
Moderate	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Severe	0	0	0	0	0	0
Breast mass	0	3 (4.3)	2 (2.9)	3 (4.4)	8 (3.9)	8 (2.9)
Mild	0	2 (2.9)	2 (2.9)	3 (4.4)	7 (3.4)	7 (2.5)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Endometrial thickening	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Adenomyosis	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Breast cyst	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Breast tenderness	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Cervical polyp	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastrointestinal disorders	1 (1.4)	3 (4.3)	4 (5.8)	3 (4.4)	10 (4.8)	11 (4.0)
Mild	0	3 (4.3)	4 (5.8)	2 (2.9)	9 (4.3)	9 (3.3)
Moderate	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Dry mouth	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	1 (1.4)	1 (1.5)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Abdominal discomfort	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Mild	0	2 (2.9)	0	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Abdominal distension	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Constipation	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Diarrhoea	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastrointestinal disorder	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Gingival pain	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Nausea	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Stomatitis	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Cardiac disorders	0	1 (1.4)	3 (4.3)	1 (1.5)	5 (2.4)	5 (1.8)
Mild	0	1 (1.4)	3 (4.3)	1 (1.5)	5 (2.4)	5 (1.8)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Ventricular extrasystoles	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Palpitations	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Sinus bradycardia	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Supraventricular extrasystoles	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Supraventricular tachycardia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Metabolism and nutrition disorders	0	2 (2.9)	1 (1.4)	2 (2.9)	5 (2.4)	5 (1.8)
Mild	0	2 (2.9)	1 (1.4)	2 (2.9)	5 (2.4)	5 (1.8)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Hyperlipidaemia	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hypertriglyceridaemia	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	1 (1.4)	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hypercholesterolaemia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Impaired fasting glucose	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hepatobiliary disorders	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Hepatic function abnormal	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Infections and infestations	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Urinary tract infection	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Nervous system disorders	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Headache	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Mild	0	1 (1.4)	0	2 (2.9)	3 (1.4)	3 (1.1)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Endocrine disorders	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hyperthyroidism	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hypothyroidism	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Axillary mass	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Limb discomfort	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	0	1 (1.4)	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Leiomyoma	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Uterine leiomyoma	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood and lymphatic system disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Anaemia	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Eye disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Eyelid oedema	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
General disorders and administration site conditions	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Chest discomfort	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.1
TRAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Oropharyngeal pain	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Pruritus	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.2
Severe TRAEs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E

No data to be reported

Data Source: Listing 16.2.7.3
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.5.3
Treatment-Related SAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)

No data to be reported

Data Source: Listing 16.2.7.2
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.4
TRAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TRAEs Leading to Drug Interruption	2 (2.9)	1 (1.4)	3 (4.3)	0	4 (1.9)	6 (2.2)
Mild	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Investigations	2 (2.9)	1 (1.4)	1 (1.4)	0	2 (1.0)	4 (1.4)
Mild	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Blood fibrinogen increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Blood parathyroid hormone increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Electrocardiogram QT prolonged	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.4
TRAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Neutrophil count decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
White blood cell count decreased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Cardiac disorders	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Mild	0	0	2 (2.9)	0	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Palpitations	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Supraventricular tachycardia	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.4
TRAEs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Blood and lymphatic system disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Anaemia	1 (1.4)	0	0	0	0	1 (0.4)
Mild	1 (1.4)	0	0	0	0	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Gastrointestinal disorders	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Nausea	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.5
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.5
TRAEs Leading to Drug Withdrawal by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
TRAEs Leading to Drug Withdrawal	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Investigations	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Blood parathyroid hormone increased	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Mild	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood pressure increased	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.6
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.5.6
Procedure-Related TEAEs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)

No data to be reported

Data Source: Listing 16.2.7.1
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.6.1
AESIs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
AESIs	5 (7.2) 8	3 (4.3) 6	8 (11.6) 12	3 (4.4) 5	14 (6.8) 23	19 (6.9) 31
Investigations	3 (4.3) 6	2 (2.9) 5	6 (8.7) 9	3 (4.4) 4	11 (5.3) 18	14 (5.1) 24
Alanine aminotransferase increased	2 (2.9) 2	1 (1.4) 1	3 (4.3) 3	0	4 (1.9) 4	6 (2.2) 6
Gamma-glutamyltransferase increased	2 (2.9) 2	0	2 (2.9) 2	2 (2.9) 2	4 (1.9) 4	6 (2.2) 6
Aspartate aminotransferase increased	2 (2.9) 2	1 (1.4) 1	2 (2.9) 2	0	3 (1.4) 3	5 (1.8) 5
Hepatic enzyme increased	0	1 (1.4) 3	0	1 (1.5) 2	2 (1.0) 5	2 (0.7) 5
Blood bilirubin increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Transaminases increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Hepatobiliary disorders	2 (2.9) 2	1 (1.4) 1	2 (2.9) 3	1 (1.5) 1	4 (1.9) 5	6 (2.2) 7
Hepatic function abnormal	2 (2.9) 2	1 (1.4) 1	2 (2.9) 3	1 (1.5) 1	4 (1.9) 5	6 (2.2) 7

Data Source: Listing 16.2.7.4
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.6.2
Serious AESIs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Serious AESIs	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hepatobiliary disorders	1 (1.4) 1	0	0	0	0	1 (0.4) 1
Hepatic function abnormal	1 (1.4) 1	0	0	0	0	1 (0.4) 1

Data Source: Listing 16.2.7.4
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.6.3
Treatment-Related AESIs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E
Treatment-Related AESIs	4 (5.8) 7	3 (4.3) 6	6 (8.7) 9	2 (2.9) 3	11 (5.3) 18	15 (5.4) 25
Investigations	3 (4.3) 6	2 (2.9) 5	5 (7.2) 8	2 (2.9) 3	9 (4.3) 16	12 (4.3) 22
Alanine aminotransferase increased	2 (2.9) 2	1 (1.4) 1	3 (4.3) 3	0	4 (1.9) 4	6 (2.2) 6
Aspartate aminotransferase increased	2 (2.9) 2	1 (1.4) 1	2 (2.9) 2	0	3 (1.4) 3	5 (1.8) 5
Gamma-glutamyltransferase increased	2 (2.9) 2	0	2 (2.9) 2	1 (1.5) 1	3 (1.4) 3	5 (1.8) 5
Hepatic enzyme increased	0	1 (1.4) 3	0	1 (1.5) 2	2 (1.0) 5	2 (0.7) 5
Transaminases increased	0	0	1 (1.4) 1	0	1 (0.5) 1	1 (0.4) 1
Hepatobiliary disorders	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	3 (1.1) 3
Hepatic function abnormal	1 (1.4) 1	1 (1.4) 1	1 (1.4) 1	0	2 (1.0) 2	3 (1.1) 3

Data Source: Listing 16.2.7.4
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.6.4
Treatment-Related Serious AESIs by SOC and PT
SS

System Organ Class (SOC) Preferred Term (PT)	Placebo N = 69 n (%) E	GS1-144 30 mg QD N = 70 n (%) E	GS1-144 60 mg QD N = 69 n (%) E	GS1-144 30 mg BID N = 68 n (%) E	Combined GS1-144 N = 207 n (%) E	Overall N = 276 n (%) E

No data to be reported

Data Source: Listing 16.2.7.4
n (%) = number and percentage of subjects with TEAEs; E = event.
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once per treatment per category.

Table 14.3.1.7.1
AESIs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
AESIs	5 (7.2)	3 (4.3)	8 (11.6)	3 (4.4)	14 (6.8)	19 (6.9)
Mild	3 (4.3)	2 (2.9)	7 (10.1)	2 (2.9)	11 (5.3)	14 (5.1)
Moderate	2 (2.9)	1 (1.4)	1 (1.4)	0	2 (1.0)	4 (1.4)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Investigations	3 (4.3)	2 (2.9)	6 (8.7)	3 (4.4)	11 (5.3)	14 (5.1)
Mild	2 (2.9)	2 (2.9)	5 (7.2)	2 (2.9)	9 (4.3)	11 (4.0)
Moderate	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
Severe	0	0	0	0	0	0
Alanine aminotransferase increased	2 (2.9)	1 (1.4)	3 (4.3)	0	4 (1.9)	6 (2.2)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Gamma-glutamyltransferase increased	2 (2.9)	0	2 (2.9)	2 (2.9)	4 (1.9)	6 (2.2)
Mild	1 (1.4)	0	2 (2.9)	1 (1.5)	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Aspartate aminotransferase increased	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.1
AESIs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Hepatic enzyme increased	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Blood bilirubin increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Transaminases increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hepatobiliary disorders	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	6 (2.2)
Mild	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Moderate	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Hepatic function abnormal	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	6 (2.2)
Mild	1 (1.4)	0	2 (2.9)	0	2 (1.0)	3 (1.1)
Moderate	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.2
Serious AESIs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Serious AESIs	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatobiliary disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatic function abnormal	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.3
Treatment-Related AESIs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Treatment-Related AESIs	4 (5.8)	3 (4.3)	6 (8.7)	2 (2.9)	11 (5.3)	15 (5.4)
Mild	3 (4.3)	2 (2.9)	5 (7.2)	2 (2.9)	9 (4.3)	12 (4.3)
Moderate	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Severe	0	0	0	0	0	0
Investigations	3 (4.3)	2 (2.9)	5 (7.2)	2 (2.9)	9 (4.3)	12 (4.3)
Mild	2 (2.9)	2 (2.9)	4 (5.8)	2 (2.9)	8 (3.9)	10 (3.6)
Moderate	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Alanine aminotransferase increased	2 (2.9)	1 (1.4)	3 (4.3)	0	4 (1.9)	6 (2.2)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Severe	0	0	0	0	0	0
Aspartate aminotransferase increased	2 (2.9)	1 (1.4)	2 (2.9)	0	3 (1.4)	5 (1.8)
Mild	1 (1.4)	1 (1.4)	2 (2.9)	0	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Gamma-glutamyltransferase increased	2 (2.9)	0	2 (2.9)	1 (1.5)	3 (1.4)	5 (1.8)
Mild	1 (1.4)	0	2 (2.9)	1 (1.5)	3 (1.4)	4 (1.4)
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.3
Treatment-Related AESIs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Hepatic enzyme increased	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Mild	0	1 (1.4)	0	1 (1.5)	2 (1.0)	2 (0.7)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Transaminases increased	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Mild	0	0	1 (1.4)	0	1 (0.5)	1 (0.4)
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Hepatobiliary disorders	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Hepatic function abnormal	1 (1.4)	1 (1.4)	1 (1.4)	0	2 (1.0)	3 (1.1)
Mild	1 (1.4)	0	1 (1.4)	0	1 (0.5)	2 (0.7)
Moderate	0	1 (1.4)	0	0	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.4
Treatment-Related Serious AESIs by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)

No data to be reported

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.5
AESIs Leading to Drug Interruption by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
AESIs Leading to Drug Interruption	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	0	0	0
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Hepatobiliary disorders	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	0	0	0
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Hepatic function abnormal	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	0	0	0
Severe	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Investigations	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.6

Serious AESIs Leading to Drug Interruption by SOC, PT and Severity

SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)

No data to be reported

Data Source: Listing 16.2.7.4

MedDRA version MedDRA 27.1 applied.

Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.7
AESIs Leading to Drug Withdrawal by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
AESIs Leading to Drug Withdrawal	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatobiliary disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatic function abnormal	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.1.7.8
Serious AESIs Leading to Drug Withdrawal by SOC, PT and Severity
SS

System Organ Class (SOC) Preferred Term (PT) Severity	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Serious AESIs Leading to Drug Withdrawal	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatobiliary disorders	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0
Hepatic function abnormal	1 (1.4)	0	0	0	0	1 (0.4)
Mild	0	0	0	0	0	0
Moderate	1 (1.4)	0	0	0	0	1 (0.4)
Severe	0	0	0	0	0	0

Data Source: Listing 16.2.7.4
MedDRA version MedDRA 27.1 applied.
Subjects were counted only once in the maximum severity per treatment per category.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Erythrocytes (10^12/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	4.556 (0.4657)	4.501 (0.3789)	4.527 (0.3875)	4.593 (0.3856)	4.539 (0.3841)	4.544 (0.4052)
		Median	4.530	4.570	4.510	4.570	4.550	4.540
		Q1 - Q3	4.270 - 4.790	4.270 - 4.750	4.250 - 4.770	4.340 - 4.755	4.290 - 4.760	4.285 - 4.765
		Min - Max	3.74 - 6.84	3.62 - 5.61	3.75 - 5.60	3.78 - 5.86	3.62 - 5.86	3.62 - 6.84
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	4.483 (0.4713)	4.425 (0.3917)	4.462 (0.3909)	4.518 (0.3690)	4.468 (0.3841)	4.472 (0.4069)
		Median	4.480	4.435	4.430	4.490	4.455	4.470
		Q1 - Q3	4.180 - 4.650	4.170 - 4.720	4.200 - 4.700	4.280 - 4.695	4.200 - 4.700	4.200 - 4.690
		Min - Max	3.68 - 6.82	3.51 - 5.51	3.59 - 5.84	3.70 - 5.72	3.51 - 5.84	3.51 - 6.82
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.073 (0.1637)	-0.076 (0.1689)	-0.049 (0.1736)	-0.075 (0.2027)	-0.066 (0.1818)	-0.068 (0.1771)
		Median	-0.110	-0.060	-0.060	-0.080	-0.070	-0.080
		Q1 - Q3	-0.190 - 0.030	-0.180 - 0.030	-0.160 - 0.060	-0.185 - 0.040	-0.180 - 0.040	-0.180 - 0.040
		Min - Max	-0.39 - 0.36	-0.54 - 0.27	-0.41 - 0.53	-0.85 - 0.56	-0.85 - 0.56	-0.85 - 0.56

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Erythrocytes (10^12/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	4.496 (0.4540)	4.428 (0.4051)	4.424 (0.3750)	4.513 (0.3408)	4.455 (0.3752)	4.465 (0.3958)
		Median	4.500	4.420	4.420	4.490	4.440	4.450
		Q1 - Q3	4.170 - 4.710	4.150 - 4.680	4.180 - 4.690	4.300 - 4.690	4.210 - 4.690	4.210 - 4.690
		Min - Max	3.66 - 6.59	3.46 - 5.71	3.64 - 5.74	3.88 - 5.70	3.46 - 5.74	3.46 - 6.59
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.066 (0.1934)	-0.077 (0.2144)	-0.087 (0.2054)	-0.077 (0.2067)	-0.080 (0.2079)	-0.077 (0.2041)
		Median	-0.070	-0.060	-0.080	-0.060	-0.070	-0.070
		Q1 - Q3	-0.220 - 0.070	-0.200 - 0.050	-0.190 - 0.030	-0.210 - 0.050	-0.200 - 0.050	-0.200 - 0.050
		Min - Max	-0.53 - 0.36	-0.50 - 0.56	-0.65 - 0.43	-0.70 - 0.44	-0.70 - 0.56	-0.70 - 0.56
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	4.486 (0.4142)	4.417 (0.4071)	4.461 (0.3299)	4.501 (0.3904)	4.458 (0.3770)	4.465 (0.3860)
		Median	4.435	4.420	4.470	4.500	4.470	4.465
		Q1 - Q3	4.240 - 4.650	4.140 - 4.690	4.220 - 4.670	4.240 - 4.720	4.210 - 4.700	4.220 - 4.690
		Min - Max	3.88 - 6.59	3.53 - 5.44	3.65 - 5.58	3.77 - 5.78	3.53 - 5.78	3.53 - 6.59

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Erythrocytes (10^12/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.085 (0.2271)	-0.089 (0.2056)	-0.050 (0.1975)	-0.078 (0.2243)	-0.072 (0.2088)	-0.075 (0.2131)
		Median	-0.080	-0.110	-0.040	-0.080	-0.070	-0.075
		Q1 - Q3	-0.220 - 0.050	-0.180 - 0.050	-0.170 - 0.090	-0.195 - 0.060	-0.180 - 0.060	-0.200 - 0.050
		Min - Max	-1.00 - 0.57	-0.65 - 0.37	-0.59 - 0.50	-0.81 - 0.53	-0.81 - 0.53	-1.00 - 0.57
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	4.514 (0.4517)	4.426 (0.4247)	4.465 (0.3253)	4.510 (0.3775)	4.466 (0.3781)	4.478 (0.3973)
		Median	4.500	4.470	4.395	4.490	4.470	4.480
		Q1 - Q3	4.270 - 4.700	4.175 - 4.630	4.260 - 4.660	4.260 - 4.720	4.250 - 4.660	4.260 - 4.700
		Min - Max	3.74 - 6.78	3.59 - 6.26	3.71 - 5.36	3.81 - 5.69	3.59 - 6.26	3.59 - 6.78
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.070 (0.2533)	-0.076 (0.2132)	-0.046 (0.2060)	-0.064 (0.2000)	-0.062 (0.2059)	-0.064 (0.2182)
		Median	-0.070	-0.095	-0.080	-0.050	-0.080	-0.080
		Q1 - Q3	-0.220 - 0.080	-0.235 - 0.055	-0.180 - 0.110	-0.170 - 0.050	-0.200 - 0.070	-0.200 - 0.080
		Min - Max	-1.04 - 0.66	-0.47 - 0.65	-0.45 - 0.60	-0.66 - 0.38	-0.66 - 0.65	-1.04 - 0.66

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Erythrocytes (10^12/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	4.480 (0.4394)	4.410 (0.4190)	4.464 (0.3445)	4.521 (0.3409)	4.464 (0.3719)	4.468 (0.3890)
		Median	4.430	4.450	4.460	4.520	4.480	4.470
		Q1 - Q3	4.240 - 4.660	4.170 - 4.610	4.230 - 4.690	4.350 - 4.720	4.230 - 4.675	4.240 - 4.670
		Min - Max	3.77 - 6.57	3.55 - 6.19	3.61 - 5.67	3.86 - 5.78	3.55 - 6.19	3.55 - 6.57
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.104 (0.1966)	-0.092 (0.2101)	-0.037 (0.2431)	-0.052 (0.2255)	-0.061 (0.2264)	-0.072 (0.2198)
		Median	-0.100	-0.120	-0.020	-0.060	-0.070	-0.080
		Q1 - Q3	-0.270 - 0.030	-0.215 - 0.010	-0.180 - 0.100	-0.200 - 0.120	-0.200 - 0.080	-0.210 - 0.060
		Min - Max	-0.48 - 0.37	-0.47 - 0.58	-0.66 - 0.54	-0.72 - 0.37	-0.72 - 0.58	-0.72 - 0.58
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	4.518 (0.4316)	4.446 (0.4394)	4.460 (0.3816)	4.544 (0.3940)	4.482 (0.4064)	4.491 (0.4122)
		Median	4.470	4.450	4.415	4.525	4.450	4.460
		Q1 - Q3	4.270 - 4.695	4.180 - 4.780	4.240 - 4.730	4.280 - 4.750	4.220 - 4.740	4.240 - 4.730
		Min - Max	3.70 - 6.70	3.63 - 6.06	3.59 - 5.74	3.83 - 5.84	3.59 - 6.06	3.59 - 6.70

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Erythrocytes (10^12/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.061 (0.2302)	-0.052 (0.2163)	-0.051 (0.2283)	-0.035 (0.2257)	-0.046 (0.2224)	-0.050 (0.2240)
		Median	-0.075	-0.020	-0.040	-0.020	-0.040	-0.040
		Q1 - Q3	-0.205 - 0.065	-0.180 - 0.060	-0.200 - 0.070	-0.180 - 0.140	-0.190 - 0.080	-0.200 - 0.070
		Min - Max	-0.62 - 0.55	-0.57 - 0.62	-0.66 - 0.56	-0.75 - 0.43	-0.75 - 0.62	-0.75 - 0.62
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	4.510 (0.4475)	4.418 (0.4098)	4.389 (0.3683)	4.528 (0.4106)	4.444 (0.3991)	4.460 (0.4116)
		Median	4.490	4.480	4.355	4.520	4.450	4.460
		Q1 - Q3	4.290 - 4.700	4.160 - 4.660	4.160 - 4.670	4.300 - 4.720	4.210 - 4.680	4.220 - 4.690
		Min - Max	3.83 - 6.85	3.46 - 5.90	3.55 - 5.59	3.70 - 6.09	3.46 - 6.09	3.46 - 6.85
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.075 (0.1989)	-0.084 (0.2001)	-0.112 (0.2162)	-0.053 (0.2481)	-0.084 (0.2219)	-0.082 (0.2161)
		Median	-0.080	-0.075	-0.110	-0.050	-0.080	-0.080
		Q1 - Q3	-0.250 - 0.065	-0.230 - 0.065	-0.280 - 0.010	-0.160 - 0.120	-0.230 - 0.080	-0.230 - 0.080
		Min - Max	-0.48 - 0.39	-0.56 - 0.38	-0.56 - 0.31	-0.87 - 0.61	-0.87 - 0.61	-0.87 - 0.61

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hematocrit (%)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	40.577 (2.6612)	40.710 (2.6213)	40.916 (2.8977)	40.910 (2.5201)	40.844 (2.6736)	40.778 (2.6682)
		Median	40.400	41.200	40.900	40.950	41.000	40.950
		Q1 - Q3	38.700 - 42.300	39.600 - 42.500	39.100 - 42.900	39.100 - 42.400	39.300 - 42.600	39.100 - 42.550
		Min - Max	35.00 - 47.20	33.30 - 45.70	34.30 - 46.40	34.80 - 47.70	33.30 - 47.70	33.30 - 47.70
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	40.010 (2.5439)	40.031 (2.5319)	40.568 (3.1302)	40.218 (2.4126)	40.270 (2.7041)	40.205 (2.6626)
		Median	39.800	40.100	40.200	40.300	40.200	40.100
		Q1 - Q3	38.400 - 41.400	38.600 - 41.500	38.450 - 42.050	38.400 - 42.100	38.500 - 41.900	38.400 - 41.800
		Min - Max	35.10 - 46.30	33.40 - 46.60	32.80 - 50.50	34.00 - 45.90	32.80 - 50.50	32.80 - 50.50
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.567 (1.5099)	-0.679 (1.5339)	-0.287 (1.9949)	-0.693 (1.5153)	-0.554 (1.6966)	-0.557 (1.6491)
		Median	-0.500	-0.500	-0.550	-0.700	-0.550	-0.500
		Q1 - Q3	-1.800 - 0.400	-1.800 - 0.300	-1.400 - 0.800	-1.800 - 0.300	-1.500 - 0.400	-1.700 - 0.400
		Min - Max	-3.30 - 3.50	-4.90 - 2.10	-5.60 - 7.40	-4.20 - 2.20	-5.60 - 7.40	-5.60 - 7.40

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hematocrit (%)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	40.216 (2.6415)	40.058 (2.7943)	40.167 (3.1146)	40.316 (2.3082)	40.179 (2.7477)	40.189 (2.7169)
		Median	40.200	40.200	40.300	40.200	40.200	40.200
		Q1 - Q3	38.600 - 42.200	38.300 - 41.400	38.200 - 42.200	38.600 - 41.800	38.400 - 41.900	38.500 - 41.900
		Min - Max	34.70 - 46.10	33.20 - 48.40	33.00 - 49.50	34.20 - 45.60	33.00 - 49.50	33.00 - 49.50
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.384 (1.8932)	-0.688 (1.9404)	-0.684 (1.9576)	-0.567 (1.8043)	-0.647 (1.8938)	-0.581 (1.8935)
		Median	-0.500	-0.700	-0.600	-0.600	-0.600	-0.600
		Q1 - Q3	-1.600 - 1.000	-1.800 - 0.500	-1.600 - 0.200	-1.700 - 0.800	-1.700 - 0.600	-1.700 - 0.600
		Min - Max	-4.60 - 4.20	-4.70 - 5.90	-6.20 - 4.30	-4.80 - 4.00	-6.20 - 5.90	-6.20 - 5.90
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	40.039 (2.4521)	40.006 (2.8516)	40.601 (2.5376)	40.294 (2.5656)	40.298 (2.6568)	40.233 (2.6054)
		Median	40.200	40.100	40.500	40.650	40.450	40.400
		Q1 - Q3	38.100 - 41.300	38.000 - 41.800	39.300 - 42.200	38.100 - 41.500	38.600 - 41.800	38.500 - 41.800
		Min - Max	35.10 - 46.50	34.00 - 46.50	33.50 - 48.20	35.10 - 45.90	33.50 - 48.20	33.50 - 48.20

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hematocrit (%)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.627 (2.0840)	-0.741 (1.8971)	-0.249 (1.8114)	-0.573 (1.9676)	-0.523 (1.8937)	-0.548 (1.9392)
		Median	-0.450	-0.800	-0.300	-0.500	-0.400	-0.400
		Q1 - Q3	-1.800 - 0.600	-1.700 - 0.200	-1.300 - 1.000	-1.750 - 0.500	-1.600 - 0.550	-1.600 - 0.600
		Min - Max	-8.30 - 6.30	-7.00 - 4.00	-5.40 - 4.60	-4.90 - 7.10	-7.00 - 7.10	-8.30 - 7.10
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	40.171 (2.4305)	40.085 (2.6106)	40.598 (2.5381)	40.367 (2.5541)	40.347 (2.5641)	40.303 (2.5282)
		Median	40.000	40.500	40.450	40.500	40.500	40.400
		Q1 - Q3	38.500 - 41.700	38.350 - 41.550	39.100 - 42.400	38.800 - 42.200	38.800 - 42.000	38.700 - 42.000
		Min - Max	35.10 - 47.50	33.90 - 46.30	33.70 - 46.40	34.50 - 46.60	33.70 - 46.60	33.70 - 47.50
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.583 (2.0600)	-0.628 (1.7685)	-0.217 (1.7255)	-0.476 (1.8203)	-0.442 (1.7704)	-0.477 (1.8433)
		Median	-0.800	-0.850	-0.650	-0.400	-0.600	-0.650
		Q1 - Q3	-1.900 - 1.000	-1.750 - 0.550	-1.400 - 1.000	-1.500 - 0.600	-1.600 - 0.700	-1.600 - 0.700
		Min - Max	-6.20 - 4.90	-3.50 - 5.10	-4.10 - 4.20	-4.50 - 5.20	-4.50 - 5.20	-6.20 - 5.20

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hematocrit (%)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	39.791 (2.7054)	39.815 (2.4421)	40.663 (2.7837)	40.529 (2.3399)	40.326 (2.5447)	40.192 (2.5907)
		Median	39.400	39.850	40.500	40.500	40.300	40.100
		Q1 - Q3	38.100 - 41.600	38.600 - 41.300	39.200 - 42.400	39.000 - 42.400	38.900 - 41.900	38.600 - 41.800
		Min - Max	34.50 - 45.70	32.80 - 45.40	34.20 - 49.70	34.90 - 46.20	32.80 - 49.70	32.80 - 49.70
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.963 (1.8537)	-0.899 (1.7870)	-0.102 (2.0722)	-0.314 (1.8815)	-0.446 (1.9361)	-0.575 (1.9255)
		Median	-1.100	-1.250	0.100	-0.400	-0.550	-0.700
		Q1 - Q3	-2.100 - 0.300	-1.950 - 0.300	-1.700 - 1.100	-1.600 - 0.900	-1.900 - 0.800	-1.900 - 0.700
		Min - Max	-5.40 - 3.40	-4.50 - 4.40	-4.70 - 4.80	-4.60 - 4.90	-4.70 - 4.90	-5.40 - 4.90
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	40.084 (2.5281)	40.099 (2.6081)	40.541 (3.1932)	40.592 (2.5499)	40.405 (2.7973)	40.326 (2.7320)
		Median	39.800	40.400	40.150	40.550	40.400	40.200
		Q1 - Q3	38.450 - 41.750	39.000 - 41.500	38.700 - 42.100	38.400 - 42.200	38.700 - 42.100	38.500 - 42.000
		Min - Max	34.40 - 46.30	33.30 - 45.80	33.40 - 49.90	36.60 - 45.90	33.30 - 49.90	33.30 - 49.90

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hematocrit (%)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.602 (1.8868)	-0.593 (1.9341)	-0.274 (2.0905)	-0.282 (1.9483)	-0.386 (1.9882)	-0.439 (1.9622)
		Median	-0.750	-0.500	-0.500	-0.400	-0.500	-0.600
		Q1 - Q3	-2.050 - 0.800	-1.800 - 0.800	-1.600 - 0.700	-1.500 - 0.700	-1.600 - 0.700	-1.700 - 0.700
		Min - Max	-4.30 - 4.00	-5.50 - 4.50	-5.00 - 5.60	-4.60 - 4.00	-5.50 - 5.60	-5.50 - 5.60
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	39.972 (2.6234)	39.999 (2.7852)	39.909 (2.9301)	40.459 (2.3539)	40.116 (2.7035)	40.080 (2.6797)
		Median	39.950	40.150	40.150	40.300	40.300	40.100
		Q1 - Q3	38.200 - 41.250	38.300 - 41.700	38.200 - 41.900	38.800 - 41.800	38.300 - 41.800	38.300 - 41.600
		Min - Max	34.80 - 46.20	32.90 - 45.80	33.30 - 49.40	35.70 - 46.90	32.90 - 49.40	32.90 - 49.40
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.777 (1.7860)	-0.726 (1.8292)	-0.892 (1.9504)	-0.444 (2.0439)	-0.692 (1.9392)	-0.713 (1.8997)
		Median	-1.050	-0.500	-1.250	-0.500	-0.800	-0.800
		Q1 - Q3	-2.000 - 0.600	-2.150 - 0.500	-2.200 - 0.600	-1.800 - 0.600	-2.100 - 0.600	-2.100 - 0.600
		Min - Max	-5.40 - 3.10	-5.20 - 2.50	-5.00 - 3.80	-5.20 - 6.30	-5.20 - 6.30	-5.40 - 6.30

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Volume (fL)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	89.497 (5.6627)	90.750 (4.8206)	90.549 (3.5423)	89.609 (5.5228)	90.308 (4.7004)	90.105 (4.9601)
		Median	90.200	91.100	90.600	90.550	90.600	90.500
		Q1 - Q3	88.000 - 92.800	89.100 - 93.600	88.200 - 93.300	86.900 - 92.800	88.300 - 93.300	88.300 - 93.100
		Min - Max	68.10 - 99.00	69.70 - 104.20	80.50 - 98.30	65.00 - 100.40	65.00 - 104.20	65.00 - 104.20
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	89.687 (5.6657)	90.750 (4.7175)	90.856 (3.1480)	89.456 (5.4736)	90.358 (4.5745)	90.189 (4.8690)
		Median	90.500	90.750	91.000	90.200	90.700	90.600
		Q1 - Q3	88.300 - 92.600	89.300 - 93.600	88.500 - 93.200	87.400 - 92.600	88.300 - 93.000	88.300 - 93.000
		Min - Max	67.90 - 98.40	70.70 - 102.80	82.40 - 97.70	64.90 - 99.60	64.90 - 102.80	64.90 - 102.80
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.190 (1.3392)	0.000 (1.0953)	0.159 (1.2715)	-0.153 (1.1482)	0.002 (1.1744)	0.049 (1.2181)
		Median	0	0	0.100	-0.050	0	0
		Q1 - Q3	-0.400 - 0.800	-0.500 - 0.900	-0.700 - 0.800	-0.900 - 0.650	-0.700 - 0.800	-0.600 - 0.800
		Min - Max	-4.60 - 3.70	-2.80 - 2.90	-2.50 - 4.60	-4.20 - 2.20	-4.20 - 4.60	-4.60 - 4.60

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Volume (fL)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	89.906 (5.9181)	90.794 (4.7056)	90.907 (3.3618)	89.609 (5.4530)	90.440 (4.6051)	90.308 (4.9569)
		Median	90.900	91.100	91.300	90.700	90.800	90.850
		Q1 - Q3	88.200 - 93.500	89.400 - 93.200	88.400 - 93.800	87.900 - 93.000	88.200 - 93.200	88.200 - 93.200
		Min - Max	67.40 - 99.50	69.80 - 102.10	83.90 - 98.00	65.20 - 98.70	65.20 - 102.10	65.20 - 102.10
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.454 (1.2721)	0.057 (1.2773)	0.216 (1.2619)	0.003 (1.2842)	0.092 (1.2714)	0.181 (1.2789)
		Median	0.400	0.100	0.200	0.200	0.200	0.200
		Q1 - Q3	-0.400 - 1.000	-0.600 - 1.000	-0.500 - 1.000	-0.800 - 0.800	-0.600 - 1.000	-0.600 - 1.000
		Min - Max	-2.20 - 4.60	-2.70 - 3.40	-3.10 - 3.20	-3.20 - 2.90	-3.20 - 3.40	-3.20 - 4.60
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	89.638 (5.9191)	90.861 (4.9435)	91.136 (3.3000)	89.875 (5.5668)	90.638 (4.6969)	90.389 (5.0346)
		Median	90.500	91.200	91.000	90.650	91.050	90.800
		Q1 - Q3	88.200 - 93.000	89.100 - 92.800	88.800 - 93.900	88.050 - 92.900	88.600 - 93.200	88.400 - 93.200
		Min - Max	66.50 - 101.80	69.80 - 102.10	84.10 - 100.00	65.90 - 99.30	65.90 - 102.10	65.90 - 102.10

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Volume (fL)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.226 (1.4707)	0.123 (1.3881)	0.445 (1.1042)	0.070 (1.5294)	0.214 (1.3530)	0.217 (1.3803)
		Median	0.250	0.100	0.300	0.150	0.200	0.200
		Q1 - Q3	-0.700 - 0.900	-0.700 - 0.900	-0.300 - 1.300	-0.950 - 1.050	-0.700 - 1.100	-0.700 - 1.100
		Min - Max	-3.10 - 6.20	-2.90 - 3.50	-2.10 - 3.00	-3.90 - 5.20	-3.90 - 5.20	-3.90 - 6.20
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	89.463 (5.9901)	90.912 (4.7913)	91.036 (3.2500)	89.830 (5.8190)	90.608 (4.7275)	90.324 (5.0821)
		Median	90.300	90.900	91.250	90.700	91.000	90.750
		Q1 - Q3	88.300 - 93.100	89.200 - 92.950	88.800 - 93.700	88.000 - 92.900	88.800 - 93.000	88.600 - 93.100
		Min - Max	67.00 - 100.50	70.60 - 103.00	84.30 - 97.10	64.80 - 100.10	64.80 - 103.00	64.80 - 103.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.112 (1.6818)	0.162 (1.5563)	0.432 (1.6665)	-0.027 (1.7376)	0.192 (1.6551)	0.172 (1.6588)
		Median	-0.100	0.300	0.300	0	0.200	0.100
		Q1 - Q3	-0.800 - 0.700	-0.900 - 1.100	-0.400 - 1.300	-1.100 - 1.000	-0.800 - 1.100	-0.800 - 1.100
		Min - Max	-3.10 - 6.80	-4.80 - 3.70	-6.00 - 5.70	-4.90 - 5.00	-6.00 - 5.70	-6.00 - 6.80

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Volume (fL)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	89.229 (5.6290)	90.684 (4.7911)	91.202 (3.2303)	89.987 (5.9344)	90.632 (4.7700)	90.282 (5.0233)
		Median	89.600	90.950	91.400	90.300	90.950	90.700
		Q1 - Q3	88.000 - 92.900	89.000 - 92.500	89.100 - 93.600	87.800 - 93.500	88.600 - 93.500	88.500 - 93.400
		Min - Max	67.70 - 97.40	70.20 - 100.00	83.90 - 99.30	64.70 - 100.70	64.70 - 100.70	64.70 - 100.70
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.122 (1.4733)	-0.066 (1.6829)	0.528 (1.4232)	0.130 (1.6543)	0.194 (1.6031)	0.115 (1.5749)
		Median	-0.100	-0.200	0.700	-0.100	0.100	0
		Q1 - Q3	-0.900 - 0.600	-1.050 - 0.850	-0.600 - 1.400	-0.900 - 1.100	-0.800 - 1.150	-0.800 - 1.100
		Min - Max	-3.30 - 5.70	-4.20 - 5.60	-3.40 - 3.80	-4.60 - 4.40	-4.60 - 5.60	-4.60 - 5.70
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	89.122 (5.6030)	90.591 (4.9451)	91.027 (3.3676)	89.750 (5.7847)	90.471 (4.7872)	90.138 (5.0238)
		Median	89.400	90.900	91.300	90.450	90.900	90.500
		Q1 - Q3	87.450 - 92.500	88.900 - 93.400	88.500 - 93.300	87.500 - 93.200	88.200 - 93.300	87.900 - 93.200
		Min - Max	68.60 - 98.70	69.70 - 103.20	84.00 - 99.50	64.90 - 99.40	64.90 - 103.20	64.90 - 103.20

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Volume (fL)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.175 (1.6409)	-0.188 (1.6715)	0.423 (1.5371)	-0.073 (1.5703)	0.055 (1.6090)	-0.002 (1.6169)
		Median	-0.200	-0.200	0.300	-0.200	0	0
		Q1 - Q3	-1.100 - 0.550	-1.100 - 0.700	-0.700 - 1.400	-1.000 - 1.100	-0.900 - 1.100	-0.900 - 1.000
		Min - Max	-4.30 - 6.80	-3.80 - 6.40	-2.70 - 4.00	-3.40 - 3.10	-3.80 - 6.40	-4.30 - 6.80
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	89.055 (5.6232)	90.850 (5.0939)	91.095 (3.0845)	89.743 (5.7733)	90.578 (4.7863)	90.205 (5.0361)
		Median	89.700	91.100	91.000	90.500	91.100	90.600
		Q1 - Q3	87.200 - 92.300	89.350 - 93.300	88.400 - 93.200	87.200 - 93.000	88.400 - 93.200	88.000 - 93.000
		Min - Max	67.20 - 97.10	70.40 - 104.40	84.70 - 99.30	63.70 - 99.50	63.70 - 104.40	63.70 - 104.40
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.264 (1.6144)	0.084 (1.6157)	0.335 (1.5709)	-0.079 (1.4131)	0.116 (1.5399)	0.023 (1.5639)
		Median	-0.250	0.050	0.300	0	0.100	0
		Q1 - Q3	-1.100 - 0.700	-0.700 - 0.850	-0.600 - 1.300	-0.900 - 0.800	-0.700 - 1.000	-0.800 - 1.000
		Min - Max	-3.80 - 5.60	-3.30 - 5.40	-5.20 - 4.80	-4.80 - 3.00	-5.20 - 5.40	-5.20 - 5.60

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Hemoglobin (pg)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	29.428 (2.2692)	29.915 (1.8333)	30.093 (1.3513)	29.512 (2.1473)	29.842 (1.8130)	29.738 (1.9411)
		Median	29.800	30.100	30.000	29.800	30.000	30.000
		Q1 - Q3	28.800 - 30.800	29.200 - 30.900	29.400 - 30.900	28.650 - 30.700	29.000 - 30.800	29.000 - 30.800
		Min - Max	20.60 - 32.30	21.70 - 33.60	25.90 - 33.60	19.30 - 33.10	19.30 - 33.60	19.30 - 33.60
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	29.454 (2.1996)	29.987 (1.8822)	30.262 (1.3308)	29.511 (2.0803)	29.921 (1.8115)	29.803 (1.9228)
		Median	29.800	30.200	30.200	29.950	30.140	30.000
		Q1 - Q3	29.100 - 30.800	29.300 - 31.000	29.350 - 31.150	28.700 - 30.700	29.000 - 30.900	29.000 - 30.900
		Min - Max	20.90 - 32.00	22.10 - 34.50	26.70 - 33.60	19.60 - 32.80	19.60 - 34.50	19.60 - 34.50
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.026 (0.5903)	0.072 (0.5968)	0.107 (0.4996)	-0.001 (0.5472)	0.060 (0.5490)	0.051 (0.5587)
		Median	-0.100	0	0.150	0	0	0
		Q1 - Q3	-0.400 - 0.400	-0.300 - 0.370	-0.200 - 0.500	-0.300 - 0.265	-0.300 - 0.400	-0.300 - 0.400
		Min - Max	-1.30 - 2.10	-1.20 - 1.70	-1.20 - 1.30	-1.60 - 2.50	-1.60 - 2.50	-1.60 - 2.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Hemoglobin (pg)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	29.401 (2.2198)	29.872 (1.8055)	30.257 (1.2716)	29.436 (2.1019)	29.855 (1.7836)	29.742 (1.9069)
		Median	29.700	30.000	30.300	30.000	30.000	30.000
		Q1 - Q3	28.900 - 30.500	29.300 - 30.500	29.300 - 31.100	28.600 - 30.600	29.200 - 30.800	29.000 - 30.700
		Min - Max	20.60 - 32.30	21.70 - 33.10	26.70 - 32.90	19.50 - 32.60	19.50 - 33.10	19.50 - 33.10
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.001 (0.5358)	-0.049 (0.5094)	0.106 (0.5916)	-0.078 (0.5006)	-0.007 (0.5386)	-0.005 (0.5369)
		Median	0	0	0.100	-0.100	0	0
		Q1 - Q3	-0.400 - 0.300	-0.400 - 0.300	-0.300 - 0.500	-0.400 - 0.200	-0.400 - 0.400	-0.400 - 0.400
		Min - Max	-1.00 - 1.30	-1.60 - 1.30	-1.50 - 1.40	-1.40 - 1.20	-1.60 - 1.40	-1.60 - 1.40
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	29.435 (2.2817)	30.026 (1.9136)	30.137 (1.2396)	29.509 (2.1351)	29.898 (1.8104)	29.783 (1.9438)
		Median	29.950	30.100	30.100	30.100	30.100	30.100
		Q1 - Q3	29.000 - 30.700	29.400 - 31.000	29.400 - 30.900	28.850 - 30.550	29.100 - 30.900	29.100 - 30.800
		Min - Max	20.60 - 32.30	21.80 - 33.50	26.60 - 32.80	20.10 - 32.50	20.10 - 33.50	20.10 - 33.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Hemoglobin (pg)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.047 (0.5269)	0.106 (0.6173)	-0.013 (0.5446)	-0.051 (0.5554)	0.016 (0.5752)	0.023 (0.5628)
		Median	0	0.100	0.100	-0.100	0	0
		Q1 - Q3	-0.400 - 0.400	-0.300 - 0.500	-0.300 - 0.400	-0.450 - 0.250	-0.350 - 0.400	-0.400 - 0.400
		Min - Max	-0.90 - 1.70	-1.30 - 2.20	-1.50 - 1.10	-1.40 - 1.30	-1.50 - 2.20	-1.50 - 2.20
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	29.372 (2.3087)	29.911 (1.7937)	30.108 (1.2113)	29.493 (2.1535)	29.843 (1.7658)	29.726 (1.9209)
		Median	29.700	30.100	30.100	29.900	30.100	29.900
		Q1 - Q3	29.000 - 30.500	29.350 - 30.750	29.300 - 31.000	28.900 - 30.700	29.200 - 30.800	29.200 - 30.800
		Min - Max	20.40 - 33.30	21.70 - 34.00	26.80 - 33.00	20.10 - 32.60	20.10 - 34.00	20.10 - 34.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.022 (0.8077)	-0.008 (0.6254)	-0.023 (0.7007)	-0.092 (0.5873)	-0.040 (0.6379)	-0.025 (0.6829)
		Median	-0.100	-0.050	0	-0.080	0	0
		Q1 - Q3	-0.300 - 0.300	-0.300 - 0.400	-0.400 - 0.400	-0.400 - 0.300	-0.300 - 0.300	-0.300 - 0.300
		Min - Max	-1.90 - 4.40	-2.30 - 1.40	-3.30 - 1.70	-2.30 - 1.00	-3.30 - 1.70	-3.30 - 4.40

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Hemoglobin (pg)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	29.372 (2.2510)	29.834 (1.8878)	30.008 (1.2689)	29.542 (2.1977)	29.798 (1.8234)	29.692 (1.9429)
		Median	29.700	30.100	29.900	29.900	29.990	29.900
		Q1 - Q3	29.000 - 30.500	29.150 - 30.900	29.200 - 31.000	28.800 - 30.760	29.100 - 30.800	29.100 - 30.700
		Min - Max	20.40 - 34.10	21.30 - 33.60	26.50 - 33.10	19.60 - 32.90	19.60 - 33.60	19.60 - 34.10
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.022 (0.7652)	-0.085 (0.5926)	-0.129 (0.5270)	-0.043 (0.6038)	-0.086 (0.5735)	-0.059 (0.6269)
		Median	-0.100	0	-0.200	-0.100	-0.100	-0.100
		Q1 - Q3	-0.400 - 0.400	-0.400 - 0.250	-0.500 - 0.300	-0.400 - 0.300	-0.400 - 0.300	-0.400 - 0.300
		Min - Max	-1.50 - 3.70	-2.10 - 1.50	-1.00 - 1.10	-1.50 - 2.60	-2.10 - 2.60	-2.10 - 3.70
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	29.228 (2.2189)	29.896 (1.9140)	29.939 (1.2322)	29.419 (2.1592)	29.759 (1.8099)	29.628 (1.9282)
		Median	29.550	30.000	29.800	29.850	29.900	29.800
		Q1 - Q3	28.900 - 30.550	29.200 - 31.100	29.200 - 30.800	28.600 - 30.500	29.100 - 30.700	29.000 - 30.700
		Min - Max	20.40 - 32.00	22.60 - 34.50	27.10 - 32.60	19.80 - 33.00	19.80 - 34.50	19.80 - 34.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ery. Mean Corpuscular Hemoglobin (pg)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.092 (0.6622)	-0.004 (0.7798)	-0.191 (0.5582)	-0.159 (0.5912)	-0.117 (0.6542)	-0.111 (0.6550)
		Median	-0.100	0.100	-0.200	-0.150	-0.100	-0.100
		Q1 - Q3	-0.550 - 0.300	-0.400 - 0.400	-0.600 - 0.200	-0.500 - 0.300	-0.500 - 0.300	-0.500 - 0.300
		Min - Max	-2.00 - 1.20	-2.60 - 2.40	-1.30 - 1.40	-2.40 - 0.90	-2.60 - 2.40	-2.60 - 2.40
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	29.098 (2.1846)	29.762 (1.8909)	30.073 (1.2602)	29.522 (2.2954)	29.789 (1.8617)	29.620 (1.9641)
		Median	29.350	29.900	30.000	29.900	29.900	29.800
		Q1 - Q3	28.600 - 30.400	29.100 - 30.850	29.300 - 30.900	28.800 - 30.700	29.100 - 30.900	28.900 - 30.800
		Min - Max	20.80 - 31.50	22.00 - 33.80	26.90 - 32.50	19.10 - 33.50	19.10 - 33.80	19.10 - 33.80
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.250 (0.6071)	-0.140 (0.5903)	-0.085 (0.6627)	-0.053 (0.6977)	-0.094 (0.6481)	-0.132 (0.6407)
		Median	-0.250	-0.100	-0.100	-0.020	-0.100	-0.100
		Q1 - Q3	-0.600 - 0	-0.500 - 0.250	-0.300 - 0.300	-0.600 - 0.400	-0.400 - 0.300	-0.500 - 0.200
		Min - Max	-1.70 - 1.90	-2.30 - 1.40	-2.40 - 1.60	-1.70 - 2.50	-2.40 - 2.50	-2.40 - 2.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hemoglobin (g/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	133.3 (9.07)	134.1 (8.96)	135.9 (9.42)	134.7 (8.60)	134.9 (8.99)	134.5 (9.02)
		Median	133.0	135.5	136.0	135.0	135.0	135.0
		Q1 - Q3	127.0 - 140.0	129.0 - 141.0	129.0 - 143.0	130.0 - 139.5	129.0 - 141.0	129.0 - 140.0
		Min - Max	113 - 155	110 - 149	115 - 159	112 - 156	110 - 159	110 - 159
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	131.3 (9.01)	132.2 (8.94)	134.7 (9.68)	132.6 (8.84)	133.2 (9.18)	132.7 (9.16)
		Median	132.0	132.0	134.5	133.0	133.0	133.0
		Q1 - Q3	125.0 - 138.0	127.0 - 137.0	129.0 - 140.5	127.0 - 139.0	127.0 - 139.0	127.0 - 139.0
		Min - Max	108 - 150	109 - 152	111 - 168	111 - 152	109 - 168	108 - 168
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-2.0 (4.34)	-1.9 (4.89)	-1.0 (4.82)	-2.1 (4.92)	-1.7 (4.87)	-1.8 (4.74)
		Median	-1.0	-2.0	-1.0	-2.0	-2.0	-2.0
		Q1 - Q3	-5.0 - 1.0	-5.0 - 1.0	-5.0 - 2.0	-5.0 - 1.5	-5.0 - 1.0	-5.0 - 1.0
		Min - Max	-11 - 7	-17 - 8	-13 - 10	-14 - 10	-17 - 10	-17 - 10

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hemoglobin (g/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	131.4 (9.56)	131.8 (9.81)	133.6 (10.04)	132.3 (8.12)	132.6 (9.35)	132.3 (9.40)
		Median	132.0	131.0	134.0	133.0	133.0	133.0
		Q1 - Q3	125.0 - 138.0	126.0 - 138.0	127.0 - 139.0	126.0 - 138.0	126.0 - 138.0	126.0 - 138.0
		Min - Max	107 - 153	109 - 163	112 - 167	111 - 153	109 - 167	107 - 167
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.9 (5.42)	-2.6 (6.11)	-2.1 (5.81)	-2.3 (5.24)	-2.3 (5.71)	-2.2 (5.63)
		Median	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0
		Q1 - Q3	-6.0 - 2.0	-7.0 - 1.0	-5.0 - 2.0	-6.0 - 1.0	-6.0 - 1.0	-6.0 - 1.0
		Min - Max	-16 - 12	-16 - 19	-17 - 12	-14 - 9	-17 - 19	-17 - 19
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	131.4 (9.63)	132.2 (10.26)	134.2 (8.59)	132.3 (8.86)	132.9 (9.28)	132.5 (9.37)
		Median	132.5	132.0	135.0	133.5	133.0	133.0
		Q1 - Q3	124.0 - 139.0	126.0 - 138.0	128.0 - 139.0	126.0 - 138.0	127.0 - 138.0	126.0 - 138.0
		Min - Max	106 - 155	108 - 161	112 - 159	112 - 151	108 - 161	106 - 161

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hemoglobin (g/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-2.1 (6.62)	-2.1 (5.92)	-1.5 (5.75)	-2.2 (5.87)	-1.9 (5.83)	-2.0 (6.02)
		Median	-4.0	-2.0	-1.0	-3.0	-2.0	-2.0
		Q1 - Q3	-6.0 - 2.0	-5.0 - 0	-5.0 - 2.0	-6.0 - 1.0	-5.5 - 1.0	-6.0 - 1.0
		Min - Max	-28 - 15	-19 - 17	-18 - 15	-14 - 15	-19 - 17	-28 - 17
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	131.8 (8.77)	131.8 (9.06)	134.3 (8.70)	132.4 (9.35)	132.8 (9.05)	132.6 (8.98)
		Median	133.0	132.5	134.0	132.0	134.0	133.0
		Q1 - Q3	127.0 - 137.0	126.0 - 137.5	130.0 - 139.0	126.0 - 141.0	127.0 - 139.0	127.0 - 138.0
		Min - Max	107 - 156	110 - 154	113 - 160	111 - 157	110 - 160	107 - 160
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-2.0 (6.31)	-2.4 (5.37)	-1.4 (6.02)	-1.9 (5.72)	-1.9 (5.69)	-1.9 (5.84)
		Median	-3.0	-2.5	-2.0	-1.0	-2.0	-2.0
		Q1 - Q3	-6.0 - 2.0	-6.5 - 1.0	-6.0 - 2.0	-5.0 - 2.0	-6.0 - 2.0	-6.0 - 2.0
		Min - Max	-16 - 20	-14 - 14	-17 - 13	-15 - 10	-17 - 14	-17 - 20

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hemoglobin (g/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	130.9 (9.48)	131.0 (8.29)	133.7 (8.64)	133.1 (8.20)	132.6 (8.42)	132.2 (8.71)
		Median	131.0	131.0	133.0	133.0	133.0	132.0
		Q1 - Q3	125.0 - 138.0	127.0 - 135.5	128.0 - 139.0	128.0 - 138.0	128.0 - 138.0	127.0 - 138.0
		Min - Max	110 - 149	107 - 153	114 - 165	112 - 151	107 - 165	107 - 165
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-2.9 (6.42)	-3.2 (4.90)	-1.7 (6.93)	-1.3 (5.73)	-2.1 (5.93)	-2.3 (6.05)
		Median	-3.0	-3.5	-2.0	-1.0	-2.0	-3.0
		Q1 - Q3	-7.0 - 0	-6.0 - -1.0	-6.0 - 2.0	-5.0 - 2.0	-6.0 - 2.0	-6.0 - 1.0
		Min - Max	-18 - 17	-15 - 10	-17 - 18	-15 - 11	-17 - 18	-18 - 18
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	131.3 (8.77)	132.2 (8.84)	133.3 (9.56)	133.1 (8.46)	132.9 (8.94)	132.5 (8.91)
		Median	131.0	132.0	132.0	133.0	132.0	132.0
		Q1 - Q3	124.5 - 138.0	127.0 - 137.0	128.0 - 139.0	127.0 - 138.0	127.0 - 138.0	127.0 - 138.0
		Min - Max	111 - 149	108 - 152	113 - 165	116 - 155	108 - 165	108 - 165

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Hemoglobin (g/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-2.2 (6.28)	-1.7 (5.57)	-2.4 (7.05)	-1.4 (5.82)	-1.8 (6.17)	-1.9 (6.19)
		Median	-3.0	-2.0	-2.0	-2.0	-2.0	-2.0
		Q1 - Q3	-5.0 - 0	-5.0 - 1.0	-6.0 - 0	-5.0 - 3.0	-6.0 - 2.0	-6.0 - 1.0
		Min - Max	-16 - 13	-15 - 15	-25 - 16	-15 - 11	-25 - 16	-25 - 16
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	130.6 (9.22)	131.0 (9.24)	131.7 (8.58)	133.0 (8.24)	131.9 (8.70)	131.5 (8.83)
		Median	131.0	132.0	132.5	133.0	132.0	132.0
		Q1 - Q3	125.0 - 136.0	125.0 - 137.0	125.0 - 137.0	128.0 - 138.0	127.0 - 137.0	126.0 - 137.0
		Min - Max	105 - 150	107 - 150	110 - 160	111 - 156	107 - 160	105 - 160
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-3.2 (6.04)	-3.1 (5.55)	-3.8 (6.51)	-1.6 (6.44)	-2.9 (6.21)	-2.9 (6.16)
		Median	-3.5	-3.0	-4.0	-1.0	-3.0	-3.0
		Q1 - Q3	-7.0 - 0	-6.0 - 1.0	-9.0 - 1.0	-5.0 - 3.0	-7.0 - 1.0	-7.0 - 1.0
		Min - Max	-20 - 12	-20 - 8	-17 - 10	-19 - 15	-20 - 15	-20 - 15

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Platelets (10^9/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	252.1 (51.06)	237.5 (52.44)	240.5 (45.92)	230.7 (47.02)	236.3 (48.51)	240.2 (49.54)
		Median	244.0	236.5	236.0	225.0	236.0	236.0
		Q1 - Q3	216.0 - 289.0	205.0 - 263.0	208.0 - 267.0	195.5 - 264.0	203.0 - 267.0	205.0 - 272.0
		Min - Max	150 - 386	129 - 411	146 - 371	152 - 330	129 - 411	129 - 411
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	252.6 (51.61)	234.4 (50.95)	245.0 (50.52)	232.0 (50.26)	237.1 (50.65)	241.0 (51.24)
		Median	240.0	224.5	237.5	222.5	227.5	231.0
		Q1 - Q3	214.0 - 298.0	203.0 - 258.0	209.5 - 280.0	200.5 - 267.5	204.0 - 270.0	205.0 - 274.0
		Min - Max	148 - 396	131 - 405	135 - 388	119 - 386	119 - 405	119 - 405
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.5 (25.53)	-3.1 (22.56)	5.0 (26.52)	1.3 (26.19)	1.0 (25.23)	0.9 (25.26)
		Median	2.0	-3.0	7.0	-1.0	-0.5	0
		Q1 - Q3	-14.0 - 16.0	-15.0 - 11.0	-11.0 - 19.0	-14.5 - 15.5	-15.0 - 16.0	-15.0 - 16.0
		Min - Max	-75 - 70	-81 - 45	-54 - 90	-57 - 83	-81 - 90	-81 - 90

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Platelets (10^9/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	255.1 (48.08)	239.7 (51.26)	239.4 (41.31)	233.6 (47.26)	237.6 (46.69)	241.9 (47.56)
		Median	245.0	234.0	237.0	232.0	234.0	237.0
		Q1 - Q3	219.0 - 292.0	207.0 - 267.0	208.0 - 266.0	203.0 - 270.0	207.0 - 269.0	208.0 - 272.0
		Min - Max	166 - 355	146 - 399	154 - 351	148 - 348	146 - 399	146 - 399
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	2.2 (27.49)	1.6 (24.63)	-0.9 (25.20)	2.7 (25.17)	1.1 (24.92)	1.4 (25.53)
		Median	5.0	5.0	-1.0	1.0	3.0	3.5
		Q1 - Q3	-15.0 - 19.0	-13.0 - 17.0	-20.0 - 14.0	-12.0 - 18.0	-13.0 - 16.0	-14.0 - 17.0
		Min - Max	-57 - 85	-109 - 52	-60 - 59	-47 - 52	-109 - 59	-109 - 85
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	256.8 (50.61)	239.5 (51.74)	247.7 (51.71)	232.4 (49.83)	240.0 (51.24)	244.2 (51.51)
		Median	252.5	228.0	240.0	227.5	232.0	235.5
		Q1 - Q3	215.0 - 289.0	201.0 - 279.0	205.0 - 289.0	196.0 - 272.0	200.0 - 278.5	206.0 - 281.0
		Min - Max	148 - 391	154 - 353	152 - 408	135 - 340	135 - 408	135 - 408

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Platelets (10^9/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	3.8 (24.15)	1.4 (26.94)	7.4 (27.50)	1.9 (29.90)	3.6 (28.09)	3.6 (27.13)
		Median	2.5	1.0	6.0	2.0	2.0	2.0
		Q1 - Q3	-13.0 - 22.0	-10.0 - 15.0	-14.0 - 24.0	-10.5 - 12.0	-11.0 - 18.5	-11.0 - 19.0
		Min - Max	-53 - 53	-79 - 65	-32 - 86	-109 - 87	-109 - 87	-109 - 87
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	254.9 (56.33)	244.4 (52.37)	242.6 (47.76)	229.0 (50.90)	238.9 (50.60)	242.8 (52.43)
		Median	251.0	239.0	232.0	230.0	233.0	237.0
		Q1 - Q3	220.0 - 292.0	206.5 - 269.0	210.0 - 275.0	196.0 - 267.0	205.0 - 270.0	206.0 - 273.0
		Min - Max	121 - 416	155 - 416	133 - 387	129 - 382	129 - 416	121 - 416
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	1.8 (31.53)	5.5 (33.47)	1.5 (27.65)	-1.1 (26.71)	2.1 (29.49)	2.0 (29.95)
		Median	1.0	7.5	1.0	-3.0	2.0	2.0
		Q1 - Q3	-17.0 - 15.0	-13.5 - 20.0	-16.0 - 16.0	-21.0 - 18.0	-16.0 - 18.0	-16.0 - 18.0
		Min - Max	-54 - 125	-106 - 111	-55 - 130	-55 - 64	-106 - 130	-106 - 130

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Platelets (10^9/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	255.1 (53.76)	238.0 (49.38)	246.3 (49.78)	228.4 (49.99)	237.7 (49.98)	242.0 (51.40)
		Median	252.0	234.5	243.0	233.0	234.0	237.0
		Q1 - Q3	214.0 - 300.0	200.0 - 273.5	210.0 - 281.0	187.0 - 274.0	199.5 - 274.5	202.0 - 280.0
		Min - Max	137 - 379	155 - 376	136 - 394	131 - 330	131 - 394	131 - 394
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	2.0 (29.80)	-0.9 (32.02)	6.2 (26.01)	-1.7 (26.24)	1.2 (28.38)	1.4 (28.69)
		Median	-2.0	-0.5	1.0	-5.0	-1.0	-1.0
		Q1 - Q3	-11.0 - 16.0	-16.5 - 21.5	-10.0 - 19.0	-21.0 - 17.0	-15.5 - 19.0	-15.0 - 18.0
		Min - Max	-65 - 121	-119 - 99	-47 - 83	-45 - 83	-119 - 99	-119 - 121
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	251.6 (49.66)	239.4 (48.74)	242.0 (48.79)	233.7 (49.15)	238.5 (48.76)	241.7 (49.21)
		Median	252.5	233.0	235.0	235.0	233.0	237.0
		Q1 - Q3	210.5 - 285.5	205.0 - 271.0	209.0 - 271.0	198.0 - 271.0	205.0 - 271.0	206.0 - 277.0
		Min - Max	157 - 355	148 - 406	132 - 387	144 - 347	132 - 406	132 - 406

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Platelets (10^9/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.8 (29.64)	0.3 (29.80)	1.0 (27.72)	2.6 (30.57)	1.3 (29.23)	0.8 (29.29)
		Median	-1.0	0	4.0	0	1.0	1.0
		Q1 - Q3	-16.0 - 15.0	-13.0 - 15.0	-18.0 - 16.0	-14.0 - 14.0	-15.0 - 15.0	-15.0 - 15.0
		Min - Max	-61 - 130	-106 - 103	-59 - 66	-43 - 163	-106 - 163	-106 - 163
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	254.6 (62.67)	237.7 (52.86)	242.7 (50.97)	230.4 (52.95)	237.1 (52.23)	241.4 (55.37)
		Median	245.0	233.0	238.5	229.0	233.0	233.0
		Q1 - Q3	209.0 - 301.5	202.0 - 265.5	207.0 - 274.0	194.0 - 267.0	203.0 - 267.0	205.0 - 272.0
		Min - Max	143 - 487	143 - 424	136 - 372	128 - 360	128 - 424	128 - 487
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	1.8 (36.43)	-0.6 (31.08)	3.3 (27.50)	-0.4 (27.51)	0.8 (28.70)	1.0 (30.70)
		Median	-1.0	-4.5	-0.5	-2.0	-1.0	-1.0
		Q1 - Q3	-17.5 - 15.5	-19.0 - 17.0	-12.0 - 22.0	-22.0 - 19.0	-18.0 - 18.0	-18.0 - 17.0
		Min - Max	-86 - 189	-123 - 83	-61 - 84	-55 - 62	-123 - 84	-123 - 189

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Mean Platelet Volume (fL)	Baseline	Observed Value						
		n	67	66	67	64	197	264
		Mean (SD)	9.607 (1.0290)	9.709 (1.0353)	9.797 (1.0610)	9.749 (1.2664)	9.752 (1.1187)	9.715 (1.0965)
		Median	9.400	9.700	9.600	9.450	9.600	9.600
		Q1 - Q3	8.900 - 10.300	8.900 - 10.300	9.100 - 10.400	8.700 - 10.750	8.900 - 10.400	8.900 - 10.300
		Min - Max	7.00 - 12.70	7.70 - 12.60	8.00 - 13.10	7.80 - 13.30	7.70 - 13.30	7.00 - 13.30
	D15	Observed Value						
		n	67	66	66	64	196	263
		Mean (SD)	9.716 (1.0019)	9.837 (1.0717)	9.791 (0.9741)	9.807 (1.2542)	9.812 (1.0989)	9.787 (1.0740)
		Median	9.700	9.850	9.650	9.550	9.700	9.700
		Q1 - Q3	9.100 - 10.300	9.000 - 10.600	9.000 - 10.500	8.700 - 10.600	9.000 - 10.600	9.000 - 10.500
		Min - Max	7.50 - 12.50	7.70 - 12.80	8.20 - 12.30	8.10 - 13.10	7.70 - 13.10	7.50 - 13.10
	D15	Change from Baseline						
		n	67	66	66	64	196	263
		Mean (SD)	0.109 (0.5131)	0.128 (0.4182)	-0.008 (0.5124)	0.058 (0.4115)	0.059 (0.4512)	0.072 (0.4673)
		Median	0.100	0.100	0.050	0.100	0.100	0.100
		Q1 - Q3	-0.100 - 0.400	-0.100 - 0.300	-0.200 - 0.300	-0.250 - 0.300	-0.200 - 0.300	-0.200 - 0.300
		Min - Max	-1.60 - 1.40	-0.90 - 1.20	-2.40 - 1.10	-1.00 - 1.30	-2.40 - 1.30	-2.40 - 1.40

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Mean Platelet Volume (fL)	D29	Observed Value						
		n	65	65	65	63	193	258
		Mean (SD)	9.626 (0.8652)	9.860 (1.2654)	9.942 (1.0809)	9.773 (1.1137)	9.859 (1.1526)	9.800 (1.0905)
		Median	9.500	9.800	9.900	9.600	9.800	9.700
		Q1 - Q3	9.100 - 10.300	9.100 - 10.600	9.100 - 10.500	8.800 - 10.600	9.000 - 10.600	9.000 - 10.400
		Min - Max	7.40 - 11.90	7.80 - 15.10	8.50 - 12.90	8.10 - 13.10	7.80 - 15.10	7.40 - 15.10
	D29	Change from Baseline						
		n	65	65	65	63	193	258
		Mean (SD)	-0.002 (0.5128)	0.183 (0.5939)	0.131 (0.6146)	0.045 (0.4620)	0.121 (0.5618)	0.090 (0.5515)
		Median	0.100	0.200	0.100	0.100	0.100	0.100
		Q1 - Q3	-0.200 - 0.300	-0.200 - 0.300	-0.100 - 0.400	-0.200 - 0.300	-0.200 - 0.400	-0.200 - 0.300
		Min - Max	-1.60 - 1.10	-0.70 - 2.80	-2.40 - 2.50	-1.10 - 1.10	-2.40 - 2.80	-2.40 - 2.80
	D43	Observed Value						
		n	64	65	65	61	191	255
		Mean (SD)	9.691 (0.9204)	9.787 (1.1746)	9.788 (1.0392)	9.769 (1.1043)	9.782 (1.1016)	9.759 (1.0581)
		Median	9.700	9.600	9.800	9.600	9.700	9.700
		Q1 - Q3	9.000 - 10.200	9.000 - 10.500	9.000 - 10.500	8.900 - 10.500	8.900 - 10.500	9.000 - 10.500
		Min - Max	7.80 - 11.70	7.60 - 14.60	8.10 - 12.60	8.00 - 12.90	7.60 - 14.60	7.60 - 14.60

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Mean Platelet Volume (fL)	D43	Change from Baseline						
		n	64	65	65	61	191	255
		Mean (SD)	0.069 (0.5145)	0.110 (0.5286)	-0.023 (0.5123)	0.057 (0.5138)	0.048 (0.5186)	0.053 (0.5167)
		Median	0	0.100	0.100	0.100	0.100	0.100
		Q1 - Q3	-0.200 - 0.400	-0.100 - 0.300	-0.200 - 0.200	-0.300 - 0.300	-0.200 - 0.300	-0.200 - 0.300
		Min - Max	-1.60 - 1.20	-1.00 - 2.30	-2.10 - 1.10	-1.80 - 1.20	-2.10 - 2.30	-2.10 - 2.30
	D57	Observed Value						
		n	63	64	64	60	188	251
		Mean (SD)	9.756 (1.0306)	9.768 (1.0957)	9.853 (1.0316)	9.799 (1.2656)	9.807 (1.1268)	9.794 (1.1016)
		Median	9.600	9.600	9.700	9.650	9.600	9.600
		Q1 - Q3	9.100 - 10.300	9.000 - 10.500	9.050 - 10.550	8.700 - 10.650	8.915 - 10.500	9.000 - 10.500
		Min - Max	7.20 - 13.00	7.75 - 14.00	8.00 - 12.80	7.70 - 12.90	7.70 - 14.00	7.20 - 14.00
	D57	Change from Baseline						
		n	63	64	64	60	188	251
		Mean (SD)	0.111 (0.6353)	0.093 (0.5425)	0.042 (0.5415)	0.072 (0.5436)	0.069 (0.5400)	0.079 (0.5644)
		Median	0.100	0.100	0.100	0.100	0.100	0.100
		Q1 - Q3	-0.200 - 0.400	-0.200 - 0.300	-0.250 - 0.300	-0.300 - 0.335	-0.200 - 0.300	-0.200 - 0.300
		Min - Max	-1.70 - 2.40	-1.40 - 1.90	-2.40 - 1.20	-1.50 - 1.80	-2.40 - 1.90	-2.40 - 2.40

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Mean Platelet Volume (fL)	D71	Observed Value						
		n	63	64	63	60	187	250
		Mean (SD)	9.787 (1.0965)	9.840 (1.1010)	9.852 (0.9776)	9.871 (1.2398)	9.854 (1.1032)	9.837 (1.0997)
		Median	9.500	9.700	9.800	9.650	9.700	9.700
		Q1 - Q3	9.000 - 10.200	9.250 - 10.550	9.100 - 10.300	8.900 - 10.800	9.000 - 10.500	9.000 - 10.400
		Min - Max	7.50 - 13.90	7.80 - 13.40	8.20 - 12.50	8.10 - 12.90	7.80 - 13.40	7.50 - 13.90
	D71	Change from Baseline						
		n	63	64	63	60	187	250
		Mean (SD)	0.143 (0.6579)	0.164 (0.6129)	0.029 (0.6007)	0.144 (0.5352)	0.112 (0.5848)	0.120 (0.6028)
		Median	0.100	0.110	0.200	0.100	0.100	0.100
		Q1 - Q3	-0.300 - 0.400	-0.150 - 0.500	-0.200 - 0.400	-0.100 - 0.400	-0.110 - 0.400	-0.200 - 0.400
		Min - Max	-1.50 - 3.30	-2.10 - 2.30	-2.50 - 1.20	-1.90 - 1.30	-2.50 - 2.30	-2.50 - 3.30
	D85	Observed Value						
		n	62	63	64	59	186	248
		Mean (SD)	9.763 (1.0593)	9.831 (1.1397)	9.830 (1.0587)	9.739 (1.1364)	9.801 (1.1062)	9.792 (1.0926)
		Median	9.550	9.700	9.600	9.600	9.650	9.600
		Q1 - Q3	9.100 - 10.200	9.000 - 10.600	9.000 - 10.600	8.900 - 10.500	8.900 - 10.600	9.000 - 10.400
		Min - Max	7.50 - 13.30	7.90 - 12.60	8.10 - 12.50	7.70 - 13.00	7.70 - 13.00	7.50 - 13.30

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Mean Platelet Volume (fL)	D85	Change from Baseline						
		n	62	63	64	59	186	248
		Mean (SD)	0.115 (0.6169)	0.174 (0.6126)	0.019 (0.5715)	0.050 (0.5841)	0.081 (0.5904)	0.090 (0.5960)
		Median	0.100	0.100	0.100	0	0.100	0.100
		Q1 - Q3	-0.100 - 0.300	-0.100 - 0.400	-0.200 - 0.400	-0.300 - 0.400	-0.200 - 0.400	-0.200 - 0.400
		Min - Max	-1.20 - 2.70	-0.90 - 2.50	-1.90 - 1.70	-1.40 - 1.90	-1.90 - 2.50	-1.90 - 2.70
	Safety Follow-up	Observed Value						
		n	62	64	64	60	188	250
		Mean (SD)	9.684 (0.9523)	9.867 (1.1852)	9.891 (0.9848)	9.759 (1.2471)	9.840 (1.1375)	9.802 (1.0948)
		Median	9.500	9.900	9.800	9.600	9.800	9.700
		Q1 - Q3	9.100 - 10.200	9.050 - 10.500	9.200 - 10.600	8.750 - 10.450	9.000 - 10.500	9.100 - 10.400
		Min - Max	7.20 - 12.20	7.38 - 13.80	8.10 - 12.20	7.90 - 13.50	7.38 - 13.80	7.20 - 13.80
	Safety Follow-up	Change from Baseline						
		n	62	64	64	60	188	250
		Mean (SD)	0.039 (0.5016)	0.207 (0.7026)	0.067 (0.6958)	0.047 (0.5635)	0.108 (0.6594)	0.091 (0.6237)
		Median	0.100	0.200	0.050	0.100	0.100	0.100
		Q1 - Q3	-0.300 - 0.300	-0.050 - 0.400	-0.200 - 0.450	-0.350 - 0.400	-0.200 - 0.400	-0.200 - 0.400
		Min - Max	-1.50 - 1.40	-2.30 - 3.30	-3.00 - 1.50	-1.60 - 1.70	-3.00 - 3.30	-3.00 - 3.30

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Leukocytes (10^9/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	5.657 (1.4004)	5.558 (1.6622)	5.465 (1.2669)	5.277 (1.1619)	5.435 (1.3813)	5.490 (1.3869)
		Median	5.490	5.230	5.190	5.130	5.160	5.265
		Q1 - Q3	4.800 - 6.360	4.550 - 6.200	4.550 - 6.380	4.540 - 5.875	4.550 - 6.200	4.590 - 6.230
		Min - Max	3.04 - 9.40	2.64 - 12.39	2.70 - 8.43	3.03 - 9.24	2.64 - 12.39	2.64 - 12.39
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	5.567 (2.0300)	5.133 (1.2563)	5.107 (1.2427)	5.183 (1.1428)	5.141 (1.2099)	5.248 (1.4671)
		Median	5.340	5.105	4.830	5.080	5.050	5.090
		Q1 - Q3	4.400 - 6.100	4.170 - 5.670	4.295 - 5.945	4.370 - 5.905	4.340 - 5.810	4.350 - 5.910
		Min - Max	2.76 - 16.18	2.78 - 8.90	3.00 - 9.03	3.10 - 9.31	2.78 - 9.31	2.76 - 16.18
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.089 (1.7174)	-0.425 (1.4026)	-0.321 (1.0530)	-0.093 (0.9291)	-0.281 (1.1515)	-0.233 (1.3157)
		Median	-0.270	-0.130	-0.250	-0.065	-0.165	-0.190
		Q1 - Q3	-0.640 - 0.200	-0.870 - 0.330	-0.850 - 0.395	-0.530 - 0.505	-0.750 - 0.380	-0.710 - 0.370
		Min - Max	-3.20 - 10.23	-6.91 - 1.70	-3.28 - 2.61	-2.40 - 2.54	-6.91 - 2.61	-6.91 - 10.23

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Leukocytes (10^9/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	5.341 (1.2431)	5.370 (1.4167)	5.156 (1.1426)	5.138 (1.0571)	5.223 (1.2159)	5.252 (1.2215)
		Median	5.460	5.370	5.280	5.150	5.290	5.290
		Q1 - Q3	4.510 - 6.220	4.380 - 6.180	4.220 - 6.040	4.250 - 5.790	4.250 - 6.040	4.350 - 6.040
		Min - Max	2.92 - 8.98	2.63 - 8.94	2.12 - 8.16	3.07 - 7.51	2.12 - 8.94	2.12 - 8.98
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.267 (0.9222)	-0.172 (1.3085)	-0.286 (0.9805)	-0.145 (0.8052)	-0.201 (1.0517)	-0.217 (1.0198)
		Median	-0.340	0.050	-0.180	-0.230	-0.170	-0.195
		Q1 - Q3	-0.760 - 0.290	-0.750 - 0.500	-0.840 - 0.260	-0.630 - 0.460	-0.710 - 0.410	-0.720 - 0.360
		Min - Max	-2.50 - 1.95	-5.47 - 2.65	-3.84 - 1.43	-2.05 - 2.23	-5.47 - 2.65	-5.47 - 2.65
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	5.338 (1.5608)	5.160 (1.3982)	5.314 (1.2164)	5.108 (1.1314)	5.195 (1.2537)	5.230 (1.3348)
		Median	5.145	5.090	5.350	5.205	5.210	5.205
		Q1 - Q3	4.410 - 6.000	4.260 - 5.800	4.390 - 6.010	4.220 - 5.720	4.345 - 5.805	4.350 - 5.880
		Min - Max	3.00 - 12.80	2.09 - 10.21	2.71 - 8.77	3.00 - 8.23	2.09 - 10.21	2.09 - 12.80

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Leukocytes (10^9/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.237 (1.2470)	-0.382 (1.1627)	-0.129 (0.8154)	-0.229 (1.0779)	-0.248 (1.0303)	-0.245 (1.0856)
		Median	-0.295	-0.270	-0.110	-0.220	-0.210	-0.240
		Q1 - Q3	-0.980 - 0.220	-0.770 - 0.360	-0.560 - 0.460	-0.830 - 0.365	-0.735 - 0.395	-0.780 - 0.350
		Min - Max	-2.27 - 6.81	-4.09 - 2.86	-2.42 - 2.07	-3.64 - 2.45	-4.09 - 2.86	-4.09 - 6.81
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	5.210 (1.2050)	5.352 (1.5584)	5.340 (1.4698)	5.159 (1.2192)	5.286 (1.4228)	5.267 (1.3702)
		Median	5.220	5.055	5.155	4.930	5.060	5.120
		Q1 - Q3	4.350 - 6.130	4.275 - 6.355	4.140 - 6.120	4.060 - 6.000	4.190 - 6.120	4.200 - 6.120
		Min - Max	2.68 - 7.94	2.73 - 9.50	3.28 - 10.50	2.68 - 8.22	2.68 - 10.50	2.68 - 10.50
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.387 (0.9836)	-0.212 (1.2014)	-0.108 (1.1879)	-0.173 (0.9119)	-0.165 (1.1074)	-0.220 (1.0804)
		Median	-0.380	-0.100	-0.105	-0.240	-0.160	-0.190
		Q1 - Q3	-0.890 - 0.140	-0.645 - 0.335	-0.890 - 0.580	-0.780 - 0.430	-0.760 - 0.490	-0.800 - 0.450
		Min - Max	-2.87 - 1.92	-4.19 - 2.83	-3.18 - 4.01	-2.04 - 2.01	-4.19 - 4.01	-4.19 - 4.01

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Leukocytes (10^9/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	5.103 (1.1757)	5.259 (1.3436)	5.381 (1.4622)	5.075 (1.2448)	5.241 (1.3528)	5.206 (1.3101)
		Median	5.100	5.070	5.090	4.860	5.070	5.070
		Q1 - Q3	4.250 - 6.000	4.315 - 5.995	4.310 - 6.090	4.020 - 5.760	4.270 - 6.010	4.260 - 6.010
		Min - Max	3.01 - 7.85	2.47 - 9.09	2.27 - 9.19	2.99 - 8.69	2.27 - 9.19	2.27 - 9.19
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.494 (1.1445)	-0.304 (1.2370)	-0.081 (0.9335)	-0.257 (0.7031)	-0.215 (0.9891)	-0.284 (1.0348)
		Median	-0.400	-0.120	-0.140	-0.300	-0.190	-0.240
		Q1 - Q3	-0.870 - 0.070	-0.830 - 0.450	-0.490 - 0.420	-0.750 - 0.380	-0.740 - 0.405	-0.760 - 0.330
		Min - Max	-4.05 - 3.01	-4.90 - 1.96	-3.40 - 2.39	-2.24 - 1.46	-4.90 - 2.39	-4.90 - 3.01
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	5.416 (1.3099)	5.227 (1.4011)	5.279 (1.3516)	5.057 (1.0547)	5.190 (1.2800)	5.246 (1.2886)
		Median	5.455	5.140	5.190	5.000	5.080	5.150
		Q1 - Q3	4.670 - 6.195	4.250 - 6.000	4.360 - 6.200	4.330 - 5.760	4.300 - 6.020	4.340 - 6.120
		Min - Max	1.73 - 9.98	2.56 - 9.10	3.00 - 8.84	3.04 - 7.81	2.56 - 9.10	1.73 - 9.98

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Leukocytes (10^9/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.144 (1.0509)	-0.346 (1.4802)	-0.170 (1.0252)	-0.309 (0.8294)	-0.274 (1.1488)	-0.242 (1.1248)
		Median	-0.120	-0.100	0.005	-0.155	-0.100	-0.100
		Q1 - Q3	-0.820 - 0.460	-0.860 - 0.440	-0.800 - 0.280	-0.880 - 0.180	-0.850 - 0.310	-0.840 - 0.330
		Min - Max	-2.56 - 2.72	-5.23 - 3.89	-3.27 - 3.06	-2.29 - 1.89	-5.23 - 3.89	-5.23 - 3.89
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	5.507 (1.4247)	5.270 (1.2558)	5.263 (1.3384)	5.051 (1.2588)	5.198 (1.2824)	5.274 (1.3226)
		Median	5.310	5.345	5.005	5.010	5.080	5.150
		Q1 - Q3	4.345 - 6.330	4.540 - 5.955	4.430 - 6.170	4.140 - 5.720	4.400 - 5.900	4.400 - 6.030
		Min - Max	2.83 - 9.69	2.84 - 8.93	2.64 - 10.12	2.75 - 10.17	2.64 - 10.17	2.64 - 10.17
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.061 (1.2084)	-0.280 (1.3602)	-0.193 (1.0855)	-0.307 (0.9098)	-0.259 (1.1346)	-0.211 (1.1540)
		Median	-0.115	0.070	-0.275	-0.350	-0.230	-0.200
		Q1 - Q3	-0.685 - 0.570	-0.600 - 0.525	-0.860 - 0.300	-0.990 - 0.270	-0.830 - 0.400	-0.780 - 0.440
		Min - Max	-4.27 - 3.04	-5.18 - 1.84	-3.63 - 3.29	-2.12 - 2.57	-5.18 - 3.29	-5.18 - 3.29

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes/Leukocytes (%)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	33.743 (7.2362)	33.525 (7.5756)	32.855 (7.3549)	34.275 (6.9307)	33.548 (7.2827)	33.597 (7.2585)
		Median	34.200	34.600	33.500	33.450	33.600	33.800
		Q1 - Q3	28.000 - 39.000	28.100 - 38.900	26.300 - 38.300	29.300 - 38.250	28.800 - 38.500	28.450 - 38.500
		Min - Max	16.40 - 48.40	16.20 - 51.80	13.50 - 47.10	19.00 - 54.80	13.50 - 54.80	13.50 - 54.80
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	33.812 (7.4927)	34.364 (8.0253)	34.212 (6.9938)	33.757 (7.2309)	34.113 (7.4040)	34.038 (7.4138)
		Median	35.100	32.750	34.700	33.750	33.750	34.300
		Q1 - Q3	30.800 - 38.500	28.800 - 40.700	28.350 - 38.800	28.600 - 38.300	28.400 - 39.600	28.900 - 39.000
		Min - Max	8.00 - 51.40	17.70 - 53.70	15.50 - 51.20	21.10 - 53.80	15.50 - 53.80	8.00 - 53.80
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.068 (6.4613)	0.839 (7.5365)	1.135 (5.6347)	-0.518 (5.6430)	0.489 (6.3575)	0.383 (6.3745)
		Median	0.700	-0.900	1.150	-1.050	-0.380	0
		Q1 - Q3	-3.400 - 3.600	-3.200 - 3.900	-1.900 - 4.750	-3.900 - 3.000	-3.100 - 3.900	-3.100 - 3.700
		Min - Max	-24.30 - 14.30	-23.70 - 24.60	-11.90 - 15.40	-16.80 - 16.20	-23.70 - 24.60	-24.30 - 24.60

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes/Leukocytes (%)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	33.973 (6.8704)	34.508 (8.7063)	32.496 (8.0576)	33.128 (7.9289)	33.389 (8.2454)	33.534 (7.9182)
		Median	34.000	33.000	32.400	33.100	32.900	33.300
		Q1 - Q3	28.800 - 38.400	29.600 - 40.300	27.600 - 38.800	28.500 - 37.600	28.000 - 39.000	28.200 - 38.800
		Min - Max	19.60 - 48.90	13.20 - 60.10	13.60 - 49.70	11.90 - 51.00	11.90 - 60.10	11.90 - 60.10
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.116 (5.3465)	1.007 (6.6884)	-0.699 (7.2637)	-1.058 (6.2563)	-0.237 (6.7757)	-0.150 (6.4430)
		Median	0	0.300	0	-0.700	0	0
		Q1 - Q3	-3.100 - 3.000	-3.800 - 3.300	-3.900 - 3.400	-4.300 - 3.600	-4.100 - 3.400	-3.800 - 3.200
		Min - Max	-11.10 - 13.00	-10.80 - 23.20	-20.00 - 20.00	-15.10 - 11.80	-20.00 - 23.20	-20.00 - 23.20
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	33.406 (7.1499)	34.042 (8.3099)	32.763 (7.3397)	32.774 (7.3500)	33.208 (7.6769)	33.257 (7.5368)
		Median	32.250	34.300	32.400	32.150	32.950	32.900
		Q1 - Q3	28.100 - 38.800	28.800 - 38.500	27.600 - 37.900	26.350 - 37.850	27.900 - 38.150	28.000 - 38.200
		Min - Max	17.70 - 48.70	7.00 - 56.90	16.00 - 49.40	19.50 - 50.30	7.00 - 56.90	7.00 - 56.90

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes/Leukocytes (%)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.348 (6.5820)	0.541 (7.5316)	-0.431 (6.2499)	-1.355 (5.6823)	-0.392 (6.5697)	-0.381 (6.5604)
		Median	-0.500	-0.300	-0.500	-1.300	-0.650	-0.650
		Q1 - Q3	-3.800 - 3.700	-4.000 - 4.400	-4.500 - 2.800	-4.000 - 2.480	-4.200 - 3.050	-4.100 - 3.200
		Min - Max	-26.40 - 18.30	-17.50 - 23.20	-16.90 - 23.80	-22.00 - 9.00	-22.00 - 23.80	-26.40 - 23.80
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	34.125 (6.9831)	33.646 (6.8843)	32.650 (7.3542)	32.929 (7.4524)	33.083 (7.2032)	33.341 (7.1501)
		Median	34.100	33.350	33.100	33.100	33.200	33.450
		Q1 - Q3	28.700 - 38.300	29.150 - 38.400	27.800 - 37.600	27.600 - 38.600	28.700 - 38.000	28.700 - 38.000
		Min - Max	17.80 - 53.30	17.80 - 48.10	12.40 - 46.30	16.90 - 50.60	12.40 - 50.60	12.40 - 53.30
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.423 (5.8195)	0.219 (5.7505)	-0.335 (7.4482)	-1.186 (5.7673)	-0.416 (6.3683)	-0.208 (6.2363)
		Median	0.200	-0.200	-0.100	-0.900	-0.400	-0.200
		Q1 - Q3	-2.500 - 3.500	-4.250 - 3.600	-4.100 - 3.300	-3.500 - 1.900	-3.700 - 3.100	-3.500 - 3.100
		Min - Max	-21.40 - 17.20	-12.10 - 18.30	-18.60 - 23.70	-21.50 - 10.30	-21.50 - 23.70	-21.50 - 23.70

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes/Leukocytes (%)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	34.842 (6.7859)	33.491 (7.8649)	33.102 (6.7467)	33.832 (6.9841)	33.471 (7.1965)	33.813 (7.1084)
		Median	34.000	33.635	32.600	33.300	32.800	33.300
		Q1 - Q3	30.500 - 40.600	28.600 - 39.550	29.000 - 37.000	28.200 - 38.000	28.600 - 38.050	29.000 - 38.500
		Min - Max	20.60 - 56.70	15.80 - 57.20	12.10 - 56.40	20.40 - 52.70	12.10 - 57.20	12.10 - 57.20
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.140 (6.4378)	0.063 (6.4084)	0.014 (5.9771)	-0.282 (6.4974)	-0.064 (6.2675)	0.236 (6.3194)
		Median	-0.400	-0.900	1.200	-0.300	-0.250	-0.300
		Q1 - Q3	-3.000 - 3.500	-2.850 - 3.300	-4.400 - 3.800	-4.100 - 4.200	-3.400 - 3.700	-3.200 - 3.600
		Min - Max	-9.60 - 22.10	-13.40 - 17.40	-14.20 - 14.70	-19.80 - 13.30	-19.80 - 17.40	-19.80 - 22.10
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	33.892 (7.5181)	34.372 (8.5668)	33.350 (7.0139)	33.522 (7.2816)	33.756 (7.6372)	33.790 (7.5936)
		Median	32.350	33.500	32.950	31.800	32.800	32.700
		Q1 - Q3	28.100 - 39.800	28.700 - 40.700	28.600 - 38.700	28.500 - 37.700	28.600 - 39.000	28.500 - 39.100
		Min - Max	19.40 - 53.10	10.50 - 51.20	19.30 - 53.30	20.50 - 54.80	10.50 - 54.80	10.50 - 54.80

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes/Leukocytes (%)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.255 (7.1758)	1.083 (6.8214)	0.365 (6.1016)	-0.604 (6.4096)	0.304 (6.4572)	0.292 (6.6277)
		Median	0.400	0.500	0.200	-0.100	0.500	0.500
		Q1 - Q3	-3.400 - 3.800	-3.000 - 3.900	-3.500 - 3.900	-4.600 - 3.500	-3.600 - 3.700	-3.600 - 3.700
		Min - Max	-21.70 - 19.00	-15.80 - 16.50	-13.30 - 18.40	-15.40 - 16.90	-15.80 - 18.40	-21.70 - 19.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	34.439 (6.9456)	34.922 (7.9334)	35.088 (7.7480)	34.693 (6.7347)	34.904 (7.4697)	34.790 (7.3343)
		Median	34.400	34.300	34.500	33.800	34.400	34.400
		Q1 - Q3	28.600 - 39.050	29.750 - 39.750	29.700 - 38.900	28.900 - 39.100	29.400 - 39.100	29.300 - 39.100
		Min - Max	21.10 - 49.80	15.10 - 55.50	15.40 - 55.30	22.30 - 51.30	15.10 - 55.50	15.10 - 55.50
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.628 (7.4169)	1.556 (7.3994)	1.789 (6.2762)	0.471 (6.4521)	1.287 (6.7284)	1.125 (6.8948)
		Median	0.450	0.750	1.850	0.300	1.200	1.100
		Q1 - Q3	-5.050 - 4.400	-3.150 - 4.150	-3.900 - 5.300	-3.500 - 4.800	-3.500 - 4.800	-3.700 - 4.700
		Min - Max	-19.80 - 21.90	-13.40 - 29.50	-17.10 - 15.60	-17.60 - 20.00	-17.60 - 29.50	-19.80 - 29.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes/Leukocytes (%)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	5.719 (1.4363)	5.570 (1.2924)	5.755 (1.5536)	5.584 (1.4273)	5.636 (1.4234)	5.657 (1.4244)
		Median	5.700	5.500	5.500	5.400	5.400	5.500
		Q1 - Q3	4.700 - 6.600	4.500 - 6.500	4.800 - 6.500	4.800 - 6.300	4.600 - 6.500	4.650 - 6.500
		Min - Max	3.20 - 9.90	3.40 - 9.40	2.90 - 9.50	2.90 - 9.76	2.90 - 9.76	2.90 - 9.90
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	5.804 (1.4889)	5.852 (1.6395)	6.018 (2.1461)	5.615 (1.3707)	5.828 (1.7468)	5.822 (1.6832)
		Median	5.500	5.600	5.750	5.500	5.600	5.600
		Q1 - Q3	4.700 - 6.600	4.900 - 6.500	4.750 - 7.050	4.700 - 6.400	4.700 - 6.600	4.700 - 6.600
		Min - Max	3.00 - 9.50	3.50 - 13.11	3.00 - 17.50	2.70 - 9.54	2.70 - 17.50	2.70 - 17.50
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.086 (1.0737)	0.281 (1.6171)	0.244 (1.8983)	0.032 (1.1307)	0.187 (1.5773)	0.161 (1.4661)
		Median	0	0.100	0.050	0	0.100	0.100
		Q1 - Q3	-0.500 - 0.900	-0.600 - 0.700	-0.500 - 0.850	-0.700 - 0.550	-0.600 - 0.700	-0.600 - 0.700
		Min - Max	-3.10 - 3.30	-2.50 - 8.68	-3.70 - 12.00	-2.00 - 3.00	-3.70 - 12.00	-3.70 - 12.00

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes/Leukocytes (%)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	6.012 (1.9464)	5.789 (1.3403)	5.816 (1.6132)	5.906 (1.5357)	5.837 (1.4927)	5.880 (1.6150)
		Median	5.600	5.700	5.800	5.500	5.600	5.600
		Q1 - Q3	4.900 - 6.700	4.900 - 6.600	4.800 - 6.500	4.800 - 6.600	4.900 - 6.600	4.900 - 6.600
		Min - Max	3.10 - 16.00	2.90 - 9.30	2.80 - 9.80	3.40 - 11.30	2.80 - 11.30	2.80 - 16.00
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.281 (1.4707)	0.201 (1.0962)	0.015 (1.2373)	0.328 (1.3949)	0.182 (1.2478)	0.206 (1.3045)
		Median	0.200	0	0	0.200	0.100	0.100
		Q1 - Q3	-0.600 - 0.900	-0.500 - 0.800	-0.800 - 0.800	-0.600 - 1.000	-0.600 - 0.900	-0.600 - 0.900
		Min - Max	-3.00 - 8.20	-1.90 - 3.99	-3.00 - 4.30	-2.10 - 7.20	-3.00 - 7.20	-3.00 - 8.20
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	6.123 (1.7804)	5.808 (1.3581)	5.921 (1.8983)	5.805 (1.9656)	5.845 (1.7468)	5.914 (1.7560)
		Median	5.750	5.600	5.600	5.350	5.500	5.600
		Q1 - Q3	4.900 - 7.200	4.900 - 6.600	4.900 - 6.700	4.700 - 6.600	4.850 - 6.600	4.900 - 6.700
		Min - Max	3.00 - 12.50	3.50 - 11.90	2.60 - 14.80	3.30 - 17.00	2.60 - 17.00	2.60 - 17.00

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes/Leukocytes (%)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.371 (1.3756)	0.221 (1.0809)	0.119 (1.5851)	0.244 (1.6171)	0.194 (1.4364)	0.238 (1.4211)
		Median	0.200	0.200	0.100	0.100	0.100	0.150
		Q1 - Q3	-0.300 - 0.900	-0.400 - 0.700	-0.600 - 0.800	-0.550 - 0.750	-0.600 - 0.700	-0.500 - 0.800
		Min - Max	-2.90 - 6.20	-2.00 - 3.10	-3.50 - 7.80	-2.30 - 10.50	-3.50 - 10.50	-3.50 - 10.50
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	6.288 (1.9398)	5.724 (1.4500)	6.141 (1.7386)	5.652 (1.4500)	5.840 (1.5597)	5.951 (1.6694)
		Median	5.800	5.500	5.800	5.400	5.700	5.700
		Q1 - Q3	4.700 - 7.200	4.800 - 6.400	5.100 - 7.200	4.600 - 6.600	4.800 - 6.700	4.800 - 6.900
		Min - Max	3.50 - 11.70	3.20 - 10.80	2.70 - 13.60	3.20 - 9.67	2.70 - 13.60	2.70 - 13.60
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.515 (1.6364)	0.117 (1.2340)	0.344 (1.4868)	0.087 (1.0097)	0.183 (1.2607)	0.266 (1.3678)
		Median	0.300	-0.100	0.100	0	0	0.100
		Q1 - Q3	-0.400 - 1.100	-0.800 - 0.500	-0.600 - 1.200	-0.700 - 0.800	-0.700 - 0.800	-0.700 - 1.000
		Min - Max	-3.40 - 6.80	-2.10 - 4.40	-2.60 - 7.10	-2.60 - 2.70	-2.60 - 7.10	-3.40 - 7.10

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes/Leukocytes (%)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	6.263 (1.9685)	5.966 (1.2084)	5.766 (1.6210)	5.745 (1.4835)	5.829 (1.4401)	5.937 (1.5952)
		Median	6.100	5.850	5.500	5.600	5.700	5.800
		Q1 - Q3	4.600 - 7.700	5.000 - 6.750	4.600 - 6.800	4.700 - 6.400	4.850 - 6.650	4.800 - 6.900
		Min - Max	2.60 - 12.70	2.80 - 9.10	3.10 - 10.90	2.70 - 9.58	2.70 - 10.90	2.60 - 12.70
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.491 (1.6215)	0.360 (1.2660)	-0.020 (1.1949)	0.180 (0.9906)	0.176 (1.1644)	0.255 (1.2972)
		Median	0.400	0.300	0.100	0.100	0.100	0.200
		Q1 - Q3	-0.400 - 1.200	-0.500 - 1.050	-0.500 - 0.600	-0.400 - 0.800	-0.500 - 0.800	-0.500 - 0.900
		Min - Max	-3.70 - 7.00	-2.80 - 4.20	-3.60 - 2.50	-1.85 - 3.20	-3.60 - 4.20	-3.70 - 7.00
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	5.863 (1.7048)	5.767 (1.4987)	5.920 (1.6633)	5.692 (1.4449)	5.795 (1.5351)	5.812 (1.5756)
		Median	5.550	5.500	5.700	5.450	5.600	5.600
		Q1 - Q3	4.500 - 7.050	4.900 - 6.300	4.800 - 6.900	4.700 - 6.300	4.800 - 6.500	4.700 - 6.600
		Min - Max	3.00 - 10.40	2.90 - 11.59	2.90 - 10.70	3.10 - 9.70	2.90 - 11.59	2.90 - 11.59

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes/Leukocytes (%)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.056 (1.3813)	0.183 (1.3033)	0.123 (1.3874)	0.126 (1.1569)	0.145 (1.2824)	0.123 (1.3053)
		Median	0.200	0	0.100	-0.050	0	0.100
		Q1 - Q3	-0.800 - 0.750	-0.600 - 0.800	-0.900 - 0.900	-0.600 - 0.700	-0.600 - 0.800	-0.700 - 0.800
		Min - Max	-3.50 - 5.40	-2.30 - 7.16	-2.60 - 5.50	-3.00 - 4.20	-3.00 - 7.16	-3.50 - 7.16
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	6.027 (1.7078)	6.059 (1.2522)	5.898 (1.3479)	5.783 (1.3794)	5.917 (1.3241)	5.944 (1.4250)
		Median	5.900	6.000	5.800	5.600	5.700	5.800
		Q1 - Q3	4.700 - 6.950	5.300 - 6.850	4.900 - 6.700	4.800 - 6.400	5.000 - 6.700	5.000 - 6.800
		Min - Max	2.40 - 11.10	3.40 - 8.50	3.30 - 9.70	3.40 - 9.80	3.30 - 9.80	2.40 - 11.10
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.231 (1.3025)	0.493 (1.1763)	0.108 (1.1695)	0.210 (1.1167)	0.274 (1.1612)	0.263 (1.1949)
		Median	0.200	0.350	0.100	0.100	0.200	0.200
		Q1 - Q3	-0.700 - 1.000	-0.300 - 1.100	-0.600 - 1.000	-0.400 - 0.800	-0.400 - 1.000	-0.400 - 1.000
		Min - Max	-3.50 - 4.50	-2.60 - 3.50	-3.00 - 3.20	-3.70 - 2.90	-3.70 - 3.50	-3.70 - 4.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils/Leukocytes (%)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	58.068 (8.0164)	58.485 (8.1259)	59.186 (7.7369)	57.636 (7.3625)	58.440 (7.7399)	58.347 (7.7969)
		Median	57.200	57.600	59.200	57.550	57.800	57.700
		Q1 - Q3	52.600 - 63.700	52.300 - 62.500	54.200 - 64.400	53.900 - 63.150	53.700 - 63.800	53.200 - 63.750
		Min - Max	40.10 - 76.60	38.40 - 77.50	39.70 - 75.70	38.20 - 76.60	38.20 - 77.50	38.20 - 77.50
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	57.935 (8.1339)	57.272 (8.4946)	57.419 (7.4183)	58.092 (7.7830)	57.591 (7.8866)	57.677 (7.9358)
		Median	57.100	59.100	57.500	58.250	57.800	57.700
		Q1 - Q3	53.600 - 61.300	51.400 - 62.800	53.150 - 63.050	52.500 - 63.700	52.000 - 63.100	52.300 - 62.800
		Min - Max	40.60 - 85.40	38.60 - 75.20	41.60 - 73.00	37.50 - 72.80	37.50 - 75.20	37.50 - 85.40
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.133 (7.4384)	-1.214 (8.4756)	-1.524 (6.3481)	0.456 (6.3740)	-0.765 (7.1681)	-0.606 (7.2283)
		Median	-0.900	0.400	-1.000	-0.050	-0.400	-0.600
		Q1 - Q3	-4.600 - 3.200	-5.900 - 3.500	-5.150 - 1.950	-2.750 - 3.650	-3.900 - 3.400	-4.400 - 3.400
		Min - Max	-16.60 - 29.80	-27.70 - 22.60	-18.10 - 11.30	-17.70 - 17.90	-27.70 - 22.60	-27.70 - 29.80

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils/Leukocytes (%)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	57.494 (7.2517)	57.216 (9.2669)	59.384 (8.5248)	58.555 (8.9387)	58.373 (8.9200)	58.155 (8.5321)
		Median	56.700	57.600	58.200	57.400	57.600	57.500
		Q1 - Q3	52.600 - 62.700	50.800 - 63.100	53.700 - 66.600	54.470 - 65.500	52.900 - 64.300	52.900 - 64.000
		Min - Max	45.20 - 74.00	28.40 - 81.80	42.90 - 78.00	35.80 - 80.50	28.40 - 81.80	28.40 - 81.80
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.479 (6.2648)	-1.256 (7.4620)	0.600 (7.8394)	0.836 (7.0566)	0.047 (7.4821)	-0.084 (7.1917)
		Median	-1.200	-0.400	0.100	0	0	-0.050
		Q1 - Q3	-4.200 - 3.800	-3.900 - 3.900	-3.800 - 4.200	-4.000 - 5.100	-3.900 - 4.500	-3.900 - 4.100
		Min - Max	-15.40 - 15.60	-25.30 - 13.80	-22.30 - 22.90	-17.90 - 16.90	-25.30 - 22.90	-25.30 - 22.90
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	58.020 (7.3858)	57.698 (8.9211)	59.075 (7.6552)	59.091 (8.1530)	58.605 (8.2529)	58.460 (8.0369)
		Median	58.700	57.900	60.300	59.950	59.050	59.000
		Q1 - Q3	52.400 - 63.700	52.500 - 63.800	53.800 - 65.700	53.500 - 65.600	53.000 - 64.750	52.600 - 64.600
		Min - Max	41.60 - 73.10	33.70 - 86.30	43.30 - 72.50	41.40 - 75.00	33.70 - 86.30	33.70 - 86.30

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils/Leukocytes (%)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.033 (7.2692)	-0.773 (8.1625)	0.291 (6.8453)	1.294 (6.4510)	0.245 (7.2247)	0.176 (7.2230)
		Median	0.150	1.100	-0.400	1.150	0.500	0.400
		Q1 - Q3	-3.600 - 4.100	-4.700 - 4.300	-3.000 - 4.700	-3.500 - 4.650	-3.500 - 4.650	-3.600 - 4.600
		Min - Max	-18.10 - 27.70	-25.20 - 17.50	-21.20 - 20.10	-11.00 - 24.00	-25.20 - 24.00	-25.20 - 27.70
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	56.965 (7.6495)	58.209 (7.6519)	58.933 (7.4239)	58.999 (8.5129)	58.705 (7.8324)	58.273 (7.8092)
		Median	56.700	58.350	58.450	59.200	58.600	58.200
		Q1 - Q3	52.000 - 63.100	53.250 - 62.750	54.300 - 63.500	53.800 - 65.400	53.800 - 63.500	53.300 - 63.400
		Min - Max	37.60 - 74.40	42.60 - 77.50	43.20 - 80.80	40.80 - 74.90	40.80 - 80.80	37.60 - 80.80
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-1.115 (6.3411)	-0.308 (6.4790)	-0.058 (8.0871)	1.184 (6.6153)	0.253 (7.0924)	-0.086 (6.9271)
		Median	-0.600	0.000	-0.050	1.800	0.300	0.000
		Q1 - Q3	-4.200 - 1.900	-4.150 - 4.250	-4.300 - 4.500	-2.400 - 3.910	-3.700 - 4.200	-3.800 - 3.700
		Min - Max	-20.10 - 15.00	-19.40 - 13.80	-21.80 - 19.00	-13.90 - 25.70	-21.80 - 25.70	-21.80 - 25.70

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils/Leukocytes (%)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	56.149 (7.4044)	58.219 (8.1896)	58.832 (7.3195)	57.847 (7.6714)	58.303 (7.7138)	57.767 (7.6807)
		Median	56.200	59.150	58.100	58.400	58.500	58.000
		Q1 - Q3	49.900 - 60.800	53.200 - 63.400	55.000 - 64.600	54.200 - 62.900	54.200 - 63.350	53.400 - 62.900
		Min - Max	34.70 - 71.00	34.00 - 76.50	33.50 - 80.60	37.90 - 74.80	33.50 - 80.60	33.50 - 80.60
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.931 (6.9219)	-0.298 (7.2943)	-0.077 (6.4752)	0.032 (7.0150)	-0.119 (6.9071)	-0.570 (6.9420)
		Median	-1.100	0.700	-0.600	-0.100	0.050	-0.100
		Q1 - Q3	-5.300 - 2.400	-3.000 - 2.850	-4.500 - 4.000	-4.200 - 5.000	-3.900 - 3.600	-4.200 - 3.500
		Min - Max	-23.30 - 10.10	-20.40 - 18.20	-11.30 - 16.90	-17.30 - 20.20	-20.40 - 20.20	-23.30 - 20.20
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	57.745 (8.2507)	57.579 (9.1750)	58.277 (7.3535)	58.135 (8.4610)	57.992 (8.3282)	57.931 (8.2939)
		Median	57.950	58.700	58.400	58.515	58.600	58.430
		Q1 - Q3	52.450 - 63.800	51.200 - 62.500	53.100 - 63.000	53.200 - 65.400	53.000 - 63.500	52.800 - 63.600
		Min - Max	38.70 - 76.40	39.12 - 85.90	32.70 - 73.00	30.20 - 72.10	30.20 - 85.90	30.20 - 85.90

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils/Leukocytes (%)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.375 (8.1331)	-1.083 (7.7590)	-0.714 (6.8882)	0.334 (7.1793)	-0.507 (7.2760)	-0.475 (7.4809)
		Median	-0.800	-0.600	-1.050	-0.250	-0.800	-0.800
		Q1 - Q3	-4.700 - 4.350	-4.100 - 3.200	-4.200 - 4.300	-4.300 - 5.100	-4.200 - 4.100	-4.200 - 4.200
		Min - Max	-22.10 - 26.00	-18.80 - 19.70	-23.00 - 13.70	-18.90 - 15.70	-23.00 - 19.70	-23.00 - 26.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	56.906 (7.7506)	56.757 (8.3935)	56.721 (8.0045)	57.023 (7.4139)	56.830 (7.9206)	56.849 (7.8645)
		Median	57.550	57.100	57.400	56.700	57.100	57.200
		Q1 - Q3	52.700 - 60.450	50.850 - 62.500	52.100 - 61.900	52.800 - 62.800	51.700 - 62.100	52.600 - 62.000
		Min - Max	36.80 - 74.00	36.60 - 77.70	37.60 - 78.50	40.30 - 72.20	36.60 - 78.50	36.60 - 78.50
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.013 (8.1068)	-1.857 (7.9987)	-1.979 (6.8233)	-0.687 (7.0955)	-1.524 (7.3191)	-1.398 (7.5071)
		Median	-0.450	-0.850	-2.400	-0.100	-1.300	-1.100
		Q1 - Q3	-5.100 - 3.950	-4.400 - 2.500	-5.800 - 3.400	-5.000 - 4.500	-4.800 - 3.400	-4.800 - 3.600
		Min - Max	-23.40 - 22.80	-30.70 - 13.30	-17.90 - 19.30	-24.50 - 17.80	-30.70 - 19.30	-30.70 - 22.80

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils/Leukocytes (%)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	1.901 (1.8553)	1.892 (1.2992)	1.723 (0.9984)	1.984 (1.6070)	1.866 (1.3214)	1.875 (1.4695)
		Median	1.400	1.600	1.600	1.700	1.600	1.600
		Q1 - Q3	0.900 - 2.300	1.000 - 2.200	0.900 - 2.300	1.150 - 2.600	1.000 - 2.400	1.000 - 2.400
		Min - Max	0.20 - 13.10	0.20 - 6.00	0.10 - 4.60	0.20 - 12.30	0.10 - 12.30	0.10 - 13.10
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	1.880 (1.4076)	1.983 (1.3780)	1.884 (1.1029)	1.996 (1.8103)	1.955 (1.4527)	1.936 (1.4393)
		Median	1.500	1.600	1.700	1.700	1.650	1.600
		Q1 - Q3	0.900 - 2.700	1.000 - 2.800	0.900 - 2.600	1.200 - 2.250	1.000 - 2.500	1.000 - 2.600
		Min - Max	0.10 - 6.60	0.20 - 7.10	0.30 - 4.70	0.20 - 14.30	0.20 - 14.30	0.10 - 14.30
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.022 (1.2738)	0.091 (0.8307)	0.159 (0.7954)	0.012 (0.7855)	0.087 (0.8027)	0.060 (0.9418)
		Median	0	0	0	0.020	0	0
		Q1 - Q3	-0.200 - 0.400	-0.400 - 0.400	-0.200 - 0.500	-0.450 - 0.400	-0.400 - 0.500	-0.300 - 0.500
		Min - Max	-7.50 - 2.10	-2.20 - 3.60	-1.90 - 3.10	-1.60 - 2.30	-2.20 - 3.60	-7.50 - 3.60

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils/Leukocytes (%)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	1.906 (1.4168)	1.964 (1.3905)	1.797 (1.1623)	1.880 (1.3885)	1.881 (1.3141)	1.887 (1.3377)
		Median	1.400	1.600	1.600	1.700	1.600	1.600
		Q1 - Q3	1.000 - 2.300	1.100 - 2.600	0.900 - 2.200	1.000 - 2.400	1.000 - 2.400	1.000 - 2.400
		Min - Max	0.30 - 6.80	0.30 - 7.50	0.30 - 5.70	0.40 - 9.90	0.30 - 9.90	0.30 - 9.90
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.040 (1.4016)	0.056 (0.8215)	0.064 (0.8368)	-0.116 (0.8011)	0.002 (0.8201)	0.011 (0.9936)
		Median	0.100	-0.100	0.100	0	0	0
		Q1 - Q3	-0.200 - 0.500	-0.300 - 0.400	-0.300 - 0.500	-0.500 - 0.300	-0.300 - 0.400	-0.300 - 0.400
		Min - Max	-8.40 - 3.10	-2.30 - 3.00	-2.50 - 3.30	-2.40 - 1.50	-2.50 - 3.30	-8.40 - 3.30
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	1.803 (1.4077)	1.945 (1.6664)	1.748 (0.9897)	1.831 (1.0831)	1.842 (1.2852)	1.833 (1.3141)
		Median	1.350	1.500	1.600	1.700	1.600	1.500
		Q1 - Q3	0.900 - 2.200	1.100 - 2.300	1.000 - 2.300	1.000 - 2.350	1.000 - 2.300	1.000 - 2.300
		Min - Max	0 - 7.80	0 - 9.60	0.10 - 4.20	0.30 - 5.60	0 - 9.60	0 - 9.60

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils/Leukocytes (%)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.065 (1.5250)	0.036 (0.9151)	0.015 (0.6668)	-0.149 (1.3174)	-0.030 (0.9949)	-0.039 (1.1463)
		Median	0.100	-0.100	0	0	0	0
		Q1 - Q3	-0.300 - 0.400	-0.500 - 0.400	-0.300 - 0.400	-0.400 - 0.450	-0.400 - 0.400	-0.400 - 0.400
		Min - Max	-8.70 - 3.30	-2.30 - 3.70	-2.00 - 2.10	-8.00 - 3.00	-8.00 - 3.70	-8.70 - 3.70
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	2.018 (1.4136)	1.883 (1.3924)	1.786 (1.0568)	1.912 (1.4200)	1.860 (1.2938)	1.899 (1.3235)
		Median	1.600	1.450	1.650	1.800	1.600	1.600
		Q1 - Q3	1.100 - 2.600	1.000 - 2.250	1.000 - 2.200	1.000 - 2.400	1.000 - 2.200	1.100 - 2.300
		Min - Max	0 - 7.70	0.20 - 7.20	0.20 - 5.20	0.20 - 7.80	0.20 - 7.80	0 - 7.80
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.143 (1.6209)	-0.031 (0.8803)	0.048 (0.7008)	-0.057 (1.3099)	-0.013 (0.9862)	0.026 (1.1743)
		Median	0.200	0	0	0	0	0
		Q1 - Q3	-0.200 - 0.600	-0.500 - 0.500	-0.300 - 0.300	-0.400 - 0.360	-0.400 - 0.400	-0.300 - 0.500
		Min - Max	-10.40 - 3.20	-2.70 - 2.70	-2.00 - 1.60	-6.00 - 5.00	-6.00 - 5.00	-10.40 - 5.00

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils/Leukocytes (%)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	2.115 (1.7295)	1.864 (1.2447)	1.815 (1.1153)	2.008 (1.3888)	1.894 (1.2492)	1.949 (1.3841)
		Median	1.400	1.650	1.700	1.700	1.700	1.700
		Q1 - Q3	1.000 - 2.400	0.900 - 2.500	1.000 - 2.400	1.000 - 2.600	1.000 - 2.500	1.000 - 2.500
		Min - Max	0.40 - 8.50	0.35 - 5.50	0.30 - 5.70	0.30 - 7.80	0.30 - 7.80	0.30 - 8.50
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.240 (1.4976)	-0.050 (0.7569)	0.085 (0.7218)	0.039 (0.9187)	0.023 (0.7996)	0.077 (1.0200)
		Median	0.200	-0.100	0.100	0.100	0	0.100
		Q1 - Q3	-0.200 - 0.700	-0.500 - 0.400	-0.300 - 0.400	-0.400 - 0.500	-0.400 - 0.400	-0.300 - 0.500
		Min - Max	-8.00 - 5.70	-1.70 - 2.60	-2.60 - 2.50	-4.50 - 2.30	-4.50 - 2.60	-8.00 - 5.70
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	1.933 (1.6339)	1.769 (1.1633)	1.917 (1.2316)	2.102 (2.1271)	1.925 (1.5523)	1.927 (1.5696)
		Median	1.400	1.400	1.700	1.750	1.600	1.500
		Q1 - Q3	0.900 - 2.050	1.000 - 2.300	1.000 - 2.700	0.900 - 2.700	1.000 - 2.500	1.000 - 2.400
		Min - Max	0.30 - 7.30	0.30 - 5.30	0.30 - 6.40	0.20 - 15.50	0.20 - 15.50	0.20 - 15.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils/Leukocytes (%)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.072 (1.2043)	-0.159 (0.7445)	0.179 (0.8976)	0.121 (0.8286)	0.044 (0.8347)	0.051 (0.9371)
		Median	0.100	-0.100	0.100	0	0	0.090
		Q1 - Q3	-0.300 - 0.550	-0.500 - 0.200	-0.200 - 0.400	-0.400 - 0.400	-0.400 - 0.400	-0.400 - 0.400
		Min - Max	-6.10 - 3.60	-2.10 - 1.40	-2.00 - 4.00	-1.40 - 3.20	-2.10 - 4.00	-6.10 - 4.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	2.077 (1.6539)	1.793 (1.2138)	1.780 (1.0459)	1.978 (1.4256)	1.848 (1.2318)	1.904 (1.3477)
		Median	1.450	1.450	1.650	1.600	1.600	1.600
		Q1 - Q3	1.000 - 2.500	1.000 - 2.300	1.000 - 2.300	1.000 - 2.700	1.000 - 2.300	1.000 - 2.400
		Min - Max	0.40 - 7.30	0.30 - 6.90	0.30 - 5.30	0.40 - 9.40	0.30 - 9.40	0.30 - 9.40
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.178 (1.5497)	-0.129 (0.7535)	0.055 (0.6465)	0.009 (0.9052)	-0.023 (0.7734)	0.026 (1.0200)
		Median	0.100	-0.100	0	-0.100	0	0
		Q1 - Q3	-0.250 - 0.650	-0.400 - 0.300	-0.300 - 0.400	-0.400 - 0.500	-0.400 - 0.400	-0.300 - 0.500
		Min - Max	-8.50 - 4.90	-2.90 - 1.20	-1.80 - 2.00	-2.90 - 2.30	-2.90 - 2.30	-8.50 - 4.90

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils/Leukocytes (%)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.561 (0.2706)	0.523 (0.3771)	0.474 (0.2495)	0.524 (0.2857)	0.507 (0.3086)	0.520 (0.3000)
		Median	0.500	0.450	0.500	0.500	0.500	0.500
		Q1 - Q3	0.400 - 0.700	0.300 - 0.600	0.300 - 0.600	0.300 - 0.700	0.300 - 0.600	0.300 - 0.600
		Min - Max	0.13 - 1.60	0 - 2.66	0 - 1.10	0.01 - 1.20	0 - 2.66	0 - 2.66
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	0.575 (0.3178)	0.531 (0.3057)	0.496 (0.2980)	0.550 (0.2702)	0.526 (0.2913)	0.538 (0.2983)
		Median	0.500	0.400	0.500	0.550	0.500	0.500
		Q1 - Q3	0.300 - 0.700	0.300 - 0.700	0.300 - 0.600	0.300 - 0.700	0.300 - 0.700	0.300 - 0.700
		Min - Max	0.10 - 2.20	0 - 1.50	0 - 1.40	0 - 1.30	0 - 1.50	0 - 2.20
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.014 (0.2533)	0.009 (0.3587)	0.021 (0.1997)	0.026 (0.2643)	0.018 (0.2815)	0.017 (0.2742)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.100 - 0.200	-0.100 - 0.200	-0.100 - 0.100	-0.100 - 0.100	-0.100 - 0.100	-0.100 - 0.200
		Min - Max	-0.90 - 0.60	-2.07 - 0.80	-0.48 - 0.50	-0.90 - 0.70	-2.07 - 0.80	-2.07 - 0.80

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils/Leukocytes (%)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	0.613 (0.3233)	0.519 (0.2880)	0.512 (0.3174)	0.540 (0.2548)	0.523 (0.2867)	0.546 (0.2981)
		Median	0.600	0.500	0.500	0.500	0.500	0.500
		Q1 - Q3	0.400 - 0.800	0.300 - 0.700	0.200 - 0.700	0.400 - 0.700	0.300 - 0.700	0.300 - 0.700
		Min - Max	0 - 1.80	0 - 1.30	0 - 1.40	0.10 - 1.20	0 - 1.40	0 - 1.80
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.047 (0.2833)	-0.009 (0.2918)	0.031 (0.2388)	0.016 (0.2633)	0.013 (0.2650)	0.021 (0.2695)
		Median	0.100	0	0	0	0	0
		Q1 - Q3	-0.200 - 0.200	-0.100 - 0.200	-0.200 - 0.200	-0.100 - 0.200	-0.100 - 0.200	-0.100 - 0.200
		Min - Max	-0.60 - 0.90	-1.75 - 0.50	-0.60 - 0.80	-0.60 - 0.70	-1.75 - 0.80	-1.75 - 0.90
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	0.606 (0.2945)	0.509 (0.2566)	0.490 (0.2986)	0.511 (0.2620)	0.503 (0.2718)	0.529 (0.2806)
		Median	0.600	0.500	0.500	0.500	0.500	0.500
		Q1 - Q3	0.400 - 0.800	0.300 - 0.700	0.300 - 0.600	0.300 - 0.700	0.300 - 0.700	0.300 - 0.700
		Min - Max	0 - 1.30	0 - 1.30	0 - 1.40	0 - 1.30	0 - 1.40	0 - 1.40

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils/Leukocytes (%)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.033 (0.2685)	-0.018 (0.3381)	0.009 (0.2196)	-0.025 (0.2455)	-0.011 (0.2727)	-0.000 (0.2718)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.100 - 0.200	-0.100 - 0.100	-0.200 - 0.200	-0.200 - 0.100	-0.100 - 0.100	-0.100 - 0.200
		Min - Max	-0.70 - 0.70	-2.12 - 0.80	-0.50 - 0.50	-0.80 - 0.60	-2.12 - 0.80	-2.12 - 0.80
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	0.605 (0.3309)	0.526 (0.2836)	0.483 (0.2559)	0.512 (0.2819)	0.507 (0.2733)	0.531 (0.2911)
		Median	0.500	0.500	0.500	0.410	0.500	0.500
		Q1 - Q3	0.400 - 0.700	0.300 - 0.600	0.300 - 0.600	0.300 - 0.700	0.300 - 0.600	0.300 - 0.700
		Min - Max	0 - 1.80	0 - 1.40	0 - 1.20	0 - 1.40	0 - 1.40	0 - 1.80
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.034 (0.2683)	-0.005 (0.3324)	0.001 (0.2341)	-0.029 (0.2523)	-0.010 (0.2761)	0.001 (0.2743)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.100 - 0.200	-0.100 - 0.200	-0.100 - 0.100	-0.200 - 0.100	-0.100 - 0.100	-0.100 - 0.100
		Min - Max	-0.60 - 1.00	-2.11 - 0.50	-0.60 - 0.70	-0.80 - 0.60	-2.11 - 0.70	-2.11 - 1.00

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils/Leukocytes (%)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	0.631 (0.3988)	0.466 (0.2499)	0.491 (0.2644)	0.553 (0.2995)	0.502 (0.2725)	0.534 (0.3130)
		Median	0.500	0.450	0.500	0.600	0.500	0.500
		Q1 - Q3	0.400 - 0.700	0.300 - 0.600	0.300 - 0.600	0.300 - 0.700	0.300 - 0.650	0.300 - 0.700
		Min - Max	0 - 2.10	0 - 1.10	0 - 1.30	0 - 1.50	0 - 1.50	0 - 2.10
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.060 (0.3468)	-0.065 (0.3353)	0.012 (0.2395)	0.013 (0.2768)	-0.014 (0.2884)	0.004 (0.3050)
		Median	0	0	0.100	0	0	0
		Q1 - Q3	-0.100 - 0.200	-0.200 - 0.100	-0.200 - 0.100	-0.100 - 0.100	-0.200 - 0.100	-0.100 - 0.100
		Min - Max	-0.60 - 1.80	-2.09 - 0.40	-0.60 - 0.70	-0.80 - 0.70	-2.09 - 0.70	-2.09 - 1.80
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	0.567 (0.2906)	0.510 (0.2375)	0.526 (0.3763)	0.562 (0.2906)	0.532 (0.3060)	0.541 (0.3021)
		Median	0.500	0.500	0.500	0.500	0.500	0.500
		Q1 - Q3	0.400 - 0.700	0.300 - 0.600	0.300 - 0.700	0.300 - 0.800	0.300 - 0.700	0.300 - 0.700
		Min - Max	0 - 1.40	0 - 1.30	0 - 2.50	0 - 1.40	0 - 2.50	0 - 2.50

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils/Leukocytes (%)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.008 (0.2602)	-0.022 (0.3220)	0.044 (0.3226)	0.032 (0.2687)	0.018 (0.3061)	0.011 (0.2951)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.150 - 0.100	-0.100 - 0.100	-0.100 - 0.100	-0.100 - 0.100	-0.100 - 0.100	-0.100 - 0.100
		Min - Max	-0.60 - 0.50	-1.96 - 0.50	-0.40 - 2.10	-0.70 - 1.00	-1.96 - 2.10	-1.96 - 2.10
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	0.552 (0.2933)	0.482 (0.2327)	0.499 (0.3066)	0.529 (0.2806)	0.502 (0.2738)	0.515 (0.2789)
		Median	0.500	0.400	0.500	0.500	0.440	0.500
		Q1 - Q3	0.300 - 0.700	0.330 - 0.600	0.300 - 0.600	0.400 - 0.700	0.300 - 0.600	0.300 - 0.700
		Min - Max	0 - 1.40	0 - 1.40	0 - 1.70	0 - 1.50	0 - 1.70	0 - 1.70
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.025 (0.2364)	-0.047 (0.3434)	0.022 (0.2219)	-0.000 (0.2366)	-0.009 (0.2742)	-0.013 (0.2651)
		Median	-0.100	0	0	0	0	0
		Q1 - Q3	-0.200 - 0.100	-0.200 - 0.100	-0.100 - 0.100	-0.160 - 0.200	-0.100 - 0.100	-0.100 - 0.100
		Min - Max	-0.50 - 0.80	-2.30 - 0.70	-0.40 - 1.10	-0.60 - 0.50	-2.30 - 1.10	-2.30 - 1.10

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils (10^9/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.1023 (0.09843)	0.1009 (0.06743)	0.0961 (0.06757)	0.1022 (0.07485)	0.0997 (0.06971)	0.1004 (0.07770)
		Median	0.0700	0.0800	0.0800	0.0900	0.0800	0.0800
		Q1 - Q3	0.0400 - 0.1300	0.0500 - 0.1300	0.0500 - 0.1300	0.0550 - 0.1400	0.0500 - 0.1300	0.0500 - 0.1300
		Min - Max	0.010 - 0.590	0.020 - 0.370	0.010 - 0.340	0.010 - 0.520	0.010 - 0.520	0.010 - 0.590
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	0.0990 (0.08142)	0.0997 (0.07221)	0.0947 (0.06812)	0.1006 (0.08347)	0.0983 (0.07453)	0.0985 (0.07617)
		Median	0.0700	0.0800	0.0700	0.0850	0.0800	0.0800
		Q1 - Q3	0.0400 - 0.1300	0.0500 - 0.1400	0.0500 - 0.1200	0.0600 - 0.1200	0.0500 - 0.1200	0.0500 - 0.1300
		Min - Max	0.010 - 0.490	0.010 - 0.450	0.010 - 0.300	0.010 - 0.660	0.010 - 0.660	0.010 - 0.660
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.0033 (0.06606)	-0.0011 (0.03944)	-0.0009 (0.04121)	-0.0016 (0.03854)	-0.0012 (0.03955)	-0.0017 (0.04748)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200
		Min - Max	-0.320 - 0.170	-0.090 - 0.120	-0.160 - 0.130	-0.100 - 0.140	-0.160 - 0.140	-0.320 - 0.170

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils (10^9/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	0.0970 (0.06567)	0.1023 (0.07181)	0.0927 (0.06625)	0.0934 (0.06210)	0.0962 (0.06670)	0.0964 (0.06633)
		Median	0.0700	0.0800	0.0700	0.0900	0.0800	0.0800
		Q1 - Q3	0.0500 - 0.1300	0.0500 - 0.1400	0.0400 - 0.1300	0.0500 - 0.1200	0.0500 - 0.1200	0.0500 - 0.1300
		Min - Max	0.010 - 0.310	0.020 - 0.340	0.020 - 0.300	0.020 - 0.410	0.020 - 0.410	0.010 - 0.410
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.0012 (0.06879)	0.0007 (0.03719)	-0.0036 (0.03909)	-0.0094 (0.04199)	-0.0040 (0.03948)	-0.0033 (0.04830)
		Median	0.0100	0	0	-0.0100	0	0
		Q1 - Q3	-0.0100 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0300 - 0.0100	-0.0200 - 0.0200	-0.0200 - 0.0200
		Min - Max	-0.380 - 0.140	-0.080 - 0.090	-0.140 - 0.120	-0.130 - 0.090	-0.140 - 0.120	-0.380 - 0.140
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	0.0959 (0.07217)	0.0933 (0.07261)	0.0933 (0.06378)	0.0905 (0.05355)	0.0924 (0.06372)	0.0933 (0.06580)
		Median	0.0750	0.0700	0.0700	0.0850	0.0750	0.0750
		Q1 - Q3	0.0500 - 0.1200	0.0500 - 0.1200	0.0500 - 0.1200	0.0600 - 0.1150	0.0500 - 0.1200	0.0500 - 0.1200
		Min - Max	0 - 0.310	0 - 0.490	0.010 - 0.350	0.010 - 0.330	0 - 0.490	0 - 0.490

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils (10^9/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.0030 (0.07082)	-0.0083 (0.04194)	-0.0030 (0.03783)	-0.0125 (0.06357)	-0.0079 (0.04868)	-0.0067 (0.05490)
		Median	0	-0.0100	0	-0.0100	0	0
		Q1 - Q3	-0.0200 - 0.0200	-0.0300 - 0.0100	-0.0200 - 0.0100	-0.0300 - 0.0200	-0.0300 - 0.0100	-0.0200 - 0.0200
		Min - Max	-0.370 - 0.150	-0.100 - 0.140	-0.120 - 0.110	-0.360 - 0.140	-0.360 - 0.140	-0.370 - 0.150
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	0.1031 (0.06917)	0.0979 (0.07939)	0.0973 (0.07263)	0.0954 (0.06691)	0.0969 (0.07295)	0.0984 (0.07195)
		Median	0.0900	0.0800	0.0800	0.0800	0.0800	0.0800
		Q1 - Q3	0.0600 - 0.1300	0.0500 - 0.1300	0.0600 - 0.1100	0.0500 - 0.1200	0.0500 - 0.1200	0.0500 - 0.1200
		Min - Max	0 - 0.310	0.010 - 0.470	0.020 - 0.380	0.010 - 0.310	0.010 - 0.470	0 - 0.470
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.0035 (0.07549)	-0.0043 (0.04450)	0.0006 (0.04346)	-0.0068 (0.05896)	-0.0035 (0.04912)	-0.0017 (0.05673)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0400	-0.0350 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0100	-0.0200 - 0.0200	-0.0200 - 0.0200
		Min - Max	-0.460 - 0.140	-0.110 - 0.150	-0.130 - 0.140	-0.280 - 0.170	-0.280 - 0.170	-0.460 - 0.170

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils (10^9/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	0.1060 (0.09340)	0.0968 (0.06901)	0.0978 (0.06979)	0.0992 (0.06692)	0.0979 (0.06826)	0.0999 (0.07520)
		Median	0.0700	0.0750	0.0800	0.0800	0.0800	0.0700
		Q1 - Q3	0.0500 - 0.1300	0.0400 - 0.1300	0.0500 - 0.1200	0.0500 - 0.1300	0.0500 - 0.1300	0.0500 - 0.1300
		Min - Max	0.010 - 0.580	0.020 - 0.370	0.010 - 0.310	0.010 - 0.360	0.010 - 0.370	0.010 - 0.580
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.0065 (0.07676)	-0.0054 (0.03846)	0.0012 (0.03393)	-0.0030 (0.04145)	-0.0025 (0.03795)	-0.0002 (0.05045)
		Median	0	-0.0050	0	0	0	0
		Q1 - Q3	-0.0200 - 0.0300	-0.0300 - 0.0100	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200
		Min - Max	-0.360 - 0.360	-0.110 - 0.080	-0.120 - 0.100	-0.160 - 0.100	-0.160 - 0.100	-0.360 - 0.360
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	0.1013 (0.07987)	0.0897 (0.06300)	0.1011 (0.07658)	0.1027 (0.09496)	0.0977 (0.07864)	0.0986 (0.07881)
		Median	0.0800	0.0700	0.0750	0.0850	0.0800	0.0800
		Q1 - Q3	0.0500 - 0.1100	0.0500 - 0.1200	0.0500 - 0.1300	0.0500 - 0.1300	0.0500 - 0.1300	0.0500 - 0.1300
		Min - Max	0.010 - 0.340	0.020 - 0.340	0.010 - 0.420	0.010 - 0.710	0.010 - 0.710	0.010 - 0.710

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Eosinophils (10^9/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.0036 (0.06038)	-0.0133 (0.03890)	0.0044 (0.05356)	-0.0005 (0.03898)	-0.0032 (0.04484)	-0.0015 (0.04910)
		Median	0.0050	-0.0100	0	0	0	0
		Q1 - Q3	-0.0150 - 0.0250	-0.0400 - 0.0100	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200	-0.0200 - 0.0200
		Min - Max	-0.250 - 0.140	-0.110 - 0.120	-0.140 - 0.270	-0.090 - 0.190	-0.140 - 0.270	-0.250 - 0.270
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	0.1114 (0.08896)	0.0976 (0.08301)	0.0941 (0.06762)	0.0971 (0.06721)	0.0963 (0.07282)	0.1000 (0.07719)
		Median	0.0800	0.0650	0.0800	0.0800	0.0700	0.0800
		Q1 - Q3	0.0500 - 0.1300	0.0500 - 0.1300	0.0500 - 0.1100	0.0600 - 0.1200	0.0500 - 0.1200	0.0500 - 0.1200
		Min - Max	0.020 - 0.410	0.020 - 0.450	0.010 - 0.330	0.020 - 0.390	0.010 - 0.450	0.010 - 0.450
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.0108 (0.07852)	-0.0047 (0.05788)	-0.0021 (0.04055)	-0.0054 (0.04428)	-0.0041 (0.04809)	-0.0004 (0.05726)
		Median	0	-0.0100	0	-0.0100	0	0
		Q1 - Q3	-0.0100 - 0.0350	-0.0300 - 0.0100	-0.0200 - 0.0100	-0.0300 - 0.0200	-0.0300 - 0.0200	-0.0200 - 0.0200
		Min - Max	-0.340 - 0.350	-0.130 - 0.310	-0.120 - 0.140	-0.170 - 0.110	-0.170 - 0.310	-0.340 - 0.350

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils (10^9/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.0374 (0.05812)	0.0283 (0.01761)	0.0262 (0.01351)	0.0322 (0.03640)	0.0289 (0.02452)	0.0310 (0.03605)
		Median	0.0300	0.0300	0.0200	0.0300	0.0300	0.0300
		Q1 - Q3	0.0200 - 0.0400	0.0200 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0400	0.0200 - 0.0400	0.0200 - 0.0400
		Min - Max	0.010 - 0.500	0 - 0.120	0 - 0.060	0 - 0.300	0 - 0.300	0 - 0.500
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	0.0303 (0.01455)	0.0266 (0.01541)	0.0254 (0.01429)	0.0276 (0.01477)	0.0266 (0.01479)	0.0275 (0.01479)
		Median	0.0300	0.0250	0.0200	0.0300	0.0200	0.0300
		Q1 - Q3	0.0200 - 0.0400	0.0100 - 0.0300	0.0150 - 0.0300	0.0200 - 0.0350	0.0200 - 0.0300	0.0200 - 0.0400
		Min - Max	0 - 0.070	0 - 0.080	0 - 0.060	0 - 0.080	0 - 0.080	0 - 0.080
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.0071 (0.05904)	-0.0017 (0.01702)	-0.0007 (0.00888)	-0.0046 (0.03642)	-0.0023 (0.02365)	-0.0035 (0.03589)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0050 - 0	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100
		Min - Max	-0.480 - 0.020	-0.100 - 0.030	-0.030 - 0.020	-0.280 - 0.040	-0.280 - 0.040	-0.480 - 0.040

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils (10^9/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	0.0321 (0.01591)	0.0274 (0.01472)	0.0264 (0.01721)	0.0270 (0.01314)	0.0269 (0.01504)	0.0282 (0.01539)
		Median	0.0300	0.0300	0.0200	0.0300	0.0200	0.0300
		Q1 - Q3	0.0200 - 0.0400	0.0200 - 0.0400	0.0100 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0400	0.0200 - 0.0400
		Min - Max	0 - 0.070	0 - 0.080	0 - 0.070	0 - 0.060	0 - 0.080	0 - 0.080
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.0055 (0.05901)	-0.0012 (0.01430)	-0.0001 (0.01216)	-0.0054 (0.03615)	-0.0022 (0.02344)	-0.0030 (0.03562)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100
		Min - Max	-0.470 - 0.030	-0.080 - 0.030	-0.020 - 0.031	-0.280 - 0.030	-0.280 - 0.031	-0.470 - 0.031
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	0.0318 (0.01548)	0.0259 (0.01343)	0.0266 (0.01610)	0.0266 (0.01566)	0.0264 (0.01501)	0.0277 (0.01528)
		Median	0.0300	0.0300	0.0200	0.0200	0.0200	0.0300
		Q1 - Q3	0.0200 - 0.0400	0.0200 - 0.0300	0.0100 - 0.0300	0.0150 - 0.0400	0.0150 - 0.0300	0.0200 - 0.0400
		Min - Max	0 - 0.060	0 - 0.060	0 - 0.080	0 - 0.070	0 - 0.080	0 - 0.080

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils (10^9/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.0056 (0.06185)	-0.0026 (0.01540)	0.0000 (0.01159)	-0.0067 (0.03660)	-0.0030 (0.02361)	-0.0037 (0.03685)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0100	-0.0100 - 0	-0.0100 - 0.0100	-0.0100 - 0	-0.0100 - 0	-0.0100 - 0.0100
		Min - Max	-0.490 - 0.030	-0.090 - 0.030	-0.030 - 0.031	-0.280 - 0.030	-0.280 - 0.031	-0.490 - 0.031
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	0.0309 (0.01508)	0.0328 (0.04744)	0.0264 (0.01585)	0.0265 (0.01618)	0.0286 (0.03073)	0.0292 (0.02768)
		Median	0.0300	0.0300	0.0200	0.0200	0.0200	0.0300
		Q1 - Q3	0.0200 - 0.0400	0.0200 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0400
		Min - Max	0 - 0.070	0.010 - 0.400	0 - 0.090	0 - 0.080	0 - 0.400	0 - 0.400
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.0066 (0.06221)	0.0040 (0.04496)	-0.0003 (0.01163)	-0.0025 (0.01307)	0.0005 (0.02824)	-0.0013 (0.03946)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100
		Min - Max	-0.490 - 0.030	-0.090 - 0.350	-0.030 - 0.030	-0.050 - 0.030	-0.090 - 0.350	-0.490 - 0.350

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils (10^9/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	0.0318 (0.02083)	0.0244 (0.01397)	0.0263 (0.01398)	0.0278 (0.01431)	0.0261 (0.01408)	0.0275 (0.01618)
		Median	0.0300	0.0200	0.0200	0.0300	0.0200	0.0200
		Q1 - Q3	0.0200 - 0.0400	0.0150 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0400	0.0200 - 0.0300	0.0200 - 0.0400
		Min - Max	0 - 0.140	0 - 0.060	0.010 - 0.070	0 - 0.060	0 - 0.070	0 - 0.140
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.0057 (0.06197)	-0.0044 (0.01624)	-0.0003 (0.01133)	-0.0013 (0.01338)	-0.0020 (0.01389)	-0.0029 (0.03305)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0100	-0.0100 - 0	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100
		Min - Max	-0.470 - 0.120	-0.090 - 0.030	-0.030 - 0.020	-0.050 - 0.020	-0.090 - 0.030	-0.470 - 0.120
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	0.0306 (0.01680)	0.0255 (0.01077)	0.0268 (0.01619)	0.0310 (0.03542)	0.0277 (0.02296)	0.0284 (0.02161)
		Median	0.0300	0.0200	0.0200	0.0200	0.0200	0.0300
		Q1 - Q3	0.0200 - 0.0400	0.0200 - 0.0300	0.0200 - 0.0400	0.0200 - 0.0300	0.0200 - 0.0400	0.0200 - 0.0400
		Min - Max	0 - 0.080	0.010 - 0.060	0 - 0.090	0 - 0.280	0 - 0.280	0 - 0.280

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Basophils (10^9/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.0072 (0.06186)	-0.0034 (0.01483)	0.0002 (0.01388)	0.0021 (0.03325)	-0.0005 (0.02218)	-0.0021 (0.03624)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0100	-0.0100 - 0	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0	-0.0100 - 0.0100
		Min - Max	-0.480 - 0.040	-0.090 - 0.020	-0.020 - 0.080	-0.040 - 0.240	-0.090 - 0.240	-0.480 - 0.240
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	0.0291 (0.01400)	0.0254 (0.01239)	0.0259 (0.01488)	0.0270 (0.01509)	0.0261 (0.01409)	0.0268 (0.01410)
		Median	0.0300	0.0200	0.0200	0.0200	0.0200	0.0200
		Q1 - Q3	0.0200 - 0.0400	0.0200 - 0.0300	0.0100 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0300	0.0200 - 0.0400
		Min - Max	0 - 0.070	0.010 - 0.060	0 - 0.070	0 - 0.080	0 - 0.080	0 - 0.080
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.0089 (0.06126)	-0.0032 (0.01606)	-0.0006 (0.00928)	-0.0017 (0.01264)	-0.0019 (0.01298)	-0.0036 (0.03233)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0100 - 0.0100	-0.0100 - 0	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100	-0.0100 - 0.0100
		Min - Max	-0.480 - 0.050	-0.100 - 0.030	-0.030 - 0.030	-0.040 - 0.020	-0.100 - 0.030	-0.480 - 0.050

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils (10^9/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	3.328 (1.1138)	3.307 (1.3564)	3.275 (1.0251)	3.047 (0.7902)	3.211 (1.0861)	3.240 (1.0922)
		Median	3.190	3.055	3.110	3.030	3.060	3.110
		Q1 - Q3	2.560 - 3.960	2.440 - 3.710	2.480 - 3.980	2.410 - 3.630	2.440 - 3.750	2.480 - 3.805
		Min - Max	1.22 - 7.14	1.36 - 9.42	1.53 - 6.03	1.64 - 5.57	1.36 - 9.42	1.22 - 9.42
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	3.316 (1.8118)	2.979 (0.9527)	2.963 (0.9465)	3.027 (0.8417)	2.990 (0.9113)	3.071 (1.2067)
		Median	2.990	2.975	2.720	2.900	2.865	2.930
		Q1 - Q3	2.510 - 3.540	2.370 - 3.640	2.220 - 3.575	2.345 - 3.465	2.350 - 3.560	2.380 - 3.560
		Min - Max	1.19 - 13.83	1.15 - 6.03	1.50 - 6.59	1.18 - 5.37	1.15 - 6.59	1.15 - 13.83
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.012 (1.6852)	-0.328 (1.3027)	-0.272 (0.8739)	-0.020 (0.7385)	-0.208 (1.0085)	-0.159 (1.2136)
		Median	-0.160	-0.020	-0.210	0.005	-0.065	-0.100
		Q1 - Q3	-0.620 - 0.210	-0.610 - 0.300	-0.605 - 0.270	-0.400 - 0.410	-0.500 - 0.310	-0.550 - 0.290
		Min - Max	-2.83 - 9.97	-6.01 - 1.97	-2.37 - 2.05	-2.12 - 1.68	-6.01 - 2.05	-6.01 - 9.97

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils (10^9/L)	D29	Observed Value						
		n	67	69	66	67	202	269
		Mean (SD)	3.094 (0.9083)	3.127 (1.0957)	3.103 (0.9164)	3.035 (0.8656)	3.089 (0.9619)	3.090 (0.9472)
		Median	3.040	3.080	3.015	3.100	3.080	3.060
		Q1 - Q3	2.390 - 3.700	2.320 - 3.740	2.280 - 3.860	2.350 - 3.540	2.320 - 3.750	2.350 - 3.740
		Min - Max	1.51 - 5.72	0.77 - 5.47	1.32 - 5.02	1.49 - 5.37	0.77 - 5.47	0.77 - 5.72
	D29	Change from Baseline						
		n	67	69	66	67	202	269
		Mean (SD)	-0.202 (0.7782)	-0.171 (1.1883)	-0.137 (0.9014)	-0.020 (0.7266)	-0.110 (0.9582)	-0.133 (0.9161)
		Median	-0.240	-0.190	-0.095	-0.040	-0.070	-0.090
		Q1 - Q3	-0.660 - 0.300	-0.520 - 0.360	-0.380 - 0.320	-0.460 - 0.300	-0.450 - 0.320	-0.480 - 0.320
		Min - Max	-2.25 - 1.44	-4.99 - 2.34	-3.64 - 1.63	-1.81 - 2.14	-4.99 - 2.34	-4.99 - 2.34
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	3.134 (1.2051)	3.031 (1.0897)	3.174 (0.9636)	3.031 (0.8552)	3.079 (0.9746)	3.093 (1.0344)
		Median	2.925	3.000	3.060	3.010	3.025	3.005
		Q1 - Q3	2.440 - 3.440	2.360 - 3.620	2.530 - 3.760	2.365 - 3.625	2.425 - 3.675	2.440 - 3.640
		Min - Max	1.50 - 9.35	0.94 - 6.79	1.29 - 6.36	1.45 - 5.64	0.94 - 6.79	0.94 - 9.35

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils (10^9/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.150 (1.1646)	-0.266 (1.1250)	-0.062 (0.7237)	-0.060 (0.8375)	-0.132 (0.9153)	-0.136 (0.9807)
		Median	-0.185	-0.110	0.010	-0.095	-0.080	-0.105
		Q1 - Q3	-0.740 - 0.230	-0.430 - 0.320	-0.390 - 0.420	-0.490 - 0.390	-0.420 - 0.380	-0.500 - 0.360
		Min - Max	-2.60 - 6.63	-4.55 - 2.58	-2.25 - 1.93	-2.30 - 2.59	-4.55 - 2.59	-4.55 - 6.63
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	2.982 (0.8231)	3.166 (1.1425)	3.180 (1.1461)	3.070 (0.9452)	3.140 (1.0801)	3.101 (1.0232)
		Median	2.960	3.030	2.970	2.940	2.950	2.955
		Q1 - Q3	2.520 - 3.510	2.205 - 3.970	2.460 - 3.600	2.300 - 3.690	2.410 - 3.690	2.430 - 3.650
		Min - Max	1.20 - 4.66	1.24 - 6.06	1.70 - 7.84	1.39 - 5.48	1.24 - 7.84	1.20 - 7.84
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.316 (0.8832)	-0.147 (1.0817)	-0.070 (1.0922)	-0.019 (0.7836)	-0.080 (0.9963)	-0.139 (0.9732)
		Median	-0.230	-0.010	-0.120	-0.030	-0.040	-0.090
		Q1 - Q3	-0.690 - 0.160	-0.460 - 0.370	-0.700 - 0.500	-0.600 - 0.290	-0.560 - 0.430	-0.610 - 0.340
		Min - Max	-3.38 - 1.12	-3.88 - 2.02	-2.38 - 3.84	-1.40 - 2.62	-3.88 - 3.84	-3.88 - 3.84

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils (10^9/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	2.882 (0.8272)	3.101 (0.9963)	3.209 (1.1264)	2.963 (0.9277)	3.092 (1.0203)	3.040 (0.9786)
		Median	2.820	2.945	3.070	2.860	2.995	2.930
		Q1 - Q3	2.290 - 3.370	2.335 - 3.980	2.370 - 3.780	2.250 - 3.560	2.330 - 3.675	2.320 - 3.580
		Min - Max	1.13 - 5.05	1.06 - 5.55	1.13 - 6.69	1.55 - 5.70	1.06 - 6.69	1.06 - 6.69
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.417 (1.0433)	-0.212 (1.1553)	-0.046 (0.8412)	-0.126 (0.6708)	-0.130 (0.9158)	-0.201 (0.9552)
		Median	-0.210	-0.075	-0.100	-0.180	-0.095	-0.130
		Q1 - Q3	-0.750 - 0.060	-0.540 - 0.490	-0.550 - 0.380	-0.530 - 0.200	-0.540 - 0.355	-0.570 - 0.300
		Min - Max	-4.32 - 1.94	-4.96 - 1.76	-2.31 - 2.90	-1.56 - 2.32	-4.96 - 2.90	-4.96 - 2.90
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	3.148 (0.9402)	3.079 (1.2075)	3.118 (1.0142)	2.970 (0.8611)	3.058 (1.0381)	3.080 (1.0138)
		Median	3.105	2.930	3.065	2.930	2.990	3.020
		Q1 - Q3	2.485 - 3.630	2.230 - 3.700	2.370 - 3.870	2.350 - 3.590	2.300 - 3.700	2.330 - 3.690
		Min - Max	0.67 - 5.64	1.16 - 7.82	1.16 - 6.02	1.12 - 5.26	1.12 - 7.82	0.67 - 7.82

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Neutrophils (10^9/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.133 (1.0023)	-0.247 (1.3759)	-0.132 (0.8961)	-0.138 (0.7329)	-0.173 (1.0415)	-0.163 (1.0302)
		Median	-0.200	-0.120	-0.125	-0.145	-0.130	-0.130
		Q1 - Q3	-0.620 - 0.525	-0.560 - 0.230	-0.460 - 0.310	-0.590 - 0.250	-0.540 - 0.260	-0.570 - 0.360
		Min - Max	-3.45 - 2.12	-4.54 - 4.11	-2.81 - 2.80	-1.96 - 1.98	-4.54 - 4.11	-4.54 - 4.11
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	3.154 (0.9766)	3.014 (0.9043)	3.031 (1.0601)	2.903 (0.8943)	2.984 (0.9531)	3.026 (0.9598)
		Median	3.100	3.005	2.940	2.780	2.910	2.940
		Q1 - Q3	2.370 - 3.875	2.320 - 3.625	2.300 - 3.500	2.210 - 3.270	2.290 - 3.500	2.300 - 3.600
		Min - Max	1.40 - 6.19	1.35 - 5.22	1.27 - 7.47	1.37 - 6.57	1.27 - 7.47	1.27 - 7.47
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.116 (1.1073)	-0.297 (1.2387)	-0.210 (0.9206)	-0.197 (0.7883)	-0.236 (1.0021)	-0.206 (1.0280)
		Median	-0.130	-0.110	-0.300	-0.190	-0.190	-0.180
		Q1 - Q3	-0.665 - 0.495	-0.485 - 0.480	-0.720 - 0.280	-0.760 - 0.240	-0.640 - 0.290	-0.640 - 0.330
		Min - Max	-4.44 - 2.38	-4.66 - 1.31	-2.58 - 3.34	-2.33 - 2.31	-4.66 - 3.34	-4.66 - 3.34

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes (10^9/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	1.8738 (0.51866)	1.8089 (0.51630)	1.7567 (0.44348)	1.8069 (0.52567)	1.7908 (0.49464)	1.8116 (0.50109)
		Median	1.7500	1.7700	1.7450	1.8200	1.7700	1.7500
		Q1 - Q3	1.5200 - 2.2400	1.4400 - 2.1200	1.4600 - 2.0500	1.4750 - 2.0800	1.4600 - 2.1100	1.4700 - 2.1250
		Min - Max	0.960 - 3.170	0.870 - 3.260	0.900 - 3.220	0.750 - 3.160	0.750 - 3.260	0.750 - 3.260
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	1.7993 (0.51547)	1.7301 (0.48507)	1.7206 (0.45807)	1.7360 (0.47593)	1.7289 (0.47100)	1.7466 (0.48255)
		Median	1.6800	1.6900	1.6600	1.6700	1.6750	1.6800
		Q1 - Q3	1.4200 - 2.1100	1.3900 - 1.9700	1.4000 - 1.9800	1.4200 - 2.0000	1.4000 - 1.9800	1.4000 - 2.0000
		Min - Max	0.770 - 3.400	0.830 - 3.380	0.890 - 2.910	0.690 - 3.150	0.690 - 3.380	0.690 - 3.400
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.0745 (0.33538)	-0.0787 (0.26714)	-0.0411 (0.30165)	-0.0709 (0.33852)	-0.0637 (0.30245)	-0.0664 (0.31044)
		Median	-0.0600	-0.0700	-0.0250	-0.0750	-0.0450	-0.0500
		Q1 - Q3	-0.2600 - 0.1000	-0.2300 - 0.0800	-0.2300 - 0.1050	-0.2800 - 0.1100	-0.2300 - 0.1000	-0.2500 - 0.1000
		Min - Max	-1.180 - 0.700	-0.720 - 0.500	-1.080 - 0.950	-1.100 - 0.990	-1.100 - 0.990	-1.180 - 0.990

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes (10^9/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	1.7975 (0.51313)	1.8058 (0.54575)	1.6510 (0.46088)	1.6827 (0.48243)	1.7141 (0.50023)	1.7348 (0.50379)
		Median	1.7200	1.7700	1.6100	1.6100	1.7000	1.7050
		Q1 - Q3	1.3600 - 2.2300	1.4600 - 2.0500	1.3300 - 2.0100	1.4100 - 1.9400	1.3900 - 2.0100	1.3800 - 2.0500
		Min - Max	1.000 - 3.120	0.800 - 3.380	0.580 - 2.580	0.560 - 3.010	0.560 - 3.380	0.560 - 3.380
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.0663 (0.31568)	0.0046 (0.31806)	-0.1202 (0.33006)	-0.1219 (0.31021)	-0.0783 (0.32350)	-0.0754 (0.32104)
		Median	-0.0400	-0.0200	-0.0500	-0.1200	-0.0500	-0.0500
		Q1 - Q3	-0.2600 - 0.1400	-0.1500 - 0.1900	-0.2600 - 0.0900	-0.2400 - 0.0700	-0.2400 - 0.1200	-0.2400 - 0.1200
		Min - Max	-0.800 - 1.020	-0.670 - 0.830	-0.930 - 0.790	-1.300 - 0.470	-1.300 - 0.830	-1.300 - 1.020
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	1.7558 (0.51140)	1.7116 (0.50482)	1.7060 (0.43191)	1.6664 (0.50608)	1.6953 (0.48004)	1.7103 (0.48773)
		Median	1.6750	1.7000	1.6600	1.6000	1.6700	1.6700
		Q1 - Q3	1.4200 - 2.0800	1.3900 - 1.9400	1.4300 - 2.0600	1.2550 - 1.9750	1.3650 - 1.9600	1.4000 - 1.9900
		Min - Max	0.530 - 2.960	0.410 - 3.120	0.820 - 2.820	0.760 - 3.240	0.410 - 3.240	0.410 - 3.240

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes (10^9/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.0882 (0.28774)	-0.0896 (0.34144)	-0.0653 (0.32687)	-0.1528 (0.37518)	-0.1017 (0.34810)	-0.0983 (0.33367)
		Median	-0.1000	-0.0600	-0.0800	-0.1450	-0.0850	-0.0900
		Q1 - Q3	-0.2500 - 0.1300	-0.2700 - 0.0800	-0.2300 - 0.1500	-0.2600 - 0.0700	-0.2500 - 0.1000	-0.2500 - 0.1000
		Min - Max	-0.930 - 0.520	-1.070 - 0.650	-0.790 - 1.290	-1.350 - 0.670	-1.350 - 1.290	-1.350 - 1.290
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	1.7711 (0.55701)	1.7597 (0.50835)	1.7082 (0.49266)	1.6795 (0.50421)	1.7168 (0.50036)	1.7303 (0.51443)
		Median	1.7300	1.6800	1.6650	1.6400	1.6600	1.6700
		Q1 - Q3	1.3600 - 2.1500	1.4100 - 2.0000	1.4100 - 2.0100	1.3200 - 1.9900	1.3800 - 2.0000	1.3700 - 2.0200
		Min - Max	0.960 - 3.610	0.800 - 3.520	0.690 - 2.970	0.750 - 3.150	0.690 - 3.520	0.690 - 3.610
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.0778 (0.34743)	-0.0449 (0.30642)	-0.0539 (0.36977)	-0.1370 (0.33876)	-0.0773 (0.33976)	-0.0775 (0.34101)
		Median	-0.0700	-0.0550	-0.0550	-0.1300	-0.0700	-0.0700
		Q1 - Q3	-0.2800 - 0.0900	-0.2300 - 0.1050	-0.2300 - 0.1600	-0.3600 - 0.0500	-0.2500 - 0.0900	-0.2700 - 0.0900
		Min - Max	-0.920 - 0.950	-0.670 - 1.110	-0.850 - 1.700	-1.000 - 0.990	-1.000 - 1.700	-1.000 - 1.700

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes (10^9/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	1.7652 (0.48528)	1.7260 (0.50387)	1.7380 (0.44858)	1.6971 (0.45830)	1.7207 (0.46941)	1.7318 (0.47286)
		Median	1.7100	1.7100	1.6600	1.6900	1.7050	1.7100
		Q1 - Q3	1.4200 - 2.0800	1.3600 - 1.9950	1.3900 - 2.0600	1.3600 - 2.0100	1.3800 - 2.0300	1.3900 - 2.0500
		Min - Max	0.770 - 3.270	0.850 - 3.250	0.910 - 2.670	0.900 - 2.940	0.850 - 3.250	0.770 - 3.270
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.0837 (0.28011)	-0.0785 (0.30769)	-0.0325 (0.33612)	-0.1194 (0.34602)	-0.0764 (0.33003)	-0.0782 (0.31782)
		Median	-0.0700	-0.0250	0	-0.1100	-0.0450	-0.0700
		Q1 - Q3	-0.2400 - 0.0900	-0.2600 - 0.1400	-0.2100 - 0.1100	-0.3100 - 0.1600	-0.2450 - 0.1400	-0.2400 - 0.1200
		Min - Max	-0.980 - 0.770	-0.960 - 0.620	-0.960 - 0.900	-0.900 - 0.490	-0.960 - 0.900	-0.980 - 0.900
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	1.8230 (0.58387)	1.7348 (0.47205)	1.7174 (0.42123)	1.6721 (0.41644)	1.7090 (0.43644)	1.7371 (0.47843)
		Median	1.7150	1.7200	1.6900	1.6250	1.6900	1.7000
		Q1 - Q3	1.4700 - 2.1550	1.4100 - 1.9800	1.4900 - 2.0100	1.3600 - 1.9000	1.4000 - 1.9800	1.4200 - 2.0000
		Min - Max	0.870 - 3.660	0.840 - 3.360	0.840 - 2.650	0.790 - 2.720	0.790 - 3.360	0.790 - 3.660

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lymphocytes (10^9/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.0077 (0.33241)	-0.0651 (0.30823)	-0.0446 (0.28895)	-0.1561 (0.33143)	-0.0871 (0.31167)	-0.0675 (0.31812)
		Median	-0.0300	-0.0200	-0.0200	-0.1350	-0.0500	-0.0500
		Q1 - Q3	-0.2000 - 0.1950	-0.2400 - 0.1700	-0.2000 - 0.1150	-0.3500 - 0.0700	-0.2600 - 0.1300	-0.2400 - 0.1400
		Min - Max	-0.720 - 1.100	-1.020 - 0.440	-0.990 - 0.650	-0.940 - 0.740	-1.020 - 0.740	-1.020 - 1.100
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	1.8819 (0.59612)	1.8184 (0.54401)	2.0098 (1.73353)	1.7394 (0.48524)	1.8573 (1.08861)	1.8633 (0.98974)
		Median	1.7650	1.7450	1.8050	1.6700	1.7200	1.7600
		Q1 - Q3	1.4250 - 2.1450	1.4550 - 2.1050	1.4400 - 2.1000	1.4100 - 2.0000	1.4400 - 2.0700	1.4400 - 2.0800
		Min - Max	0.980 - 3.870	0.750 - 3.260	1.040 - 15.400	0.760 - 3.300	0.750 - 15.400	0.750 - 15.400
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.0352 (0.34712)	0.0219 (0.30852)	0.2301 (1.79323)	-0.0910 (0.33166)	0.0556 (1.07299)	0.0506 (0.94720)
		Median	0.0300	0.0300	0	-0.0600	0	0
		Q1 - Q3	-0.2150 - 0.2450	-0.1650 - 0.2250	-0.1500 - 0.2300	-0.2100 - 0.1100	-0.1800 - 0.1700	-0.1900 - 0.2000
		Min - Max	-0.720 - 1.160	-0.630 - 0.880	-1.000 - 14.360	-1.050 - 0.490	-1.050 - 14.360	-1.050 - 14.360

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes (10^9/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.3210 (0.10279)	0.3057 (0.10214)	0.3122 (0.10646)	0.2915 (0.08852)	0.3032 (0.09929)	0.3076 (0.10029)
		Median	0.3000	0.2950	0.2900	0.2800	0.2900	0.2900
		Q1 - Q3	0.2400 - 0.4000	0.2300 - 0.3500	0.2400 - 0.3600	0.2250 - 0.3550	0.2300 - 0.3600	0.2300 - 0.3700
		Min - Max	0.110 - 0.550	0.120 - 0.600	0.130 - 0.610	0.110 - 0.500	0.110 - 0.610	0.110 - 0.610
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	0.3225 (0.14602)	0.2959 (0.08971)	0.3044 (0.11894)	0.2926 (0.10145)	0.2976 (0.10354)	0.3039 (0.11588)
		Median	0.2900	0.2850	0.2950	0.2850	0.2900	0.2900
		Q1 - Q3	0.2400 - 0.3800	0.2300 - 0.3600	0.2150 - 0.3500	0.2300 - 0.3500	0.2300 - 0.3500	0.2300 - 0.3600
		Min - Max	0.150 - 0.980	0.150 - 0.610	0.110 - 0.750	0.080 - 0.630	0.080 - 0.750	0.080 - 0.980
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.0014 (0.09989)	-0.0099 (0.08333)	-0.0065 (0.08061)	0.0012 (0.07934)	-0.0051 (0.08087)	-0.0035 (0.08589)
		Median	0	0.0100	0	0	0	0
		Q1 - Q3	-0.0500 - 0.0300	-0.0700 - 0.0400	-0.0500 - 0.0300	-0.0450 - 0.0450	-0.0500 - 0.0400	-0.0500 - 0.0400
		Min - Max	-0.160 - 0.500	-0.220 - 0.170	-0.190 - 0.260	-0.200 - 0.200	-0.220 - 0.260	-0.220 - 0.500

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes (10^9/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	0.3204 (0.12835)	0.3080 (0.09815)	0.2978 (0.09971)	0.2984 (0.07986)	0.3014 (0.09272)	0.3061 (0.10279)
		Median	0.3100	0.3100	0.2900	0.2900	0.3000	0.3000
		Q1 - Q3	0.2300 - 0.3800	0.2400 - 0.3500	0.2300 - 0.3600	0.2400 - 0.3300	0.2400 - 0.3500	0.2300 - 0.3600
		Min - Max	0.140 - 0.900	0.090 - 0.610	0.110 - 0.620	0.150 - 0.480	0.090 - 0.620	0.090 - 0.900
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.0015 (0.08668)	0.0020 (0.08107)	-0.0152 (0.07121)	0.0069 (0.07604)	-0.0021 (0.07647)	-0.0012 (0.07897)
		Median	0	0.0100	-0.0200	0.0100	0	0
		Q1 - Q3	-0.0400 - 0.0300	-0.0500 - 0.0500	-0.0600 - 0.0300	-0.0400 - 0.0400	-0.0500 - 0.0400	-0.0500 - 0.0400
		Min - Max	-0.220 - 0.430	-0.190 - 0.200	-0.210 - 0.130	-0.170 - 0.270	-0.210 - 0.270	-0.220 - 0.430
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	0.3215 (0.11227)	0.2975 (0.09640)	0.3121 (0.11621)	0.2922 (0.09926)	0.3007 (0.10413)	0.3059 (0.10638)
		Median	0.3050	0.2900	0.3000	0.2700	0.2800	0.2900
		Q1 - Q3	0.2400 - 0.3900	0.2300 - 0.3400	0.2400 - 0.3600	0.2200 - 0.3450	0.2300 - 0.3450	0.2300 - 0.3600
		Min - Max	0.120 - 0.660	0.080 - 0.710	0.090 - 0.670	0.120 - 0.570	0.080 - 0.710	0.080 - 0.710

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes (10^9/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.0029 (0.07619)	-0.0084 (0.07740)	-0.0009 (0.08015)	-0.0017 (0.06526)	-0.0037 (0.07441)	-0.0021 (0.07477)
		Median	0	-0.0100	0	-0.0100	-0.0050	0
		Q1 - Q3	-0.0600 - 0.0400	-0.0600 - 0.0400	-0.0400 - 0.0400	-0.0450 - 0.0350	-0.0500 - 0.0400	-0.0500 - 0.0400
		Min - Max	-0.120 - 0.280	-0.280 - 0.130	-0.210 - 0.340	-0.140 - 0.140	-0.280 - 0.340	-0.280 - 0.340
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	0.3226 (0.11253)	0.3018 (0.10600)	0.3285 (0.13102)	0.2870 (0.09055)	0.3060 (0.11145)	0.3101 (0.11173)
		Median	0.2900	0.2750	0.2900	0.2600	0.2800	0.2900
		Q1 - Q3	0.2400 - 0.4000	0.2450 - 0.3400	0.2400 - 0.4000	0.2200 - 0.3400	0.2400 - 0.3600	0.2400 - 0.3700
		Min - Max	0.140 - 0.600	0.110 - 0.690	0.120 - 0.850	0.120 - 0.580	0.110 - 0.850	0.110 - 0.850
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.0018 (0.08206)	-0.0060 (0.08517)	0.0155 (0.08482)	-0.0068 (0.06881)	0.0009 (0.08044)	0.0011 (0.08069)
		Median	0	0	0.0100	-0.0100	0	0
		Q1 - Q3	-0.0500 - 0.0300	-0.0700 - 0.0300	-0.0300 - 0.0500	-0.0400 - 0.0300	-0.0400 - 0.0400	-0.0500 - 0.0400
		Min - Max	-0.200 - 0.350	-0.190 - 0.280	-0.220 - 0.260	-0.170 - 0.200	-0.220 - 0.280	-0.220 - 0.350

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes (10^9/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	0.3183 (0.12589)	0.3115 (0.09800)	0.3088 (0.11985)	0.2886 (0.09025)	0.3032 (0.10347)	0.3070 (0.10943)
		Median	0.2800	0.3000	0.2800	0.2900	0.2900	0.2900
		Q1 - Q3	0.2400 - 0.3900	0.2500 - 0.3500	0.2200 - 0.3700	0.2300 - 0.3400	0.2300 - 0.3500	0.2300 - 0.3600
		Min - Max	0.100 - 0.720	0.120 - 0.650	0.130 - 0.690	0.110 - 0.550	0.110 - 0.690	0.100 - 0.720
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.0025 (0.10469)	0.0037 (0.08349)	-0.0044 (0.07557)	-0.0052 (0.06518)	-0.0019 (0.07508)	-0.0020 (0.08322)
		Median	-0.0100	0	0	0	0	0
		Q1 - Q3	-0.0600 - 0.0400	-0.0350 - 0.0500	-0.0500 - 0.0400	-0.0300 - 0.0300	-0.0400 - 0.0400	-0.0500 - 0.0400
		Min - Max	-0.260 - 0.430	-0.210 - 0.210	-0.220 - 0.200	-0.180 - 0.160	-0.220 - 0.210	-0.260 - 0.430
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	0.3133 (0.10983)	0.2978 (0.10700)	0.3145 (0.12385)	0.2852 (0.07938)	0.2994 (0.10564)	0.3029 (0.10664)
		Median	0.3000	0.2800	0.2900	0.2800	0.2800	0.2800
		Q1 - Q3	0.2450 - 0.3800	0.2400 - 0.3600	0.2300 - 0.4000	0.2400 - 0.3300	0.2400 - 0.3500	0.2400 - 0.3600
		Min - Max	0.150 - 0.620	0.110 - 0.840	0.090 - 0.730	0.100 - 0.570	0.090 - 0.840	0.090 - 0.840

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.1
Summary of Hematology
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Monocytes (10^9/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.0080 (0.07488)	-0.0094 (0.08294)	0.0015 (0.08351)	-0.0105 (0.06725)	-0.0060 (0.07829)	-0.0065 (0.07732)
		Median	-0.0100	-0.0200	0	-0.0100	-0.0100	-0.0100
		Q1 - Q3	-0.0500 - 0.0400	-0.0700 - 0.0400	-0.0500 - 0.0600	-0.0500 - 0.0300	-0.0600 - 0.0400	-0.0600 - 0.0400
		Min - Max	-0.180 - 0.200	-0.170 - 0.290	-0.220 - 0.260	-0.150 - 0.130	-0.220 - 0.290	-0.220 - 0.290
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	0.3305 (0.12913)	0.3197 (0.10531)	0.3086 (0.10429)	0.2903 (0.08468)	0.3066 (0.09906)	0.3125 (0.10744)
		Median	0.2950	0.3000	0.2950	0.2900	0.3000	0.3000
		Q1 - Q3	0.2350 - 0.3950	0.2500 - 0.3850	0.2300 - 0.3600	0.2300 - 0.3600	0.2400 - 0.3600	0.2400 - 0.3600
		Min - Max	0.140 - 0.790	0.140 - 0.590	0.130 - 0.740	0.120 - 0.510	0.120 - 0.740	0.120 - 0.790
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.0097 (0.09616)	0.0144 (0.08942)	-0.0045 (0.06916)	-0.0052 (0.07087)	0.0018 (0.07741)	0.0037 (0.08228)
		Median	0	0.0100	0	0	0	0
		Q1 - Q3	-0.0450 - 0.0500	-0.0450 - 0.0550	-0.0400 - 0.0400	-0.0400 - 0.0400	-0.0400 - 0.0500	-0.0400 - 0.0500
		Min - Max	-0.210 - 0.320	-0.200 - 0.280	-0.190 - 0.170	-0.170 - 0.200	-0.200 - 0.280	-0.210 - 0.320

Data Source: Listing 16.2.8.1.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	D15	Placebo (N=69)	Normal	60 (87.0)	4 (5.8)	0	64 (92.8)
			Abnormal NCS	2 (2.9)	3 (4.3)	0	5 (7.2)
			Abnormal CS	0	0	0	0
			Total	62 (89.9)	7 (10.1)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (88.6)	1 (1.4)	0	63 (90.0)
			Abnormal NCS	1 (1.4)	4 (5.7)	0	5 (7.1)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	63 (90.0)	5 (7.1)	2 (2.9)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	2 (2.9)	0	61 (89.7)
			Abnormal NCS	1 (1.5)	6 (8.8)	0	7 (10.3)
			Abnormal CS	0	0	0	0
			Total	60 (88.2)	8 (11.8)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (86.8)	3 (4.4)	0	62 (91.2)
			Abnormal NCS	1 (1.5)	5 (7.4)	0	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	60 (88.2)	8 (11.8)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	D15	Combined GS1-144 (N=207)	Normal	180 (87.4)	6 (2.9)	0	186 (90.3)
			Abnormal NCS	3 (1.5)	15 (7.3)	0	18 (8.7)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	183 (88.8)	21 (10.2)	2 (1.0)	206 (100)
	D29	Placebo (N=69)	Normal	58 (86.6)	3 (4.5)	0	61 (91.0)
			Abnormal NCS	2 (3.0)	4 (6.0)	0	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	60 (89.6)	7 (10.4)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	2 (2.9)	0	62 (89.9)
			Abnormal NCS	2 (2.9)	3 (4.3)	0	5 (7.2)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	62 (89.9)	5 (7.2)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (83.6)	6 (9.0)	0	62 (92.5)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	59 (88.1)	8 (11.9)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	D29	GS1-144 30 mg BID (N=68)	Normal	59 (88.1)	5 (7.5)	0	64 (95.5)
			Abnormal NCS	0	3 (4.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	59 (88.1)	8 (11.9)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	175 (86.2)	13 (6.4)	0	188 (92.6)
			Abnormal NCS	5 (2.5)	8 (3.9)	0	13 (6.4)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	180 (88.7)	21 (10.3)	2 (1.0)	203 (100)
	D43	Placebo (N=69)	Normal	58 (87.9)	5 (7.6)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	59 (89.4)	7 (10.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (85.5)	2 (2.9)	1 (1.4)	62 (89.9)
			Abnormal NCS	3 (4.3)	3 (4.3)	0	6 (8.7)
			Abnormal CS	0	0	1 (1.4)	1 (1.4)
			Total	62 (89.9)	5 (7.2)	2 (2.9)	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	D43	GS1-144 60 mg QD (N=69)	Normal	58 (86.6)	5 (7.5)	0	63 (94.0)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	59 (88.1)	8 (11.9)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (85.9)	4 (6.3)	0	59 (92.2)
			Abnormal NCS	2 (3.1)	3 (4.7)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	57 (89.1)	7 (10.9)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	172 (86.0)	11 (5.5)	1 (0.5)	184 (92.0)
			Abnormal NCS	6 (3.0)	9 (4.5)	0	15 (7.5)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	178 (89.0)	20 (10.0)	2 (1.0)	200 (100)
	D57	Placebo (N=69)	Normal	57 (87.7)	3 (4.6)	0	60 (92.3)
			Abnormal NCS	2 (3.1)	3 (4.6)	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	59 (90.8)	6 (9.2)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	D57	GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	1 (1.5)	1 (1.5)	61 (89.7)
			Abnormal NCS	2 (2.9)	4 (5.9)	0	6 (8.8)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	61 (89.7)	5 (7.4)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (84.8)	4 (6.1)	0	60 (90.9)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.6)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	58 (87.9)	8 (12.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	3 (4.8)	0	59 (93.7)
			Abnormal NCS	0	4 (6.3)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	56 (88.9)	7 (11.1)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	171 (86.8)	8 (4.1)	1 (0.5)	180 (91.4)
			Abnormal NCS	4 (2.0)	11 (5.6)	0	15 (7.6)
			Abnormal CS	0	1 (0.5)	1 (0.5)	2 (1.0)
			Total	175 (88.8)	20 (10.2)	2 (1.0)	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Erythrocytes (10^12/L)	D71	Placebo (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	0	3 (4.6)	0	3 (4.6)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	59 (90.8)	6 (9.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	57 (83.8)	1 (1.5)	1 (1.5)	59 (86.8)
			Abnormal NCS	4 (5.9)	4 (5.9)	0	8 (11.8)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	61 (89.7)	5 (7.4)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (86.2)	5 (7.7)	0	61 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	58 (89.2)	7 (10.8)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	5 (7.9)	0	61 (96.8)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	56 (88.9)	7 (11.1)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	D71	Combined GS1-144 (N=207)	Normal	169 (86.2)	11 (5.6)	1 (0.5)	181 (92.3)
			Abnormal NCS	6 (3.1)	8 (4.1)	0	14 (7.1)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	175 (89.3)	19 (9.7)	2 (1.0)	196 (100)
	D85	Placebo (N=69)	Normal	57 (89.1)	3 (4.7)	0	60 (93.8)
			Abnormal NCS	1 (1.6)	3 (4.7)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	58 (86.6)	3 (4.5)	1 (1.5)	62 (92.5)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	60 (89.6)	5 (7.5)	2 (3.0)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (84.8)	5 (7.6)	0	61 (92.4)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	58 (87.9)	8 (12.1)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	D85	GS1-144 30 mg BID (N=68)	Normal	55 (88.7)	3 (4.8)	0	58 (93.5)
			Abnormal NCS	0	4 (6.5)	0	4 (6.5)
			Abnormal CS	0	0	0	0
			Total	55 (88.7)	7 (11.3)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	169 (86.7)	11 (5.6)	1 (0.5)	181 (92.8)
			Abnormal NCS	4 (2.1)	9 (4.6)	0	13 (6.7)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	173 (88.7)	20 (10.3)	2 (1.0)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	57 (89.1)	4 (6.3)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (88.2)	2 (2.9)	1 (1.5)	63 (92.6)
			Abnormal NCS	1 (1.5)	3 (4.4)	0	4 (5.9)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	61 (89.7)	5 (7.4)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	5 (7.6)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	59 (89.4)	7 (10.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	3 (4.8)	0	57 (90.5)
			Abnormal NCS	2 (3.2)	4 (6.3)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	56 (88.9)	7 (11.1)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	172 (87.3)	10 (5.1)	1 (0.5)	183 (92.9)
			Abnormal NCS	4 (2.0)	9 (4.6)	0	13 (6.6)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	176 (89.3)	19 (9.6)	2 (1.0)	197 (100)
Hematocrit (%)	D15	Placebo (N=69)	Normal	63 (91.3)	2 (2.9)	0	65 (94.2)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hematocrit (%)	D15	GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	1 (1.4)	0	65 (92.9)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	66 (94.3)	2 (2.9)	2 (2.9)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	2 (2.9)	0	61 (89.7)
			Abnormal NCS	4 (5.9)	3 (4.4)	0	7 (10.3)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (89.7)	3 (4.4)	0	64 (94.1)
			Abnormal NCS	1 (1.5)	3 (4.4)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	62 (91.2)	6 (8.8)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	184 (89.3)	6 (2.9)	0	190 (92.2)
			Abnormal NCS	7 (3.4)	7 (3.4)	0	14 (6.8)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	191 (92.7)	13 (6.3)	2 (1.0)	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Hematocrit (%)	D29	Placebo (N=69)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	1 (1.4)	0	64 (92.8)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	65 (94.2)	2 (2.9)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (83.6)	2 (3.0)	0	58 (86.6)
			Abnormal NCS	6 (9.0)	3 (4.5)	0	9 (13.4)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (89.6)	2 (3.0)	0	62 (92.5)
			Abnormal NCS	1 (1.5)	4 (6.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	61 (91.0)	6 (9.0)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hematocrit (%)	D29	Combined GS1-144 (N=207)	Normal	179 (88.2)	5 (2.5)	0	184 (90.6)
			Abnormal NCS	9 (4.4)	8 (3.9)	0	17 (8.4)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	188 (92.6)	13 (6.4)	2 (1.0)	203 (100)
	D43	Placebo (N=69)	Normal	61 (92.4)	4 (6.1)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (89.9)	0	1 (1.4)	63 (91.3)
			Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.2)
			Abnormal CS	0	0	1 (1.4)	1 (1.4)
			Total	65 (94.2)	2 (2.9)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Hematocrit (%)	D43	GS1-144 30 mg BID (N=68)	Normal	57 (89.1)	5 (7.8)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	179 (89.5)	8 (4.0)	1 (0.5)	188 (94.0)
			Abnormal NCS	6 (3.0)	5 (2.5)	0	11 (5.5)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	185 (92.5)	13 (6.5)	2 (1.0)	200 (100)
	D57	Placebo (N=69)	Normal	60 (92.3)	2 (3.1)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	0	0	63 (92.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	64 (94.1)	2 (2.9)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hematocrit (%)	D57	GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	3 (4.5)	0	61 (92.4)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.1)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	5 (7.9)	0	60 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	176 (89.3)	8 (4.1)	0	184 (93.4)
			Abnormal NCS	5 (2.5)	5 (2.5)	0	10 (5.1)
			Abnormal CS	1 (0.5)	0	2 (1.0)	3 (1.5)
			Total	182 (92.4)	13 (6.6)	2 (1.0)	197 (100)
	D71	Placebo (N=69)	Normal	59 (90.8)	3 (4.6)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (93.8)	4 (6.2)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Hematocrit (%)	D71	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	64 (94.1)	2 (2.9)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (87.7)	4 (6.2)	0	61 (93.8)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	4 (6.3)	0	61 (96.8)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	177 (90.3)	9 (4.6)	0	186 (94.9)
			Abnormal NCS	4 (2.0)	4 (2.0)	0	8 (4.1)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	181 (92.3)	13 (6.6)	2 (1.0)	196 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Hematocrit (%)	D85	Placebo (N=69)	Normal	59 (92.2)	1 (1.6)	0	60 (93.8)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	2 (3.0)	2 (3.0)
			Total	63 (94.0)	2 (3.0)	2 (3.0)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	55 (83.3)	2 (3.0)	0	57 (86.4)
			Abnormal NCS	6 (9.1)	3 (4.5)	0	9 (13.6)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (88.7)	3 (4.8)	0	58 (93.5)
			Abnormal NCS	1 (1.6)	3 (4.8)	0	4 (6.5)
			Abnormal CS	0	0	0	0
			Total	56 (90.3)	6 (9.7)	0	62 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Hematocrit (%)	D85	Combined GS1-144 (N=207)	Normal	173 (88.7)	6 (3.1)	0	179 (91.8)
			Abnormal NCS	7 (3.6)	7 (3.6)	0	14 (7.2)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	180 (92.3)	13 (6.7)	2 (1.0)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	57 (89.1)	1 (1.6)	0	58 (90.6)
			Abnormal NCS	2 (3.1)	3 (4.7)	0	5 (7.8)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	64 (94.1)	2 (2.9)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (86.4)	3 (4.5)	0	60 (90.9)
			Abnormal NCS	4 (6.1)	2 (3.0)	0	6 (9.1)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Hematocrit (%)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	4 (6.3)	0	60 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	175 (88.8)	8 (4.1)	0	183 (92.9)
			Abnormal NCS	7 (3.6)	5 (2.5)	0	12 (6.1)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	182 (92.4)	13 (6.6)	2 (1.0)	197 (100)
Ery. Mean Corpuscular Volume (fL)	D15	Placebo (N=69)	Normal	64 (92.8)	0	0	64 (92.8)
			Abnormal NCS	1 (1.4)	4 (5.8)	0	5 (7.2)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	0	0	67 (95.7)
			Abnormal NCS	0	3 (4.3)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Volume (fL)	D15	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	1 (1.5)	3 (4.4)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	198 (96.1)	1 (0.5)	0	199 (96.6)
			Abnormal NCS	1 (0.5)	6 (2.9)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	199 (96.6)	7 (3.4)	0	206 (100)
	D29	Placebo (N=69)	Normal	63 (94.0)	0	0	63 (94.0)
			Abnormal NCS	0	4 (6.0)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Volume (fL)	D29	GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	0	0	66 (95.7)
			Abnormal NCS	0	3 (4.3)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (92.5)	2 (3.0)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	195 (96.1)	2 (1.0)	0	197 (97.0)
			Abnormal NCS	1 (0.5)	5 (2.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	196 (96.6)	7 (3.4)	0	203 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Volume (fL)	D43	Placebo (N=69)	Normal	61 (92.4)	0	0	61 (92.4)
			Abnormal NCS	1 (1.5)	4 (6.1)	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	0	0	66 (95.7)
			Abnormal NCS	0	3 (4.3)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (92.2)	2 (3.1)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Volume (fL)	D43	Combined GS1-144 (N=207)	Normal	192 (96.0)	2 (1.0)	0	194 (97.0)
			Abnormal NCS	1 (0.5)	5 (2.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	193 (96.5)	7 (3.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	59 (90.8)	0	0	59 (90.8)
			Abnormal NCS	2 (3.1)	4 (6.2)	0	6 (9.2)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	0	3 (4.4)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Volume (fL)	D57	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	0	0	58 (92.1)
			Abnormal NCS	1 (1.6)	4 (6.3)	0	5 (7.9)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (95.9)	0	0	189 (95.9)
			Abnormal NCS	1 (0.5)	7 (3.6)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	190 (96.4)	7 (3.6)	0	197 (100)
	D71	Placebo (N=69)	Normal	61 (93.8)	0	0	61 (93.8)
			Abnormal NCS	0	4 (6.2)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Volume (fL)	D71	GS1-144 60 mg QD (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	0	0	57 (90.5)
			Abnormal NCS	2 (3.2)	4 (6.3)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	187 (95.4)	1 (0.5)	0	188 (95.9)
			Abnormal NCS	2 (1.0)	6 (3.1)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	189 (96.4)	7 (3.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	59 (92.2)	0	0	59 (92.2)
			Abnormal NCS	1 (1.6)	4 (6.3)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Volume (fL)	D85	GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	0	3 (4.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (91.9)	1 (1.6)	0	58 (93.5)
			Abnormal NCS	1 (1.6)	3 (4.8)	0	4 (6.5)
			Abnormal CS	0	0	0	0
			Total	58 (93.5)	4 (6.5)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	187 (95.9)	1 (0.5)	0	188 (96.4)
			Abnormal NCS	1 (0.5)	6 (3.1)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	188 (96.4)	7 (3.6)	0	195 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ery. Mean Corpuscular Volume (fL)	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	0	0	59 (92.2)
			Abnormal NCS	1 (1.6)	4 (6.3)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	0	0	64 (94.1)
			Abnormal NCS	1 (1.5)	3 (4.4)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	1 (1.6)	0	60 (95.2)
			Abnormal NCS	0	3 (4.8)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ery. Mean Corpuscular Volume (fL)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	189 (95.9)	1 (0.5)	0	190 (96.4)
			Abnormal NCS	1 (0.5)	6 (3.0)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	190 (96.4)	7 (3.6)	0	197 (100)
Ery. Mean Corpuscular Hemoglobin (pg)	D15	Placebo (N=69)	Normal	62 (89.9)	1 (1.4)	0	63 (91.3)
			Abnormal NCS	0	6 (8.7)	0	6 (8.7)
			Abnormal CS	0	0	0	0
			Total	62 (89.9)	7 (10.1)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	1 (1.4)	0	65 (92.9)
			Abnormal NCS	1 (1.4)	4 (5.7)	0	5 (7.1)
			Abnormal CS	0	0	0	0
			Total	65 (92.9)	5 (7.1)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	D15	GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	0	4 (5.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	193 (93.7)	2 (1.0)	0	195 (94.7)
			Abnormal NCS	1 (0.5)	10 (4.9)	0	11 (5.3)
			Abnormal CS	0	0	0	0
			Total	194 (94.2)	12 (5.8)	0	206 (100)
	D29	Placebo (N=69)	Normal	60 (89.6)	1 (1.5)	0	61 (91.0)
			Abnormal NCS	0	6 (9.0)	0	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	60 (89.6)	7 (10.4)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	0	3 (4.3)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	64 (92.8)	5 (7.2)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	D29	GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (92.5)	1 (1.5)	0	63 (94.0)
			Abnormal NCS	0	4 (6.0)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	191 (94.1)	3 (1.5)	0	194 (95.6)
			Abnormal NCS	0	9 (4.4)	0	9 (4.4)
			Abnormal CS	0	0	0	0
			Total	191 (94.1)	12 (5.9)	0	203 (100)
	D43	Placebo (N=69)	Normal	59 (89.4)	1 (1.5)	0	60 (90.9)
			Abnormal NCS	0	6 (9.1)	0	6 (9.1)
			Abnormal CS	0	0	0	0
			Total	59 (89.4)	7 (10.6)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	D43	GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	0	3 (4.3)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	64 (92.8)	5 (7.2)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (92.2)	1 (1.6)	0	60 (93.8)
			Abnormal NCS	0	4 (6.3)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	188 (94.0)	3 (1.5)	0	191 (95.5)
			Abnormal NCS	0	9 (4.5)	0	9 (4.5)
			Abnormal CS	0	0	0	0
			Total	188 (94.0)	12 (6.0)	0	200 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	D57	Placebo (N=69)	Normal	57 (87.7)	1 (1.5)	0	58 (89.2)
			Abnormal NCS	1 (1.5)	6 (9.2)	0	7 (10.8)
			Abnormal CS	0	0	0	0
			Total	58 (89.2)	7 (10.8)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	3 (4.4)	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	1 (1.6)	0	59 (93.7)
			Abnormal NCS	0	4 (6.3)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	58 (92.1)	5 (7.9)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	D57	Combined GS1-144 (N=207)	Normal	185 (93.9)	5 (2.5)	0	190 (96.4)
			Abnormal NCS	0	7 (3.6)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	185 (93.9)	12 (6.1)	0	197 (100)
	D71	Placebo (N=69)	Normal	57 (87.7)	2 (3.1)	0	59 (90.8)
			Abnormal NCS	1 (1.5)	5 (7.7)	0	6 (9.2)
			Abnormal CS	0	0	0	0
			Total	58 (89.2)	7 (10.8)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	0	3 (4.4)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	0	2 (3.1)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	D71	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	1 (1.6)	0	59 (93.7)
			Abnormal NCS	0	4 (6.3)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	58 (92.1)	5 (7.9)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	184 (93.9)	3 (1.5)	0	187 (95.4)
			Abnormal NCS	0	9 (4.6)	0	9 (4.6)
			Abnormal CS	0	0	0	0
			Total	184 (93.9)	12 (6.1)	0	196 (100)
	D85	Placebo (N=69)	Normal	57 (89.1)	1 (1.6)	0	58 (90.6)
			Abnormal NCS	0	6 (9.4)	0	6 (9.4)
			Abnormal CS	0	0	0	0
			Total	57 (89.1)	7 (10.9)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (91.0)	2 (3.0)	0	63 (94.0)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	D85	GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (91.9)	1 (1.6)	0	58 (93.5)
			Abnormal NCS	0	4 (6.5)	0	4 (6.5)
			Abnormal CS	0	0	0	0
			Total	57 (91.9)	5 (8.1)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	182 (93.3)	4 (2.1)	0	186 (95.4)
			Abnormal NCS	1 (0.5)	8 (4.1)	0	9 (4.6)
			Abnormal CS	0	0	0	0
			Total	183 (93.8)	12 (6.2)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	57 (89.1)	3 (4.7)	0	60 (93.8)
			Abnormal NCS	0	4 (6.3)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	57 (89.1)	7 (10.9)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	0	3 (4.4)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	1 (1.6)	0	58 (92.1)
			Abnormal NCS	1 (1.6)	4 (6.3)	0	5 (7.9)
			Abnormal CS	0	0	0	0
			Total	58 (92.1)	5 (7.9)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	184 (93.4)	3 (1.5)	0	187 (94.9)
			Abnormal NCS	1 (0.5)	9 (4.6)	0	10 (5.1)
			Abnormal CS	0	0	0	0
			Total	185 (93.9)	12 (6.1)	0	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Hemoglobin (g/L)	D15	Placebo (N=69)	Normal	62 (89.9)	5 (7.2)	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	64 (92.8)	5 (7.2)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	0	0	65 (92.9)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	1 (1.4)	0	1 (1.4)	2 (2.9)
			Total	68 (97.1)	1 (1.4)	1 (1.4)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	3 (4.4)	0	63 (92.6)
			Abnormal NCS	2 (2.9)	3 (4.4)	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	62 (91.2)	6 (8.8)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
			Abnormal NCS	1 (1.5)	4 (5.9)	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hemoglobin (g/L)	D15	Combined GS1-144 (N=207)	Normal	187 (90.8)	4 (1.9)	0	191 (92.7)
			Abnormal NCS	5 (2.4)	8 (3.9)	0	13 (6.3)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	193 (93.7)	12 (5.8)	1 (0.5)	206 (100)
	D29	Placebo (N=69)	Normal	60 (89.6)	2 (3.0)	0	62 (92.5)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	1 (1.4)	0	1 (1.4)	2 (2.9)
			Total	67 (97.1)	1 (1.4)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (89.6)	4 (6.0)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	61 (91.0)	6 (9.0)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hemoglobin (g/L)	D29	GS1-144 30 mg BID (N=68)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	185 (91.1)	8 (3.9)	0	193 (95.1)
			Abnormal NCS	4 (2.0)	4 (2.0)	0	8 (3.9)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	190 (93.6)	12 (5.9)	1 (0.5)	203 (100)
	D43	Placebo (N=69)	Normal	59 (89.4)	3 (4.5)	0	62 (93.9)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	0	1 (1.4)	64 (92.8)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	67 (97.1)	1 (1.4)	1 (1.4)	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hemoglobin (g/L)	D43	GS1-144 60 mg QD (N=69)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	61 (91.0)	6 (9.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (92.2)	3 (4.7)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	182 (91.0)	6 (3.0)	1 (0.5)	189 (94.5)
			Abnormal NCS	5 (2.5)	5 (2.5)	0	10 (5.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	188 (94.0)	11 (5.5)	1 (0.5)	200 (100)
	D57	Placebo (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	60 (92.3)	5 (7.7)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hemoglobin (g/L)	D57	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	0	0	63 (92.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (2.9)
			Total	66 (97.1)	1 (1.5)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	4 (6.1)	0	62 (93.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	60 (90.9)	6 (9.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	2 (3.2)	0	59 (93.7)
			Abnormal NCS	2 (3.2)	2 (3.2)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.4)	6 (3.0)	0	184 (93.4)
			Abnormal NCS	6 (3.0)	4 (2.0)	0	10 (5.1)
			Abnormal CS	1 (0.5)	1 (0.5)	1 (0.5)	3 (1.5)
			Total	185 (93.9)	11 (5.6)	1 (0.5)	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Hemoglobin (g/L)	D71	Placebo (N=69)	Normal	58 (89.2)	4 (6.2)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	0	0	64 (94.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (2.9)
			Total	66 (97.1)	1 (1.5)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (87.7)	4 (6.2)	0	61 (93.8)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	0	60 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hemoglobin (g/L)	D71	Combined GS1-144 (N=207)	Normal	179 (91.3)	6 (3.1)	0	185 (94.4)
			Abnormal NCS	5 (2.6)	4 (2.0)	0	9 (4.6)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	185 (94.4)	10 (5.1)	1 (0.5)	196 (100)
	D85	Placebo (N=69)	Normal	58 (90.6)	3 (4.7)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	65 (97.0)	1 (1.5)	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	5 (7.6)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	60 (90.9)	6 (9.1)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hemoglobin (g/L)	D85	GS1-144 30 mg BID (N=68)	Normal	58 (93.5)	3 (4.8)	0	61 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	58 (93.5)	4 (6.5)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	180 (92.3)	9 (4.6)	0	189 (96.9)
			Abnormal NCS	3 (1.5)	2 (1.0)	0	5 (2.6)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	183 (93.8)	11 (5.6)	1 (0.5)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	57 (89.1)	4 (6.3)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	59 (92.2)	5 (7.8)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	1 (1.5)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (2.9)
			Total	66 (97.1)	1 (1.5)	1 (1.5)	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Hemoglobin (g/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	4 (6.1)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	182 (92.4)	7 (3.6)	0	189 (95.9)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.0)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	186 (94.4)	10 (5.1)	1 (0.5)	197 (100)
Platelets (10^9/L)	D15	Placebo (N=69)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Platelets (10^9/L)	D15	GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	2 (2.9)	0	67 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (94.3)	4 (5.7)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	197 (95.6)	2 (1.0)	0	199 (96.6)
			Abnormal NCS	3 (1.5)	4 (1.9)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	200 (97.1)	6 (2.9)	0	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Platelets (10^9/L)	D29	Placebo (N=69)	Normal	61 (91.0)	3 (4.5)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	0	3 (4.3)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Platelets (10^9/L)	D29	Combined GS1-144 (N=207)	Normal	197 (97.0)	1 (0.5)	0	198 (97.5)
			Abnormal NCS	0	5 (2.5)	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	197 (97.0)	6 (3.0)	0	203 (100)
	D43	Placebo (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
			Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	0	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Platelets (10^9/L)	D43	GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	190 (95.0)	1 (0.5)	0	191 (95.5)
			Abnormal NCS	4 (2.0)	5 (2.5)	0	9 (4.5)
			Abnormal CS	0	0	0	0
			Total	194 (97.0)	6 (3.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	60 (92.3)	0	0	60 (92.3)
			Abnormal NCS	2 (3.1)	3 (4.6)	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Platelets (10^9/L)	D57	GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.4)	3 (1.5)	0	191 (97.0)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	191 (97.0)	6 (3.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	0	2 (3.1)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Platelets (10^9/L)	D71	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.9)	3 (1.5)	0	191 (97.4)
			Abnormal NCS	2 (1.0)	3 (1.5)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	190 (96.9)	6 (3.1)	0	196 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Platelets (10^9/L)	D85	Placebo (N=69)	Normal	61 (95.3)	1 (1.6)	0	62 (96.9)
			Abnormal NCS	0	2 (3.1)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (92.5)	2 (3.0)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (98.4)	1 (1.6)	0	62 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (98.4)	1 (1.6)	0	62 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Platelets (10^9/L)	D85	Combined GS1-144 (N=207)	Normal	187 (95.9)	3 (1.5)	0	190 (97.4)
			Abnormal NCS	2 (1.0)	3 (1.5)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	189 (96.9)	6 (3.1)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	1 (1.6)	0	60 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Platelets (10^9/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (95.9)	2 (1.0)	0	191 (97.0)
			Abnormal NCS	2 (1.0)	4 (2.0)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	191 (97.0)	6 (3.0)	0	197 (100)
Mean Platelet Volume (fL)	D15	Placebo (N=69)	Normal	56 (83.6)	3 (4.5)	0	59 (88.1)
			Abnormal NCS	1 (1.5)	7 (10.4)	0	8 (11.9)
			Abnormal CS	0	0	0	0
			Total	57 (85.1)	10 (14.9)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (93.9)	0	0	62 (93.9)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Mean Platelet Volume (fL)	D15	GS1-144 60 mg QD (N=69)	Normal	60 (90.9)	2 (3.0)	0	62 (93.9)
			Abnormal NCS	0	4 (6.1)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	60 (90.9)	6 (9.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	51 (79.7)	2 (3.1)	0	53 (82.8)
			Abnormal NCS	2 (3.1)	9 (14.1)	0	11 (17.2)
			Abnormal CS	0	0	0	0
			Total	53 (82.8)	11 (17.2)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	173 (88.3)	4 (2.0)	0	177 (90.3)
			Abnormal NCS	3 (1.5)	16 (8.2)	0	19 (9.7)
			Abnormal CS	0	0	0	0
			Total	176 (89.8)	20 (10.2)	0	196 (100)
	D29	Placebo (N=69)	Normal	57 (87.7)	2 (3.1)	0	59 (90.8)
			Abnormal NCS	0	6 (9.2)	0	6 (9.2)
			Abnormal CS	0	0	0	0
			Total	57 (87.7)	8 (12.3)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Mean Platelet Volume (fL)	D29	GS1-144 30 mg QD (N=70)	Normal	60 (92.3)	1 (1.5)	0	61 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	1 (1.5)	3 (4.6)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	59 (90.8)	6 (9.2)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	50 (79.4)	4 (6.3)	0	54 (85.7)
			Abnormal NCS	2 (3.2)	7 (11.1)	0	9 (14.3)
			Abnormal CS	0	0	0	0
			Total	52 (82.5)	11 (17.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	168 (87.0)	8 (4.1)	0	176 (91.2)
			Abnormal NCS	5 (2.6)	12 (6.2)	0	17 (8.8)
			Abnormal CS	0	0	0	0
			Total	173 (89.6)	20 (10.4)	0	193 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Mean Platelet Volume (fL)	D43	Placebo (N=69)	Normal	56 (87.5)	1 (1.6)	0	57 (89.1)
			Abnormal NCS	0	7 (10.9)	0	7 (10.9)
			Abnormal CS	0	0	0	0
			Total	56 (87.5)	8 (12.5)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (93.8)	1 (1.5)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (87.7)	2 (3.1)	0	59 (90.8)
			Abnormal NCS	2 (3.1)	4 (6.2)	0	6 (9.2)
			Abnormal CS	0	0	0	0
			Total	59 (90.8)	6 (9.2)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	49 (80.3)	3 (4.9)	0	52 (85.2)
			Abnormal NCS	1 (1.6)	8 (13.1)	0	9 (14.8)
			Abnormal CS	0	0	0	0
			Total	50 (82.0)	11 (18.0)	0	61 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Mean Platelet Volume (fL)	D43	Combined GS1-144 (N=207)	Normal	167 (87.4)	6 (3.1)	0	173 (90.6)
			Abnormal NCS	4 (2.1)	14 (7.3)	0	18 (9.4)
			Abnormal CS	0	0	0	0
			Total	171 (89.5)	20 (10.5)	0	191 (100)
	D57	Placebo (N=69)	Normal	54 (85.7)	2 (3.2)	0	56 (88.9)
			Abnormal NCS	2 (3.2)	5 (7.9)	0	7 (11.1)
			Abnormal CS	0	0	0	0
			Total	56 (88.9)	7 (11.1)	0	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (89.1)	2 (3.1)	0	59 (92.2)
			Abnormal NCS	1 (1.6)	4 (6.3)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Mean Platelet Volume (fL)	D57	GS1-144 30 mg BID (N=68)	Normal	46 (76.7)	3 (5.0)	0	49 (81.7)
			Abnormal NCS	4 (6.7)	7 (11.7)	0	11 (18.3)
			Abnormal CS	0	0	0	0
			Total	50 (83.3)	10 (16.7)	0	60 (100)
		Combined GS1-144 (N=207)	Normal	163 (86.7)	6 (3.2)	0	169 (89.9)
			Abnormal NCS	6 (3.2)	13 (6.9)	0	19 (10.1)
			Abnormal CS	0	0	0	0
			Total	169 (89.9)	19 (10.1)	0	188 (100)
	D71	Placebo (N=69)	Normal	55 (87.3)	2 (3.2)	0	57 (90.5)
			Abnormal NCS	1 (1.6)	5 (7.9)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	56 (88.9)	7 (11.1)	0	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Mean Platelet Volume (fL)	D71	GS1-144 60 mg QD (N=69)	Normal	55 (87.3)	3 (4.8)	0	58 (92.1)
			Abnormal NCS	2 (3.2)	3 (4.8)	0	5 (7.9)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		GS1-144 30 mg BID (N=68)	Normal	46 (76.7)	3 (5.0)	0	49 (81.7)
			Abnormal NCS	4 (6.7)	7 (11.7)	0	11 (18.3)
			Abnormal CS	0	0	0	0
			Total	50 (83.3)	10 (16.7)	0	60 (100)
		Combined GS1-144 (N=207)	Normal	161 (86.1)	7 (3.7)	0	168 (89.8)
			Abnormal NCS	7 (3.7)	12 (6.4)	0	19 (10.2)
			Abnormal CS	0	0	0	0
			Total	168 (89.8)	19 (10.2)	0	187 (100)
	D85	Placebo (N=69)	Normal	54 (87.1)	2 (3.2)	0	56 (90.3)
			Abnormal NCS	1 (1.6)	5 (8.1)	0	6 (9.7)
			Abnormal CS	0	0	0	0
			Total	55 (88.7)	7 (11.3)	0	62 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Mean Platelet Volume (fL)	D85	GS1-144 30 mg QD (N=70)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (87.5)	3 (4.7)	0	59 (92.2)
			Abnormal NCS	2 (3.1)	3 (4.7)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	48 (81.4)	3 (5.1)	0	51 (86.4)
			Abnormal NCS	1 (1.7)	7 (11.9)	0	8 (13.6)
			Abnormal CS	0	0	0	0
			Total	49 (83.1)	10 (16.9)	0	59 (100)
		Combined GS1-144 (N=207)	Normal	164 (88.2)	7 (3.8)	0	171 (91.9)
			Abnormal NCS	3 (1.6)	12 (6.5)	0	15 (8.1)
			Abnormal CS	0	0	0	0
			Total	167 (89.8)	19 (10.2)	0	186 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Mean Platelet Volume (fL)	Safety Follow-up	Placebo (N=69)	Normal	52 (83.9)	2 (3.2)	0	54 (87.1)
			Abnormal NCS	3 (4.8)	5 (8.1)	0	8 (12.9)
			Abnormal CS	0	0	0	0
			Total	55 (88.7)	7 (11.3)	0	62 (100)
		GS1-144 30 mg QD (N=70)	Normal	57 (89.1)	2 (3.1)	0	59 (92.2)
			Abnormal NCS	4 (6.3)	1 (1.6)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (89.1)	5 (7.8)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	48 (80.0)	2 (3.3)	0	50 (83.3)
			Abnormal NCS	2 (3.3)	8 (13.3)	0	10 (16.7)
			Abnormal CS	0	0	0	0
			Total	50 (83.3)	10 (16.7)	0	60 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Mean Platelet Volume (fL)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	162 (86.2)	9 (4.8)	0	171 (91.0)
			Abnormal NCS	7 (3.7)	10 (5.3)	0	17 (9.0)
			Abnormal CS	0	0	0	0
			Total	169 (89.9)	19 (10.1)	0	188 (100)
Leukocytes (10^9/L)	D15	Placebo (N=69)	Normal	60 (87.0)	2 (2.9)	0	62 (89.9)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Total	64 (92.8)	5 (7.2)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (87.1)	2 (2.9)	2 (2.9)	65 (92.9)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	2 (2.9)	0	0	2 (2.9)
			Total	64 (91.4)	4 (5.7)	2 (2.9)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (89.7)	1 (1.5)	0	62 (91.2)
			Abnormal NCS	4 (5.9)	1 (1.5)	0	5 (7.4)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Leukocytes (10^9/L)	D15	GS1-144 30 mg BID (N=68)	Normal	60 (88.2)	4 (5.9)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	2 (2.9)	0	0	2 (2.9)
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	182 (88.3)	7 (3.4)	2 (1.0)	191 (92.7)
			Abnormal NCS	7 (3.4)	3 (1.5)	0	10 (4.9)
			Abnormal CS	4 (1.9)	0	1 (0.5)	5 (2.4)
			Total	193 (93.7)	10 (4.9)	3 (1.5)	206 (100)
	D29	Placebo (N=69)	Normal	58 (86.6)	3 (4.5)	0	61 (91.0)
			Abnormal NCS	4 (6.0)	2 (3.0)	0	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	2 (2.9)	1 (1.4)	63 (91.3)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	2 (2.9)	1 (1.4)	1 (1.4)	4 (5.8)
			Total	63 (91.3)	4 (5.8)	2 (2.9)	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Leukocytes (10^9/L)	D29	GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	1 (1.5)	1 (1.5)	2 (3.0)
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	184 (90.6)	5 (2.5)	1 (0.5)	190 (93.6)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.0)
			Abnormal CS	3 (1.5)	2 (1.0)	2 (1.0)	7 (3.4)
			Total	190 (93.6)	10 (4.9)	3 (1.5)	203 (100)
	D43	Placebo (N=69)	Normal	56 (84.8)	3 (4.5)	0	59 (89.4)
			Abnormal NCS	4 (6.1)	2 (3.0)	0	6 (9.1)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (92.4)	5 (7.6)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Leukocytes (10^9/L)	D43	GS1-144 30 mg QD (N=70)	Normal	61 (88.4)	1 (1.4)	0	62 (89.9)
			Abnormal NCS	0	2 (2.9)	1 (1.4)	3 (4.3)
			Abnormal CS	2 (2.9)	1 (1.4)	1 (1.4)	4 (5.8)
			Total	63 (91.3)	4 (5.8)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	1 (1.5)	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (90.6)	1 (1.6)	0	59 (92.2)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	2 (3.1)	0	0	2 (3.1)
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	180 (90.0)	3 (1.5)	1 (0.5)	184 (92.0)
			Abnormal NCS	4 (2.0)	5 (2.5)	1 (0.5)	10 (5.0)
			Abnormal CS	4 (2.0)	1 (0.5)	1 (0.5)	6 (3.0)
			Total	188 (94.0)	9 (4.5)	3 (1.5)	200 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Leukocytes (10^9/L)	D57	Placebo (N=69)	Normal	58 (89.2)	1 (1.5)	0	59 (90.8)
			Abnormal NCS	0	3 (4.6)	0	3 (4.6)
			Abnormal CS	2 (3.1)	1 (1.5)	0	3 (4.6)
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	2 (2.9)	1 (1.5)	62 (91.2)
			Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
			Abnormal CS	0	1 (1.5)	1 (1.5)	2 (2.9)
			Total	62 (91.2)	4 (5.9)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	1 (1.5)	1 (1.5)	61 (92.4)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	60 (95.2)	3 (4.8)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Leukocytes (10^9/L)	D57	Combined GS1-144 (N=207)	Normal	177 (89.8)	5 (2.5)	2 (1.0)	184 (93.4)
			Abnormal NCS	5 (2.5)	3 (1.5)	0	8 (4.1)
			Abnormal CS	3 (1.5)	1 (0.5)	1 (0.5)	5 (2.5)
			Total	185 (93.9)	9 (4.6)	3 (1.5)	197 (100)
	D71	Placebo (N=69)	Normal	57 (87.7)	2 (3.1)	0	59 (90.8)
			Abnormal NCS	1 (1.5)	3 (4.6)	0	4 (6.2)
			Abnormal CS	2 (3.1)	0	0	2 (3.1)
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (88.2)	2 (2.9)	1 (1.5)	63 (92.6)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	1 (1.5)	1 (1.5)	1 (1.5)	3 (4.4)
			Total	62 (91.2)	4 (5.9)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (93.8)	1 (1.5)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Leukocytes (10^9/L)	D71	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	0	60 (95.2)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	179 (91.3)	5 (2.6)	1 (0.5)	185 (94.4)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.1)
			Abnormal CS	2 (1.0)	1 (0.5)	2 (1.0)	5 (2.6)
			Total	184 (93.9)	9 (4.6)	3 (1.5)	196 (100)
	D85	Placebo (N=69)	Normal	57 (89.1)	3 (4.7)	0	60 (93.8)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	1 (1.6)	0	1 (1.6)
			Total	59 (92.2)	5 (7.8)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	57 (85.1)	2 (3.0)	1 (1.5)	60 (89.6)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	2 (3.0)	1 (1.5)	1 (1.5)	4 (6.0)
			Total	61 (91.0)	4 (6.0)	2 (3.0)	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Leukocytes (10^9/L)	D85	GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	1 (1.5)	0	59 (89.4)
			Abnormal NCS	5 (7.6)	1 (1.5)	0	6 (9.1)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (93.5)	1 (1.6)	0	59 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	60 (96.8)	2 (3.2)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	173 (88.7)	4 (2.1)	1 (0.5)	178 (91.3)
			Abnormal NCS	9 (4.6)	3 (1.5)	0	12 (6.2)
			Abnormal CS	2 (1.0)	1 (0.5)	2 (1.0)	5 (2.6)
			Total	184 (94.4)	8 (4.1)	3 (1.5)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	57 (89.1)	4 (6.3)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Leukocytes (10^9/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	58 (85.3)	3 (4.4)	1 (1.5)	62 (91.2)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	3 (4.4)	0	1 (1.5)	4 (5.9)
			Total	62 (91.2)	4 (5.9)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	1 (1.5)	1 (1.5)	61 (92.4)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	1 (1.6)	0	57 (90.5)
			Abnormal NCS	4 (6.3)	1 (1.6)	0	5 (7.9)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	173 (87.8)	5 (2.5)	2 (1.0)	180 (91.4)
			Abnormal NCS	8 (4.1)	3 (1.5)	0	11 (5.6)
			Abnormal CS	5 (2.5)	0	1 (0.5)	6 (3.0)
			Total	186 (94.4)	8 (4.1)	3 (1.5)	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes/Leukocytes (%)	D15	Placebo (N=69)	Normal	58 (84.1)	5 (7.2)	0	63 (91.3)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.8)
			Abnormal CS	2 (2.9)	0	0	2 (2.9)
			Total	62 (89.9)	7 (10.1)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (84.3)	4 (5.7)	1 (1.4)	64 (91.4)
			Abnormal NCS	5 (7.1)	1 (1.4)	0	6 (8.6)
			Abnormal CS	0	0	0	0
			Total	64 (91.4)	5 (7.1)	1 (1.4)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	3 (4.4)	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes/Leukocytes (%)	D15	Combined GS1-144 (N=207)	Normal	189 (91.7)	7 (3.4)	1 (0.5)	197 (95.6)
			Abnormal NCS	6 (2.9)	3 (1.5)	0	9 (4.4)
			Abnormal CS	0	0	0	0
			Total	195 (94.7)	10 (4.9)	1 (0.5)	206 (100)
	D29	Placebo (N=69)	Normal	58 (86.6)	4 (6.0)	0	62 (92.5)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	60 (89.6)	7 (10.4)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	3 (4.3)	1 (1.4)	64 (92.8)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.8)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	63 (91.3)	5 (7.2)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (92.5)	0	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes/Leukocytes (%)	D29	GS1-144 30 mg BID (N=68)	Normal	61 (91.0)	2 (3.0)	0	63 (94.0)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	183 (90.1)	5 (2.5)	1 (0.5)	189 (93.1)
			Abnormal NCS	8 (3.9)	5 (2.5)	0	13 (6.4)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	192 (94.6)	10 (4.9)	1 (0.5)	203 (100)
	D43	Placebo (N=69)	Normal	56 (84.8)	4 (6.1)	0	60 (90.9)
			Abnormal NCS	3 (4.5)	3 (4.5)	0	6 (9.1)
			Abnormal CS	0	0	0	0
			Total	59 (89.4)	7 (10.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	4 (5.8)	1 (1.4)	65 (94.2)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	63 (91.3)	5 (7.2)	1 (1.4)	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lymphocytes/Leukocytes (%)	D43	GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (92.2)	3 (4.7)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	184 (92.0)	7 (3.5)	1 (0.5)	192 (96.0)
			Abnormal NCS	5 (2.5)	3 (1.5)	0	8 (4.0)
			Abnormal CS	0	0	0	0
			Total	189 (94.5)	10 (5.0)	1 (0.5)	200 (100)
	D57	Placebo (N=69)	Normal	56 (86.2)	5 (7.7)	0	61 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	58 (89.2)	7 (10.8)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lymphocytes/Leukocytes (%)	D57	GS1-144 30 mg QD (N=70)	Normal	60 (88.2)	4 (5.9)	1 (1.5)	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	62 (91.2)	5 (7.4)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	0	0	62 (93.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	3 (4.8)	0	59 (93.7)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.4)	7 (3.6)	1 (0.5)	186 (94.4)
			Abnormal NCS	7 (3.6)	3 (1.5)	0	10 (5.1)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	186 (94.4)	10 (5.1)	1 (0.5)	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes/Leukocytes (%)	D71	Placebo (N=69)	Normal	55 (84.6)	3 (4.6)	0	58 (89.2)
			Abnormal NCS	2 (3.1)	4 (6.2)	0	6 (9.2)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	58 (89.2)	7 (10.8)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	2 (2.9)	1 (1.5)	62 (91.2)
			Abnormal NCS	3 (4.4)	3 (4.4)	0	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	62 (91.2)	5 (7.4)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	0	0	62 (95.4)
			Abnormal NCS	2 (3.1)	1 (1.5)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	3 (4.8)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes/Leukocytes (%)	D71	Combined GS1-144 (N=207)	Normal	179 (91.3)	5 (2.6)	1 (0.5)	185 (94.4)
			Abnormal NCS	6 (3.1)	5 (2.6)	0	11 (5.6)
			Abnormal CS	0	0	0	0
			Total	185 (94.4)	10 (5.1)	1 (0.5)	196 (100)
	D85	Placebo (N=69)	Normal	51 (79.7)	3 (4.7)	0	54 (84.4)
			Abnormal NCS	6 (9.4)	4 (6.3)	0	10 (15.6)
			Abnormal CS	0	0	0	0
			Total	57 (89.1)	7 (10.9)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	58 (86.6)	3 (4.5)	1 (1.5)	62 (92.5)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (91.0)	5 (7.5)	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes/Leukocytes (%)	D85	GS1-144 30 mg BID (N=68)	Normal	56 (90.3)	4 (6.5)	0	60 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	58 (93.5)	4 (6.5)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	178 (91.3)	7 (3.6)	1 (0.5)	186 (95.4)
			Abnormal NCS	5 (2.6)	3 (1.5)	0	8 (4.1)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	184 (94.4)	10 (5.1)	1 (0.5)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	56 (87.5)	4 (6.3)	0	60 (93.8)
			Abnormal NCS	1 (1.6)	3 (4.7)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	57 (89.1)	7 (10.9)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	1 (1.5)	1 (1.5)	61 (89.7)
			Abnormal NCS	3 (4.4)	4 (5.9)	0	7 (10.3)
			Abnormal CS	0	0	0	0
			Total	62 (91.2)	5 (7.4)	1 (1.5)	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes/Leukocytes (%)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	0	0	58 (87.9)
			Abnormal NCS	7 (10.6)	1 (1.5)	0	8 (12.1)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	4 (6.3)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	174 (88.3)	5 (2.5)	1 (0.5)	180 (91.4)
			Abnormal NCS	12 (6.1)	5 (2.5)	0	17 (8.6)
			Abnormal CS	0	0	0	0
			Total	186 (94.4)	10 (5.1)	1 (0.5)	197 (100)
Monocytes/Leukocytes (%)	D15	Placebo (N=69)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Monocytes/Leukocytes (%)	D15	GS1-144 30 mg QD (N=70)	Normal	68 (97.1)	0	0	68 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	199 (96.6)	2 (1.0)	0	201 (97.6)
			Abnormal NCS	4 (1.9)	1 (0.5)	0	5 (2.4)
			Abnormal CS	0	0	0	0
			Total	203 (98.5)	3 (1.5)	0	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Monocytes/Leukocytes (%)	D29	Placebo (N=69)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Monocytes/Leukocytes (%)	D29	Combined GS1-144 (N=207)	Normal	195 (96.1)	3 (1.5)	0	198 (97.5)
			Abnormal NCS	5 (2.5)	0	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	200 (98.5)	3 (1.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Monocytes/Leukocytes (%)	D43	GS1-144 30 mg BID (N=68)	Normal	61 (95.3)	2 (3.1)	0	63 (98.4)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	192 (96.0)	3 (1.5)	0	195 (97.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	2 (1.0)	0	0	2 (1.0)
			Total	197 (98.5)	3 (1.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	62 (95.4)	0	0	62 (95.4)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Monocytes/Leukocytes (%)	D57	GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	2 (3.2)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.0)	2 (1.0)	0	193 (98.0)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	194 (98.5)	3 (1.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	60 (92.3)	0	0	60 (92.3)
			Abnormal NCS	5 (7.7)	0	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Monocytes/Leukocytes (%)	D71	GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	2 (3.2)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (96.4)	3 (1.5)	0	192 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	193 (98.5)	3 (1.5)	0	196 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Monocytes/Leukocytes (%)	D85	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (96.8)	2 (3.2)	0	62 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	60 (96.8)	2 (3.2)	0	62 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Monocytes/Leukocytes (%)	D85	Combined GS1-144 (N=207)	Normal	187 (95.9)	3 (1.5)	0	190 (97.4)
			Abnormal NCS	5 (2.6)	0	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	192 (98.5)	3 (1.5)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	61 (95.3)	0	0	61 (95.3)
			Abnormal NCS	3 (4.7)	0	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Monocytes/Leukocytes (%)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	2 (3.2)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (98.5)	3 (1.5)	0	197 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)
Neutrophils/Leukocytes (%)	D15	Placebo (N=69)	Normal	61 (88.4)	3 (4.3)	0	64 (92.8)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	2 (2.9)	0	0	2 (2.9)
			Total	64 (92.8)	5 (7.2)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (88.6)	3 (4.3)	1 (1.4)	66 (94.3)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.7)
			Abnormal CS	0	0	0	0
			Total	65 (92.9)	4 (5.7)	1 (1.4)	70 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils/Leukocytes (%)	D15	GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	2 (2.9)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	192 (93.2)	7 (3.4)	1 (0.5)	200 (97.1)
			Abnormal NCS	5 (2.4)	1 (0.5)	0	6 (2.9)
			Abnormal CS	0	0	0	0
			Total	197 (95.6)	8 (3.9)	1 (0.5)	206 (100)
	D29	Placebo (N=69)	Normal	60 (89.6)	4 (6.0)	0	64 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils/Leukocytes (%)	D29	GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	2 (2.9)	1 (1.4)	63 (91.3)
			Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.2)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	64 (92.8)	4 (5.8)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (91.0)	2 (3.0)	0	63 (94.0)
			Abnormal NCS	4 (6.0)	0	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	185 (91.1)	6 (3.0)	1 (0.5)	192 (94.6)
			Abnormal NCS	8 (3.9)	2 (1.0)	0	10 (4.9)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	194 (95.6)	8 (3.9)	1 (0.5)	203 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Neutrophils/Leukocytes (%)	D43	Placebo (N=69)	Normal	59 (89.4)	3 (4.5)	0	62 (93.9)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (88.4)	3 (4.3)	1 (1.4)	65 (94.2)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	64 (92.8)	4 (5.8)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	2 (3.0)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (96.9)	2 (3.1)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils/Leukocytes (%)	D43	Combined GS1-144 (N=207)	Normal	188 (94.0)	7 (3.5)	1 (0.5)	196 (98.0)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	191 (95.5)	8 (4.0)	1 (0.5)	200 (100)
	D57	Placebo (N=69)	Normal	59 (90.8)	3 (4.6)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	3 (4.4)	1 (1.5)	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	4 (5.9)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils/Leukocytes (%)	D57	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	2 (3.2)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (92.9)	7 (3.6)	1 (0.5)	191 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	8 (4.1)	1 (0.5)	197 (100)
	D71	Placebo (N=69)	Normal	56 (86.2)	3 (4.6)	0	59 (90.8)
			Abnormal NCS	3 (4.6)	2 (3.1)	0	5 (7.7)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	2 (2.9)	1 (1.5)	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	4 (5.9)	1 (1.5)	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Neutrophils/Leukocytes (%)	D71	GS1-144 60 mg QD (N=69)	Normal	61 (93.8)	2 (3.1)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	182 (92.9)	6 (3.1)	1 (0.5)	189 (96.4)
			Abnormal NCS	5 (2.6)	2 (1.0)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	187 (95.4)	8 (4.1)	1 (0.5)	196 (100)
	D85	Placebo (N=69)	Normal	57 (89.1)	3 (4.7)	0	60 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils/Leukocytes (%)	D85	GS1-144 30 mg QD (N=70)	Normal	57 (85.1)	3 (4.5)	1 (1.5)	61 (91.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	62 (92.5)	4 (6.0)	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	2 (3.0)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (91.9)	2 (3.2)	0	59 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	60 (96.8)	2 (3.2)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	176 (90.3)	7 (3.6)	1 (0.5)	184 (94.4)
			Abnormal NCS	7 (3.6)	1 (0.5)	0	8 (4.1)
			Abnormal CS	3 (1.5)	0	0	3 (1.5)
			Total	186 (95.4)	8 (4.1)	1 (0.5)	195 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils/Leukocytes (%)	Safety Follow-up	Placebo (N=69)	Normal	56 (87.5)	3 (4.7)	0	59 (92.2)
			Abnormal NCS	3 (4.7)	2 (3.1)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	1 (1.5)	1 (1.5)	61 (89.7)
			Abnormal NCS	4 (5.9)	2 (2.9)	0	6 (8.8)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	63 (92.6)	4 (5.9)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	2 (3.0)	0	60 (90.9)
			Abnormal NCS	5 (7.6)	0	0	5 (7.6)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	2 (3.2)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils/Leukocytes (%)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	177 (89.8)	5 (2.5)	1 (0.5)	183 (92.9)
			Abnormal NCS	10 (5.1)	2 (1.0)	0	12 (6.1)
			Abnormal CS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Total	188 (95.4)	8 (4.1)	1 (0.5)	197 (100)
Eosinophils/Leukocytes (%)	D15	Placebo (N=69)	Normal	63 (91.3)	2 (2.9)	0	65 (94.2)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	1 (1.4)	0	67 (95.7)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	68 (97.1)	2 (2.9)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Eosinophils/Leukocytes (%)	D15	GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	195 (94.7)	4 (1.9)	0	199 (96.6)
			Abnormal NCS	4 (1.9)	3 (1.5)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	199 (96.6)	7 (3.4)	0	206 (100)
	D29	Placebo (N=69)	Normal	62 (92.5)	3 (4.5)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	1 (1.4)	0	67 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils/Leukocytes (%)	D29	GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (94.0)	3 (4.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	194 (95.6)	5 (2.5)	0	199 (98.0)
			Abnormal NCS	2 (1.0)	2 (1.0)	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	196 (96.6)	7 (3.4)	0	203 (100)
	D43	Placebo (N=69)	Normal	61 (92.4)	3 (4.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils/Leukocytes (%)	D43	GS1-144 30 mg QD (N=70)	Normal	62 (89.9)	0	0	62 (89.9)
			Abnormal NCS	5 (7.2)	2 (2.9)	0	7 (10.1)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (92.2)	4 (6.3)	0	63 (98.4)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	185 (92.5)	5 (2.5)	0	190 (95.0)
			Abnormal NCS	7 (3.5)	2 (1.0)	0	9 (4.5)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	193 (96.5)	7 (3.5)	0	200 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils/Leukocytes (%)	D57	Placebo (N=69)	Normal	60 (92.3)	3 (4.6)	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	1 (1.6)	0	60 (95.2)
			Abnormal NCS	0	3 (4.8)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils/Leukocytes (%)	D57	Combined GS1-144 (N=207)	Normal	187 (94.9)	2 (1.0)	0	189 (95.9)
			Abnormal NCS	3 (1.5)	5 (2.5)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	190 (96.4)	7 (3.6)	0	197 (100)
	D71	Placebo (N=69)	Normal	59 (90.8)	4 (6.2)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils/Leukocytes (%)	D71	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	3 (4.8)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.9)	5 (2.6)	0	191 (97.4)
			Abnormal NCS	3 (1.5)	2 (1.0)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	189 (96.4)	7 (3.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	58 (90.6)	4 (6.3)	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils/Leukocytes (%)	D85	GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (91.9)	0	0	57 (91.9)
			Abnormal NCS	1 (1.6)	4 (6.5)	0	5 (8.1)
			Abnormal CS	0	0	0	0
			Total	58 (93.5)	4 (6.5)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	185 (94.9)	1 (0.5)	0	186 (95.4)
			Abnormal NCS	3 (1.5)	6 (3.1)	0	9 (4.6)
			Abnormal CS	0	0	0	0
			Total	188 (96.4)	7 (3.6)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	4 (6.3)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils/Leukocytes (%)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	3 (4.8)	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.4)	4 (2.0)	0	192 (97.5)
			Abnormal NCS	2 (1.0)	3 (1.5)	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	190 (96.4)	7 (3.6)	0	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils/Leukocytes (%)	D15	Placebo (N=69)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (90.0)	2 (2.9)	0	65 (92.9)
			Abnormal NCS	4 (5.7)	1 (1.4)	0	5 (7.1)
			Abnormal CS	0	0	0	0
			Total	67 (95.7)	3 (4.3)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	0	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	4 (5.9)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils/Leukocytes (%)	D15	Combined GS1-144 (N=207)	Normal	189 (91.7)	6 (2.9)	0	195 (94.7)
			Abnormal NCS	8 (3.9)	3 (1.5)	0	11 (5.3)
			Abnormal CS	0	0	0	0
			Total	197 (95.6)	9 (4.4)	0	206 (100)
	D29	Placebo (N=69)	Normal	60 (89.6)	1 (1.5)	0	61 (91.0)
			Abnormal NCS	4 (6.0)	2 (3.0)	0	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	1 (1.4)	0	64 (92.8)
			Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.2)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils/Leukocytes (%)	D29	GS1-144 30 mg BID (N=68)	Normal	60 (89.6)	4 (6.0)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	184 (90.6)	6 (3.0)	0	190 (93.6)
			Abnormal NCS	10 (4.9)	3 (1.5)	0	13 (6.4)
			Abnormal CS	0	0	0	0
			Total	194 (95.6)	9 (4.4)	0	203 (100)
	D43	Placebo (N=69)	Normal	57 (86.4)	3 (4.5)	0	60 (90.9)
			Abnormal NCS	6 (9.1)	0	0	6 (9.1)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	2 (2.9)	0	67 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils/Leukocytes (%)	D43	GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	3 (4.7)	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	186 (93.0)	6 (3.0)	0	192 (96.0)
			Abnormal NCS	5 (2.5)	3 (1.5)	0	8 (4.0)
			Abnormal CS	0	0	0	0
			Total	191 (95.5)	9 (4.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	58 (89.2)	1 (1.5)	0	59 (90.8)
			Abnormal NCS	4 (6.2)	2 (3.1)	0	6 (9.2)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils/Leukocytes (%)	D57	GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	1 (1.5)	0	62 (91.2)
			Abnormal NCS	4 (5.9)	2 (2.9)	0	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	2 (3.0)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	3 (4.8)	0	59 (93.7)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	179 (90.9)	6 (3.0)	0	185 (93.9)
			Abnormal NCS	9 (4.6)	3 (1.5)	0	12 (6.1)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	9 (4.6)	0	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils/Leukocytes (%)	D71	Placebo (N=69)	Normal	56 (86.2)	1 (1.5)	0	57 (87.7)
			Abnormal NCS	6 (9.2)	2 (3.1)	0	8 (12.3)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	3 (4.4)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (92.3)	2 (3.1)	0	62 (95.4)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	3 (4.8)	0	59 (93.7)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils/Leukocytes (%)	D71	Combined GS1-144 (N=207)	Normal	180 (91.8)	8 (4.1)	0	188 (95.9)
			Abnormal NCS	7 (3.6)	1 (0.5)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	187 (95.4)	9 (4.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	58 (90.6)	1 (1.6)	0	59 (92.2)
			Abnormal NCS	3 (4.7)	2 (3.1)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	0	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Basophils/Leukocytes (%)	D85	GS1-144 30 mg BID (N=68)	Normal	56 (90.3)	2 (3.2)	0	58 (93.5)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.5)
			Abnormal CS	0	0	0	0
			Total	59 (95.2)	3 (4.8)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	182 (93.3)	4 (2.1)	0	186 (95.4)
			Abnormal NCS	5 (2.6)	4 (2.1)	0	9 (4.6)
			Abnormal CS	0	0	0	0
			Total	187 (95.9)	8 (4.1)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	58 (90.6)	2 (3.1)	0	60 (93.8)
			Abnormal NCS	3 (4.7)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils/Leukocytes (%)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	1 (1.5)	0	62 (93.9)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	185 (93.9)	5 (2.5)	0	190 (96.4)
			Abnormal NCS	4 (2.0)	3 (1.5)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	189 (95.9)	8 (4.1)	0	197 (100)
Eosinophils (10^9/L)	D15	Placebo (N=69)	Normal	66 (95.7)	2 (2.9)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Eosinophils (10^9/L)	D15	GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	0	0	69 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	200 (97.1)	2 (1.0)	0	202 (98.1)
			Abnormal NCS	2 (1.0)	2 (1.0)	0	4 (1.9)
			Abnormal CS	0	0	0	0
			Total	202 (98.1)	4 (1.9)	0	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Eosinophils (10^9/L)	D29	Placebo (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (95.5)	3 (4.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Eosinophils (10^9/L)	D29	Combined GS1-144 (N=207)	Normal	199 (98.0)	4 (2.0)	0	203 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	199 (98.0)	4 (2.0)	0	203 (100)
	D43	Placebo (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	0	0	66 (95.7)
			Abnormal NCS	3 (4.3)	0	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils (10^9/L)	D43	GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	2 (3.1)	0	62 (96.9)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	190 (95.0)	3 (1.5)	0	193 (96.5)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	196 (98.0)	4 (2.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Eosinophils (10^9/L)	D57	GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.0)	3 (1.5)	0	194 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	193 (98.0)	4 (2.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	61 (93.8)	2 (3.1)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Eosinophils (10^9/L)	D71	GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (96.9)	3 (1.5)	0	193 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	192 (98.0)	4 (2.0)	0	196 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Eosinophils (10^9/L)	D85	Placebo (N=69)	Normal	61 (95.3)	2 (3.1)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (93.5)	0	0	58 (93.5)
			Abnormal NCS	1 (1.6)	3 (4.8)	0	4 (6.5)
			Abnormal CS	0	0	0	0
			Total	59 (95.2)	3 (4.8)	0	62 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Eosinophils (10^9/L)	D85	Combined GS1-144 (N=207)	Normal	189 (96.9)	1 (0.5)	0	190 (97.4)
			Abnormal NCS	2 (1.0)	3 (1.5)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	191 (97.9)	4 (2.1)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	2 (3.1)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Eosinophils (10^9/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	3 (4.8)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (97.5)	3 (1.5)	0	195 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	193 (98.0)	4 (2.0)	0	197 (100)
Basophils (10^9/L)	D15	Placebo (N=69)	Normal	65 (94.2)	2 (2.9)	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	1 (1.4)	0	68 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	69 (98.6)	1 (1.4)	0	70 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils (10^9/L)	D15	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	200 (97.1)	3 (1.5)	0	203 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	203 (98.5)	3 (1.5)	0	206 (100)
	D29	Placebo (N=69)	Normal	62 (92.5)	2 (3.0)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils (10^9/L)	D29	GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (97.0)	2 (3.0)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	196 (96.6)	3 (1.5)	0	199 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	200 (98.5)	3 (1.5)	0	203 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils (10^9/L)	D43	Placebo (N=69)	Normal	63 (95.5)	2 (3.0)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	1 (1.4)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (95.3)	2 (3.1)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils (10^9/L)	D43	Combined GS1-144 (N=207)	Normal	193 (96.5)	3 (1.5)	0	196 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	197 (98.5)	3 (1.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	62 (95.4)	2 (3.1)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils (10^9/L)	D57	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.0)	1 (0.5)	0	192 (97.5)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	195 (99.0)	2 (1.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	59 (90.8)	2 (3.1)	0	61 (93.8)
			Abnormal NCS	4 (6.2)	0	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Basophils (10^9/L)	D71	GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (98.0)	2 (1.0)	0	194 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	194 (99.0)	2 (1.0)	0	196 (100)
	D85	Placebo (N=69)	Normal	60 (93.8)	2 (3.1)	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils (10^9/L)	D85	GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (95.2)	1 (1.6)	0	60 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (98.4)	1 (1.6)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.9)	2 (1.0)	0	193 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	193 (99.0)	2 (1.0)	0	195 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils (10^9/L)	Safety Follow-up	Placebo (N=69)	Normal	61 (95.3)	2 (3.1)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Basophils (10^9/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	192 (97.5)	2 (1.0)	0	194 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	195 (99.0)	2 (1.0)	0	197 (100)
Neutrophils (10^9/L)	D15	Placebo (N=69)	Normal	59 (85.5)	3 (4.3)	0	62 (89.9)
			Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.8)
			Abnormal CS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Total	62 (89.9)	7 (10.1)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	58 (82.9)	3 (4.3)	1 (1.4)	62 (88.6)
			Abnormal NCS	4 (5.7)	3 (4.3)	0	7 (10.0)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	62 (88.6)	7 (10.0)	1 (1.4)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	1 (1.5)	0	60 (88.2)
			Abnormal NCS	6 (8.8)	1 (1.5)	0	7 (10.3)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils (10^9/L)	D15	GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	3 (4.4)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	180 (87.4)	7 (3.4)	1 (0.5)	188 (91.3)
			Abnormal NCS	12 (5.8)	4 (1.9)	0	16 (7.8)
			Abnormal CS	0	1 (0.5)	1 (0.5)	2 (1.0)
			Total	192 (93.2)	12 (5.8)	2 (1.0)	206 (100)
	D29	Placebo (N=69)	Normal	59 (88.1)	4 (6.0)	0	63 (94.0)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	60 (89.6)	7 (10.4)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (85.5)	1 (1.4)	1 (1.4)	61 (88.4)
			Abnormal NCS	2 (2.9)	5 (7.2)	0	7 (10.1)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	61 (88.4)	7 (10.1)	1 (1.4)	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils (10^9/L)	D29	GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	0	1 (1.5)	63 (95.5)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (88.1)	2 (3.0)	0	61 (91.0)
			Abnormal NCS	5 (7.5)	1 (1.5)	0	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	180 (89.1)	3 (1.5)	2 (1.0)	185 (91.6)
			Abnormal NCS	8 (4.0)	7 (3.5)	0	15 (7.4)
			Abnormal CS	0	2 (1.0)	0	2 (1.0)
			Total	188 (93.1)	12 (5.9)	2 (1.0)	202 (100)
	D43	Placebo (N=69)	Normal	55 (83.3)	4 (6.1)	0	59 (89.4)
			Abnormal NCS	4 (6.1)	3 (4.5)	0	7 (10.6)
			Abnormal CS	0	0	0	0
			Total	59 (89.4)	7 (10.6)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils (10^9/L)	D43	GS1-144 30 mg QD (N=70)	Normal	58 (84.1)	2 (2.9)	0	60 (87.0)
			Abnormal NCS	3 (4.3)	3 (4.3)	1 (1.4)	7 (10.1)
			Abnormal CS	0	2 (2.9)	0	2 (2.9)
			Total	61 (88.4)	7 (10.1)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	0	1 (1.5)	62 (92.5)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (92.2)	1 (1.6)	0	60 (93.8)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	178 (89.0)	3 (1.5)	1 (0.5)	182 (91.0)
			Abnormal NCS	7 (3.5)	7 (3.5)	1 (0.5)	15 (7.5)
			Abnormal CS	1 (0.5)	2 (1.0)	0	3 (1.5)
			Total	186 (93.0)	12 (6.0)	2 (1.0)	200 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Neutrophils (10^9/L)	D57	Placebo (N=69)	Normal	55 (84.6)	4 (6.2)	0	59 (90.8)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	2 (3.1)	1 (1.5)	0	3 (4.6)
			Total	58 (89.2)	7 (10.8)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	3 (4.4)	1 (1.5)	63 (92.6)
			Abnormal NCS	1 (1.5)	3 (4.4)	0	4 (5.9)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	60 (88.2)	7 (10.3)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	2 (3.0)	1 (1.5)	62 (93.9)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	0	60 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils (10^9/L)	D57	Combined GS1-144 (N=207)	Normal	176 (89.3)	7 (3.6)	2 (1.0)	185 (93.9)
			Abnormal NCS	6 (3.0)	4 (2.0)	0	10 (5.1)
			Abnormal CS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Total	183 (92.9)	12 (6.1)	2 (1.0)	197 (100)
	D71	Placebo (N=69)	Normal	55 (84.6)	4 (6.2)	0	59 (90.8)
			Abnormal NCS	1 (1.5)	3 (4.6)	0	4 (6.2)
			Abnormal CS	2 (3.1)	0	0	2 (3.1)
			Total	58 (89.2)	7 (10.8)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	2 (2.9)	1 (1.5)	62 (91.2)
			Abnormal NCS	1 (1.5)	3 (4.4)	0	4 (5.9)
			Abnormal CS	0	2 (2.9)	0	2 (2.9)
			Total	60 (88.2)	7 (10.3)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (90.8)	1 (1.5)	0	60 (92.3)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils (10^9/L)	D71	GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	2 (3.2)	0	58 (92.1)
			Abnormal NCS	4 (6.3)	1 (1.6)	0	5 (7.9)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	174 (88.8)	5 (2.6)	1 (0.5)	180 (91.8)
			Abnormal NCS	8 (4.1)	5 (2.6)	0	13 (6.6)
			Abnormal CS	0	2 (1.0)	1 (0.5)	3 (1.5)
			Total	182 (92.9)	12 (6.1)	2 (1.0)	196 (100)
	D85	Placebo (N=69)	Normal	57 (89.1)	5 (7.8)	0	62 (96.9)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	1 (1.6)	0	1 (1.6)
			Total	57 (89.1)	7 (10.9)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	55 (82.1)	2 (3.0)	1 (1.5)	58 (86.6)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.5)
			Abnormal CS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Total	59 (88.1)	7 (10.4)	1 (1.5)	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils (10^9/L)	D85	GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	0	1 (1.5)	60 (90.9)
			Abnormal NCS	4 (6.1)	1 (1.5)	0	5 (7.6)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (91.9)	2 (3.2)	0	59 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	59 (95.2)	3 (4.8)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	171 (87.7)	4 (2.1)	2 (1.0)	177 (90.8)
			Abnormal NCS	8 (4.1)	5 (2.6)	0	13 (6.7)
			Abnormal CS	2 (1.0)	3 (1.5)	0	5 (2.6)
			Total	181 (92.8)	12 (6.2)	2 (1.0)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	55 (85.9)	5 (7.8)	0	60 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	57 (89.1)	7 (10.9)	0	64 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Neutrophils (10^9/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	57 (83.8)	3 (4.4)	1 (1.5)	61 (89.7)
			Abnormal NCS	2 (2.9)	3 (4.4)	0	5 (7.4)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Total	60 (88.2)	7 (10.3)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (84.8)	0	1 (1.5)	57 (86.4)
			Abnormal NCS	6 (9.1)	1 (1.5)	0	7 (10.6)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	2 (3.2)	0	58 (92.1)
			Abnormal NCS	4 (6.3)	1 (1.6)	0	5 (7.9)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	169 (85.8)	5 (2.5)	2 (1.0)	176 (89.3)
			Abnormal NCS	12 (6.1)	5 (2.5)	0	17 (8.6)
			Abnormal CS	2 (1.0)	2 (1.0)	0	4 (2.0)
			Total	183 (92.9)	12 (6.1)	2 (1.0)	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes (10^9/L)	D15	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
			Abnormal NCS	4 (5.8)	0	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	1 (1.4)	0	65 (92.9)
			Abnormal NCS	2 (2.9)	3 (4.3)	0	5 (7.1)
			Abnormal CS	0	0	0	0
			Total	66 (94.3)	4 (5.7)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	3 (4.4)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (89.7)	3 (4.4)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes (10^9/L)	D15	Combined GS1-144 (N=207)	Normal	187 (90.8)	7 (3.4)	0	194 (94.2)
			Abnormal NCS	5 (2.4)	7 (3.4)	0	12 (5.8)
			Abnormal CS	0	0	0	0
			Total	192 (93.2)	14 (6.8)	0	206 (100)
	D29	Placebo (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	1 (1.4)	0	61 (88.4)
			Abnormal NCS	5 (7.2)	3 (4.3)	0	8 (11.6)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	55 (82.1)	3 (4.5)	0	58 (86.6)
			Abnormal NCS	6 (9.0)	2 (3.0)	0	8 (11.9)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	62 (92.5)	5 (7.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes (10^9/L)	D29	GS1-144 30 mg BID (N=68)	Normal	59 (88.1)	3 (4.5)	0	62 (92.5)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	174 (85.7)	7 (3.4)	0	181 (89.2)
			Abnormal NCS	14 (6.9)	7 (3.4)	0	21 (10.3)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	189 (93.1)	14 (6.9)	0	203 (100)
	D43	Placebo (N=69)	Normal	60 (90.9)	1 (1.5)	0	61 (92.4)
			Abnormal NCS	5 (7.6)	0	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (88.4)	2 (2.9)	0	63 (91.3)
			Abnormal NCS	4 (5.8)	2 (2.9)	0	6 (8.7)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes (10^9/L)	D43	GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	2 (3.0)	0	63 (94.0)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (85.9)	3 (4.7)	0	58 (90.6)
			Abnormal NCS	4 (6.3)	1 (1.6)	0	5 (7.8)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	177 (88.5)	7 (3.5)	0	184 (92.0)
			Abnormal NCS	9 (4.5)	6 (3.0)	0	15 (7.5)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	187 (93.5)	13 (6.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	57 (87.7)	1 (1.5)	0	58 (89.2)
			Abnormal NCS	7 (10.8)	0	0	7 (10.8)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes (10^9/L)	D57	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	1 (1.5)	3 (4.4)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (86.4)	3 (4.5)	0	60 (90.9)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.6)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	3 (4.8)	0	57 (90.5)
			Abnormal NCS	5 (7.9)	1 (1.6)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	174 (88.3)	7 (3.6)	0	181 (91.9)
			Abnormal NCS	9 (4.6)	6 (3.0)	0	15 (7.6)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	184 (93.4)	13 (6.6)	0	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes (10^9/L)	D71	Placebo (N=69)	Normal	59 (90.8)	0	0	59 (90.8)
			Abnormal NCS	5 (7.7)	1 (1.5)	0	6 (9.2)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	1 (1.5)	0	60 (88.2)
			Abnormal NCS	5 (7.4)	3 (4.4)	0	8 (11.8)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	53 (84.1)	3 (4.8)	0	56 (88.9)
			Abnormal NCS	6 (9.5)	1 (1.6)	0	7 (11.1)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes (10^9/L)	D71	Combined GS1-144 (N=207)	Normal	170 (86.7)	7 (3.6)	0	177 (90.3)
			Abnormal NCS	13 (6.6)	6 (3.1)	0	19 (9.7)
			Abnormal CS	0	0	0	0
			Total	183 (93.4)	13 (6.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	57 (89.1)	0	0	57 (89.1)
			Abnormal NCS	6 (9.4)	1 (1.6)	0	7 (10.9)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	1 (1.5)	0	61 (91.0)
			Abnormal NCS	3 (4.5)	3 (4.5)	0	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (90.9)	3 (4.5)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes (10^9/L)	D85	GS1-144 30 mg BID (N=68)	Normal	56 (90.3)	2 (3.2)	0	58 (93.5)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.5)
			Abnormal CS	0	0	0	0
			Total	59 (95.2)	3 (4.8)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	176 (90.3)	6 (3.1)	0	182 (93.3)
			Abnormal NCS	7 (3.6)	6 (3.1)	0	13 (6.7)
			Abnormal CS	0	0	0	0
			Total	183 (93.8)	12 (6.2)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	3 (4.7)	0	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	2 (2.9)	0	63 (92.6)
			Abnormal NCS	3 (4.4)	2 (2.9)	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lymphocytes (10^9/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	0	3 (4.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	2 (3.2)	0	57 (90.5)
			Abnormal NCS	5 (7.9)	1 (1.6)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	177 (89.8)	6 (3.0)	0	183 (92.9)
			Abnormal NCS	8 (4.1)	6 (3.0)	0	14 (7.1)
			Abnormal CS	0	0	0	0
			Total	185 (93.9)	12 (6.1)	0	197 (100)
Monocytes (10^9/L)	D15	Placebo (N=69)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	0	0	0	0
			Abnormal CS	2 (2.9)	0	0	2 (2.9)
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	D15	GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	0	0	69 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	202 (98.1)	0	0	202 (98.1)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (1.9)
			Abnormal CS	0	0	0	0
			Total	205 (99.5)	1 (0.5)	0	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	D29	Placebo (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Monocytes (10^9/L)	D29	Combined GS1-144 (N=207)	Normal	199 (98.0)	1 (0.5)	0	200 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	202 (99.5)	1 (0.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	0	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Monocytes (10^9/L)	D43	GS1-144 30 mg BID (N=68)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		Combined GS1-144 (N=207)	Normal	194 (97.0)	0	0	194 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	199 (99.5)	1 (0.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	D57	GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (98.5)	0	0	194 (98.5)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	196 (99.5)	1 (0.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	62 (95.4)	0	0	62 (95.4)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	D71	GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.5)	0	0	193 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	195 (99.5)	1 (0.5)	0	196 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	D85	Placebo (N=69)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	0	0	63 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (100)	0	0	62 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (100)	0	0	62 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	D85	Combined GS1-144 (N=207)	Normal	191 (97.9)	0	0	191 (97.9)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (2.1)
			Abnormal CS	0	0	0	0
			Total	194 (99.5)	1 (0.5)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.2
Shift of Hematology by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	196 (99.5)	0	0	196 (99.5)
			Abnormal NCS	0	1 (0.5)	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	196 (99.5)	1 (0.5)	0	197 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	Placebo (N=69)	Normal	54 (78.3)	2 (2.9)	0	56 (81.2)
		Abnormal NCS	7 (10.1)	5 (7.2)	0	12 (17.4)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	62 (89.9)	7 (10.1)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	57 (81.4)	1 (1.4)	0	58 (82.9)
		Abnormal NCS	6 (8.6)	4 (5.7)	0	10 (14.3)
		Abnormal CS	0	0	2 (2.9)	2 (2.9)
		Total	63 (90.0)	5 (7.1)	2 (2.9)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	55 (80.9)	2 (2.9)	0	57 (83.8)
		Abnormal NCS	5 (7.4)	5 (7.4)	0	10 (14.7)
		Abnormal CS	0	1 (1.5)	0	1 (1.5)
		Total	60 (88.2)	8 (11.8)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	56 (82.4)	1 (1.5)	0	57 (83.8)
		Abnormal NCS	3 (4.4)	7 (10.3)	0	10 (14.7)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	60 (88.2)	8 (11.8)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Erythrocytes (10^12/L)	Combined GS1-144 (N=207)	Normal	168 (81.6)	4 (1.9)	0	172 (83.5)
		Abnormal NCS	14 (6.8)	16 (7.8)	0	30 (14.6)
		Abnormal CS	1 (0.5)	1 (0.5)	2 (1.0)	4 (1.9)
		Total	183 (88.8)	21 (10.2)	2 (1.0)	206 (100)
Hematocrit (%)	Placebo (N=69)	Normal	56 (81.2)	1 (1.4)	0	57 (82.6)
		Abnormal NCS	7 (10.1)	3 (4.3)	0	10 (14.5)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	65 (94.2)	4 (5.8)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	59 (84.3)	0	0	59 (84.3)
		Abnormal NCS	7 (10.0)	2 (2.9)	0	9 (12.9)
		Abnormal CS	0	0	2 (2.9)	2 (2.9)
		Total	66 (94.3)	2 (2.9)	2 (2.9)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	45 (66.2)	2 (2.9)	0	47 (69.1)
		Abnormal NCS	17 (25.0)	3 (4.4)	0	20 (29.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	63 (92.6)	5 (7.4)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Hematocrit (%)	GS1-144 30 mg BID (N=68)	Normal	56 (82.4)	1 (1.5)	0	57 (83.8)
		Abnormal NCS	5 (7.4)	5 (7.4)	0	10 (14.7)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	62 (91.2)	6 (8.8)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	160 (77.7)	3 (1.5)	0	163 (79.1)
		Abnormal NCS	29 (14.1)	10 (4.9)	0	39 (18.9)
		Abnormal CS	2 (1.0)	0	2 (1.0)	4 (1.9)
		Total	191 (92.7)	13 (6.3)	2 (1.0)	206 (100)
Ery. Mean Corpuscular Volume (fL)	Placebo (N=69)	Normal	62 (89.9)	0	0	62 (89.9)
		Abnormal NCS	3 (4.3)	4 (5.8)	0	7 (10.1)
		Abnormal CS	0	0	0	0
		Total	65 (94.2)	4 (5.8)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	0	0	66 (94.3)
		Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.7)
		Abnormal CS	0	0	0	0
		Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ery. Mean Corpuscular Volume (fL)	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	0	0	62 (91.2)
		Abnormal NCS	2 (2.9)	4 (5.9)	0	6 (8.8)
		Abnormal CS	0	0	0	0
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	196 (95.1)	0	0	196 (95.1)
		Abnormal NCS	3 (1.5)	7 (3.4)	0	10 (4.9)
		Abnormal CS	0	0	0	0
		Total	199 (96.6)	7 (3.4)	0	206 (100)
Ery. Mean Corpuscular Hemoglobin (pg)	Placebo (N=69)	Normal	60 (87.0)	0	0	60 (87.0)
		Abnormal NCS	2 (2.9)	7 (10.1)	0	9 (13.0)
		Abnormal CS	0	0	0	0
		Total	62 (89.9)	7 (10.1)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ery. Mean Corpuscular Hemoglobin (pg)	GS1-144 30 mg QD (N=70)	Normal	63 (90.0)	0	0	63 (90.0)
		Abnormal NCS	2 (2.9)	5 (7.1)	0	7 (10.0)
		Abnormal CS	0	0	0	0
		Total	65 (92.9)	5 (7.1)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
		Abnormal NCS	0	2 (2.9)	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
		Abnormal NCS	1 (1.5)	4 (5.9)	0	5 (7.4)
		Abnormal CS	0	0	0	0
		Total	63 (92.6)	5 (7.4)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	191 (92.7)	1 (0.5)	0	192 (93.2)
		Abnormal NCS	3 (1.5)	11 (5.3)	0	14 (6.8)
		Abnormal CS	0	0	0	0
		Total	194 (94.2)	12 (5.8)	0	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Hemoglobin (g/L)	Placebo (N=69)	Normal	57 (82.6)	2 (2.9)	0	59 (85.5)
		Abnormal NCS	5 (7.2)	3 (4.3)	0	8 (11.6)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	64 (92.8)	5 (7.2)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	61 (87.1)	0	0	61 (87.1)
		Abnormal NCS	6 (8.6)	1 (1.4)	0	7 (10.0)
		Abnormal CS	1 (1.4)	0	1 (1.4)	2 (2.9)
		Total	68 (97.1)	1 (1.4)	1 (1.4)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	57 (83.8)	2 (2.9)	0	59 (86.8)
		Abnormal NCS	5 (7.4)	3 (4.4)	0	8 (11.8)
		Abnormal CS	0	1 (1.5)	0	1 (1.5)
		Total	62 (91.2)	6 (8.8)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	58 (85.3)	1 (1.5)	0	59 (86.8)
		Abnormal NCS	4 (5.9)	4 (5.9)	0	8 (11.8)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	63 (92.6)	5 (7.4)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Hemoglobin (g/L)	Combined GS1-144 (N=207)	Normal	176 (85.4)	3 (1.5)	0	179 (86.9)
		Abnormal NCS	15 (7.3)	8 (3.9)	0	23 (11.2)
		Abnormal CS	2 (1.0)	1 (0.5)	1 (0.5)	4 (1.9)
		Total	193 (93.7)	12 (5.8)	1 (0.5)	206 (100)
Platelets (10^9/L)	Placebo (N=69)	Normal	59 (85.5)	0	0	59 (85.5)
		Abnormal NCS	7 (10.1)	3 (4.3)	0	10 (14.5)
		Abnormal CS	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	63 (90.0)	0	0	63 (90.0)
		Abnormal NCS	3 (4.3)	4 (5.7)	0	7 (10.0)
		Abnormal CS	0	0	0	0
		Total	66 (94.3)	4 (5.7)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Platelets (10^9/L)	GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	191 (92.7)	0	0	191 (92.7)
		Abnormal NCS	8 (3.9)	6 (2.9)	0	14 (6.8)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	200 (97.1)	6 (2.9)	0	206 (100)
Mean Platelet Volume (fL)	Placebo (N=69)	Normal	50 (74.6)	1 (1.5)	0	51 (76.1)
		Abnormal NCS	7 (10.4)	9 (13.4)	0	16 (23.9)
		Abnormal CS	0	0	0	0
		Total	57 (85.1)	10 (14.9)	0	67 (100)
	GS1-144 30 mg QD (N=70)	Normal	59 (89.4)	0	0	59 (89.4)
		Abnormal NCS	4 (6.1)	3 (4.5)	0	7 (10.6)
		Abnormal CS	0	0	0	0
		Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Mean Platelet Volume (fL)	GS1-144 60 mg QD (N=69)	Normal	57 (86.4)	1 (1.5)	0	58 (87.9)
		Abnormal NCS	3 (4.5)	5 (7.6)	0	8 (12.1)
		Abnormal CS	0	0	0	0
		Total	60 (90.9)	6 (9.1)	0	66 (100)
	GS1-144 30 mg BID (N=68)	Normal	47 (73.4)	1 (1.6)	0	48 (75.0)
		Abnormal NCS	6 (9.4)	10 (15.6)	0	16 (25.0)
		Abnormal CS	0	0	0	0
		Total	53 (82.8)	11 (17.2)	0	64 (100)
	Combined GS1-144 (N=207)	Normal	163 (83.2)	2 (1.0)	0	165 (84.2)
		Abnormal NCS	13 (6.6)	18 (9.2)	0	31 (15.8)
		Abnormal CS	0	0	0	0
		Total	176 (89.8)	20 (10.2)	0	196 (100)
Leukocytes (10^9/L)	Placebo (N=69)	Normal	50 (72.5)	0	0	50 (72.5)
		Abnormal NCS	7 (10.1)	3 (4.3)	0	10 (14.5)
		Abnormal CS	7 (10.1)	2 (2.9)	0	9 (13.0)
		Total	64 (92.8)	5 (7.2)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Leukocytes (10^9/L)	GS1-144 30 mg QD (N=70)	Normal	57 (81.4)	1 (1.4)	0	58 (82.9)
		Abnormal NCS	4 (5.7)	2 (2.9)	1 (1.4)	7 (10.0)
		Abnormal CS	3 (4.3)	1 (1.4)	1 (1.4)	5 (7.1)
		Total	64 (91.4)	4 (5.7)	2 (2.9)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	53 (77.9)	0	0	53 (77.9)
		Abnormal NCS	9 (13.2)	1 (1.5)	0	10 (14.7)
		Abnormal CS	3 (4.4)	1 (1.5)	1 (1.5)	5 (7.4)
		Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	54 (79.4)	1 (1.5)	0	55 (80.9)
		Abnormal NCS	6 (8.8)	3 (4.4)	0	9 (13.2)
		Abnormal CS	4 (5.9)	0	0	4 (5.9)
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	164 (79.6)	2 (1.0)	0	166 (80.6)
		Abnormal NCS	19 (9.2)	6 (2.9)	1 (0.5)	26 (12.6)
		Abnormal CS	10 (4.9)	2 (1.0)	2 (1.0)	14 (6.8)
		Total	193 (93.7)	10 (4.9)	3 (1.5)	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes/Leukocytes (%)	Placebo (N=69)	Normal	46 (66.7)	2 (2.9)	0	48 (69.6)
		Abnormal NCS	12 (17.4)	5 (7.2)	0	17 (24.6)
		Abnormal CS	4 (5.8)	0	0	4 (5.8)
		Total	62 (89.9)	7 (10.1)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	49 (70.0)	1 (1.4)	1 (1.4)	51 (72.9)
		Abnormal NCS	13 (18.6)	4 (5.7)	0	17 (24.3)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	64 (91.4)	5 (7.1)	1 (1.4)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	52 (76.5)	0	0	52 (76.5)
		Abnormal NCS	14 (20.6)	1 (1.5)	0	15 (22.1)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	55 (80.9)	2 (2.9)	0	57 (83.8)
		Abnormal NCS	8 (11.8)	2 (2.9)	0	10 (14.7)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes/Leukocytes (%)	Combined GS1-144 (N=207)	Normal	156 (75.7)	3 (1.5)	1 (0.5)	160 (77.7)
		Abnormal NCS	35 (17.0)	7 (3.4)	0	42 (20.4)
		Abnormal CS	4 (1.9)	0	0	4 (1.9)
		Total	195 (94.7)	10 (4.9)	1 (0.5)	206 (100)
Monocytes/Leukocytes (%)	Placebo (N=69)	Normal	55 (79.7)	0	0	55 (79.7)
		Abnormal NCS	13 (18.8)	0	0	13 (18.8)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	69 (100)	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	61 (87.1)	0	0	61 (87.1)
		Abnormal NCS	8 (11.4)	0	0	8 (11.4)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	57 (83.8)	0	0	57 (83.8)
		Abnormal NCS	9 (13.2)	1 (1.5)	0	10 (14.7)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes/Leukocytes (%)	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	180 (87.4)	1 (0.5)	0	181 (87.9)
		Abnormal NCS	20 (9.7)	2 (1.0)	0	22 (10.7)
		Abnormal CS	3 (1.5)	0	0	3 (1.5)
		Total	203 (98.5)	3 (1.5)	0	206 (100)
Neutrophils/Leukocytes (%)	Placebo (N=69)	Normal	52 (75.4)	2 (2.9)	0	54 (78.3)
		Abnormal NCS	8 (11.6)	3 (4.3)	0	11 (15.9)
		Abnormal CS	4 (5.8)	0	0	4 (5.8)
		Total	64 (92.8)	5 (7.2)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	51 (72.9)	1 (1.4)	1 (1.4)	53 (75.7)
		Abnormal NCS	11 (15.7)	2 (2.9)	0	13 (18.6)
		Abnormal CS	3 (4.3)	1 (1.4)	0	4 (5.7)
		Total	65 (92.9)	4 (5.7)	1 (1.4)	70 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Neutrophils/Leukocytes (%)	GS1-144 60 mg QD (N=69)	Normal	55 (80.9)	2 (2.9)	0	57 (83.8)
		Abnormal NCS	9 (13.2)	0	0	9 (13.2)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	56 (82.4)	2 (2.9)	0	58 (85.3)
		Abnormal NCS	9 (13.2)	0	0	9 (13.2)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	162 (78.6)	5 (2.4)	1 (0.5)	168 (81.6)
		Abnormal NCS	29 (14.1)	2 (1.0)	0	31 (15.0)
		Abnormal CS	6 (2.9)	1 (0.5)	0	7 (3.4)
		Total	197 (95.6)	8 (3.9)	1 (0.5)	206 (100)
Eosinophils/Leukocytes (%)	Placebo (N=69)	Normal	61 (88.4)	2 (2.9)	0	63 (91.3)
		Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.2)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Eosinophils/Leukocytes (%)	GS1-144 30 mg QD (N=70)	Normal	59 (84.3)	0	0	59 (84.3)
		Abnormal NCS	9 (12.9)	2 (2.9)	0	11 (15.7)
		Abnormal CS	0	0	0	0
		Total	68 (97.1)	2 (2.9)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	61 (89.7)	0	0	61 (89.7)
		Abnormal NCS	6 (8.8)	1 (1.5)	0	7 (10.3)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	60 (88.2)	0	0	60 (88.2)
		Abnormal NCS	2 (2.9)	4 (5.9)	0	6 (8.8)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	180 (87.4)	0	0	180 (87.4)
		Abnormal NCS	17 (8.3)	7 (3.4)	0	24 (11.7)
		Abnormal CS	2 (1.0)	0	0	2 (1.0)
		Total	199 (96.6)	7 (3.4)	0	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils/Leukocytes (%)	Placebo (N=69)	Normal	55 (79.7)	0	0	55 (79.7)
		Abnormal NCS	11 (15.9)	3 (4.3)	0	14 (20.3)
		Abnormal CS	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	58 (82.9)	1 (1.4)	0	59 (84.3)
		Abnormal NCS	9 (12.9)	2 (2.9)	0	11 (15.7)
		Abnormal CS	0	0	0	0
		Total	67 (95.7)	3 (4.3)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	58 (85.3)	0	0	58 (85.3)
		Abnormal NCS	8 (11.8)	2 (2.9)	0	10 (14.7)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	53 (77.9)	2 (2.9)	0	55 (80.9)
		Abnormal NCS	11 (16.2)	2 (2.9)	0	13 (19.1)
		Abnormal CS	0	0	0	0
		Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils/Leukocytes (%)	Combined GS1-144 (N=207)	Normal	169 (82.0)	3 (1.5)	0	172 (83.5)
		Abnormal NCS	28 (13.6)	6 (2.9)	0	34 (16.5)
		Abnormal CS	0	0	0	0
		Total	197 (95.6)	9 (4.4)	0	206 (100)
Eosinophils (10^9/L)	Placebo (N=69)	Normal	62 (89.9)	1 (1.4)	0	63 (91.3)
		Abnormal NCS	5 (7.2)	1 (1.4)	0	6 (8.7)
		Abnormal CS	0	0	0	0
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	0	0	66 (94.3)
		Abnormal NCS	4 (5.7)	0	0	4 (5.7)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	0	0	62 (91.2)
		Abnormal NCS	5 (7.4)	1 (1.5)	0	6 (8.8)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Eosinophils (10^9/L)	GS1-144 30 mg BID (N=68)	Normal	61 (89.7)	0	0	61 (89.7)
		Abnormal NCS	3 (4.4)	3 (4.4)	0	6 (8.8)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	65 (95.6)	3 (4.4)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	189 (91.7)	0	0	189 (91.7)
		Abnormal NCS	12 (5.8)	4 (1.9)	0	16 (7.8)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	202 (98.1)	4 (1.9)	0	206 (100)
Basophils (10^9/L)	Placebo (N=69)	Normal	59 (85.5)	2 (2.9)	0	61 (88.4)
		Abnormal NCS	8 (11.6)	0	0	8 (11.6)
		Abnormal CS	0	0	0	0
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	1 (1.4)	0	68 (97.1)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	69 (98.6)	1 (1.4)	0	70 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Basophils (10^9/L)	GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	3 (4.4)	0	0	3 (4.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	194 (94.2)	2 (1.0)	0	196 (95.1)
		Abnormal NCS	8 (3.9)	1 (0.5)	0	9 (4.4)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	203 (98.5)	3 (1.5)	0	206 (100)
Neutrophils (10^9/L)	Placebo (N=69)	Normal	49 (71.0)	2 (2.9)	0	51 (73.9)
		Abnormal NCS	7 (10.1)	3 (4.3)	0	10 (14.5)
		Abnormal CS	6 (8.7)	2 (2.9)	0	8 (11.6)
		Total	62 (89.9)	7 (10.1)	0	69 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Neutrophils (10^9/L)	GS1-144 30 mg QD (N=70)	Normal	51 (72.9)	1 (1.4)	0	52 (74.3)
		Abnormal NCS	8 (11.4)	4 (5.7)	1 (1.4)	13 (18.6)
		Abnormal CS	3 (4.3)	2 (2.9)	0	5 (7.1)
		Total	62 (88.6)	7 (10.0)	1 (1.4)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	53 (77.9)	0	0	53 (77.9)
		Abnormal NCS	10 (14.7)	1 (1.5)	0	11 (16.2)
		Abnormal CS	2 (2.9)	1 (1.5)	1 (1.5)	4 (5.9)
		Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	52 (76.5)	1 (1.5)	0	53 (77.9)
		Abnormal NCS	11 (16.2)	2 (2.9)	0	13 (19.1)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	65 (95.6)	3 (4.4)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	156 (75.7)	2 (1.0)	0	158 (76.7)
		Abnormal NCS	29 (14.1)	7 (3.4)	1 (0.5)	37 (18.0)
		Abnormal CS	7 (3.4)	3 (1.5)	1 (0.5)	11 (5.3)
		Total	192 (93.2)	12 (5.8)	2 (1.0)	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes (10^9/L)	Placebo (N=69)	Normal	51 (73.9)	0	0	51 (73.9)
		Abnormal NCS	16 (23.2)	1 (1.4)	0	17 (24.6)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	54 (77.1)	0	0	54 (77.1)
		Abnormal NCS	12 (17.1)	4 (5.7)	0	16 (22.9)
		Abnormal CS	0	0	0	0
		Total	66 (94.3)	4 (5.7)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	51 (75.0)	1 (1.5)	0	52 (76.5)
		Abnormal NCS	10 (14.7)	4 (5.9)	0	14 (20.6)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	63 (92.6)	5 (7.4)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	50 (73.5)	3 (4.4)	0	53 (77.9)
		Abnormal NCS	11 (16.2)	2 (2.9)	0	13 (19.1)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	63 (92.6)	5 (7.4)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lymphocytes (10^9/L)	Combined GS1-144 (N=207)	Normal	155 (75.2)	4 (1.9)	0	159 (77.2)
		Abnormal NCS	33 (16.0)	10 (4.9)	0	43 (20.9)
		Abnormal CS	4 (1.9)	0	0	4 (1.9)
		Total	192 (93.2)	14 (6.8)	0	206 (100)
Monocytes (10^9/L)	Placebo (N=69)	Normal	61 (88.4)	0	0	61 (88.4)
		Abnormal NCS	6 (8.7)	0	0	6 (8.7)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	69 (100)	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	0	0	67 (95.7)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	0	0	63 (92.6)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.1.3
Shift of Hematology by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Monocytes (10^9/L)	GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	0	0	65 (95.6)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	195 (94.7)	0	0	195 (94.7)
		Abnormal NCS	8 (3.9)	1 (0.5)	0	9 (4.4)
		Abnormal CS	2 (1.0)	0	0	2 (1.0)
		Total	205 (99.5)	1 (0.5)	0	206 (100)

Data Source: Listing 16.2.8.1.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase (U/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	20.325 (8.2113)	19.785 (8.6983)	20.956 (9.3039)	19.965 (7.9273)	20.234 (8.6384)	20.257 (8.5190)
		Median	18.600	18.000	17.600	17.000	17.830	18.000
		Q1 - Q3	14.400 - 24.000	14.000 - 23.000	14.400 - 27.000	14.100 - 24.500	14.000 - 25.000	14.000 - 25.000
		Min - Max	6.00 - 46.00	9.30 - 53.00	4.00 - 45.00	10.00 - 47.81	4.00 - 53.00	4.00 - 53.00
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	20.250 (9.0918)	20.607 (13.8058)	20.471 (10.3324)	20.741 (11.8085)	20.606 (12.0263)	20.517 (11.3467)
		Median	17.920	17.350	18.500	17.000	17.650	17.700
		Q1 - Q3	14.300 - 24.000	14.000 - 21.000	13.000 - 25.400	14.000 - 23.400	14.000 - 23.900	14.000 - 24.000
		Min - Max	6.00 - 61.00	8.00 - 103.00	4.00 - 67.00	10.00 - 82.90	4.00 - 103.00	4.00 - 103.00
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.075 (7.7012)	0.822 (12.8244)	-0.175 (7.5975)	0.776 (8.7359)	0.478 (9.9687)	0.339 (9.4407)
		Median	0	0	-1.065	0	-0.300	-0.100
		Q1 - Q3	-3.600 - 2.100	-3.000 - 2.000	-3.950 - 2.500	-2.635 - 2.300	-3.180 - 2.000	-3.400 - 2.000
		Min - Max	-20.00 - 37.00	-24.00 - 93.70	-22.00 - 37.00	-26.35 - 43.20	-26.35 - 93.70	-26.35 - 93.70

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase (U/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	20.139 (9.2864)	19.600 (10.4109)	21.150 (10.5130)	26.003 (55.9993)	22.224 (33.2367)	21.707 (29.1806)
		Median	19.000	17.000	18.000	17.000	17.000	18.000
		Q1 - Q3	15.000 - 22.300	14.000 - 23.000	13.000 - 27.000	13.100 - 23.000	14.000 - 23.100	14.000 - 23.000
		Min - Max	5.00 - 63.00	2.33 - 73.00	4.00 - 60.00	7.00 - 472.10	2.33 - 472.10	2.33 - 472.10
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.319 (6.9719)	-0.338 (6.6262)	0.434 (8.1611)	6.097 (53.3224)	2.041 (31.2055)	1.455 (27.2802)
		Median	-1.000	-0.700	0	-1.000	-0.500	-0.600
		Q1 - Q3	-3.000 - 3.200	-4.000 - 3.000	-3.800 - 2.900	-3.800 - 2.000	-3.800 - 2.200	-3.380 - 2.800
		Min - Max	-21.00 - 30.00	-18.00 - 20.00	-23.00 - 27.00	-18.65 - 432.40	-23.00 - 432.40	-23.00 - 432.40
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	19.228 (8.1012)	18.523 (7.5680)	20.039 (9.8392)	22.629 (29.4810)	20.345 (18.1574)	20.068 (16.2453)
		Median	18.000	17.000	17.600	17.150	17.000	17.000
		Q1 - Q3	14.000 - 22.000	14.000 - 21.000	13.000 - 26.000	13.950 - 23.000	13.200 - 23.000	13.700 - 22.700
		Min - Max	3.00 - 49.00	8.00 - 51.00	5.00 - 50.00	8.00 - 247.20	5.00 - 247.20	3.00 - 247.20

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase (U/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.268 (6.5978)	-1.414 (5.7452)	-0.676 (7.5996)	3.352 (26.8276)	0.358 (16.2054)	-0.045 (14.4355)
		Median	-1.000	-1.000	-1.000	-0.050	-1.000	-1.000
		Q1 - Q3	-4.000 - 2.000	-4.000 - 2.000	-4.000 - 2.700	-2.000 - 1.900	-3.500 - 2.000	-3.600 - 2.000
		Min - Max	-24.00 - 24.00	-21.00 - 12.00	-25.00 - 20.30	-26.74 - 207.50	-26.74 - 207.50	-26.74 - 207.50
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	19.786 (9.8940)	19.650 (9.5549)	21.850 (20.8977)	18.678 (7.6550)	20.076 (14.0116)	20.004 (13.0940)
		Median	17.000	16.900	17.500	18.000	17.000	17.000
		Q1 - Q3	14.200 - 20.300	13.000 - 22.500	12.300 - 24.900	13.000 - 22.800	13.000 - 23.000	13.000 - 23.000
		Min - Max	6.00 - 65.00	10.00 - 56.00	3.00 - 171.00	8.00 - 51.18	3.00 - 171.00	3.00 - 171.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.802 (9.7453)	-0.316 (8.2667)	1.018 (19.9215)	-0.275 (5.3378)	0.144 (12.8208)	-0.091 (12.1199)
		Median	-2.000	-1.000	-0.950	-0.100	-1.000	-1.000
		Q1 - Q3	-5.000 - 2.900	-4.000 - 1.510	-4.300 - 2.700	-3.000 - 2.000	-4.000 - 2.000	-4.000 - 2.250
		Min - Max	-29.00 - 37.00	-25.00 - 28.00	-32.00 - 145.00	-15.00 - 19.00	-32.00 - 145.00	-32.00 - 145.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase (U/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	35.546 (122.0404)	19.735 (9.3986)	19.192 (8.0336)	18.393 (8.1063)	19.124 (8.5281)	23.214 (61.4114)
		Median	17.000	18.500	17.400	17.000	17.450	17.200
		Q1 - Q3	14.000 - 23.000	13.000 - 22.450	13.200 - 23.200	13.000 - 20.900	13.000 - 22.750	13.000 - 23.000
		Min - Max	1.40 - 999.00	8.00 - 62.00	7.00 - 46.00	9.00 - 61.70	7.00 - 62.00	1.40 - 999.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	14.958 (120.7617)	-0.231 (7.6709)	-1.468 (8.2434)	-0.560 (6.5794)	-0.747 (7.5208)	3.164 (60.6505)
		Median	0	-0.250	-0.700	-1.000	-0.500	-0.200
		Q1 - Q3	-4.000 - 3.300	-4.000 - 2.950	-4.500 - 2.400	-3.000 - 1.600	-4.000 - 2.000	-4.000 - 2.600
		Min - Max	-34.00 - 969.00	-23.00 - 24.00	-30.00 - 19.00	-27.39 - 28.10	-30.00 - 28.10	-34.00 - 969.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	18.196 (7.2845)	19.934 (10.8038)	22.201 (15.9671)	18.169 (6.3585)	20.130 (11.8343)	19.654 (10.9109)
		Median	17.000	17.000	17.450	16.300	17.000	17.000
		Q1 - Q3	14.000 - 22.050	13.000 - 21.000	14.000 - 25.500	14.000 - 21.000	13.950 - 22.500	14.000 - 22.050
		Min - Max	6.00 - 47.00	8.00 - 74.00	5.00 - 96.00	8.00 - 42.70	5.00 - 96.00	5.00 - 96.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase (U/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-2.245 (7.5224)	0.371 (8.0372)	1.369 (12.5269)	-0.784 (6.5228)	0.336 (9.4057)	-0.300 (9.0339)
		Median	-1.000	-1.000	-0.250	0	-0.650	-0.855
		Q1 - Q3	-4.500 - 1.050	-3.900 - 3.000	-2.000 - 3.900	-3.000 - 2.000	-3.000 - 3.000	-3.650 - 2.200
		Min - Max	-34.00 - 12.00	-16.00 - 30.00	-27.00 - 55.00	-28.38 - 25.80	-28.38 - 55.00	-34.00 - 55.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	19.152 (8.9062)	19.595 (9.1560)	19.243 (11.5851)	19.215 (7.3147)	19.356 (9.4933)	19.306 (9.3363)
		Median	17.000	17.000	17.000	18.000	17.000	17.000
		Q1 - Q3	13.000 - 21.500	14.000 - 21.850	12.000 - 22.800	15.000 - 23.000	14.000 - 22.200	13.110 - 22.000
		Min - Max	6.00 - 50.00	9.00 - 66.00	5.00 - 71.00	9.00 - 41.50	5.00 - 71.00	5.00 - 71.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.575 (10.1153)	0.055 (6.5026)	-1.301 (10.8598)	0.246 (7.0814)	-0.338 (8.3609)	-0.641 (8.8189)
		Median	-1.850	-0.100	-2.450	0	-0.800	-1.000
		Q1 - Q3	-5.150 - 1.385	-2.900 - 2.050	-5.500 - 1.000	-2.000 - 2.000	-3.200 - 2.000	-4.000 - 2.000
		Min - Max	-36.00 - 29.00	-16.60 - 17.00	-28.00 - 48.00	-24.28 - 24.10	-28.00 - 48.00	-36.00 - 48.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase (U/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	22.965 (5.5040)	22.513 (5.7478)	22.741 (5.5797)	21.980 (4.5527)	22.414 (5.3090)	22.552 (5.3536)
		Median	22.700	21.000	22.000	22.000	21.400	22.000
		Q1 - Q3	19.000 - 26.000	19.000 - 24.700	19.000 - 25.000	18.000 - 25.550	19.000 - 25.000	19.000 - 25.000
		Min - Max	11.00 - 43.00	13.70 - 43.00	12.80 - 42.00	13.11 - 33.00	12.80 - 43.00	11.00 - 43.00
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	23.132 (6.6195)	23.887 (10.2143)	23.238 (7.1171)	22.001 (6.0917)	23.050 (8.0259)	23.071 (7.6857)
		Median	22.000	21.050	22.000	20.500	21.000	21.200
		Q1 - Q3	19.000 - 25.000	19.000 - 25.000	18.450 - 25.750	18.000 - 23.200	19.000 - 25.000	19.000 - 25.000
		Min - Max	13.90 - 46.00	14.00 - 92.60	12.60 - 54.00	14.00 - 52.10	12.60 - 92.60	12.60 - 92.60
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.167 (5.3089)	1.374 (10.4372)	0.634 (4.7975)	0.022 (4.6856)	0.683 (7.1883)	0.554 (6.7605)
		Median	-0.500	0.215	0.170	0	0	0
		Q1 - Q3	-2.600 - 2.000	-2.000 - 3.100	-2.150 - 2.800	-2.000 - 1.000	-2.000 - 2.000	-2.000 - 2.000
		Min - Max	-15.00 - 24.00	-16.00 - 78.90	-11.60 - 17.00	-7.80 - 27.30	-16.00 - 78.90	-16.00 - 78.90

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase (U/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	22.209 (4.8191)	22.502 (6.4307)	23.392 (6.1884)	33.422 (88.1351)	26.400 (50.8819)	25.360 (44.1941)
		Median	22.000	21.000	22.860	21.000	22.000	22.000
		Q1 - Q3	19.000 - 25.000	19.000 - 25.000	18.600 - 26.600	18.000 - 26.000	18.600 - 26.000	18.700 - 25.700
		Min - Max	13.00 - 37.00	15.00 - 57.00	12.70 - 43.00	13.00 - 741.60	12.70 - 741.60	12.70 - 741.60
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.835 (4.5120)	-0.138 (4.6031)	0.808 (4.5812)	11.487 (87.3434)	4.011 (50.3430)	2.809 (43.7328)
		Median	0	0	0.400	0	0	0
		Q1 - Q3	-3.000 - 1.800	-2.100 - 2.000	-2.000 - 3.000	-2.000 - 1.800	-2.000 - 2.000	-2.100 - 2.000
		Min - Max	-14.40 - 15.00	-16.00 - 14.00	-14.00 - 13.00	-7.00 - 713.90	-16.00 - 713.90	-16.00 - 713.90
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	21.849 (6.5814)	22.432 (5.5145)	22.309 (6.6577)	22.069 (5.8259)	22.275 (5.9883)	22.169 (6.1308)
		Median	21.000	21.300	20.700	20.900	21.000	21.000
		Q1 - Q3	17.700 - 24.000	19.000 - 25.000	18.000 - 24.700	18.800 - 25.500	18.800 - 25.000	18.000 - 25.000
		Min - Max	4.80 - 46.00	15.00 - 42.00	13.00 - 48.00	12.00 - 43.60	12.00 - 48.00	4.80 - 48.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase (U/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.242 (4.9710)	-0.208 (4.7005)	-0.275 (4.9785)	0.449 (4.6415)	-0.020 (4.7639)	-0.323 (4.8356)
		Median	-0.400	-1.000	-0.700	-0.050	-0.750	-0.700
		Q1 - Q3	-3.100 - 1.500	-2.100 - 1.500	-3.000 - 1.200	-2.350 - 2.300	-2.750 - 2.000	-3.000 - 2.000
		Min - Max	-18.80 - 11.00	-16.00 - 15.00	-11.60 - 18.40	-8.00 - 15.90	-16.00 - 18.40	-18.80 - 18.40
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	22.959 (6.6128)	22.543 (6.7436)	22.595 (9.6329)	21.380 (4.4469)	22.189 (7.2720)	22.380 (7.1096)
		Median	22.000	20.950	20.000	20.000	20.100	21.000
		Q1 - Q3	18.200 - 25.000	18.500 - 24.950	18.300 - 24.000	18.000 - 24.300	18.000 - 24.800	18.000 - 25.000
		Min - Max	14.00 - 49.00	14.00 - 48.00	11.40 - 83.00	14.28 - 34.00	11.40 - 83.00	11.40 - 83.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.205 (6.0179)	-0.138 (6.1212)	0.018 (9.6819)	-0.144 (3.4582)	-0.088 (6.9054)	-0.117 (6.6852)
		Median	0	-0.440	-1.000	0	-0.070	0
		Q1 - Q3	-4.000 - 2.300	-3.000 - 2.300	-4.000 - 1.900	-1.700 - 2.500	-3.000 - 2.000	-3.000 - 2.000
		Min - Max	-19.00 - 20.00	-18.00 - 25.30	-12.00 - 65.00	-8.00 - 7.80	-18.00 - 65.00	-19.00 - 65.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase (U/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	28.848 (51.4097)	22.605 (6.7516)	22.144 (5.0670)	21.817 (5.4929)	22.199 (5.8127)	23.855 (26.1575)
		Median	21.000	20.250	21.000	21.000	21.000	21.000
		Q1 - Q3	19.000 - 25.000	18.850 - 24.450	19.000 - 25.000	17.000 - 25.000	18.050 - 25.000	18.600 - 25.000
		Min - Max	6.40 - 433.00	15.00 - 51.00	12.80 - 36.00	14.80 - 40.70	12.80 - 51.00	6.40 - 433.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	5.684 (50.8922)	-0.076 (5.6035)	-0.396 (5.2412)	0.293 (3.7680)	-0.063 (4.9393)	1.368 (25.7301)
		Median	-1.000	-1.000	0	0	0	0
		Q1 - Q3	-4.000 - 3.000	-3.000 - 3.000	-2.700 - 2.000	-1.700 - 2.000	-2.000 - 2.000	-3.000 - 2.100
		Min - Max	-23.00 - 405.00	-16.00 - 16.00	-16.00 - 15.00	-10.00 - 16.60	-16.00 - 16.60	-23.00 - 405.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	21.908 (5.6302)	22.665 (7.9522)	22.976 (7.4795)	20.592 (4.2804)	22.103 (6.8542)	22.055 (6.5642)
		Median	21.350	21.000	21.745	19.300	21.000	21.000
		Q1 - Q3	19.000 - 24.450	18.000 - 26.000	18.100 - 24.400	18.000 - 22.900	18.000 - 24.000	18.010 - 24.000
		Min - Max	9.90 - 49.00	12.00 - 68.00	11.60 - 54.00	13.00 - 39.00	11.60 - 68.00	9.90 - 68.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase (U/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-1.181 (5.1321)	0.168 (5.3836)	0.398 (5.9702)	-0.932 (3.6188)	-0.108 (5.1173)	-0.372 (5.1320)
		Median	-1.000	-0.500	0	-1.000	-0.550	-0.990
		Q1 - Q3	-4.300 - 1.000	-3.000 - 3.000	-3.000 - 2.700	-3.000 - 1.500	-3.000 - 2.000	-3.000 - 2.000
		Min - Max	-20.00 - 14.00	-12.00 - 25.00	-18.00 - 22.00	-10.00 - 8.00	-18.00 - 25.00	-20.00 - 25.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	22.334 (5.4425)	22.285 (6.0089)	21.618 (5.7450)	20.874 (4.2654)	21.610 (5.4199)	21.788 (5.4239)
		Median	22.000	21.000	20.350	20.100	20.800	21.000
		Q1 - Q3	18.000 - 26.000	18.900 - 24.000	18.000 - 23.400	17.300 - 23.000	18.000 - 23.300	18.000 - 24.000
		Min - Max	13.00 - 38.00	14.00 - 50.00	13.20 - 45.00	15.00 - 33.30	13.20 - 50.00	13.00 - 50.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.946 (5.9425)	-0.174 (4.7780)	-0.929 (5.6398)	-0.634 (3.7617)	-0.574 (4.7883)	-0.665 (5.0859)
		Median	-0.700	0	-1.000	-1.000	-1.000	-1.000
		Q1 - Q3	-4.000 - 2.500	-3.200 - 3.000	-3.700 - 1.200	-3.000 - 1.500	-3.000 - 2.000	-3.400 - 2.000
		Min - Max	-23.00 - 18.00	-13.00 - 12.00	-20.00 - 20.00	-10.00 - 13.20	-20.00 - 20.00	-23.00 - 20.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Gamma Glutamyl Transferase (U/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	20.242 (11.4106)	20.138 (10.4014)	24.387 (13.3406)	22.735 (20.3916)	22.407 (15.2750)	21.866 (14.4173)
		Median	17.000	17.100	21.000	16.535	18.000	17.380
		Q1 - Q3	12.000 - 24.000	13.000 - 23.000	15.100 - 30.300	12.650 - 23.000	14.000 - 26.000	13.200 - 25.350
		Min - Max	7.16 - 69.00	6.00 - 52.00	9.00 - 71.50	9.00 - 124.20	6.00 - 124.20	6.00 - 124.20
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	19.400 (10.7453)	23.614 (35.1430)	23.595 (14.5017)	25.969 (40.7604)	24.385 (32.0728)	23.134 (28.3366)
		Median	17.000	17.400	18.300	18.000	18.000	18.000
		Q1 - Q3	12.000 - 22.000	12.000 - 24.000	15.000 - 29.000	12.800 - 25.450	13.000 - 25.400	13.000 - 25.000
		Min - Max	7.74 - 63.00	6.00 - 302.00	9.00 - 72.00	7.00 - 334.30	6.00 - 334.30	6.00 - 334.30
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.842 (6.8911)	3.476 (33.0069)	-0.563 (7.4694)	3.235 (28.5072)	2.063 (25.5725)	1.334 (22.4199)
		Median	0	0	-1.000	0	0	0
		Q1 - Q3	-3.000 - 1.300	-2.000 - 1.000	-3.000 - 1.000	-1.100 - 1.850	-2.000 - 1.100	-2.300 - 1.300
		Min - Max	-36.00 - 23.00	-16.00 - 274.00	-20.00 - 34.00	-32.50 - 228.20	-32.50 - 274.00	-36.00 - 274.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Gamma Glutamyl Transferase (U/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	18.397 (8.3020)	19.198 (9.1838)	23.583 (15.3141)	27.562 (54.9310)	23.406 (33.2069)	22.163 (29.1488)
		Median	16.000	17.000	19.000	16.000	17.000	17.000
		Q1 - Q3	12.000 - 23.700	13.000 - 23.740	14.600 - 28.000	12.000 - 24.000	13.000 - 24.000	13.000 - 24.000
		Min - Max	6.00 - 46.00	7.00 - 54.00	10.00 - 92.00	8.00 - 454.50	7.00 - 454.50	6.00 - 454.50
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.712 (6.7155)	-0.826 (4.6288)	-0.054 (9.7456)	4.816 (43.5034)	1.291 (25.7460)	0.546 (22.5945)
		Median	-0.200	0	-0.900	0	0	0
		Q1 - Q3	-3.000 - 1.060	-2.000 - 1.400	-3.000 - 1.100	-2.600 - 2.000	-2.700 - 2.000	-2.900 - 1.500
		Min - Max	-35.00 - 10.00	-23.00 - 6.60	-29.00 - 42.00	-37.00 - 348.40	-37.00 - 348.40	-37.00 - 348.40
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	18.707 (8.9694)	19.099 (11.1986)	23.249 (13.2793)	26.855 (50.7341)	22.971 (30.4349)	21.913 (26.8090)
		Median	15.700	16.000	19.000	15.950	17.000	17.000
		Q1 - Q3	12.000 - 23.000	13.000 - 22.000	14.790 - 28.000	11.900 - 23.000	13.000 - 23.000	13.000 - 23.000
		Min - Max	8.00 - 50.00	6.00 - 67.00	9.00 - 79.70	6.00 - 404.80	6.00 - 404.80	6.00 - 404.80

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Gamma Glutamyl Transferase (U/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.495 (7.5829)	-0.925 (6.2113)	-0.388 (6.6308)	4.578 (39.0105)	1.016 (22.7068)	0.393 (20.0616)
		Median	-1.000	-1.000	-0.690	-0.200	-0.600	-0.745
		Q1 - Q3	-3.000 - 1.360	-3.000 - 1.100	-2.900 - 2.000	-2.950 - 1.150	-2.900 - 1.800	-3.000 - 1.680
		Min - Max	-35.00 - 22.80	-20.00 - 27.00	-24.00 - 19.00	-43.10 - 298.70	-43.10 - 298.70	-43.10 - 298.70
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	19.072 (11.8642)	19.485 (11.3967)	23.055 (13.5902)	20.252 (14.7602)	20.926 (13.3026)	20.466 (12.9633)
		Median	15.000	16.750	19.510	15.000	17.000	17.000
		Q1 - Q3	12.000 - 21.400	12.000 - 25.000	14.000 - 25.900	11.200 - 23.000	12.600 - 25.000	12.000 - 24.000
		Min - Max	7.21 - 75.00	5.00 - 81.00	8.00 - 78.00	8.00 - 82.00	5.00 - 82.00	5.00 - 82.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-1.135 (10.0306)	-0.532 (7.4051)	-0.622 (9.6540)	-0.695 (12.4829)	-0.614 (9.9473)	-0.743 (9.9513)
		Median	-1.000	0	-0.015	-1.000	-0.100	-0.650
		Q1 - Q3	-3.000 - 2.000	-2.500 - 2.000	-3.000 - 2.800	-2.000 - 1.000	-3.000 - 2.000	-3.000 - 2.000
		Min - Max	-42.00 - 36.90	-22.00 - 41.00	-25.00 - 34.00	-53.60 - 62.00	-53.60 - 62.00	-53.60 - 62.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Gamma Glutamyl Transferase (U/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	21.834 (19.1019)	20.080 (12.2798)	23.121 (13.4701)	20.860 (19.0357)	21.339 (15.1082)	21.463 (16.1573)
		Median	15.700	17.000	19.000	16.000	17.000	17.000
		Q1 - Q3	12.000 - 22.000	13.000 - 25.100	15.000 - 26.700	11.700 - 22.000	13.000 - 24.350	12.400 - 24.000
		Min - Max	7.00 - 116.00	7.00 - 85.00	9.00 - 71.00	7.00 - 139.00	7.00 - 139.00	7.00 - 139.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.628 (14.5038)	0.063 (7.8833)	-0.397 (8.5049)	-0.087 (7.4583)	-0.138 (7.9257)	0.302 (9.9739)
		Median	-0.600	0	0	0	0	0
		Q1 - Q3	-3.000 - 2.300	-2.000 - 2.000	-2.000 - 2.300	-2.000 - 1.200	-2.000 - 2.000	-2.000 - 2.000
		Min - Max	-20.00 - 94.00	-21.00 - 45.00	-26.00 - 38.00	-25.00 - 33.00	-26.00 - 45.00	-26.00 - 94.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	19.531 (11.8614)	20.603 (14.4146)	25.251 (24.3588)	20.466 (15.7014)	22.124 (18.7480)	21.486 (17.3236)
		Median	15.900	17.000	19.490	15.000	17.000	17.000
		Q1 - Q3	11.000 - 22.000	12.000 - 24.800	13.400 - 24.300	12.000 - 23.900	12.620 - 24.000	12.000 - 24.000
		Min - Max	8.00 - 60.00	7.00 - 78.00	8.00 - 156.00	7.00 - 105.70	7.00 - 156.00	7.00 - 156.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Gamma Glutamyl Transferase (U/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.647 (6.7003)	0.764 (8.0298)	1.574 (18.4541)	-0.481 (6.2947)	0.637 (12.1920)	0.321 (11.0969)
		Median	0	-0.380	0	0	0	0
		Q1 - Q3	-3.000 - 2.000	-3.000 - 3.000	-4.000 - 2.000	-2.000 - 1.400	-2.895 - 2.000	-3.000 - 2.000
		Min - Max	-20.00 - 20.00	-15.00 - 33.00	-32.00 - 118.00	-22.71 - 16.00	-32.00 - 118.00	-32.00 - 118.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	19.840 (15.8983)	19.057 (10.1706)	23.702 (20.5768)	20.373 (15.0738)	21.034 (15.8601)	20.741 (15.8472)
		Median	15.100	16.380	18.000	16.000	17.000	17.000
		Q1 - Q3	11.500 - 22.000	12.000 - 22.500	13.100 - 24.400	12.000 - 22.000	12.200 - 22.500	12.000 - 22.000
		Min - Max	8.00 - 118.00	6.00 - 54.00	6.40 - 132.00	7.00 - 91.00	6.00 - 132.00	6.00 - 132.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.326 (14.6226)	-0.791 (5.2750)	0.222 (15.9230)	-0.573 (6.9794)	-0.382 (10.4497)	-0.368 (11.5814)
		Median	-1.000	-0.500	-1.000	0	-0.600	-0.900
		Q1 - Q3	-4.000 - 1.355	-4.000 - 1.415	-4.000 - 1.000	-2.000 - 2.000	-3.000 - 1.100	-3.000 - 1.200
		Min - Max	-37.00 - 96.00	-17.00 - 22.00	-27.00 - 99.00	-33.20 - 22.00	-33.20 - 99.00	-37.00 - 99.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase (U/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	82.417 (19.0461)	82.613 (18.6017)	80.994 (18.8175)	79.967 (18.2839)	81.204 (18.5124)	81.507 (18.6198)
		Median	82.000	83.000	79.000	80.000	80.000	80.450
		Q1 - Q3	70.000 - 93.000	70.000 - 90.000	68.000 - 89.000	66.750 - 94.000	67.000 - 91.000	68.000 - 91.500
		Min - Max	34.00 - 141.80	50.00 - 139.00	43.00 - 130.30	42.00 - 130.00	42.00 - 139.00	34.00 - 141.80
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	81.765 (17.3978)	84.813 (23.8523)	79.502 (17.8197)	79.273 (19.0025)	81.231 (20.4924)	81.365 (19.7322)
		Median	83.000	81.500	77.700	77.000	79.200	80.000
		Q1 - Q3	70.000 - 93.000	68.000 - 96.000	68.000 - 91.250	65.000 - 93.350	67.000 - 92.100	67.310 - 92.700
		Min - Max	36.00 - 120.80	54.00 - 206.00	41.00 - 119.00	42.00 - 140.10	41.00 - 206.00	36.00 - 206.00
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.652 (8.1657)	2.201 (15.9600)	-1.316 (7.3523)	-0.694 (9.4105)	0.084 (11.6072)	-0.100 (10.8374)
		Median	0.900	0.500	-2.000	-1.000	-0.600	-0.200
		Q1 - Q3	-4.000 - 4.000	-4.000 - 4.000	-5.300 - 2.220	-6.000 - 3.900	-5.000 - 4.000	-5.000 - 4.000
		Min - Max	-29.00 - 15.00	-23.00 - 114.00	-21.80 - 18.00	-27.00 - 46.10	-27.00 - 114.00	-29.00 - 114.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase (U/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	79.985 (17.9342)	81.267 (19.1097)	79.996 (18.3492)	79.030 (18.9438)	80.109 (18.7361)	80.078 (18.5075)
		Median	77.000	79.000	78.000	77.400	78.000	78.000
		Q1 - Q3	68.700 - 91.000	69.000 - 91.000	65.000 - 95.500	67.000 - 92.000	67.000 - 92.000	67.000 - 91.000
		Min - Max	36.00 - 123.00	48.00 - 143.00	46.00 - 119.00	35.00 - 160.60	35.00 - 160.60	35.00 - 160.60
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-2.287 (8.4205)	-1.210 (8.3267)	-0.729 (7.7229)	-0.728 (12.0352)	-0.892 (9.4977)	-1.238 (9.2466)
		Median	-1.000	-1.000	0	-1.000	-0.770	-1.000
		Q1 - Q3	-8.000 - 2.000	-5.600 - 4.000	-6.000 - 3.000	-7.500 - 3.000	-6.000 - 4.000	-6.500 - 3.000
		Min - Max	-25.70 - 17.00	-29.00 - 18.00	-15.10 - 24.00	-38.00 - 66.60	-38.00 - 66.60	-38.00 - 66.60
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	80.765 (18.4102)	81.873 (19.6485)	79.945 (18.9327)	79.448 (18.7669)	80.451 (19.0634)	80.529 (18.8695)
		Median	81.850	79.000	79.000	79.900	79.000	79.900
		Q1 - Q3	68.000 - 92.000	69.000 - 93.000	65.000 - 93.000	66.000 - 91.500	66.350 - 92.000	67.000 - 92.000
		Min - Max	31.00 - 123.00	51.00 - 154.00	48.00 - 128.92	38.00 - 147.20	38.00 - 154.00	31.00 - 154.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase (U/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.587 (9.2386)	-0.603 (10.1935)	-0.781 (8.9513)	-0.009 (11.9833)	-0.472 (10.3754)	-0.749 (10.0998)
		Median	-1.000	-1.000	0	-1.500	-1.000	-1.000
		Q1 - Q3	-6.000 - 2.000	-6.000 - 5.200	-5.000 - 5.000	-6.600 - 8.000	-6.000 - 6.000	-6.000 - 5.200
		Min - Max	-28.60 - 21.30	-36.00 - 20.00	-23.90 - 30.10	-31.00 - 53.20	-36.00 - 53.20	-36.00 - 53.20
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	81.084 (20.1746)	82.120 (19.8169)	79.723 (17.1107)	76.894 (17.7763)	79.646 (18.3263)	80.002 (18.7724)
		Median	80.000	81.000	79.500	76.900	79.000	79.050
		Q1 - Q3	68.000 - 93.580	68.000 - 89.500	66.000 - 90.400	65.000 - 87.040	66.000 - 89.000	67.000 - 90.000
		Min - Max	32.00 - 133.00	52.00 - 151.00	49.00 - 119.00	36.00 - 132.00	36.00 - 151.00	32.00 - 151.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-1.410 (11.9499)	-0.064 (11.4244)	-1.029 (8.3380)	-2.332 (9.4574)	-1.113 (9.8401)	-1.186 (10.3801)
		Median	0	0.920	-1.500	-1.000	-0.760	-0.250
		Q1 - Q3	-8.000 - 6.000	-5.000 - 5.650	-6.000 - 5.000	-8.000 - 3.000	-6.000 - 4.000	-6.000 - 5.000
		Min - Max	-31.00 - 34.00	-33.00 - 37.00	-21.70 - 16.00	-31.00 - 25.00	-33.00 - 37.00	-33.00 - 37.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase (U/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	80.607 (19.3934)	82.883 (20.0332)	79.640 (17.5297)	77.667 (16.4023)	80.131 (18.1375)	80.250 (18.4215)
		Median	79.000	82.000	77.000	75.400	78.600	78.700
		Q1 - Q3	68.000 - 93.000	67.500 - 91.500	67.000 - 91.000	67.000 - 91.200	67.000 - 91.100	67.000 - 91.900
		Min - Max	35.00 - 137.00	51.00 - 156.00	49.00 - 121.00	45.00 - 114.10	45.00 - 156.00	35.00 - 156.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.888 (12.4404)	0.700 (11.1766)	-0.569 (8.5844)	-1.559 (9.5679)	-0.447 (9.8527)	-0.806 (10.5495)
		Median	-2.000	0.765	-1.000	-1.000	-0.100	-1.000
		Q1 - Q3	-8.000 - 4.100	-4.000 - 8.000	-6.000 - 3.300	-9.600 - 4.800	-6.350 - 6.000	-7.000 - 5.200
		Min - Max	-35.00 - 26.00	-46.00 - 22.80	-23.00 - 23.00	-34.00 - 23.50	-46.00 - 23.50	-46.00 - 26.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	80.636 (17.0632)	84.336 (21.3370)	79.553 (18.7256)	78.345 (16.3942)	80.800 (19.0578)	80.760 (18.5547)
		Median	80.500	83.000	73.000	79.600	80.000	80.000
		Q1 - Q3	70.000 - 92.250	68.000 - 95.600	68.000 - 90.000	65.000 - 91.000	67.500 - 91.650	68.000 - 92.000
		Min - Max	30.00 - 119.00	48.00 - 164.00	47.00 - 128.00	38.00 - 111.00	38.00 - 164.00	30.00 - 164.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase (U/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-1.382 (9.2459)	1.837 (11.7402)	-1.198 (9.4100)	-0.881 (8.9312)	-0.059 (10.1696)	-0.385 (9.9491)
		Median	0	3.000	-1.000	-2.000	-0.545	-0.165
		Q1 - Q3	-5.500 - 4.000	-4.000 - 7.000	-5.000 - 2.000	-6.700 - 4.000	-6.000 - 6.000	-6.000 - 5.000
		Min - Max	-29.90 - 21.90	-31.00 - 36.20	-26.00 - 40.00	-19.19 - 28.00	-31.00 - 40.00	-31.00 - 40.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	80.651 (18.2064)	82.115 (20.7030)	78.652 (17.2627)	77.749 (16.0676)	79.559 (18.1825)	79.826 (18.1594)
		Median	79.000	81.000	76.000	78.000	78.000	78.000
		Q1 - Q3	70.720 - 91.000	68.500 - 89.550	68.300 - 92.000	66.000 - 87.000	67.620 - 89.100	69.000 - 90.000
		Min - Max	32.00 - 130.00	48.00 - 162.00	45.00 - 114.45	43.00 - 127.00	43.00 - 162.00	32.00 - 162.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.950 (9.3982)	-0.678 (11.8018)	-1.539 (10.2463)	-2.017 (10.2444)	-1.394 (10.7674)	-1.531 (10.4335)
		Median	-2.000	-0.500	-3.000	-2.000	-1.600	-2.000
		Q1 - Q3	-8.900 - 3.500	-5.890 - 4.500	-6.000 - 2.900	-8.000 - 3.000	-7.000 - 4.000	-7.000 - 4.000
		Min - Max	-25.00 - 19.00	-42.00 - 28.00	-34.80 - 40.00	-22.16 - 49.00	-42.00 - 49.00	-42.00 - 49.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lactate Dehydrogenase (U/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	189.492 (29.8057)	187.342 (29.2605)	186.424 (32.9241)	183.167 (29.8815)	185.664 (30.6304)	186.621 (30.4178)
		Median	185.000	182.500	181.300	184.500	183.000	183.080
		Q1 - Q3	170.000 - 207.000	168.000 - 204.000	168.000 - 199.200	161.000 - 200.000	165.600 - 202.000	166.000 - 204.000
		Min - Max	127.00 - 264.00	130.00 - 288.00	129.20 - 263.00	123.89 - 267.00	123.89 - 288.00	123.89 - 288.00
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	188.622 (46.7023)	185.282 (29.2021)	183.353 (34.1231)	186.908 (33.6122)	185.182 (32.2324)	186.045 (36.3432)
		Median	182.940	180.500	179.700	185.500	181.500	182.000
		Q1 - Q3	160.000 - 201.000	165.000 - 201.000	160.000 - 204.000	163.850 - 204.150	163.200 - 203.000	163.000 - 203.000
		Min - Max	130.00 - 460.00	128.00 - 270.00	123.00 - 274.00	124.00 - 319.00	123.00 - 319.00	123.00 - 460.00
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.870 (36.8902)	-2.059 (23.2113)	-2.975 (23.2932)	3.741 (21.3752)	-0.447 (22.7337)	-0.553 (26.9155)
		Median	-6.000	-3.035	-2.000	0.635	-1.375	-2.000
		Q1 - Q3	-18.000 - 6.500	-13.000 - 7.000	-16.500 - 10.000	-13.050 - 13.695	-13.200 - 11.000	-15.000 - 9.000
		Min - Max	-54.00 - 233.00	-90.00 - 61.00	-86.00 - 76.00	-26.00 - 56.00	-90.00 - 76.00	-90.00 - 233.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lactate Dehydrogenase (U/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	184.502 (28.2134)	187.034 (24.8393)	181.641 (34.6438)	197.871 (100.3831)	188.831 (62.7503)	187.756 (56.1754)
		Median	184.000	186.100	175.000	182.800	181.000	181.900
		Q1 - Q3	162.000 - 202.000	171.000 - 198.000	162.500 - 195.000	165.000 - 204.000	165.000 - 201.000	165.000 - 201.000
		Min - Max	119.30 - 254.00	138.00 - 254.00	107.10 - 294.00	136.00 - 963.00	107.10 - 963.00	107.10 - 963.00
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-5.646 (21.5775)	-0.748 (22.9940)	-4.766 (22.4354)	14.686 (95.2861)	3.020 (58.1300)	0.870 (51.6310)
		Median	-7.000	2.000	-4.000	3.000	-1.000	-2.000
		Q1 - Q3	-21.000 - 7.000	-8.000 - 12.000	-17.600 - 6.000	-13.000 - 13.330	-13.450 - 10.700	-15.000 - 10.000
		Min - Max	-52.00 - 48.00	-108.00 - 48.00	-76.00 - 60.00	-44.10 - 756.00	-108.00 - 756.00	-108.00 - 756.00
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	185.845 (25.8447)	186.958 (28.9798)	180.373 (32.0498)	180.011 (28.6397)	182.529 (29.9621)	183.352 (28.9834)
		Median	184.500	183.000	176.000	179.050	178.500	181.000
		Q1 - Q3	169.000 - 197.000	168.000 - 209.000	157.000 - 195.000	156.800 - 194.100	159.000 - 200.000	162.000 - 199.000
		Min - Max	140.40 - 269.00	127.00 - 268.00	124.10 - 266.00	119.00 - 268.00	119.00 - 268.00	119.00 - 269.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lactate Dehydrogenase (U/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-4.926 (25.5425)	-0.823 (25.7010)	-6.034 (21.8673)	-2.019 (18.0456)	-2.952 (22.1911)	-3.442 (23.0338)
		Median	-3.450	0	-3.100	-2.000	-2.000	-2.000
		Q1 - Q3	-23.000 - 9.000	-11.190 - 12.000	-19.000 - 4.000	-14.050 - 7.500	-13.530 - 8.000	-15.000 - 8.000
		Min - Max	-57.40 - 92.00	-101.00 - 97.00	-83.00 - 56.00	-43.00 - 47.00	-101.00 - 97.00	-101.00 - 97.00
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	182.416 (31.3733)	186.910 (27.5442)	176.747 (30.6427)	178.379 (28.7377)	180.777 (29.1950)	181.184 (29.6974)
		Median	179.000	183.500	170.055	177.000	178.000	178.000
		Q1 - Q3	159.000 - 198.000	169.000 - 201.050	158.000 - 195.000	157.000 - 196.000	160.000 - 196.100	160.000 - 197.000
		Min - Max	121.90 - 265.00	126.00 - 262.00	125.00 - 247.00	118.53 - 263.00	118.53 - 263.00	118.53 - 265.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-7.287 (24.3799)	-0.624 (24.5415)	-10.303 (22.7094)	-3.255 (15.0200)	-4.708 (21.5704)	-5.348 (22.2801)
		Median	-6.000	-0.850	-6.650	-4.000	-4.000	-4.500
		Q1 - Q3	-24.000 - 7.000	-11.500 - 15.000	-19.000 - 1.330	-14.000 - 8.000	-15.000 - 8.000	-18.000 - 8.000
		Min - Max	-65.00 - 56.00	-93.00 - 56.00	-110.00 - 34.00	-40.00 - 27.00	-110.00 - 56.00	-110.00 - 56.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lactate Dehydrogenase (U/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	189.282 (70.1367)	185.081 (28.1855)	184.088 (37.8259)	179.898 (30.1406)	183.086 (32.1931)	184.629 (44.6696)
		Median	183.000	183.000	181.000	176.100	181.500	182.000
		Q1 - Q3	162.000 - 199.000	164.500 - 197.000	162.000 - 203.000	160.000 - 196.700	161.500 - 198.000	162.000 - 198.000
		Min - Max	126.00 - 702.00	133.10 - 299.00	119.30 - 376.00	115.25 - 267.00	115.25 - 376.00	115.25 - 702.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.421 (62.1246)	-2.453 (25.5326)	-3.562 (34.0170)	-1.737 (23.3436)	-2.591 (27.8853)	-2.050 (39.1676)
		Median	-11.000	-0.500	-6.000	-5.000	-5.000	-6.000
		Q1 - Q3	-19.000 - 1.000	-13.090 - 13.500	-14.110 - 3.000	-15.900 - 8.700	-14.950 - 8.850	-16.600 - 7.000
		Min - Max	-65.00 - 452.00	-114.00 - 76.00	-92.00 - 204.00	-37.00 - 102.00	-114.00 - 204.00	-114.00 - 452.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	180.084 (28.2912)	186.042 (27.7059)	181.699 (32.4409)	180.020 (29.9459)	182.644 (30.0371)	182.014 (29.5837)
		Median	177.000	182.000	177.500	179.000	180.500	180.000
		Q1 - Q3	161.500 - 200.000	169.000 - 202.000	161.000 - 197.000	158.500 - 202.000	162.000 - 201.000	162.000 - 201.000
		Min - Max	122.00 - 254.00	138.00 - 257.00	128.60 - 272.00	110.52 - 270.00	110.52 - 272.00	110.52 - 272.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Lactate Dehydrogenase (U/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-8.676 (21.3921)	-1.619 (24.2072)	-5.350 (22.6487)	-1.614 (18.3898)	-2.874 (21.9084)	-4.302 (21.8851)
		Median	-9.050	-1.000	-4.250	-4.000	-3.000	-4.250
		Q1 - Q3	-21.000 - 3.000	-10.000 - 13.000	-17.000 - 6.700	-13.000 - 11.000	-13.700 - 9.000	-16.570 - 7.000
		Min - Max	-69.00 - 69.00	-110.00 - 55.00	-84.00 - 71.00	-39.00 - 46.00	-110.00 - 71.00	-110.00 - 71.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	182.695 (30.5836)	183.109 (27.7560)	182.268 (29.7614)	181.039 (28.5160)	182.165 (28.5488)	182.295 (29.0018)
		Median	180.250	185.000	177.500	180.000	180.000	180.000
		Q1 - Q3	163.000 - 199.500	161.000 - 197.500	161.000 - 198.000	160.000 - 198.000	161.000 - 198.000	161.000 - 198.000
		Min - Max	123.00 - 250.00	125.00 - 296.00	127.10 - 267.00	116.00 - 266.00	116.00 - 296.00	116.00 - 296.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-7.143 (19.6617)	-4.801 (25.1325)	-4.721 (23.2159)	-1.119 (15.3715)	-3.597 (21.7326)	-4.467 (21.2616)
		Median	-7.000	-1.700	-4.550	-1.000	-2.000	-3.000
		Q1 - Q3	-22.000 - 3.500	-12.000 - 7.400	-16.000 - 9.000	-13.000 - 10.000	-14.000 - 8.000	-16.000 - 7.000
		Min - Max	-39.00 - 60.00	-120.00 - 73.00	-79.00 - 37.00	-34.90 - 39.00	-120.00 - 73.00	-120.00 - 73.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Bilirubin (umol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	12.193 (4.1586)	10.678 (3.1144)	12.170 (4.0036)	12.208 (4.5724)	11.678 (3.9816)	11.807 (4.0251)
		Median	11.340	10.350	11.900	11.150	11.100	11.190
		Q1 - Q3	9.700 - 13.900	8.870 - 12.400	9.600 - 14.070	8.650 - 15.720	8.900 - 13.900	9.000 - 13.900
		Min - Max	4.30 - 27.90	5.30 - 19.00	4.80 - 26.60	5.18 - 27.20	4.80 - 27.20	4.30 - 27.90
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	12.041 (4.3815)	10.336 (3.6691)	11.860 (4.2166)	11.898 (3.5383)	11.355 (3.8692)	11.527 (4.0067)
		Median	11.000	9.700	11.100	11.400	10.900	10.900
		Q1 - Q3	9.200 - 14.400	7.700 - 13.000	9.000 - 13.750	9.100 - 14.750	8.400 - 13.700	8.500 - 13.700
		Min - Max	5.50 - 31.70	3.90 - 22.10	5.20 - 27.20	5.20 - 21.00	3.90 - 27.20	3.90 - 31.70
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.152 (3.3347)	-0.342 (2.4750)	-0.314 (2.7573)	-0.310 (3.0987)	-0.322 (2.7722)	-0.280 (2.9181)
		Median	-0.600	-0.350	-0.150	-0.200	-0.200	-0.200
		Q1 - Q3	-1.900 - 1.700	-2.050 - 1.300	-1.900 - 1.550	-2.400 - 1.600	-2.100 - 1.400	-2.100 - 1.600
		Min - Max	-7.90 - 8.30	-5.80 - 6.40	-7.60 - 6.30	-8.20 - 7.20	-8.20 - 7.20	-8.20 - 8.30

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Bilirubin (umol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	11.095 (3.1532)	10.394 (3.5831)	12.058 (4.3917)	12.563 (5.4574)	11.659 (4.6070)	11.519 (4.2939)
		Median	11.200	9.700	11.300	11.100	10.910	11.000
		Q1 - Q3	8.900 - 12.600	7.700 - 12.900	8.500 - 14.600	9.200 - 15.100	8.300 - 14.400	8.500 - 13.900
		Min - Max	5.10 - 19.00	4.20 - 18.90	4.90 - 27.70	5.10 - 42.00	4.20 - 42.00	4.20 - 42.00
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.044 (3.6234)	-0.310 (2.3396)	-0.110 (3.2433)	0.307 (4.9005)	-0.040 (3.6321)	-0.289 (3.6492)
		Median	-0.800	-0.300	-0.200	-0.200	-0.200	-0.200
		Q1 - Q3	-2.600 - 1.400	-1.600 - 1.100	-2.100 - 2.000	-1.600 - 1.540	-1.600 - 1.540	-1.900 - 1.500
		Min - Max	-10.60 - 5.87	-7.40 - 5.00	-7.08 - 8.70	-8.70 - 31.60	-8.70 - 31.60	-10.60 - 31.60
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	11.240 (3.7714)	10.282 (3.4454)	11.227 (3.3487)	11.801 (3.9315)	11.085 (3.6144)	11.123 (3.6474)
		Median	10.350	10.100	11.100	11.950	10.950	10.800
		Q1 - Q3	8.900 - 12.800	7.800 - 12.400	8.900 - 13.100	8.550 - 14.050	8.400 - 13.230	8.500 - 13.100
		Min - Max	3.00 - 23.00	4.60 - 19.20	3.10 - 21.80	4.00 - 22.80	3.10 - 22.80	3.00 - 23.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Bilirubin (umol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.954 (3.7233)	-0.422 (2.5207)	-0.941 (3.5049)	-0.596 (3.1782)	-0.651 (3.0807)	-0.726 (3.2472)
		Median	-0.850	-0.100	-0.600	-0.100	-0.250	-0.450
		Q1 - Q3	-3.600 - 1.200	-1.800 - 1.100	-3.300 - 1.200	-2.350 - 1.330	-2.370 - 1.200	-2.600 - 1.200
		Min - Max	-11.90 - 7.90	-7.80 - 5.50	-16.90 - 8.20	-12.70 - 6.20	-16.90 - 8.20	-16.90 - 8.20
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	11.024 (4.3075)	9.936 (3.7377)	10.861 (3.7980)	11.819 (3.7089)	10.848 (3.8082)	10.892 (3.9302)
		Median	10.400	9.600	10.300	11.000	10.300	10.300
		Q1 - Q3	8.200 - 12.500	7.150 - 12.050	8.500 - 12.400	9.300 - 14.300	8.200 - 12.900	8.200 - 12.900
		Min - Max	4.80 - 27.50	2.60 - 22.20	4.70 - 28.90	5.20 - 21.00	2.60 - 28.90	2.60 - 28.90
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-1.131 (3.5709)	-0.719 (2.7086)	-1.324 (3.0772)	-0.610 (3.0584)	-0.887 (2.9506)	-0.948 (3.1106)
		Median	-1.100	-0.850	-1.450	-0.400	-0.800	-0.850
		Q1 - Q3	-3.300 - 0.900	-2.520 - 1.050	-3.300 - 0.600	-2.400 - 1.400	-2.600 - 1.000	-3.000 - 1.000
		Min - Max	-9.70 - 7.30	-7.90 - 5.80	-7.30 - 8.00	-10.70 - 5.59	-10.70 - 8.00	-10.70 - 8.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Bilirubin (umol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	10.766 (3.0815)	9.838 (2.9971)	10.889 (4.1320)	11.198 (3.9021)	10.624 (3.7251)	10.659 (3.5705)
		Median	10.900	9.700	10.600	10.600	10.150	10.300
		Q1 - Q3	8.600 - 12.600	7.750 - 11.950	8.500 - 12.200	8.400 - 13.300	8.100 - 12.450	8.200 - 12.500
		Min - Max	3.60 - 20.10	3.10 - 18.10	1.20 - 26.60	4.60 - 20.90	1.20 - 26.60	1.20 - 26.60
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.389 (3.3713)	-0.818 (2.6144)	-1.163 (3.5188)	-1.231 (3.4731)	-1.065 (3.2064)	-1.146 (3.2447)
		Median	-1.000	-0.550	-1.300	-1.100	-1.100	-1.100
		Q1 - Q3	-3.100 - 1.200	-2.100 - 1.000	-3.700 - 0.600	-3.200 - 0.900	-2.800 - 0.900	-3.000 - 0.900
		Min - Max	-11.20 - 3.60	-7.90 - 4.60	-8.80 - 7.60	-12.20 - 6.00	-12.20 - 7.60	-12.20 - 7.60
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	11.598 (5.0394)	9.935 (3.5786)	11.065 (3.6415)	11.871 (3.4617)	10.938 (3.6328)	11.100 (4.0243)
		Median	10.600	9.600	10.750	11.400	10.450	10.500
		Q1 - Q3	8.650 - 12.950	7.800 - 11.400	8.600 - 12.500	9.500 - 14.900	8.450 - 12.800	8.550 - 12.880
		Min - Max	3.80 - 36.00	3.50 - 20.10	4.70 - 23.70	5.90 - 20.50	3.50 - 23.70	3.50 - 36.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Bilirubin (umol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.557 (3.4739)	-0.640 (2.8811)	-1.120 (3.4459)	-0.558 (3.1525)	-0.775 (3.1605)	-0.721 (3.2350)
		Median	-0.900	-1.000	-1.750	-0.200	-1.000	-1.000
		Q1 - Q3	-2.950 - 1.510	-2.350 - 0.700	-3.000 - 0.900	-2.400 - 1.400	-2.500 - 1.100	-2.600 - 1.200
		Min - Max	-8.20 - 9.10	-8.90 - 6.90	-8.60 - 9.80	-10.30 - 10.15	-10.30 - 10.15	-10.30 - 10.15
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	10.992 (3.0688)	9.925 (3.4854)	10.352 (3.3955)	11.593 (3.6948)	10.602 (3.5764)	10.697 (3.4572)
		Median	10.650	9.500	9.800	11.600	10.200	10.200
		Q1 - Q3	9.100 - 12.450	7.700 - 11.550	7.700 - 12.800	8.400 - 13.700	7.900 - 12.900	8.100 - 12.800
		Min - Max	5.20 - 22.10	5.10 - 18.90	2.80 - 22.70	5.90 - 21.20	2.80 - 22.70	2.80 - 22.70
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.085 (3.5528)	-0.700 (2.7404)	-1.683 (2.8689)	-0.840 (3.1524)	-1.074 (2.9379)	-1.077 (3.0928)
		Median	-0.700	-0.700	-1.700	-0.400	-1.000	-0.900
		Q1 - Q3	-2.700 - 1.050	-2.600 - 1.000	-3.900 - 0.500	-2.400 - 1.100	-3.100 - 0.900	-3.000 - 0.900
		Min - Max	-15.30 - 6.80	-6.50 - 6.20	-7.30 - 7.00	-12.70 - 6.80	-12.70 - 7.00	-15.30 - 7.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Direct Bilirubin (umol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	3.228 (1.7572)	2.602 (0.9009)	3.195 (1.6132)	2.983 (1.3099)	2.925 (1.3228)	3.001 (1.4463)
		Median	2.880	2.545	2.900	2.900	2.800	2.800
		Q1 - Q3	1.800 - 4.000	2.000 - 3.200	2.200 - 3.800	2.150 - 3.800	2.100 - 3.560	2.000 - 3.700
		Min - Max	0.80 - 9.00	1.10 - 5.40	1.20 - 11.70	0.60 - 7.00	0.60 - 11.70	0.60 - 11.70
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	3.132 (1.6900)	2.468 (1.0102)	3.093 (1.4876)	2.950 (1.0631)	2.833 (1.2282)	2.908 (1.3617)
		Median	2.700	2.300	2.900	3.000	2.750	2.700
		Q1 - Q3	1.800 - 4.100	1.600 - 3.200	2.150 - 3.600	2.200 - 3.700	1.900 - 3.600	1.900 - 3.600
		Min - Max	1.10 - 8.40	0.80 - 5.50	0.90 - 9.10	0.80 - 5.03	0.80 - 9.10	0.80 - 9.10
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.096 (0.8335)	-0.134 (0.7281)	-0.098 (0.8775)	-0.033 (0.8521)	-0.089 (0.8180)	-0.091 (0.8204)
		Median	0	-0.100	-0.050	0	-0.050	0
		Q1 - Q3	-0.500 - 0.400	-0.500 - 0.300	-0.450 - 0.400	-0.500 - 0.450	-0.500 - 0.400	-0.500 - 0.400
		Min - Max	-2.80 - 2.60	-2.00 - 1.70	-2.90 - 2.40	-2.40 - 1.93	-2.90 - 2.40	-2.90 - 2.60

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Direct Bilirubin (umol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	2.790 (1.2946)	2.462 (0.8660)	3.117 (1.5633)	3.361 (2.8373)	2.975 (1.9563)	2.929 (1.8143)
		Median	2.700	2.400	2.800	3.000	2.700	2.700
		Q1 - Q3	1.700 - 3.700	1.800 - 3.000	2.100 - 3.800	2.200 - 3.900	2.000 - 3.500	1.900 - 3.600
		Min - Max	0.70 - 6.60	0.90 - 5.00	1.10 - 10.70	0.90 - 24.30	0.90 - 24.30	0.70 - 24.30
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.399 (1.0101)	-0.134 (0.6690)	-0.064 (1.0271)	0.353 (2.6950)	0.050 (1.7072)	-0.061 (1.5737)
		Median	-0.300	-0.200	0	-0.100	-0.100	-0.100
		Q1 - Q3	-0.900 - 0.100	-0.500 - 0.300	-0.500 - 0.500	-0.400 - 0.600	-0.500 - 0.400	-0.500 - 0.400
		Min - Max	-4.90 - 1.70	-2.40 - 1.30	-3.10 - 2.50	-1.80 - 21.10	-3.10 - 21.10	-4.90 - 21.10
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	2.923 (1.5296)	2.535 (1.0384)	2.985 (1.2537)	2.971 (1.0225)	2.825 (1.1248)	2.850 (1.2353)
		Median	2.550	2.500	3.000	3.000	2.800	2.800
		Q1 - Q3	1.800 - 3.760	1.800 - 3.100	2.200 - 3.700	2.300 - 3.735	2.100 - 3.400	2.000 - 3.500
		Min - Max	1.10 - 8.60	0.90 - 6.90	0.60 - 7.80	0.20 - 5.60	0.20 - 7.80	0.20 - 8.60

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Direct Bilirubin (umol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.299 (0.9473)	-0.061 (0.7292)	-0.196 (1.4576)	-0.110 (0.7729)	-0.122 (1.0386)	-0.166 (1.0178)
		Median	-0.200	-0.100	-0.100	-0.150	-0.100	-0.100
		Q1 - Q3	-0.800 - 0.200	-0.500 - 0.400	-0.800 - 0.600	-0.500 - 0.350	-0.500 - 0.400	-0.600 - 0.400
		Min - Max	-3.40 - 1.50	-2.30 - 1.60	-8.00 - 4.00	-2.90 - 1.50	-8.00 - 4.00	-8.00 - 4.00
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	2.847 (1.5723)	2.413 (1.0175)	2.836 (1.2761)	2.957 (1.0625)	2.729 (1.1429)	2.758 (1.2609)
		Median	2.470	2.250	2.605	2.800	2.500	2.500
		Q1 - Q3	1.700 - 3.400	1.750 - 3.200	2.000 - 3.400	2.200 - 3.600	1.900 - 3.300	1.900 - 3.400
		Min - Max	0.80 - 8.80	0.90 - 5.20	0.90 - 8.10	1.00 - 5.71	0.90 - 8.10	0.80 - 8.80
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.364 (1.0209)	-0.170 (0.7705)	-0.369 (1.2221)	-0.122 (0.7561)	-0.221 (0.9437)	-0.257 (0.9634)
		Median	-0.200	-0.250	-0.300	-0.100	-0.200	-0.200
		Q1 - Q3	-1.000 - 0.300	-0.600 - 0.400	-0.900 - 0.100	-0.600 - 0.400	-0.600 - 0.300	-0.700 - 0.300
		Min - Max	-3.20 - 1.70	-2.30 - 1.60	-4.30 - 5.20	-2.40 - 1.70	-4.30 - 5.20	-4.30 - 5.20

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Direct Bilirubin (umol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	2.809 (1.2946)	2.404 (0.9264)	2.900 (1.3848)	2.793 (1.0337)	2.694 (1.1449)	2.722 (1.1824)
		Median	2.500	2.400	2.800	2.670	2.500	2.500
		Q1 - Q3	1.700 - 3.600	1.650 - 3.000	2.100 - 3.500	2.100 - 3.700	1.900 - 3.300	1.800 - 3.400
		Min - Max	1.10 - 6.60	0.90 - 5.30	0.90 - 10.00	1.00 - 5.10	0.90 - 10.00	0.90 - 10.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.402 (1.1988)	-0.179 (0.7473)	-0.317 (0.9925)	-0.286 (0.9637)	-0.259 (0.9022)	-0.295 (0.9839)
		Median	-0.100	-0.200	-0.300	-0.300	-0.200	-0.200
		Q1 - Q3	-0.800 - 0.300	-0.600 - 0.200	-0.900 - 0.400	-0.860 - 0.300	-0.800 - 0.300	-0.800 - 0.300
		Min - Max	-4.50 - 3.20	-2.00 - 2.60	-3.20 - 1.90	-2.80 - 1.90	-3.20 - 2.60	-4.50 - 3.20
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	2.949 (1.7021)	2.343 (0.8695)	2.882 (1.2442)	2.983 (1.1017)	2.731 (1.1125)	2.784 (1.2828)
		Median	2.500	2.300	2.800	2.900	2.600	2.600
		Q1 - Q3	1.800 - 3.610	1.700 - 2.800	2.100 - 3.600	2.300 - 3.600	1.900 - 3.400	1.900 - 3.400
		Min - Max	0.50 - 9.90	0.90 - 5.50	0.90 - 8.80	1.10 - 5.90	0.90 - 8.80	0.50 - 9.90

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Direct Bilirubin (umol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.259 (1.0547)	-0.243 (0.8084)	-0.323 (1.0621)	-0.096 (0.8323)	-0.222 (0.9090)	-0.231 (0.9449)
		Median	-0.200	-0.300	-0.300	-0.100	-0.300	-0.225
		Q1 - Q3	-0.700 - 0.400	-0.600 - 0.200	-0.900 - 0.300	-0.600 - 0.500	-0.800 - 0.350	-0.750 - 0.400
		Min - Max	-3.50 - 2.20	-2.10 - 1.50	-3.20 - 2.00	-2.00 - 2.82	-3.20 - 2.82	-3.50 - 2.82
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	2.795 (1.2680)	2.402 (0.7747)	2.780 (1.3056)	2.895 (1.0967)	2.687 (1.0936)	2.713 (1.1372)
		Median	2.450	2.400	2.550	2.800	2.500	2.500
		Q1 - Q3	1.900 - 3.360	1.790 - 2.900	1.900 - 3.500	2.000 - 3.500	1.900 - 3.300	1.900 - 3.300
		Min - Max	0.80 - 6.00	1.10 - 5.00	0.90 - 8.60	0.70 - 6.10	0.70 - 8.60	0.70 - 8.60
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.377 (1.1774)	-0.197 (0.6727)	-0.413 (1.0424)	-0.192 (0.8828)	-0.268 (0.8787)	-0.294 (0.9593)
		Median	-0.250	-0.150	-0.400	-0.100	-0.200	-0.200
		Q1 - Q3	-0.900 - 0.350	-0.600 - 0.300	-0.900 - 0.200	-0.700 - 0.300	-0.700 - 0.300	-0.700 - 0.300
		Min - Max	-6.40 - 1.40	-1.90 - 1.00	-3.70 - 1.60	-2.90 - 2.00	-3.70 - 2.00	-6.40 - 2.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Protein (g/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	74.726 (4.2623)	74.250 (4.0416)	75.141 (4.2200)	75.050 (3.9459)	74.810 (4.0714)	74.789 (4.1123)
		Median	75.900	73.720	75.000	74.900	74.800	74.900
		Q1 - Q3	71.700 - 77.800	72.000 - 77.200	71.900 - 78.300	72.900 - 77.600	72.000 - 77.600	72.000 - 77.600
		Min - Max	64.20 - 82.10	63.50 - 83.80	65.60 - 86.10	66.10 - 85.30	63.50 - 86.10	63.50 - 86.10
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	74.605 (4.4093)	74.122 (3.5353)	74.811 (4.5202)	74.696 (4.3825)	74.539 (4.1538)	74.556 (4.2113)
		Median	74.300	74.100	74.650	74.900	74.350	74.300
		Q1 - Q3	71.300 - 77.000	71.790 - 76.100	71.300 - 77.500	71.615 - 77.400	71.500 - 77.200	71.400 - 77.100
		Min - Max	63.70 - 84.70	66.90 - 82.60	66.60 - 87.00	66.00 - 88.10	66.00 - 88.10	63.70 - 88.10
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.121 (2.9487)	-0.128 (2.9060)	-0.297 (3.0271)	-0.354 (3.2087)	-0.258 (3.0350)	-0.224 (3.0089)
		Median	0	0	-0.250	-0.400	-0.035	0
		Q1 - Q3	-2.100 - 2.100	-1.700 - 1.500	-2.350 - 1.550	-2.550 - 1.850	-2.300 - 1.700	-2.200 - 1.800
		Min - Max	-7.70 - 6.90	-8.50 - 6.60	-10.50 - 7.30	-7.20 - 8.60	-10.50 - 8.60	-10.50 - 8.60

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Protein (g/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	73.577 (4.1814)	73.287 (3.7107)	74.182 (4.1488)	73.999 (4.2973)	73.818 (4.0551)	73.758 (4.0803)
		Median	73.300	73.300	73.600	73.700	73.600	73.600
		Q1 - Q3	70.600 - 76.900	71.000 - 75.800	70.800 - 77.590	71.000 - 76.900	71.000 - 76.100	70.900 - 76.100
		Min - Max	63.50 - 82.90	63.70 - 83.10	67.00 - 86.30	65.00 - 83.70	63.70 - 86.30	63.50 - 86.30
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.043 (3.8431)	-1.008 (3.2707)	-0.901 (3.8923)	-1.077 (3.0424)	-0.995 (3.4030)	-1.007 (3.5101)
		Median	-1.100	-1.000	-0.400	-0.900	-0.900	-1.000
		Q1 - Q3	-3.500 - 1.700	-3.100 - 1.000	-3.200 - 1.300	-3.000 - 0.900	-3.100 - 1.000	-3.100 - 1.100
		Min - Max	-8.80 - 8.40	-9.50 - 5.60	-13.90 - 11.50	-7.50 - 5.60	-13.90 - 11.50	-13.90 - 11.50
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	73.438 (4.0964)	73.888 (4.1100)	74.365 (4.1423)	73.967 (4.3574)	74.073 (4.1855)	73.916 (4.1650)
		Median	73.500	73.500	74.300	73.150	73.800	73.600
		Q1 - Q3	71.000 - 76.000	72.000 - 76.000	71.000 - 77.100	70.950 - 76.850	71.400 - 76.850	71.300 - 76.600
		Min - Max	64.30 - 81.10	63.30 - 84.90	65.60 - 87.90	64.00 - 84.20	63.30 - 87.90	63.30 - 87.90

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Protein (g/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.218 (3.1528)	-0.407 (3.6678)	-0.718 (4.1805)	-1.172 (3.8644)	-0.756 (3.9012)	-0.870 (3.7292)
		Median	-1.300	-0.300	-0.300	-1.250	-0.550	-0.800
		Q1 - Q3	-3.000 - 1.000	-2.900 - 1.900	-2.900 - 1.600	-3.650 - 1.395	-3.050 - 1.600	-3.000 - 1.500
		Min - Max	-7.50 - 5.70	-9.60 - 9.00	-16.80 - 9.60	-11.60 - 7.90	-16.80 - 9.60	-16.80 - 9.60
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	73.663 (4.9161)	73.495 (4.3645)	73.965 (3.9968)	73.464 (3.9976)	73.643 (4.1130)	73.648 (4.3163)
		Median	73.190	73.500	74.150	73.300	73.700	73.475
		Q1 - Q3	70.100 - 75.900	70.005 - 76.250	71.000 - 76.700	71.000 - 75.600	70.700 - 76.300	70.600 - 76.200
		Min - Max	59.90 - 87.32	64.90 - 85.30	63.20 - 81.70	64.20 - 85.10	63.20 - 85.30	59.90 - 87.32
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.969 (3.8383)	-0.873 (3.8432)	-1.158 (3.9727)	-1.534 (3.5614)	-1.180 (3.7906)	-1.128 (3.7962)
		Median	-1.200	-0.700	-1.000	-1.800	-1.100	-1.150
		Q1 - Q3	-4.000 - 1.000	-3.465 - 1.450	-3.300 - 1.600	-3.500 - 0.500	-3.300 - 1.200	-3.400 - 1.200
		Min - Max	-8.50 - 9.52	-9.10 - 10.00	-11.30 - 6.40	-9.50 - 7.30	-11.30 - 10.00	-11.30 - 10.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Protein (g/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	72.974 (3.9331)	73.295 (3.7290)	74.372 (3.8077)	73.993 (3.9946)	73.876 (3.8489)	73.651 (3.8822)
		Median	73.100	72.500	74.200	73.500	73.250	73.200
		Q1 - Q3	70.000 - 76.000	70.900 - 75.200	71.800 - 76.300	71.000 - 76.300	71.000 - 76.100	70.900 - 76.000
		Min - Max	64.00 - 81.40	65.00 - 85.00	65.20 - 84.70	66.50 - 88.20	65.00 - 88.20	64.00 - 88.20
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.658 (3.4149)	-1.073 (3.6564)	-0.800 (3.5958)	-1.006 (3.5439)	-0.961 (3.5839)	-1.134 (3.5489)
		Median	-2.000	-1.150	-0.900	-1.100	-1.100	-1.300
		Q1 - Q3	-4.320 - -0.380	-3.700 - 1.600	-3.100 - 1.600	-3.000 - 1.500	-3.300 - 1.500	-3.500 - 1.200
		Min - Max	-8.00 - 8.80	-9.10 - 6.50	-11.10 - 6.10	-8.20 - 10.40	-11.10 - 10.40	-11.10 - 10.40
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	73.361 (3.9053)	74.067 (3.4099)	74.129 (4.0955)	74.105 (3.6862)	74.100 (3.7212)	73.918 (3.7733)
		Median	73.800	74.000	73.650	74.800	74.100	74.100
		Q1 - Q3	70.850 - 76.000	72.000 - 76.100	71.500 - 77.500	71.100 - 76.500	71.600 - 76.700	71.400 - 76.250
		Min - Max	62.60 - 81.20	66.00 - 84.00	63.30 - 83.10	66.00 - 82.80	63.30 - 84.00	62.60 - 84.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Protein (g/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-1.256 (3.3885)	-0.237 (3.8245)	-0.995 (4.2897)	-0.893 (3.1300)	-0.703 (3.7834)	-0.839 (3.6915)
		Median	-1.470	-0.230	-1.100	-0.900	-0.800	-0.950
		Q1 - Q3	-3.300 - 1.200	-2.900 - 2.430	-3.200 - 1.600	-3.200 - 0.400	-3.010 - 1.725	-3.110 - 1.610
		Min - Max	-12.40 - 5.60	-8.00 - 7.80	-15.60 - 7.90	-7.90 - 5.90	-15.60 - 7.90	-15.60 - 7.90
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	72.935 (3.9738)	73.019 (3.7998)	73.128 (3.4891)	73.347 (3.1442)	73.160 (3.4812)	73.105 (3.6016)
		Median	72.700	72.800	73.000	73.400	73.000	73.000
		Q1 - Q3	70.000 - 76.150	69.950 - 76.100	71.230 - 75.300	70.800 - 75.300	71.000 - 75.600	70.600 - 75.600
		Min - Max	65.64 - 81.40	66.30 - 82.30	64.00 - 82.20	66.00 - 81.40	64.00 - 82.30	64.00 - 82.30
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.663 (2.9450)	-1.213 (3.4554)	-2.001 (3.5018)	-1.723 (2.8780)	-1.641 (3.2981)	-1.646 (3.2096)
		Median	-1.900	-1.050	-1.300	-1.500	-1.400	-1.500
		Q1 - Q3	-4.000 - 1.000	-4.100 - 1.000	-4.000 - 0	-3.900 - -0.070	-4.000 - 0.300	-4.000 - 0.400
		Min - Max	-7.40 - 4.30	-8.20 - 9.00	-11.90 - 5.50	-8.10 - 7.20	-11.90 - 9.00	-11.90 - 9.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Albumin (g/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	45.323 (2.6223)	45.071 (2.1651)	45.739 (2.2758)	45.804 (2.3606)	45.535 (2.2811)	45.482 (2.3678)
		Median	45.100	45.000	45.600	45.600	45.500	45.500
		Q1 - Q3	43.900 - 47.000	43.400 - 46.960	44.200 - 47.000	44.000 - 47.350	44.000 - 47.000	43.965 - 47.000
		Min - Max	37.30 - 51.90	40.00 - 50.40	39.70 - 51.80	40.80 - 52.30	39.70 - 52.30	37.30 - 52.30
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	45.224 (3.2038)	45.210 (2.3770)	45.501 (2.4649)	45.662 (2.2938)	45.456 (2.3754)	45.398 (2.6037)
		Median	45.300	45.000	45.400	45.710	45.400	45.400
		Q1 - Q3	43.800 - 46.900	43.900 - 47.100	43.500 - 47.050	43.650 - 47.200	43.700 - 47.200	43.800 - 47.100
		Min - Max	28.80 - 50.67	40.30 - 51.20	40.40 - 51.20	40.30 - 51.50	40.30 - 51.50	28.80 - 51.50
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.099 (2.1842)	0.140 (1.9329)	-0.219 (1.8159)	-0.142 (1.9393)	-0.072 (1.8944)	-0.079 (1.9670)
		Median	0.200	0.150	-0.295	0.150	0	0
		Q1 - Q3	-1.400 - 1.500	-1.300 - 1.600	-1.350 - 1.000	-1.550 - 1.200	-1.400 - 1.200	-1.400 - 1.200
		Min - Max	-8.50 - 6.20	-3.40 - 5.30	-5.60 - 3.80	-4.80 - 3.70	-5.60 - 5.30	-8.50 - 6.20

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Albumin (g/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	44.852 (2.8890)	44.561 (2.5988)	45.201 (2.8384)	45.353 (2.4519)	45.034 (2.6438)	44.988 (2.7023)
		Median	45.000	44.900	45.090	45.400	45.000	45.000
		Q1 - Q3	42.550 - 46.600	42.800 - 46.400	43.300 - 46.400	43.700 - 47.100	43.200 - 46.500	43.100 - 46.500
		Min - Max	37.00 - 53.60	38.60 - 51.70	37.40 - 52.30	40.00 - 51.60	37.40 - 52.30	37.00 - 53.60
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.396 (2.6042)	-0.521 (2.1601)	-0.481 (2.4000)	-0.394 (1.7996)	-0.466 (2.1246)	-0.449 (2.2482)
		Median	-0.600	-0.750	-0.400	-0.400	-0.600	-0.600
		Q1 - Q3	-1.700 - 0.900	-2.000 - 0.900	-2.000 - 1.000	-1.500 - 0.800	-1.800 - 0.960	-1.800 - 0.900
		Min - Max	-6.70 - 8.50	-6.10 - 4.80	-6.40 - 5.50	-4.70 - 3.60	-6.40 - 5.50	-6.70 - 8.50
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	44.770 (2.6038)	44.756 (2.4130)	45.159 (2.5951)	45.507 (2.7178)	45.131 (2.5800)	45.042 (2.5857)
		Median	44.635	44.500	45.000	46.000	45.000	45.000
		Q1 - Q3	43.000 - 46.100	43.100 - 46.600	43.400 - 46.600	43.300 - 47.450	43.305 - 46.900	43.200 - 46.800
		Min - Max	38.50 - 52.30	38.00 - 50.10	40.00 - 52.30	39.00 - 50.20	38.00 - 52.30	38.00 - 52.30

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Albumin (g/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.458 (2.5655)	-0.326 (2.2821)	-0.523 (2.2105)	-0.319 (2.1449)	-0.390 (2.2058)	-0.407 (2.2954)
		Median	-0.800	-0.300	-0.200	-0.600	-0.350	-0.500
		Q1 - Q3	-1.800 - 1.000	-1.800 - 1.020	-2.000 - 0.800	-1.750 - 1.150	-1.800 - 1.000	-1.800 - 1.000
		Min - Max	-7.60 - 9.10	-5.50 - 6.80	-8.40 - 5.00	-5.00 - 6.00	-8.40 - 6.80	-8.40 - 9.10
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	45.033 (2.9288)	44.660 (2.6473)	45.194 (2.3654)	45.305 (2.3401)	45.045 (2.4625)	45.042 (2.5801)
		Median	44.800	44.450	45.150	45.500	45.100	45.075
		Q1 - Q3	43.300 - 46.300	42.650 - 46.750	43.500 - 46.560	43.500 - 46.700	43.100 - 46.700	43.100 - 46.600
		Min - Max	34.00 - 53.80	38.00 - 51.00	40.30 - 51.70	40.20 - 51.00	38.00 - 51.70	34.00 - 53.80
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.092 (2.4274)	-0.405 (2.3022)	-0.579 (2.0891)	-0.491 (1.9555)	-0.491 (2.1151)	-0.392 (2.1987)
		Median	-0.140	-0.520	-0.400	-0.500	-0.440	-0.400
		Q1 - Q3	-1.800 - 1.800	-2.000 - 1.800	-2.000 - 0.600	-1.500 - 0.800	-2.000 - 0.900	-1.990 - 1.000
		Min - Max	-5.40 - 6.60	-5.10 - 3.90	-4.50 - 6.20	-5.40 - 4.70	-5.40 - 6.20	-5.40 - 6.60

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Albumin (g/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	44.751 (2.3607)	44.463 (2.1324)	45.710 (2.4692)	45.485 (2.6096)	45.205 (2.4559)	45.092 (2.4360)
		Median	44.600	44.150	45.430	45.000	45.000	44.800
		Q1 - Q3	43.300 - 45.900	42.800 - 46.450	43.700 - 47.700	43.700 - 47.200	43.400 - 47.000	43.400 - 46.700
		Min - Max	36.70 - 52.70	40.40 - 48.50	40.50 - 52.60	39.10 - 54.80	39.10 - 54.80	36.70 - 54.80
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.375 (2.2546)	-0.603 (2.2670)	-0.086 (2.2756)	-0.312 (2.1543)	-0.338 (2.2331)	-0.347 (2.2342)
		Median	-0.700	-0.825	-0.300	-0.600	-0.600	-0.600
		Q1 - Q3	-2.000 - 1.000	-2.250 - 1.000	-1.800 - 1.300	-1.900 - 1.400	-2.000 - 1.150	-2.000 - 1.000
		Min - Max	-4.20 - 6.60	-5.80 - 4.30	-4.00 - 7.10	-5.20 - 4.60	-5.80 - 7.10	-5.80 - 7.10
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	44.876 (2.6594)	44.961 (2.5607)	45.410 (2.7858)	45.605 (2.9099)	45.319 (2.7517)	45.210 (2.7309)
		Median	44.900	45.100	45.100	45.500	45.200	45.050
		Q1 - Q3	43.100 - 46.100	43.100 - 46.400	43.100 - 47.100	43.600 - 47.200	43.350 - 46.850	43.250 - 46.800
		Min - Max	37.80 - 51.60	39.00 - 52.00	39.00 - 52.30	40.00 - 55.50	39.00 - 55.50	37.80 - 55.50

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Albumin (g/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.259 (2.1292)	-0.074 (2.3733)	-0.362 (2.4620)	-0.192 (2.2180)	-0.209 (2.3464)	-0.221 (2.2909)
		Median	-0.550	-0.400	-0.450	0.100	-0.150	-0.250
		Q1 - Q3	-1.405 - 1.000	-2.000 - 1.400	-1.800 - 1.000	-1.600 - 1.100	-1.700 - 1.050	-1.650 - 1.000
		Min - Max	-5.90 - 7.00	-5.70 - 6.00	-6.60 - 6.00	-5.10 - 6.70	-6.60 - 6.70	-6.60 - 7.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	44.542 (2.3450)	44.325 (2.1255)	44.775 (2.4845)	45.315 (2.5059)	44.792 (2.3961)	44.731 (2.3816)
		Median	44.250	44.000	44.800	45.500	44.600	44.600
		Q1 - Q3	43.065 - 46.100	42.850 - 45.950	43.000 - 45.900	43.500 - 46.700	43.000 - 46.400	43.000 - 46.200
		Min - Max	40.00 - 50.40	40.30 - 49.04	40.30 - 53.90	40.50 - 51.80	40.30 - 53.90	40.00 - 53.90
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.540 (2.2207)	-0.727 (2.1726)	-0.930 (2.0502)	-0.583 (1.8539)	-0.749 (2.0285)	-0.698 (2.0748)
		Median	-0.700	-0.500	-0.820	-0.700	-0.700	-0.700
		Q1 - Q3	-1.860 - 0.700	-2.350 - 1.000	-2.420 - 0.500	-2.000 - 1.000	-2.200 - 1.000	-2.100 - 0.800
		Min - Max	-5.92 - 7.30	-7.60 - 4.00	-5.20 - 3.20	-5.10 - 3.80	-7.60 - 4.00	-7.60 - 7.30

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Globulin (g/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	29.419 (3.8309)	29.179 (3.5036)	29.411 (3.3328)	29.247 (3.4856)	29.279 (3.4263)	29.314 (3.5251)
		Median	29.100	28.950	29.000	29.050	29.000	29.000
		Q1 - Q3	26.700 - 31.600	26.800 - 31.370	27.000 - 31.300	26.950 - 31.000	26.900 - 31.300	26.900 - 31.385
		Min - Max	22.08 - 40.00	22.60 - 40.60	23.90 - 36.40	20.50 - 39.00	20.50 - 40.60	20.50 - 40.60
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	29.307 (3.5193)	28.912 (3.0505)	29.304 (3.4948)	29.042 (3.8991)	29.084 (3.4813)	29.140 (3.4858)
		Median	29.000	28.750	28.850	28.800	28.800	28.900
		Q1 - Q3	26.800 - 31.600	26.900 - 31.200	26.950 - 31.150	26.400 - 31.550	26.700 - 31.200	26.700 - 31.300
		Min - Max	24.00 - 37.80	20.80 - 35.40	22.80 - 38.10	19.40 - 41.18	19.40 - 41.18	19.40 - 41.18
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.111 (2.5383)	-0.267 (2.3107)	-0.093 (2.0464)	-0.205 (2.2727)	-0.189 (2.2044)	-0.170 (2.2882)
		Median	0	0.070	0	-0.200	0	0
		Q1 - Q3	-1.300 - 1.500	-1.800 - 1.260	-1.350 - 1.000	-1.950 - 1.000	-1.600 - 1.100	-1.540 - 1.300
		Min - Max	-6.90 - 5.30	-5.50 - 4.50	-5.70 - 7.00	-7.30 - 4.98	-7.30 - 7.00	-7.30 - 7.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Globulin (g/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	28.729 (3.4379)	28.726 (3.0495)	28.986 (3.0168)	28.670 (3.3780)	28.793 (3.1387)	28.777 (3.2091)
		Median	27.800	28.900	28.300	28.000	28.300	28.150
		Q1 - Q3	26.100 - 31.700	26.600 - 31.000	26.600 - 31.300	26.000 - 31.300	26.400 - 31.200	26.300 - 31.300
		Min - Max	23.00 - 36.70	21.80 - 35.70	24.00 - 36.40	20.00 - 36.90	20.00 - 36.90	20.00 - 36.90
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.653 (3.0044)	-0.487 (2.4505)	-0.424 (2.5874)	-0.660 (2.1265)	-0.523 (2.3867)	-0.556 (2.5486)
		Median	-1.000	-0.400	-0.100	-0.700	-0.500	-0.700
		Q1 - Q3	-2.200 - 0.800	-2.000 - 1.100	-1.900 - 1.100	-2.000 - 0.900	-2.000 - 1.000	-2.000 - 0.990
		Min - Max	-7.00 - 7.90	-6.30 - 5.00	-8.00 - 6.00	-6.80 - 3.80	-8.00 - 6.00	-8.00 - 7.90
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	28.666 (3.5927)	29.133 (3.4767)	29.207 (3.3121)	28.438 (3.4016)	28.935 (3.3985)	28.868 (3.4428)
		Median	28.050	29.000	28.900	28.000	28.650	28.600
		Q1 - Q3	25.900 - 31.530	27.000 - 30.800	26.900 - 31.000	25.950 - 30.250	26.500 - 30.750	26.200 - 30.900
		Min - Max	22.60 - 38.10	21.80 - 39.10	22.70 - 36.40	20.80 - 38.00	20.80 - 39.10	20.80 - 39.10

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Globulin (g/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.770 (2.6088)	-0.081 (2.4212)	-0.203 (3.0162)	-0.876 (2.7892)	-0.376 (2.7576)	-0.474 (2.7219)
		Median	-1.000	-0.600	0	-0.850	-0.600	-0.700
		Q1 - Q3	-2.000 - 1.000	-1.500 - 1.800	-1.900 - 1.650	-2.250 - 0.950	-1.950 - 1.150	-2.000 - 1.100
		Min - Max	-7.50 - 8.00	-5.40 - 6.00	-8.40 - 9.08	-8.70 - 6.40	-8.70 - 9.08	-8.70 - 9.08
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	28.628 (3.5997)	28.839 (3.4440)	28.767 (3.3667)	28.167 (3.2537)	28.600 (3.3544)	28.607 (3.4099)
		Median	28.300	28.700	28.500	27.700	28.300	28.300
		Q1 - Q3	26.000 - 30.700	26.775 - 30.925	26.100 - 31.200	26.000 - 30.500	26.200 - 30.800	26.100 - 30.800
		Min - Max	21.90 - 36.50	22.00 - 37.30	21.40 - 35.47	19.80 - 36.30	19.80 - 37.30	19.80 - 37.30
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.888 (2.8761)	-0.463 (2.8596)	-0.593 (2.9080)	-1.041 (2.4479)	-0.691 (2.7488)	-0.740 (2.7766)
		Median	-0.900	-0.250	-0.595	-0.780	-0.600	-0.695
		Q1 - Q3	-2.800 - 1.500	-2.685 - 1.250	-2.000 - 1.200	-2.400 - 0.200	-2.300 - 1.000	-2.600 - 1.000
		Min - Max	-9.10 - 4.60	-6.40 - 6.10	-7.60 - 5.73	-8.50 - 6.50	-8.50 - 6.50	-9.10 - 6.50

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Globulin (g/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	28.214 (3.6126)	28.832 (3.5277)	28.665 (3.3251)	28.506 (3.0093)	28.672 (3.2866)	28.558 (3.3695)
		Median	28.000	28.000	28.400	28.300	28.285	28.100
		Q1 - Q3	25.800 - 30.600	26.350 - 30.900	26.200 - 30.000	26.500 - 30.000	26.405 - 30.550	26.200 - 30.600
		Min - Max	21.00 - 36.40	23.00 - 39.60	23.00 - 36.00	19.40 - 36.00	19.40 - 39.60	19.40 - 39.60
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.302 (3.0830)	-0.470 (2.5751)	-0.719 (2.8427)	-0.702 (2.4812)	-0.627 (2.6270)	-0.795 (2.7570)
		Median	-1.000	-0.400	-1.000	-0.500	-0.650	-0.900
		Q1 - Q3	-3.300 - 0.550	-2.200 - 1.135	-2.000 - 1.200	-2.300 - 0.900	-2.200 - 1.000	-2.400 - 0.900
		Min - Max	-9.00 - 10.30	-5.70 - 5.50	-7.10 - 8.00	-7.30 - 5.80	-7.30 - 8.00	-9.00 - 10.30
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	28.640 (3.7457)	29.106 (3.3182)	28.720 (3.2204)	28.497 (3.2114)	28.780 (3.2444)	28.746 (3.3677)
		Median	28.260	29.200	28.250	28.500	28.600	28.560
		Q1 - Q3	25.450 - 31.845	26.600 - 31.000	27.000 - 30.800	26.330 - 30.200	26.900 - 30.700	26.200 - 30.950
		Min - Max	19.92 - 39.70	22.00 - 39.70	21.20 - 35.30	22.40 - 35.90	21.20 - 39.70	19.92 - 39.70

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Globulin (g/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.850 (2.9516)	-0.163 (2.7194)	-0.640 (2.8545)	-0.711 (2.3567)	-0.500 (2.6542)	-0.586 (2.7287)
		Median	-0.800	-0.100	-0.100	-0.900	-0.500	-0.650
		Q1 - Q3	-3.000 - 0.850	-2.100 - 2.100	-1.800 - 1.360	-2.300 - 1.000	-2.100 - 1.420	-2.200 - 1.090
		Min - Max	-8.40 - 7.10	-6.60 - 5.10	-9.00 - 5.60	-6.40 - 4.00	-9.00 - 5.60	-9.00 - 7.10
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	28.412 (3.8609)	28.694 (3.5352)	28.357 (2.9357)	28.033 (3.3024)	28.369 (3.2639)	28.380 (3.4122)
		Median	28.050	28.100	28.685	27.500	28.100	28.100
		Q1 - Q3	25.600 - 31.030	26.000 - 31.100	26.200 - 30.100	25.600 - 29.600	26.000 - 30.600	26.000 - 30.700
		Min - Max	20.68 - 38.30	20.60 - 36.80	20.60 - 34.10	20.90 - 37.00	20.60 - 37.00	20.60 - 38.30
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.111 (2.5644)	-0.487 (2.6838)	-1.077 (2.7038)	-1.145 (2.1113)	-0.895 (2.5270)	-0.948 (2.5330)
		Median	-1.100	-0.700	-1.000	-1.000	-1.000	-1.000
		Q1 - Q3	-2.950 - 0.705	-2.100 - 1.400	-2.300 - 0.400	-3.000 - 0.400	-2.400 - 0.700	-2.400 - 0.700
		Min - Max	-7.50 - 6.90	-5.80 - 7.50	-9.30 - 4.90	-6.00 - 3.40	-9.30 - 7.50	-9.30 - 7.50

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Creatinine (umol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	58.680 (7.2427)	58.566 (7.9748)	57.696 (7.2717)	58.733 (8.2751)	58.331 (7.8254)	58.418 (7.6724)
		Median	57.000	56.700	57.000	58.750	58.000	58.000
		Q1 - Q3	53.800 - 63.000	53.000 - 65.000	52.000 - 63.000	53.000 - 64.150	52.400 - 64.000	52.650 - 64.000
		Min - Max	44.00 - 77.00	45.00 - 76.20	43.60 - 72.60	40.00 - 76.00	40.00 - 76.20	40.00 - 77.00
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	58.917 (8.0259)	58.682 (8.7546)	58.016 (7.5025)	57.714 (9.0401)	58.143 (8.4302)	58.337 (8.3229)
		Median	58.000	57.850	58.750	57.250	57.850	58.000
		Q1 - Q3	53.600 - 63.400	52.000 - 64.700	52.650 - 62.700	52.000 - 62.050	52.000 - 63.000	52.400 - 63.000
		Min - Max	40.00 - 83.00	39.00 - 90.00	36.75 - 76.00	39.00 - 85.00	36.75 - 90.00	36.75 - 90.00
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.237 (4.5170)	0.116 (6.0022)	0.129 (5.4986)	-1.020 (4.8130)	-0.254 (5.4652)	-0.131 (5.2399)
		Median	0	0.150	0.250	-0.850	0	0
		Q1 - Q3	-3.000 - 3.930	-3.000 - 3.000	-3.000 - 3.150	-3.395 - 2.000	-3.000 - 2.900	-3.000 - 3.000
		Min - Max	-9.15 - 13.00	-14.00 - 25.00	-16.30 - 14.50	-15.00 - 9.00	-16.30 - 25.00	-16.30 - 25.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Creatinine (umol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	59.154 (8.1538)	56.897 (7.9340)	57.390 (8.0941)	57.589 (8.4903)	57.288 (8.1384)	57.751 (8.1671)
		Median	57.000	56.000	57.000	57.000	57.000	57.000
		Q1 - Q3	53.000 - 66.000	52.300 - 62.000	51.600 - 63.000	52.000 - 64.900	51.700 - 62.700	52.000 - 63.000
		Min - Max	46.00 - 82.00	41.90 - 79.90	41.00 - 73.00	36.00 - 78.90	36.00 - 79.90	36.00 - 82.00
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.748 (5.8373)	-1.416 (4.8979)	-0.405 (4.9500)	-1.142 (4.8169)	-0.992 (4.8832)	-0.560 (5.1801)
		Median	0	-1.670	0	-1.000	-1.000	-1.000
		Q1 - Q3	-3.000 - 3.300	-4.800 - 2.200	-4.000 - 3.000	-4.000 - 3.000	-4.100 - 3.000	-4.000 - 3.000
		Min - Max	-10.00 - 19.80	-13.50 - 11.00	-10.00 - 9.00	-16.00 - 9.00	-16.00 - 11.00	-16.00 - 19.80
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	58.401 (7.5541)	57.605 (8.1016)	56.765 (7.9367)	57.101 (9.1344)	57.162 (8.3580)	57.470 (8.1696)
		Median	57.185	57.000	56.300	57.500	57.000	57.000
		Q1 - Q3	52.000 - 63.000	52.000 - 63.000	50.900 - 63.000	51.000 - 63.850	51.000 - 63.000	51.800 - 63.000
		Min - Max	46.80 - 84.20	42.40 - 74.80	39.00 - 73.00	35.00 - 77.00	35.00 - 77.00	35.00 - 84.20

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Creatinine (umol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.041 (5.4022)	-0.708 (5.0660)	-1.031 (4.9915)	-1.551 (4.9944)	-1.086 (5.0050)	-0.827 (5.1161)
		Median	-0.100	-1.000	-1.000	-0.950	-1.000	-1.000
		Q1 - Q3	-4.400 - 4.000	-4.000 - 2.000	-4.300 - 2.000	-3.050 - 2.000	-4.000 - 2.000	-4.000 - 2.000
		Min - Max	-10.00 - 12.20	-12.00 - 14.70	-12.20 - 12.00	-17.00 - 6.00	-17.00 - 14.70	-17.00 - 14.70
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	58.713 (8.3474)	56.925 (8.6184)	57.166 (7.9027)	57.550 (8.7510)	57.206 (8.3900)	57.580 (8.3889)
		Median	57.000	56.725	57.000	58.000	57.000	57.000
		Q1 - Q3	53.040 - 64.000	51.465 - 62.200	53.000 - 63.000	52.000 - 63.100	52.200 - 62.800	52.600 - 63.000
		Min - Max	46.00 - 87.00	41.00 - 81.50	39.44 - 73.00	37.00 - 77.00	37.00 - 81.50	37.00 - 87.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.118 (6.9052)	-1.397 (5.2837)	-0.581 (5.2395)	-1.208 (5.2484)	-1.063 (5.2426)	-0.770 (5.7090)
		Median	0	-1.000	0.250	-1.000	-0.900	-0.875
		Q1 - Q3	-4.000 - 3.000	-4.550 - 2.000	-4.000 - 2.900	-4.700 - 3.000	-4.100 - 2.000	-4.000 - 2.300
		Min - Max	-14.00 - 32.60	-14.00 - 9.00	-15.40 - 11.10	-15.00 - 13.00	-15.40 - 13.00	-15.40 - 32.60

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Creatinine (umol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	58.279 (8.1841)	56.013 (7.9306)	57.174 (7.2689)	57.799 (8.9342)	56.972 (8.0551)	57.298 (8.0915)
		Median	57.000	55.950	57.000	57.000	56.870	56.900
		Q1 - Q3	52.900 - 63.000	49.900 - 60.000	52.400 - 63.000	51.000 - 64.000	51.000 - 62.195	51.700 - 62.390
		Min - Max	44.00 - 94.00	42.30 - 83.00	40.75 - 73.00	37.00 - 76.00	37.00 - 83.00	37.00 - 94.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.316 (6.7102)	-2.309 (5.1416)	-0.584 (4.8442)	-0.959 (5.4536)	-1.303 (5.1773)	-1.057 (5.6009)
		Median	0	-2.050	0	-1.000	-1.000	-0.900
		Q1 - Q3	-4.000 - 2.000	-5.200 - 1.000	-3.000 - 2.200	-3.700 - 2.000	-4.000 - 2.000	-4.000 - 2.000
		Min - Max	-15.00 - 24.50	-15.00 - 9.70	-15.60 - 8.20	-18.00 - 11.30	-18.00 - 11.30	-18.00 - 24.50
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	58.247 (8.5754)	57.056 (7.6963)	56.780 (7.1642)	56.512 (8.9071)	56.788 (7.9013)	57.147 (8.0801)
		Median	56.000	57.000	57.500	57.500	57.000	57.000
		Q1 - Q3	52.000 - 63.500	52.300 - 61.500	51.100 - 61.600	50.000 - 63.000	51.300 - 62.000	51.600 - 62.200
		Min - Max	45.50 - 91.00	40.00 - 79.50	36.70 - 71.00	36.00 - 79.70	36.00 - 79.70	36.00 - 91.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Creatinine (umol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.217 (5.8899)	-1.465 (5.0016)	-0.968 (5.3589)	-2.246 (5.7996)	-1.548 (5.3859)	-1.221 (5.5325)
		Median	0.150	-1.000	-0.365	-1.850	-1.100	-1.000
		Q1 - Q3	-4.000 - 3.150	-4.000 - 1.600	-4.000 - 2.500	-5.700 - 2.600	-4.175 - 2.000	-4.050 - 2.360
		Min - Max	-16.00 - 16.60	-14.70 - 9.00	-17.50 - 9.90	-16.00 - 10.00	-17.50 - 10.00	-17.50 - 16.60
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	58.797 (7.2934)	57.879 (8.7546)	56.713 (7.3991)	57.842 (8.6871)	57.476 (8.2778)	57.800 (8.0541)
		Median	58.000	57.000	56.400	57.800	57.000	57.000
		Q1 - Q3	54.195 - 63.200	53.100 - 62.150	51.600 - 61.000	52.000 - 64.000	52.000 - 63.000	53.000 - 63.000
		Min - Max	44.00 - 77.00	41.00 - 81.00	43.10 - 77.35	39.00 - 75.00	39.00 - 81.00	39.00 - 81.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.239 (5.3622)	-0.630 (5.8348)	-1.095 (5.7712)	-0.915 (4.9274)	-0.877 (5.5137)	-0.603 (5.4878)
		Median	1.000	-1.000	-0.200	-0.400	-0.800	0
		Q1 - Q3	-3.850 - 4.080	-4.800 - 3.345	-5.000 - 2.900	-4.000 - 2.300	-4.600 - 2.900	-4.000 - 3.000
		Min - Max	-13.00 - 12.40	-14.00 - 13.00	-20.90 - 10.00	-14.00 - 12.00	-20.90 - 13.00	-20.90 - 13.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea (mmol/L)	Baseline	Observed Value						
		n	69	69	67	66	202	271
		Mean (SD)	4.957 (1.1637)	5.089 (1.2352)	4.786 (1.1645)	5.251 (1.1019)	5.041 (1.1795)	5.020 (1.1739)
		Median	4.800	4.900	4.800	5.035	4.900	4.870
		Q1 - Q3	4.240 - 5.680	4.280 - 5.740	3.890 - 5.570	4.480 - 5.920	4.180 - 5.740	4.200 - 5.700
		Min - Max	2.53 - 8.77	2.20 - 9.10	2.30 - 7.60	3.42 - 7.93	2.20 - 9.10	2.20 - 9.10
	D15	Observed Value						
		n	69	70	66	66	202	271
		Mean (SD)	5.228 (1.3148)	5.130 (1.3745)	4.887 (1.2300)	5.263 (1.1914)	5.094 (1.2730)	5.128 (1.2827)
		Median	5.170	4.965	4.600	5.220	5.015	5.050
		Q1 - Q3	4.300 - 6.190	4.280 - 5.790	4.000 - 5.800	4.500 - 5.890	4.200 - 5.840	4.200 - 5.890
		Min - Max	2.40 - 8.86	2.41 - 9.00	3.09 - 9.70	2.90 - 8.47	2.41 - 9.70	2.40 - 9.70
	D15	Change from Baseline						
		n	69	69	66	66	201	270
		Mean (SD)	0.270 (0.9130)	0.037 (1.1200)	0.092 (1.1339)	0.012 (1.1743)	0.047 (1.1374)	0.104 (1.0872)
		Median	0.130	0.040	0.005	0.015	0.010	0.050
		Q1 - Q3	-0.400 - 0.700	-0.600 - 0.680	-0.530 - 0.740	-0.740 - 0.650	-0.610 - 0.690	-0.530 - 0.700
		Min - Max	-1.50 - 2.47	-2.70 - 2.70	-2.40 - 4.00	-2.75 - 3.70	-2.75 - 4.00	-2.75 - 4.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea (mmol/L)	D29	Observed Value						
		n	67	69	65	65	199	266
		Mean (SD)	5.003 (1.1520)	5.201 (1.2996)	5.036 (1.3064)	5.296 (1.2747)	5.178 (1.2916)	5.134 (1.2581)
		Median	4.900	5.100	4.850	5.270	5.020	5.000
		Q1 - Q3	4.200 - 5.870	4.380 - 6.000	4.080 - 5.800	4.400 - 6.140	4.200 - 6.000	4.200 - 5.960
		Min - Max	2.30 - 7.28	2.70 - 9.60	2.80 - 8.11	2.31 - 8.49	2.31 - 9.60	2.30 - 9.60
	D29	Change from Baseline						
		n	67	68	65	65	198	265
		Mean (SD)	0.099 (1.1231)	0.106 (1.0399)	0.232 (1.1796)	0.087 (1.1445)	0.141 (1.1178)	0.130 (1.1172)
		Median	0	-0.065	0.110	0.040	0.070	0.040
		Q1 - Q3	-0.610 - 0.800	-0.530 - 0.540	-0.500 - 1.200	-0.580 - 0.740	-0.560 - 0.700	-0.580 - 0.740
		Min - Max	-2.44 - 3.10	-2.10 - 3.60	-2.24 - 3.08	-3.14 - 2.70	-3.14 - 3.60	-3.14 - 3.60
	D43	Observed Value						
		n	66	69	65	62	196	262
		Mean (SD)	5.052 (1.2455)	5.104 (1.1718)	4.977 (1.1320)	5.284 (1.2069)	5.119 (1.1707)	5.102 (1.1879)
		Median	5.010	5.000	4.710	5.435	5.000	5.000
		Q1 - Q3	4.200 - 5.700	4.400 - 5.700	4.300 - 5.850	4.350 - 5.970	4.300 - 5.880	4.300 - 5.880
		Min - Max	2.70 - 8.49	3.00 - 9.03	2.80 - 9.10	2.54 - 8.44	2.54 - 9.10	2.54 - 9.10

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea (mmol/L)	D43	Change from Baseline						
		n	66	68	65	62	195	261
		Mean (SD)	0.178 (1.0206)	0.009 (0.9791)	0.172 (1.1338)	0.016 (1.1505)	0.066 (1.0849)	0.094 (1.0682)
		Median	0.130	0.100	0.300	-0.190	0.120	0.120
		Q1 - Q3	-0.550 - 0.760	-0.760 - 0.640	-0.540 - 0.900	-0.640 - 0.770	-0.640 - 0.790	-0.600 - 0.790
		Min - Max	-3.08 - 2.47	-2.50 - 2.20	-3.20 - 2.50	-3.97 - 2.65	-3.97 - 2.65	-3.97 - 2.65
	D57	Observed Value						
		n	65	68	64	61	193	258
		Mean (SD)	4.974 (1.1377)	5.137 (1.1490)	4.975 (1.0704)	5.144 (1.2545)	5.085 (1.1553)	5.057 (1.1497)
		Median	4.940	4.895	4.805	4.960	4.900	4.915
		Q1 - Q3	4.240 - 5.690	4.410 - 5.895	4.240 - 5.675	4.250 - 6.000	4.300 - 5.850	4.270 - 5.800
		Min - Max	2.41 - 8.34	2.90 - 8.40	2.90 - 7.30	2.71 - 8.01	2.71 - 8.40	2.41 - 8.40
	D57	Change from Baseline						
		n	65	67	64	61	192	257
		Mean (SD)	0.090 (0.9619)	0.057 (0.9968)	0.184 (1.1309)	-0.149 (1.1376)	0.034 (1.0909)	0.048 (1.0582)
		Median	0.170	0.100	0.265	-0.070	0.070	0.100
		Q1 - Q3	-0.400 - 0.640	-0.700 - 0.600	-0.605 - 0.885	-0.870 - 0.600	-0.700 - 0.690	-0.650 - 0.670
		Min - Max	-2.97 - 2.37	-1.97 - 3.50	-2.50 - 3.10	-3.67 - 2.00	-3.67 - 3.50	-3.67 - 3.50

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea (mmol/L)	D71	Observed Value						
		n	65	68	63	61	192	257
		Mean (SD)	5.176 (1.1932)	5.051 (1.1179)	5.094 (1.2427)	5.303 (1.3439)	5.145 (1.2325)	5.153 (1.2204)
		Median	5.100	5.065	5.000	5.350	5.050	5.060
		Q1 - Q3	4.390 - 5.800	4.240 - 5.800	4.300 - 5.840	4.300 - 6.300	4.285 - 5.920	4.290 - 5.910
		Min - Max	2.50 - 9.19	2.80 - 8.40	2.91 - 9.10	2.60 - 9.56	2.60 - 9.56	2.50 - 9.56
	D71	Change from Baseline						
		n	65	67	63	61	191	256
		Mean (SD)	0.292 (1.1257)	-0.033 (1.1919)	0.316 (1.1372)	0.011 (1.1575)	0.096 (1.1674)	0.146 (1.1579)
		Median	0.300	-0.100	0.200	0.050	0.050	0.120
		Q1 - Q3	-0.500 - 0.960	-0.710 - 0.700	-0.380 - 1.100	-0.900 - 0.730	-0.650 - 0.900	-0.600 - 0.935
		Min - Max	-2.22 - 3.72	-3.30 - 3.50	-2.20 - 2.78	-3.59 - 3.53	-3.59 - 3.53	-3.59 - 3.72
	D85	Observed Value						
		n	64	67	64	61	192	256
		Mean (SD)	5.039 (1.3255)	5.134 (1.1623)	5.046 (1.0964)	5.261 (1.1835)	5.145 (1.1450)	5.119 (1.1908)
		Median	5.090	4.900	4.970	5.190	4.980	5.000
		Q1 - Q3	4.100 - 5.780	4.230 - 5.860	4.205 - 5.690	4.570 - 6.050	4.230 - 5.865	4.225 - 5.855
		Min - Max	2.30 - 8.60	2.80 - 8.21	3.03 - 8.50	3.05 - 8.40	2.80 - 8.50	2.30 - 8.60

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea (mmol/L)	D85	Change from Baseline						
		n	64	66	64	61	191	255
		Mean (SD)	0.146 (1.0688)	0.016 (1.1388)	0.255 (1.0047)	-0.031 (1.1046)	0.081 (1.0860)	0.097 (1.0800)
		Median	-0.100	0.100	0.460	-0.120	0.100	0.020
		Q1 - Q3	-0.520 - 0.990	-0.600 - 0.770	-0.460 - 0.860	-0.700 - 0.600	-0.600 - 0.790	-0.600 - 0.800
		Min - Max	-2.63 - 2.90	-3.70 - 3.20	-1.53 - 3.20	-3.72 - 2.46	-3.72 - 3.20	-3.72 - 3.20
	Safety Follow-up	Observed Value						
		n	64	68	64	61	193	257
		Mean (SD)	5.103 (1.3240)	5.238 (1.3144)	5.220 (1.2983)	5.367 (1.3004)	5.272 (1.2995)	5.230 (1.3051)
		Median	4.965	5.055	4.955	5.240	5.100	5.040
		Q1 - Q3	4.100 - 6.060	4.175 - 5.845	4.400 - 6.050	4.640 - 6.350	4.360 - 6.000	4.300 - 6.000
		Min - Max	2.64 - 7.90	3.01 - 8.89	3.01 - 9.03	2.56 - 8.13	2.56 - 9.03	2.56 - 9.03
	Safety Follow-up	Change from Baseline						
		n	64	67	64	61	192	256
		Mean (SD)	0.221 (1.2854)	0.121 (1.1398)	0.428 (1.2028)	0.046 (1.0752)	0.199 (1.1473)	0.205 (1.1808)
		Median	0.225	0.080	0.500	0.040	0.155	0.200
		Q1 - Q3	-0.560 - 1.150	-0.420 - 0.780	-0.385 - 1.285	-0.600 - 0.780	-0.480 - 0.950	-0.500 - 0.990
		Min - Max	-2.90 - 2.56	-3.50 - 3.30	-2.60 - 3.25	-3.07 - 2.50	-3.50 - 3.30	-3.50 - 3.30

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea Nitrogen (mmol/L)	Baseline	Observed Value						
		n	0	0	2	2	4	4
		Mean (SD)			5.210 (0.7354)	6.250 (0.2121)	5.730 (0.7455)	5.730 (0.7455)
		Median			5.210	6.250	5.915	5.915
		Q1 - Q3			4.690 - 5.730	6.100 - 6.400	5.210 - 6.250	5.210 - 6.250
		Min - Max			4.69 - 5.73	6.10 - 6.40	4.69 - 6.40	4.69 - 6.40
	D15	Observed Value						
		n	0	0	2	2	4	4
		Mean (SD)			4.610 (0.2404)	7.295 (1.2092)	5.953 (1.7058)	5.953 (1.7058)
		Median			4.610	7.295	5.610	5.610
		Q1 - Q3			4.440 - 4.780	6.440 - 8.150	4.610 - 7.295	4.610 - 7.295
		Min - Max			4.44 - 4.78	6.44 - 8.15	4.44 - 8.15	4.44 - 8.15
	D15	Change from Baseline						
		n	0	0	2	2	4	4
		Mean (SD)			-0.600 (0.4950)	1.045 (0.9970)	0.223 (1.1467)	0.223 (1.1467)
		Median			-0.600	1.045	0.045	0.045
		Q1 - Q3			-0.950 - -0.250	0.340 - 1.750	-0.600 - 1.045	-0.600 - 1.045
		Min - Max			-0.95 - -0.25	0.34 - 1.75	-0.95 - 1.75	-0.95 - 1.75

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic		Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea Nitrogen (mmol/L)	D29	Observed Value							
		n	0		0	2	2	4	4
		Mean (SD)				5.650 (1.0607)	6.480 (0.8061)	6.065 (0.9062)	6.065 (0.9062)
		Median				5.650	6.480	6.155	6.155
		Q1 - Q3				4.900 - 6.400	5.910 - 7.050	5.405 - 6.725	5.405 - 6.725
		Min - Max				4.90 - 6.40	5.91 - 7.05	4.90 - 7.05	4.90 - 7.05
	D29	Change from Baseline							
		n	0		0	2	2	4	4
		Mean (SD)				0.440 (0.3253)	0.230 (0.5940)	0.335 (0.4093)	0.335 (0.4093)
		Median				0.440	0.230	0.430	0.430
		Q1 - Q3				0.210 - 0.670	-0.190 - 0.650	0.010 - 0.660	0.010 - 0.660
		Min - Max				0.21 - 0.67	-0.19 - 0.65	-0.19 - 0.67	-0.19 - 0.67
	D43	Observed Value							
		n	0		0	2	2	4	4
		Mean (SD)				6.200 (1.2021)	7.750 (0.2970)	6.975 (1.1454)	6.975 (1.1454)
		Median				6.200	7.750	7.295	7.295
		Q1 - Q3				5.350 - 7.050	7.540 - 7.960	6.200 - 7.750	6.200 - 7.750
		Min - Max				5.35 - 7.05	7.54 - 7.96	5.35 - 7.96	5.35 - 7.96

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea Nitrogen (mmol/L)	D43	Change from Baseline						
		n	0	0	2	2	4	4
		Mean (SD)			0.990 (0.4667)	1.500 (0.0849)	1.245 (0.4021)	1.245 (0.4021)
		Median			0.990	1.500	1.380	1.380
		Q1 - Q3			0.660 - 1.320	1.440 - 1.560	0.990 - 1.500	0.990 - 1.500
		Min - Max			0.66 - 1.32	1.44 - 1.56	0.66 - 1.56	0.66 - 1.56
	D57	Observed Value						
		n	0	0	2	2	4	4
		Mean (SD)			6.035 (1.2657)	5.785 (0.5728)	5.910 (0.8150)	5.910 (0.8150)
		Median			6.035	5.785	5.785	5.785
		Q1 - Q3			5.140 - 6.930	5.380 - 6.190	5.260 - 6.560	5.260 - 6.560
		Min - Max			5.14 - 6.93	5.38 - 6.19	5.14 - 6.93	5.14 - 6.93
	D57	Change from Baseline						
		n	0	0	2	2	4	4
		Mean (SD)			0.825 (0.5303)	-0.465 (0.3606)	0.180 (0.8317)	0.180 (0.8317)
		Median			0.825	-0.465	0.120	0.120
		Q1 - Q3			0.450 - 1.200	-0.720 - -0.210	-0.465 - 0.825	-0.465 - 0.825
		Min - Max			0.45 - 1.20	-0.72 - -0.21	-0.72 - 1.20	-0.72 - 1.20

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea Nitrogen (mmol/L)	D71	Observed Value						
		n	0	0	2	2	4	4
		Mean (SD)			5.030 (2.0082)	6.680 (0.9051)	5.855 (1.5890)	5.855 (1.5890)
		Median			5.030	6.680	6.245	6.245
		Q1 - Q3			3.610 - 6.450	6.040 - 7.320	4.825 - 6.885	4.825 - 6.885
		Min - Max			3.61 - 6.45	6.04 - 7.32	3.61 - 7.32	3.61 - 7.32
	D71	Change from Baseline						
		n	0	0	2	2	4	4
		Mean (SD)			-0.180 (1.2728)	0.430 (0.6930)	0.125 (0.9078)	0.125 (0.9078)
		Median			-0.180	0.430	0.330	0.330
		Q1 - Q3			-1.080 - 0.720	-0.060 - 0.920	-0.570 - 0.820	-0.570 - 0.820
		Min - Max			-1.08 - 0.72	-0.06 - 0.92	-1.08 - 0.92	-1.08 - 0.92
	D85	Observed Value						
		n	0	0	2	2	4	4
		Mean (SD)			6.225 (1.1384)	6.180 (0.0990)	6.203 (0.6603)	6.203 (0.6603)
		Median			6.225	6.180	6.180	6.180
		Q1 - Q3			5.420 - 7.030	6.110 - 6.250	5.765 - 6.640	5.765 - 6.640
		Min - Max			5.42 - 7.03	6.11 - 6.25	5.42 - 7.03	5.42 - 7.03

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urea Nitrogen (mmol/L)	D85	Change from Baseline						
		n	0	0	2	2	4	4
		Mean (SD)			1.015 (0.4031)	-0.070 (0.3111)	0.473 (0.6920)	0.473 (0.6920)
		Median			1.015	-0.070	0.440	0.440
		Q1 - Q3			0.730 - 1.300	-0.290 - 0.150	-0.070 - 1.015	-0.070 - 1.015
		Min - Max			0.73 - 1.30	-0.29 - 0.15	-0.29 - 1.30	-0.29 - 1.30
	Safety Follow-up	Observed Value						
		n	0	0	2	2	4	4
		Mean (SD)			4.855 (0.5869)	6.090 (0.3818)	5.473 (0.8196)	5.473 (0.8196)
		Median			4.855	6.090	5.545	5.545
		Q1 - Q3			4.440 - 5.270	5.820 - 6.360	4.855 - 6.090	4.855 - 6.090
		Min - Max			4.44 - 5.27	5.82 - 6.36	4.44 - 6.36	4.44 - 6.36
	Safety Follow-up	Change from Baseline						
		n	0	0	2	2	4	4
		Mean (SD)			-0.355 (0.1485)	-0.160 (0.5940)	-0.258 (0.3710)	-0.258 (0.3710)
		Median			-0.355	-0.160	-0.355	-0.355
		Q1 - Q3			-0.460 - -0.250	-0.580 - 0.260	-0.520 - 0.005	-0.520 - 0.005
		Min - Max			-0.46 - -0.25	-0.58 - 0.26	-0.58 - 0.26	-0.58 - 0.26

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urate (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.2852 (0.06742)	0.2848 (0.06353)	0.2805 (0.05601)	0.2881 (0.05833)	0.2844 (0.05919)	0.2846 (0.06123)
		Median	0.2800	0.2825	0.2700	0.2820	0.2810	0.2805
		Q1 - Q3	0.2340 - 0.3140	0.2342 - 0.3190	0.2410 - 0.3110	0.2535 - 0.3140	0.2420 - 0.3143	0.2410 - 0.3142
		Min - Max	0.183 - 0.489	0.184 - 0.480	0.163 - 0.458	0.169 - 0.443	0.163 - 0.480	0.163 - 0.489
	D15	Observed Value						
		n	69	70	67	68	205	274
		Mean (SD)	0.2939 (0.07559)	0.2775 (0.05540)	0.2851 (0.05785)	0.2840 (0.07122)	0.2821 (0.06163)	0.2851 (0.06548)
		Median	0.2810	0.2695	0.2840	0.2815	0.2774	0.2780
		Q1 - Q3	0.2440 - 0.3290	0.2398 - 0.3120	0.2510 - 0.3209	0.2360 - 0.3180	0.2400 - 0.3160	0.2400 - 0.3200
		Min - Max	0.164 - 0.508	0.169 - 0.422	0.150 - 0.463	0.141 - 0.571	0.141 - 0.571	0.141 - 0.571
	D15	Change from Baseline						
		n	69	70	67	68	205	274
		Mean (SD)	0.0087 (0.04457)	-0.0073 (0.03594)	0.0046 (0.03839)	-0.0041 (0.04008)	-0.0024 (0.03829)	0.0004 (0.04017)
		Median	0.0077	-0.0073	0.0050	-0.0050	-0.0010	0
		Q1 - Q3	-0.0200 - 0.0330	-0.0230 - 0.0155	-0.0180 - 0.0270	-0.0280 - 0.0195	-0.0230 - 0.0212	-0.0230 - 0.0230
		Min - Max	-0.073 - 0.131	-0.112 - 0.067	-0.123 - 0.139	-0.103 - 0.128	-0.123 - 0.139	-0.123 - 0.139

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urate (mmol/L)	D29	Observed Value						
		n	67	69	67	66	202	269
		Mean (SD)	0.2906 (0.07746)	0.2761 (0.05169)	0.2757 (0.05756)	0.2772 (0.06157)	0.2764 (0.05673)	0.2799 (0.06268)
		Median	0.2810	0.2830	0.2730	0.2727	0.2750	0.2780
		Q1 - Q3	0.2450 - 0.3280	0.2410 - 0.3071	0.2340 - 0.3180	0.2420 - 0.2945	0.2370 - 0.3071	0.2407 - 0.3131
		Min - Max	0.172 - 0.586	0.168 - 0.380	0.136 - 0.414	0.158 - 0.511	0.136 - 0.511	0.136 - 0.586
	D29	Change from Baseline						
		n	67	69	67	66	202	269
		Mean (SD)	0.0053 (0.04361)	-0.0082 (0.04341)	-0.0051 (0.04529)	-0.0108 (0.02979)	-0.0080 (0.04004)	-0.0047 (0.04128)
		Median	-0.0010	-0.0060	-0.0045	-0.0064	-0.0060	-0.0050
		Q1 - Q3	-0.0208 - 0.0265	-0.0330 - 0.0243	-0.0289 - 0.0160	-0.0290 - 0.0060	-0.0316 - 0.0120	-0.0283 - 0.0140
		Min - Max	-0.109 - 0.118	-0.160 - 0.118	-0.095 - 0.172	-0.089 - 0.068	-0.160 - 0.172	-0.160 - 0.172
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	0.2848 (0.07375)	0.2700 (0.05772)	0.2727 (0.05288)	0.2728 (0.06757)	0.2718 (0.05927)	0.2750 (0.06328)
		Median	0.2815	0.2640	0.2680	0.2709	0.2680	0.2700
		Q1 - Q3	0.2386 - 0.3170	0.2250 - 0.3100	0.2380 - 0.3090	0.2335 - 0.2975	0.2318 - 0.3090	0.2325 - 0.3100
		Min - Max	0.156 - 0.575	0.172 - 0.411	0.118 - 0.397	0.143 - 0.477	0.118 - 0.477	0.118 - 0.575

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urate (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.0010 (0.04047)	-0.0143 (0.04363)	-0.0082 (0.03431)	-0.0155 (0.03315)	-0.0126 (0.03740)	-0.0097 (0.03844)
		Median	0.0010	-0.0110	-0.0090	-0.0120	-0.0115	-0.0090
		Q1 - Q3	-0.0210 - 0.0250	-0.0330 - 0.0080	-0.0260 - 0.0106	-0.0340 - 0.0055	-0.0315 - 0.0080	-0.0310 - 0.0106
		Min - Max	-0.107 - 0.086	-0.227 - 0.081	-0.124 - 0.101	-0.107 - 0.079	-0.227 - 0.101	-0.227 - 0.101
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	0.2808 (0.07670)	0.2692 (0.05452)	0.2722 (0.05275)	0.2759 (0.07095)	0.2723 (0.05949)	0.2744 (0.06414)
		Median	0.2680	0.2695	0.2666	0.2700	0.2690	0.2686
		Q1 - Q3	0.2241 - 0.3170	0.2360 - 0.3069	0.2350 - 0.3090	0.2280 - 0.3110	0.2350 - 0.3090	0.2316 - 0.3110
		Min - Max	0.137 - 0.589	0.163 - 0.407	0.164 - 0.393	0.146 - 0.546	0.146 - 0.546	0.137 - 0.589
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.0048 (0.04682)	-0.0154 (0.04364)	-0.0093 (0.04099)	-0.0116 (0.04048)	-0.0121 (0.04163)	-0.0103 (0.04300)
		Median	-0.0010	-0.0090	-0.0125	-0.0140	-0.0110	-0.0070
		Q1 - Q3	-0.0330 - 0.0170	-0.0350 - 0.0125	-0.0340 - 0.0110	-0.0420 - 0.0129	-0.0360 - 0.0120	-0.0340 - 0.0130
		Min - Max	-0.113 - 0.100	-0.224 - 0.049	-0.130 - 0.092	-0.119 - 0.103	-0.224 - 0.103	-0.224 - 0.103

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urate (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	0.2853 (0.07678)	0.2661 (0.05186)	0.2750 (0.05103)	0.2737 (0.07749)	0.2715 (0.06086)	0.2749 (0.06531)
		Median	0.2700	0.2623	0.2740	0.2640	0.2650	0.2665
		Q1 - Q3	0.2210 - 0.3264	0.2345 - 0.3039	0.2385 - 0.3090	0.2260 - 0.3040	0.2355 - 0.3040	0.2340 - 0.3090
		Min - Max	0.172 - 0.543	0.173 - 0.426	0.140 - 0.399	0.097 - 0.492	0.097 - 0.492	0.097 - 0.543
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.0003 (0.04224)	-0.0185 (0.04206)	-0.0055 (0.04197)	-0.0137 (0.04971)	-0.0127 (0.04473)	-0.0096 (0.04437)
		Median	-0.0050	-0.0150	-0.0010	-0.0060	-0.0102	-0.0080
		Q1 - Q3	-0.0330 - 0.0200	-0.0357 - 0.0037	-0.0260 - 0.0240	-0.0380 - 0.0145	-0.0320 - 0.0140	-0.0330 - 0.0145
		Min - Max	-0.081 - 0.095	-0.244 - 0.073	-0.130 - 0.096	-0.276 - 0.084	-0.276 - 0.096	-0.276 - 0.096
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	0.2803 (0.06608)	0.2705 (0.05427)	0.2845 (0.05838)	0.2759 (0.06989)	0.2770 (0.06099)	0.2778 (0.06217)
		Median	0.2800	0.2710	0.2830	0.2610	0.2712	0.2745
		Q1 - Q3	0.2310 - 0.3145	0.2380 - 0.3090	0.2461 - 0.3070	0.2310 - 0.3130	0.2398 - 0.3090	0.2393 - 0.3098
		Min - Max	0.152 - 0.497	0.113 - 0.384	0.138 - 0.500	0.158 - 0.460	0.113 - 0.500	0.113 - 0.500

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Urate (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.0021 (0.04283)	-0.0144 (0.04549)	0.0031 (0.05145)	-0.0116 (0.04320)	-0.0076 (0.04728)	-0.0062 (0.04621)
		Median	-0.0080	-0.0110	-0.0002	-0.0050	-0.0050	-0.0060
		Q1 - Q3	-0.0310 - 0.0265	-0.0410 - 0.0150	-0.0320 - 0.0340	-0.0430 - 0.0210	-0.0348 - 0.0225	-0.0340 - 0.0236
		Min - Max	-0.093 - 0.109	-0.223 - 0.060	-0.149 - 0.176	-0.144 - 0.072	-0.223 - 0.176	-0.223 - 0.176
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	0.2862 (0.06578)	0.2680 (0.05215)	0.2764 (0.06019)	0.2758 (0.06824)	0.2733 (0.06016)	0.2765 (0.06171)
		Median	0.2790	0.2700	0.2740	0.2680	0.2720	0.2748
		Q1 - Q3	0.2363 - 0.3280	0.2360 - 0.3023	0.2300 - 0.3040	0.2360 - 0.3116	0.2350 - 0.3040	0.2360 - 0.3116
		Min - Max	0.158 - 0.455	0.130 - 0.411	0.135 - 0.420	0.139 - 0.486	0.130 - 0.486	0.130 - 0.486
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.0023 (0.04659)	-0.0166 (0.03981)	-0.0035 (0.05155)	-0.0132 (0.03877)	-0.0111 (0.04392)	-0.0078 (0.04488)
		Median	-0.0030	-0.0110	-0.0044	-0.0120	-0.0090	-0.0080
		Q1 - Q3	-0.0218 - 0.0280	-0.0395 - 0.0125	-0.0430 - 0.0330	-0.0400 - 0.0114	-0.0400 - 0.0170	-0.0360 - 0.0180
		Min - Max	-0.111 - 0.117	-0.172 - 0.054	-0.122 - 0.167	-0.099 - 0.070	-0.172 - 0.167	-0.172 - 0.167

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Cholesterol (mmol/L)	Baseline	Observed Value						
		n	68	70	68	68	206	274
		Mean (SD)	5.488 (0.8899)	5.286 (0.8247)	5.508 (1.0399)	5.428 (1.0096)	5.406 (0.9612)	5.426 (0.9431)
		Median	5.515	5.335	5.435	5.250	5.355	5.395
		Q1 - Q3	4.815 - 6.135	4.830 - 5.920	4.945 - 6.080	4.815 - 6.075	4.840 - 5.990	4.840 - 6.000
		Min - Max	3.19 - 7.32	3.31 - 7.02	3.16 - 8.39	3.07 - 8.16	3.07 - 8.39	3.07 - 8.39
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	5.470 (0.9264)	5.360 (0.8133)	5.487 (0.9459)	5.505 (1.0952)	5.449 (0.9546)	5.455 (0.9460)
		Median	5.400	5.365	5.470	5.410	5.425	5.420
		Q1 - Q3	4.990 - 6.030	4.790 - 6.050	4.790 - 6.180	4.785 - 6.410	4.790 - 6.140	4.800 - 6.090
		Min - Max	2.92 - 7.94	3.34 - 6.93	3.55 - 8.52	2.69 - 8.09	2.69 - 8.52	2.69 - 8.52
	D15	Change from Baseline						
		n	68	70	67	68	205	273
		Mean (SD)	-0.003 (0.4744)	0.074 (0.5146)	-0.050 (0.7176)	0.076 (0.5308)	0.034 (0.5934)	0.025 (0.5655)
		Median	-0.025	0.160	-0.030	0.100	0.070	0.040
		Q1 - Q3	-0.265 - 0.295	-0.260 - 0.380	-0.400 - 0.200	-0.285 - 0.335	-0.300 - 0.340	-0.290 - 0.320
		Min - Max	-1.22 - 1.19	-1.34 - 1.11	-2.26 - 1.96	-1.01 - 1.81	-2.26 - 1.96	-2.26 - 1.96

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Cholesterol (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	5.415 (1.0045)	5.334 (0.8581)	5.423 (1.0089)	5.401 (0.9664)	5.386 (0.9418)	5.393 (0.9560)
		Median	5.460	5.300	5.390	5.380	5.340	5.350
		Q1 - Q3	4.670 - 6.080	4.720 - 5.800	4.770 - 6.090	4.720 - 6.040	4.740 - 5.950	4.720 - 6.030
		Min - Max	2.72 - 7.68	2.91 - 7.55	3.49 - 8.24	3.27 - 8.22	2.91 - 8.24	2.72 - 8.24
	D29	Change from Baseline						
		n	66	69	66	67	202	268
		Mean (SD)	-0.028 (0.5235)	0.048 (0.5247)	-0.110 (0.8876)	-0.007 (0.5246)	-0.022 (0.6653)	-0.024 (0.6324)
		Median	-0.040	-0.040	-0.110	-0.050	-0.050	-0.050
		Q1 - Q3	-0.450 - 0.250	-0.310 - 0.320	-0.470 - 0.220	-0.290 - 0.200	-0.360 - 0.280	-0.375 - 0.270
		Min - Max	-1.14 - 1.61	-1.16 - 1.45	-3.06 - 2.64	-1.13 - 1.75	-3.06 - 2.64	-3.06 - 2.64
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	5.397 (0.9198)	5.327 (0.8771)	5.429 (0.8894)	5.417 (1.1179)	5.390 (0.9607)	5.392 (0.9490)
		Median	5.475	5.400	5.460	5.365	5.415	5.430
		Q1 - Q3	4.710 - 5.870	4.750 - 5.950	4.870 - 6.010	4.645 - 6.035	4.750 - 5.980	4.750 - 5.950
		Min - Max	3.63 - 8.36	2.95 - 7.28	3.43 - 7.99	3.02 - 8.71	2.95 - 8.71	2.95 - 8.71

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Cholesterol (mmol/L)	D43	Change from Baseline						
		n	65	69	66	64	199	264
		Mean (SD)	-0.031 (0.6362)	0.041 (0.6437)	-0.098 (0.8683)	0.028 (0.6189)	-0.010 (0.7181)	-0.015 (0.6977)
		Median	-0.060	0.080	-0.085	0.010	-0.010	-0.020
		Q1 - Q3	-0.440 - 0.260	-0.350 - 0.470	-0.400 - 0.270	-0.390 - 0.355	-0.380 - 0.370	-0.385 - 0.335
		Min - Max	-1.48 - 2.78	-1.58 - 1.65	-3.11 - 2.34	-1.51 - 1.68	-3.11 - 2.34	-3.11 - 2.78
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	5.282 (0.9004)	5.254 (0.8962)	5.433 (0.8326)	5.387 (0.9502)	5.356 (0.8922)	5.338 (0.8931)
		Median	5.200	5.360	5.385	5.490	5.410	5.335
		Q1 - Q3	4.630 - 5.840	4.590 - 5.865	4.890 - 5.900	4.600 - 5.910	4.770 - 5.900	4.760 - 5.880
		Min - Max	3.03 - 7.70	3.06 - 7.42	3.99 - 8.93	3.52 - 7.88	3.06 - 8.93	3.03 - 8.93
	D57	Change from Baseline						
		n	64	68	65	63	196	260
		Mean (SD)	-0.169 (0.5694)	-0.030 (0.6553)	-0.125 (0.8573)	0.016 (0.6771)	-0.047 (0.7334)	-0.077 (0.6976)
		Median	-0.170	0.020	-0.060	0.020	0.015	-0.060
		Q1 - Q3	-0.565 - 0.245	-0.430 - 0.415	-0.570 - 0.410	-0.370 - 0.350	-0.460 - 0.400	-0.480 - 0.375
		Min - Max	-1.63 - 1.24	-1.83 - 1.39	-3.10 - 2.09	-1.92 - 2.04	-3.10 - 2.09	-3.10 - 2.09

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Cholesterol (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	5.306 (0.8270)	5.370 (0.7784)	5.509 (0.8686)	5.465 (0.9948)	5.447 (0.8797)	5.412 (0.8675)
		Median	5.340	5.365	5.480	5.420	5.455	5.450
		Q1 - Q3	4.820 - 5.880	4.850 - 5.955	4.960 - 5.970	4.710 - 6.140	4.805 - 6.045	4.810 - 5.980
		Min - Max	3.22 - 7.04	3.62 - 7.55	3.80 - 9.27	3.53 - 8.09	3.53 - 9.27	3.22 - 9.27
	D71	Change from Baseline						
		n	64	68	64	63	195	259
		Mean (SD)	-0.148 (0.6251)	0.086 (0.5665)	-0.049 (0.8256)	0.095 (0.6518)	0.045 (0.6872)	-0.003 (0.6764)
		Median	-0.045	0.035	0.115	0.120	0.100	0.050
		Q1 - Q3	-0.530 - 0.335	-0.325 - 0.415	-0.505 - 0.465	-0.340 - 0.520	-0.360 - 0.450	-0.390 - 0.420
		Min - Max	-2.42 - 1.12	-1.40 - 1.52	-3.00 - 2.06	-1.38 - 1.52	-3.00 - 2.06	-3.00 - 2.06
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	5.399 (0.8457)	5.442 (0.7235)	5.485 (1.0193)	5.450 (1.0255)	5.459 (0.9264)	5.444 (0.9060)
		Median	5.535	5.450	5.435	5.450	5.450	5.450
		Q1 - Q3	4.700 - 5.940	4.980 - 6.020	4.800 - 6.080	4.810 - 6.210	4.860 - 6.080	4.815 - 6.015
		Min - Max	3.66 - 7.91	3.61 - 6.89	3.65 - 9.26	2.98 - 7.52	2.98 - 9.26	2.98 - 9.26

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Cholesterol (mmol/L)	D85	Change from Baseline						
		n	63	67	65	63	195	258
		Mean (SD)	-0.041 (0.5435)	0.161 (0.5996)	-0.065 (1.0361)	0.079 (0.6466)	0.059 (0.7867)	0.035 (0.7351)
		Median	-0.070	0.170	-0.050	0.130	0.080	0.030
		Q1 - Q3	-0.320 - 0.320	-0.140 - 0.580	-0.580 - 0.330	-0.300 - 0.450	-0.320 - 0.430	-0.320 - 0.390
		Min - Max	-1.61 - 1.25	-1.25 - 1.67	-2.46 - 3.84	-1.41 - 1.67	-2.46 - 3.84	-2.46 - 3.84
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	5.280 (0.8433)	5.319 (0.7859)	5.459 (0.9699)	5.367 (1.1504)	5.381 (0.9722)	5.357 (0.9417)
		Median	5.360	5.440	5.405	5.470	5.430	5.390
		Q1 - Q3	4.720 - 5.805	4.820 - 5.805	4.820 - 5.930	4.630 - 6.110	4.780 - 5.890	4.760 - 5.880
		Min - Max	3.18 - 6.92	3.15 - 6.81	3.02 - 9.37	3.21 - 9.46	3.02 - 9.46	3.02 - 9.46
	Safety Follow-up	Change from Baseline						
		n	63	68	65	63	196	259
		Mean (SD)	-0.176 (0.5349)	0.036 (0.6235)	-0.047 (1.0482)	-0.032 (0.6136)	-0.014 (0.7843)	-0.053 (0.7339)
		Median	-0.130	0.040	-0.170	-0.090	-0.040	-0.080
		Q1 - Q3	-0.290 - 0.130	-0.375 - 0.345	-0.580 - 0.410	-0.450 - 0.300	-0.490 - 0.345	-0.460 - 0.280
		Min - Max	-1.72 - 1.09	-1.27 - 1.94	-2.83 - 5.07	-1.28 - 1.74	-2.83 - 5.07	-2.83 - 5.07

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triglycerides (mmol/L)	Baseline	Observed Value						
		n	68	70	68	68	206	274
		Mean (SD)	1.463 (0.8860)	1.435 (0.7903)	1.431 (0.6279)	1.245 (0.6281)	1.371 (0.6898)	1.394 (0.7427)
		Median	1.265	1.275	1.250	1.085	1.190	1.240
		Q1 - Q3	0.910 - 1.650	0.920 - 1.690	0.970 - 1.965	0.840 - 1.450	0.910 - 1.670	0.910 - 1.660
		Min - Max	0.42 - 4.90	0.51 - 4.30	0.52 - 3.11	0.48 - 4.83	0.48 - 4.83	0.42 - 4.90
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	1.267 (0.6704)	1.457 (0.8767)	1.394 (0.7195)	1.239 (0.5591)	1.364 (0.7338)	1.340 (0.7185)
		Median	1.090	1.285	1.255	1.095	1.215	1.180
		Q1 - Q3	0.870 - 1.500	0.840 - 1.760	0.940 - 1.580	0.880 - 1.455	0.900 - 1.610	0.880 - 1.600
		Min - Max	0.35 - 4.03	0.44 - 5.85	0.51 - 4.59	0.43 - 3.62	0.43 - 5.85	0.35 - 5.85
	D15	Change from Baseline						
		n	68	70	67	68	205	273
		Mean (SD)	-0.187 (0.4560)	0.021 (0.6967)	-0.048 (0.5485)	-0.006 (0.5119)	-0.010 (0.5902)	-0.054 (0.5643)
		Median	-0.125	0.020	-0.110	0.005	-0.040	-0.070
		Q1 - Q3	-0.450 - 0.015	-0.280 - 0.270	-0.350 - 0.240	-0.245 - 0.275	-0.270 - 0.270	-0.330 - 0.220
		Min - Max	-1.44 - 0.95	-2.34 - 3.35	-1.57 - 2.48	-2.15 - 1.61	-2.34 - 3.35	-2.34 - 3.35

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triglycerides (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	1.346 (0.7647)	1.353 (0.6341)	1.400 (0.6437)	1.256 (0.5127)	1.337 (0.6002)	1.339 (0.6434)
		Median	1.180	1.190	1.270	1.120	1.190	1.185
		Q1 - Q3	0.850 - 1.530	0.890 - 1.590	0.930 - 1.690	0.860 - 1.690	0.900 - 1.640	0.880 - 1.610
		Min - Max	0.48 - 4.37	0.39 - 3.31	0.42 - 3.55	0.38 - 2.72	0.38 - 3.55	0.38 - 4.37
	D29	Change from Baseline						
		n	66	69	66	67	202	268
		Mean (SD)	-0.114 (0.5012)	-0.056 (0.6499)	-0.046 (0.4828)	0.006 (0.5555)	-0.032 (0.5660)	-0.052 (0.5510)
		Median	-0.075	-0.020	-0.035	-0.020	-0.025	-0.040
		Q1 - Q3	-0.420 - 0.160	-0.420 - 0.220	-0.310 - 0.250	-0.220 - 0.210	-0.310 - 0.220	-0.325 - 0.220
		Min - Max	-1.63 - 1.39	-2.34 - 1.86	-1.62 - 0.80	-2.55 - 1.91	-2.55 - 1.91	-2.55 - 1.91
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	1.377 (1.9752)	1.414 (0.7528)	1.492 (0.8479)	1.458 (1.9861)	1.454 (1.2969)	1.435 (1.4904)
		Median	1.020	1.220	1.190	1.095	1.190	1.120
		Q1 - Q3	0.760 - 1.370	0.770 - 1.840	0.930 - 1.710	0.840 - 1.520	0.880 - 1.665	0.840 - 1.610
		Min - Max	0.40 - 16.67	0.45 - 3.77	0.55 - 4.30	0.50 - 16.66	0.45 - 16.66	0.40 - 16.67

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triglycerides (mmol/L)	D43	Change from Baseline						
		n	65	69	66	64	199	264
		Mean (SD)	-0.072 (1.6840)	0.005 (0.5198)	0.050 (0.6407)	0.211 (1.5230)	0.086 (0.9866)	0.047 (1.1948)
		Median	-0.180	-0.020	-0.005	-0.035	-0.020	-0.060
		Q1 - Q3	-0.440 - 0.050	-0.240 - 0.340	-0.240 - 0.270	-0.235 - 0.255	-0.240 - 0.280	-0.290 - 0.220
		Min - Max	-3.71 - 12.21	-2.03 - 1.22	-1.89 - 2.19	-0.71 - 11.83	-2.03 - 11.83	-3.71 - 12.21
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	1.259 (0.5666)	1.460 (0.8543)	1.460 (0.8354)	1.197 (0.5266)	1.376 (0.7640)	1.347 (0.7208)
		Median	1.160	1.280	1.195	1.100	1.160	1.160
		Q1 - Q3	0.940 - 1.420	0.875 - 1.750	0.940 - 1.790	0.820 - 1.410	0.880 - 1.610	0.890 - 1.540
		Min - Max	0.41 - 4.08	0.44 - 5.34	0.53 - 4.07	0.43 - 2.77	0.43 - 5.34	0.41 - 5.34
	D57	Change from Baseline						
		n	64	68	65	63	196	260
		Mean (SD)	-0.191 (0.6349)	0.051 (0.7028)	0.009 (0.5734)	-0.045 (0.5491)	0.006 (0.6124)	-0.042 (0.6226)
		Median	-0.140	-0.025	-0.070	-0.020	-0.030	-0.045
		Q1 - Q3	-0.335 - 0.140	-0.235 - 0.380	-0.270 - 0.130	-0.300 - 0.190	-0.250 - 0.210	-0.270 - 0.185
		Min - Max	-3.20 - 1.19	-2.20 - 1.94	-0.89 - 1.96	-2.83 - 1.61	-2.83 - 1.96	-3.20 - 1.96

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triglycerides (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	1.585 (3.0453)	1.514 (0.9653)	1.459 (0.8377)	1.338 (0.7680)	1.439 (0.8622)	1.476 (1.6865)
		Median	0.980	1.285	1.200	1.110	1.185	1.150
		Q1 - Q3	0.750 - 1.490	0.850 - 1.790	0.950 - 1.660	0.790 - 1.750	0.865 - 1.735	0.840 - 1.710
		Min - Max	0.42 - 25.19	0.43 - 5.76	0.59 - 4.99	0.41 - 4.88	0.41 - 5.76	0.41 - 25.19
	D71	Change from Baseline						
		n	64	68	64	63	195	259
		Mean (SD)	0.140 (2.6851)	0.105 (0.7435)	0.020 (0.6719)	0.096 (0.6552)	0.074 (0.6900)	0.091 (1.4558)
		Median	-0.135	0.035	-0.045	-0.060	-0.010	-0.060
		Q1 - Q3	-0.510 - 0.070	-0.240 - 0.375	-0.365 - 0.300	-0.290 - 0.280	-0.300 - 0.320	-0.340 - 0.290
		Min - Max	-2.51 - 20.73	-2.56 - 2.58	-1.83 - 2.52	-1.85 - 3.00	-2.56 - 3.00	-2.56 - 20.73
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	1.322 (1.0483)	1.419 (0.7723)	1.478 (1.6339)	1.248 (0.5680)	1.384 (1.0972)	1.369 (1.0836)
		Median	1.100	1.220	1.145	1.250	1.190	1.155
		Q1 - Q3	0.800 - 1.470	0.890 - 1.660	0.900 - 1.610	0.760 - 1.570	0.860 - 1.595	0.840 - 1.585
		Min - Max	0.51 - 8.52	0.54 - 4.22	0.41 - 13.61	0.45 - 3.31	0.41 - 13.61	0.41 - 13.61

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triglycerides (mmol/L)	D85	Change from Baseline						
		n	63	67	65	63	195	258
		Mean (SD)	-0.120 (0.8219)	0.016 (0.6041)	0.026 (1.5293)	0.006 (0.4658)	0.016 (0.9824)	-0.017 (0.9460)
		Median	-0.080	0.070	-0.140	-0.050	-0.070	-0.075
		Q1 - Q3	-0.420 - 0.170	-0.230 - 0.310	-0.400 - 0.110	-0.220 - 0.230	-0.280 - 0.240	-0.300 - 0.230
		Min - Max	-2.69 - 4.06	-2.13 - 1.72	-1.48 - 11.50	-1.97 - 1.03	-2.13 - 11.50	-2.69 - 11.50
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	1.248 (0.5505)	1.354 (0.7456)	1.560 (1.5912)	1.317 (0.5868)	1.411 (1.0724)	1.371 (0.9723)
		Median	1.125	1.040	1.120	1.170	1.120	1.120
		Q1 - Q3	0.890 - 1.560	0.835 - 1.635	0.940 - 1.620	0.910 - 1.630	0.870 - 1.630	0.880 - 1.620
		Min - Max	0.42 - 3.44	0.38 - 3.89	0.60 - 12.77	0.48 - 3.51	0.38 - 12.77	0.38 - 12.77
	Safety Follow-up	Change from Baseline						
		n	63	68	65	63	196	259
		Mean (SD)	-0.213 (0.6168)	-0.049 (0.6060)	0.128 (1.5222)	0.073 (0.5646)	0.049 (0.9968)	-0.015 (0.9247)
		Median	-0.100	-0.025	-0.060	0.120	0	-0.030
		Q1 - Q3	-0.400 - 0.140	-0.250 - 0.265	-0.410 - 0.310	-0.220 - 0.300	-0.310 - 0.285	-0.340 - 0.230
		Min - Max	-2.87 - 1.31	-2.46 - 1.31	-2.08 - 10.66	-2.37 - 1.54	-2.46 - 10.66	-2.87 - 10.66

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
LDL Cholesterol (mmol/L)	Baseline	Observed Value						
		n	68	70	68	68	206	274
		Mean (SD)	3.234 (0.8064)	3.198 (0.7001)	3.374 (0.8738)	3.266 (0.7733)	3.279 (0.7844)	3.267 (0.7887)
		Median	3.240	3.250	3.400	3.205	3.305	3.275
		Q1 - Q3	2.770 - 3.780	2.740 - 3.670	2.800 - 4.085	2.745 - 3.795	2.750 - 3.740	2.750 - 3.750
		Min - Max	1.30 - 5.16	1.70 - 4.98	1.53 - 5.67	1.45 - 5.41	1.45 - 5.67	1.30 - 5.67
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	3.269 (0.8630)	3.262 (0.6768)	3.380 (0.8137)	3.317 (0.8575)	3.319 (0.7831)	3.306 (0.8026)
		Median	3.110	3.385	3.465	3.260	3.375	3.350
		Q1 - Q3	2.770 - 3.810	2.800 - 3.740	2.940 - 3.905	2.775 - 3.880	2.820 - 3.840	2.800 - 3.820
		Min - Max	1.18 - 6.19	1.82 - 4.66	1.52 - 5.42	1.14 - 5.35	1.14 - 5.42	1.14 - 6.19
	D15	Change from Baseline						
		n	68	70	67	68	205	273
		Mean (SD)	0.050 (0.3858)	0.064 (0.3921)	-0.020 (0.5745)	0.050 (0.4443)	0.032 (0.4743)	0.037 (0.4533)
		Median	0.010	0.045	0	0.005	0.010	0.010
		Q1 - Q3	-0.200 - 0.305	-0.080 - 0.260	-0.220 - 0.140	-0.185 - 0.240	-0.160 - 0.250	-0.170 - 0.260
		Min - Max	-0.70 - 1.03	-1.12 - 1.10	-2.23 - 1.65	-1.28 - 1.88	-2.23 - 1.88	-2.23 - 1.88

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
LDL Cholesterol (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	3.238 (0.8550)	3.243 (0.7630)	3.343 (0.8524)	3.256 (0.7810)	3.280 (0.7966)	3.270 (0.8101)
		Median	3.290	3.250	3.250	3.180	3.210	3.225
		Q1 - Q3	2.650 - 3.750	2.710 - 3.710	2.840 - 3.970	2.770 - 3.730	2.770 - 3.810	2.750 - 3.810
		Min - Max	1.22 - 5.52	1.47 - 4.95	1.30 - 5.17	1.52 - 5.35	1.30 - 5.35	1.22 - 5.52
	D29	Change from Baseline						
		n	66	69	66	67	202	268
		Mean (SD)	0.024 (0.4604)	0.042 (0.4405)	-0.055 (0.7662)	0.005 (0.4476)	-0.002 (0.5682)	0.005 (0.5430)
		Median	0.015	0.040	-0.040	-0.040	-0.020	-0.010
		Q1 - Q3	-0.270 - 0.260	-0.260 - 0.240	-0.300 - 0.250	-0.220 - 0.270	-0.280 - 0.260	-0.275 - 0.260
		Min - Max	-0.83 - 1.73	-0.94 - 1.17	-2.47 - 2.28	-1.14 - 1.54	-2.47 - 2.28	-2.47 - 2.28
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	3.202 (0.8094)	3.207 (0.7599)	3.321 (0.7467)	3.222 (0.8911)	3.250 (0.7977)	3.238 (0.7993)
		Median	3.280	3.150	3.310	3.250	3.255	3.255
		Q1 - Q3	2.590 - 3.740	2.630 - 3.860	2.920 - 3.770	2.610 - 3.665	2.780 - 3.755	2.700 - 3.740
		Min - Max	1.73 - 5.67	1.24 - 4.70	1.17 - 5.04	1.32 - 5.80	1.17 - 5.80	1.17 - 5.80

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
LDL Cholesterol (mmol/L)	D43	Change from Baseline						
		n	65	69	66	64	199	264
		Mean (SD)	0.005 (0.5642)	0.007 (0.5154)	-0.067 (0.6954)	-0.005 (0.5348)	-0.022 (0.5849)	-0.015 (0.5789)
		Median	-0.060	0.030	-0.005	-0.045	0	-0.020
		Q1 - Q3	-0.290 - 0.250	-0.280 - 0.290	-0.300 - 0.260	-0.290 - 0.285	-0.290 - 0.280	-0.290 - 0.275
		Min - Max	-1.20 - 2.76	-1.09 - 1.54	-2.75 - 1.81	-1.54 - 1.48	-2.75 - 1.81	-2.75 - 2.76
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	3.151 (0.8084)	3.186 (0.7803)	3.301 (0.7225)	3.281 (0.8298)	3.255 (0.7757)	3.229 (0.7836)
		Median	3.150	3.260	3.235	3.120	3.220	3.205
		Q1 - Q3	2.570 - 3.720	2.685 - 3.750	2.850 - 3.740	2.800 - 3.790	2.810 - 3.770	2.740 - 3.760
		Min - Max	1.21 - 4.70	1.42 - 5.17	1.42 - 5.69	1.73 - 5.18	1.42 - 5.69	1.21 - 5.69
	D57	Change from Baseline						
		n	64	68	65	63	196	260
		Mean (SD)	-0.054 (0.4322)	-0.010 (0.4601)	-0.112 (0.6974)	0.062 (0.5628)	-0.021 (0.5815)	-0.029 (0.5479)
		Median	-0.100	-0.030	0	0.030	0.010	-0.025
		Q1 - Q3	-0.320 - 0.195	-0.265 - 0.295	-0.370 - 0.240	-0.220 - 0.280	-0.340 - 0.280	-0.325 - 0.265
		Min - Max	-1.09 - 1.51	-1.15 - 1.45	-3.01 - 1.51	-1.42 - 1.91	-3.01 - 1.91	-3.01 - 1.91

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
LDL Cholesterol (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	3.163 (0.7888)	3.225 (0.6546)	3.347 (0.7477)	3.293 (0.8410)	3.287 (0.7471)	3.256 (0.7580)
		Median	3.150	3.340	3.280	3.100	3.260	3.220
		Q1 - Q3	2.650 - 3.750	2.800 - 3.620	2.980 - 3.800	2.720 - 3.810	2.910 - 3.730	2.800 - 3.750
		Min - Max	1.31 - 5.32	1.72 - 4.50	1.49 - 5.67	1.68 - 5.67	1.49 - 5.67	1.31 - 5.67
	D71	Change from Baseline						
		n	64	68	64	63	195	259
		Mean (SD)	-0.046 (0.5176)	0.029 (0.4133)	-0.063 (0.6721)	0.074 (0.5412)	0.013 (0.5500)	-0.001 (0.5418)
		Median	-0.065	0.030	0.075	0.020	0.050	0.010
		Q1 - Q3	-0.285 - 0.280	-0.185 - 0.260	-0.395 - 0.280	-0.280 - 0.440	-0.260 - 0.280	-0.270 - 0.280
		Min - Max	-1.93 - 1.46	-1.19 - 1.49	-3.00 - 1.54	-0.89 - 1.66	-3.00 - 1.66	-3.00 - 1.66
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	3.219 (0.8324)	3.273 (0.6660)	3.328 (0.7623)	3.309 (0.8715)	3.303 (0.7654)	3.282 (0.7816)
		Median	3.400	3.340	3.355	3.280	3.335	3.350
		Q1 - Q3	2.655 - 3.780	2.740 - 3.670	2.850 - 3.770	2.790 - 3.760	2.790 - 3.725	2.745 - 3.745
		Min - Max	1.51 - 5.36	1.87 - 4.86	1.78 - 5.38	1.27 - 5.22	1.27 - 5.38	1.27 - 5.38

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
LDL Cholesterol (mmol/L)	D85	Change from Baseline						
		n	63	67	65	63	195	258
		Mean (SD)	0.025 (0.4091)	0.084 (0.4386)	-0.080 (0.7731)	0.090 (0.5362)	0.031 (0.6007)	0.030 (0.5592)
		Median	-0.010	0.120	0	0.100	0.060	0.040
		Q1 - Q3	-0.180 - 0.220	-0.120 - 0.370	-0.360 - 0.300	-0.170 - 0.370	-0.230 - 0.340	-0.220 - 0.310
		Min - Max	-0.88 - 1.63	-1.05 - 1.58	-2.53 - 2.24	-1.24 - 1.83	-2.53 - 2.24	-2.53 - 2.24
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	3.137 (0.8038)	3.188 (0.6479)	3.289 (0.7107)	3.250 (0.9174)	3.242 (0.7609)	3.216 (0.7714)
		Median	3.070	3.250	3.350	3.130	3.240	3.220
		Q1 - Q3	2.620 - 3.760	2.845 - 3.570	2.890 - 3.610	2.630 - 3.930	2.810 - 3.640	2.770 - 3.650
		Min - Max	1.30 - 5.04	1.49 - 4.60	1.42 - 4.92	1.44 - 6.54	1.42 - 6.54	1.30 - 6.54
	Safety Follow-up	Change from Baseline						
		n	63	68	65	63	196	259
		Mean (SD)	-0.066 (0.4166)	-0.006 (0.4894)	-0.082 (0.7328)	0.001 (0.4779)	-0.029 (0.5767)	-0.038 (0.5416)
		Median	-0.040	0.015	-0.080	-0.030	-0.030	-0.030
		Q1 - Q3	-0.260 - 0.150	-0.295 - 0.215	-0.410 - 0.320	-0.290 - 0.220	-0.305 - 0.230	-0.290 - 0.200
		Min - Max	-1.38 - 1.08	-1.03 - 1.22	-2.78 - 1.86	-0.89 - 1.64	-2.78 - 1.86	-2.78 - 1.86

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
HDL Cholesterol (mmol/L)	Baseline	Observed Value						
		n	68	70	68	68	206	274
		Mean (SD)	1.602 (0.3682)	1.500 (0.2770)	1.552 (0.3320)	1.577 (0.3142)	1.543 (0.3085)	1.557 (0.3246)
		Median	1.590	1.460	1.540	1.570	1.515	1.530
		Q1 - Q3	1.410 - 1.850	1.320 - 1.680	1.300 - 1.765	1.390 - 1.780	1.330 - 1.720	1.330 - 1.770
		Min - Max	0.92 - 2.43	1.02 - 2.39	0.96 - 2.53	1.01 - 2.43	0.96 - 2.53	0.92 - 2.53
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	1.616 (0.3414)	1.490 (0.3003)	1.551 (0.3627)	1.610 (0.3472)	1.550 (0.3394)	1.566 (0.3405)
		Median	1.620	1.420	1.530	1.570	1.505	1.560
		Q1 - Q3	1.390 - 1.860	1.290 - 1.710	1.295 - 1.795	1.375 - 1.820	1.310 - 1.760	1.320 - 1.800
		Min - Max	0.96 - 2.39	0.96 - 2.44	0.86 - 2.45	0.99 - 2.72	0.86 - 2.72	0.86 - 2.72
	D15	Change from Baseline						
		n	68	70	67	68	205	273
		Mean (SD)	0.009 (0.1287)	-0.011 (0.1495)	0.001 (0.1635)	0.034 (0.1780)	0.008 (0.1642)	0.008 (0.1559)
		Median	0.030	-0.025	0.020	0.020	0	0.020
		Q1 - Q3	-0.065 - 0.090	-0.090 - 0.070	-0.120 - 0.110	-0.110 - 0.170	-0.110 - 0.110	-0.100 - 0.110
		Min - Max	-0.31 - 0.23	-0.42 - 0.38	-0.41 - 0.35	-0.38 - 0.61	-0.42 - 0.61	-0.42 - 0.61

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
HDL Cholesterol (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	1.587 (0.3566)	1.498 (0.2722)	1.572 (0.4108)	1.590 (0.3258)	1.553 (0.3411)	1.561 (0.3447)
		Median	1.540	1.480	1.500	1.540	1.510	1.520
		Q1 - Q3	1.340 - 1.870	1.290 - 1.630	1.330 - 1.830	1.350 - 1.830	1.320 - 1.770	1.320 - 1.790
		Min - Max	0.94 - 2.48	1.03 - 2.20	0.77 - 3.29	1.01 - 2.45	0.77 - 3.29	0.77 - 3.29
	D29	Change from Baseline						
		n	66	69	66	67	202	268
		Mean (SD)	-0.010 (0.1536)	-0.009 (0.1506)	0.025 (0.2539)	0.016 (0.1753)	0.011 (0.1970)	0.005 (0.1872)
		Median	-0.015	0.010	0	0.010	0.010	0.010
		Q1 - Q3	-0.100 - 0.100	-0.100 - 0.090	-0.090 - 0.100	-0.090 - 0.070	-0.100 - 0.090	-0.100 - 0.090
		Min - Max	-0.43 - 0.34	-0.42 - 0.32	-0.63 - 1.49	-0.40 - 0.79	-0.63 - 1.49	-0.63 - 1.49
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	1.592 (0.3489)	1.514 (0.2911)	1.538 (0.3527)	1.584 (0.3487)	1.545 (0.3310)	1.556 (0.3355)
		Median	1.605	1.510	1.520	1.525	1.520	1.530
		Q1 - Q3	1.370 - 1.830	1.360 - 1.680	1.270 - 1.790	1.340 - 1.845	1.320 - 1.790	1.330 - 1.790
		Min - Max	0.69 - 2.51	0.91 - 2.25	0.84 - 2.41	0.68 - 2.49	0.68 - 2.49	0.68 - 2.51

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
HDL Cholesterol (mmol/L)	D43	Change from Baseline						
		n	65	69	66	64	199	264
		Mean (SD)	-0.014 (0.1971)	0.008 (0.1700)	-0.007 (0.2193)	0.003 (0.1812)	0.001 (0.1903)	-0.002 (0.1917)
		Median	0.010	0.020	-0.005	-0.020	0	0
		Q1 - Q3	-0.140 - 0.140	-0.060 - 0.110	-0.140 - 0.110	-0.125 - 0.105	-0.110 - 0.110	-0.120 - 0.110
		Min - Max	-0.75 - 0.47	-0.58 - 0.29	-0.72 - 0.60	-0.46 - 0.48	-0.72 - 0.60	-0.75 - 0.60
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	1.562 (0.3401)	1.488 (0.2690)	1.553 (0.3542)	1.595 (0.3494)	1.544 (0.3270)	1.548 (0.3297)
		Median	1.570	1.465	1.540	1.570	1.520	1.525
		Q1 - Q3	1.310 - 1.790	1.300 - 1.680	1.290 - 1.840	1.320 - 1.820	1.310 - 1.760	1.310 - 1.780
		Min - Max	0.88 - 2.48	0.97 - 2.48	0.89 - 2.47	0.97 - 2.57	0.89 - 2.57	0.88 - 2.57
	D57	Change from Baseline						
		n	64	68	65	63	196	260
		Mean (SD)	-0.048 (0.1961)	-0.015 (0.1457)	0.007 (0.1983)	0.011 (0.1509)	0.001 (0.1661)	-0.011 (0.1748)
		Median	-0.010	0.005	-0.020	0.020	0.005	0
		Q1 - Q3	-0.175 - 0.085	-0.115 - 0.085	-0.110 - 0.140	-0.060 - 0.100	-0.100 - 0.100	-0.110 - 0.100
		Min - Max	-0.72 - 0.35	-0.40 - 0.25	-0.50 - 0.49	-0.53 - 0.40	-0.53 - 0.49	-0.72 - 0.49

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
HDL Cholesterol (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	1.572 (0.4020)	1.490 (0.2850)	1.620 (0.4888)	1.612 (0.3974)	1.572 (0.4002)	1.572 (0.3999)
		Median	1.530	1.465	1.610	1.630	1.530	1.530
		Q1 - Q3	1.320 - 1.910	1.310 - 1.690	1.330 - 1.820	1.340 - 1.860	1.330 - 1.790	1.320 - 1.810
		Min - Max	0.36 - 2.29	0.98 - 2.39	0.93 - 4.32	0.97 - 3.17	0.93 - 4.32	0.36 - 4.32
	D71	Change from Baseline						
		n	64	68	64	63	195	259
		Mean (SD)	-0.040 (0.2254)	-0.013 (0.1565)	0.069 (0.4034)	0.028 (0.1976)	0.027 (0.2737)	0.010 (0.2637)
		Median	-0.050	-0.015	0.020	0.020	0.020	0.010
		Q1 - Q3	-0.170 - 0.120	-0.135 - 0.110	-0.085 - 0.165	-0.070 - 0.120	-0.110 - 0.120	-0.120 - 0.120
		Min - Max	-0.61 - 0.41	-0.44 - 0.35	-0.40 - 2.89	-0.43 - 0.74	-0.44 - 2.89	-0.61 - 2.89
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	1.603 (0.3690)	1.527 (0.2774)	1.573 (0.3542)	1.619 (0.3532)	1.572 (0.3301)	1.579 (0.3396)
		Median	1.585	1.490	1.550	1.620	1.530	1.535
		Q1 - Q3	1.300 - 1.895	1.370 - 1.710	1.320 - 1.790	1.380 - 1.870	1.355 - 1.780	1.350 - 1.805
		Min - Max	0.68 - 2.44	0.98 - 2.36	0.78 - 2.37	0.90 - 2.78	0.78 - 2.78	0.68 - 2.78

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
HDL Cholesterol (mmol/L)	D85	Change from Baseline						
		n	63	67	65	63	195	258
		Mean (SD)	-0.004 (0.2044)	0.021 (0.1492)	0.035 (0.2261)	0.035 (0.1919)	0.030 (0.1904)	0.022 (0.1941)
		Median	0.010	0.030	0.050	0.010	0.020	0.020
		Q1 - Q3	-0.120 - 0.110	-0.090 - 0.100	-0.110 - 0.190	-0.100 - 0.170	-0.100 - 0.150	-0.100 - 0.140
		Min - Max	-0.45 - 0.49	-0.31 - 0.43	-0.45 - 0.80	-0.54 - 0.60	-0.54 - 0.80	-0.54 - 0.80
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	1.576 (0.3558)	1.521 (0.2811)	1.534 (0.3314)	1.574 (0.3321)	1.542 (0.3144)	1.551 (0.3247)
		Median	1.560	1.525	1.530	1.560	1.540	1.540
		Q1 - Q3	1.280 - 1.835	1.335 - 1.690	1.310 - 1.700	1.290 - 1.840	1.320 - 1.740	1.310 - 1.790
		Min - Max	0.96 - 2.41	0.90 - 2.46	0.84 - 2.41	1.01 - 2.33	0.84 - 2.46	0.84 - 2.46
	Safety Follow-up	Change from Baseline						
		n	63	68	65	63	196	259
		Mean (SD)	-0.030 (0.2072)	0.012 (0.1333)	-0.007 (0.2282)	-0.002 (0.1838)	0.001 (0.1844)	-0.006 (0.1902)
		Median	-0.010	0	0	0.010	0	0
		Q1 - Q3	-0.180 - 0.100	-0.080 - 0.100	-0.170 - 0.150	-0.140 - 0.110	-0.120 - 0.120	-0.130 - 0.110
		Min - Max	-0.69 - 0.45	-0.38 - 0.30	-0.62 - 0.84	-0.44 - 0.36	-0.62 - 0.84	-0.69 - 0.84

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Potassium (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	4.120 (0.2773)	4.191 (0.3032)	4.098 (0.3033)	4.148 (0.2728)	4.146 (0.2946)	4.139 (0.2901)
		Median	4.070	4.200	4.110	4.130	4.170	4.130
		Q1 - Q3	3.940 - 4.290	4.020 - 4.320	3.910 - 4.300	3.950 - 4.300	3.930 - 4.300	3.940 - 4.300
		Min - Max	3.43 - 5.30	3.53 - 4.97	3.40 - 4.83	3.52 - 4.93	3.40 - 4.97	3.40 - 5.30
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	4.136 (0.3487)	4.140 (0.2964)	4.108 (0.3198)	4.108 (0.2805)	4.119 (0.2982)	4.123 (0.3111)
		Median	4.080	4.155	4.090	4.065	4.100	4.100
		Q1 - Q3	3.910 - 4.280	3.960 - 4.350	3.900 - 4.305	3.900 - 4.310	3.920 - 4.310	3.920 - 4.310
		Min - Max	3.62 - 5.90	3.45 - 5.25	3.42 - 5.00	3.55 - 4.90	3.42 - 5.25	3.42 - 5.90
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.016 (0.3092)	-0.051 (0.3199)	0.005 (0.3611)	-0.040 (0.3006)	-0.029 (0.3274)	-0.017 (0.3230)
		Median	0	-0.075	-0.005	-0.065	-0.030	-0.030
		Q1 - Q3	-0.160 - 0.140	-0.250 - 0.180	-0.180 - 0.180	-0.190 - 0.115	-0.200 - 0.140	-0.190 - 0.140
		Min - Max	-0.53 - 1.60	-0.89 - 0.60	-0.93 - 1.00	-0.82 - 0.96	-0.93 - 1.00	-0.93 - 1.60

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Potassium (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	4.100 (0.2643)	4.151 (0.2637)	4.062 (0.2233)	4.121 (0.2461)	4.112 (0.2467)	4.109 (0.2507)
		Median	4.090	4.130	4.040	4.140	4.100	4.100
		Q1 - Q3	3.950 - 4.200	4.010 - 4.300	3.900 - 4.200	3.930 - 4.300	3.940 - 4.270	3.940 - 4.240
		Min - Max	3.44 - 4.70	3.53 - 4.90	3.65 - 4.74	3.55 - 4.68	3.53 - 4.90	3.44 - 4.90
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.020 (0.2948)	-0.047 (0.3295)	-0.041 (0.3047)	-0.022 (0.2975)	-0.037 (0.3097)	-0.032 (0.3056)
		Median	-0.020	-0.080	-0.050	0	-0.040	-0.040
		Q1 - Q3	-0.130 - 0.160	-0.190 - 0.130	-0.200 - 0.200	-0.240 - 0.180	-0.200 - 0.180	-0.200 - 0.160
		Min - Max	-0.70 - 0.63	-1.13 - 0.90	-0.74 - 0.80	-0.71 - 0.59	-1.13 - 0.90	-1.13 - 0.90
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	4.097 (0.3192)	4.114 (0.3045)	4.128 (0.2783)	4.124 (0.2234)	4.122 (0.2706)	4.116 (0.2830)
		Median	4.090	4.100	4.120	4.115	4.110	4.110
		Q1 - Q3	3.860 - 4.290	3.960 - 4.290	3.950 - 4.310	3.985 - 4.250	3.960 - 4.270	3.940 - 4.280
		Min - Max	3.47 - 5.06	3.40 - 5.03	3.49 - 4.98	3.67 - 4.67	3.40 - 5.03	3.40 - 5.06

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Potassium (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.022 (0.3177)	-0.084 (0.3557)	0.026 (0.2893)	-0.025 (0.2893)	-0.029 (0.3155)	-0.027 (0.3154)
		Median	-0.030	-0.130	0.080	-0.040	-0.035	-0.035
		Q1 - Q3	-0.220 - 0.130	-0.250 - 0.120	-0.200 - 0.220	-0.195 - 0.150	-0.225 - 0.190	-0.220 - 0.170
		Min - Max	-0.97 - 0.70	-1.09 - 0.90	-0.53 - 0.80	-0.80 - 0.76	-1.09 - 0.90	-1.09 - 0.90
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	4.108 (0.2572)	4.121 (0.3028)	4.121 (0.2880)	4.153 (0.2602)	4.131 (0.2837)	4.125 (0.2771)
		Median	4.080	4.100	4.100	4.100	4.100	4.100
		Q1 - Q3	3.930 - 4.230	3.950 - 4.300	3.960 - 4.280	3.960 - 4.330	3.960 - 4.300	3.950 - 4.300
		Min - Max	3.65 - 4.98	3.10 - 5.21	3.48 - 4.90	3.70 - 4.74	3.10 - 5.21	3.10 - 5.21
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.012 (0.2701)	-0.087 (0.3259)	0.015 (0.3600)	0.001 (0.3155)	-0.024 (0.3360)	-0.021 (0.3204)
		Median	-0.060	-0.075	-0.005	0.060	-0.010	-0.030
		Q1 - Q3	-0.170 - 0.190	-0.255 - 0.145	-0.200 - 0.200	-0.220 - 0.230	-0.220 - 0.200	-0.200 - 0.200
		Min - Max	-0.55 - 0.60	-1.03 - 0.52	-0.95 - 1.10	-1.08 - 0.52	-1.08 - 1.10	-1.08 - 1.10

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Potassium (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	4.106 (0.2543)	4.162 (0.2756)	4.146 (0.3124)	4.156 (0.2586)	4.155 (0.2818)	4.143 (0.2756)
		Median	4.120	4.100	4.100	4.100	4.100	4.100
		Q1 - Q3	3.910 - 4.200	4.000 - 4.320	3.950 - 4.310	3.990 - 4.360	3.980 - 4.325	3.970 - 4.300
		Min - Max	3.61 - 4.79	3.55 - 4.90	3.75 - 5.24	3.63 - 4.74	3.55 - 5.24	3.55 - 5.24
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.014 (0.2746)	-0.046 (0.3435)	0.044 (0.3144)	0.004 (0.3107)	-0.000 (0.3241)	-0.003 (0.3121)
		Median	0	-0.070	0.040	0.010	0.010	0.010
		Q1 - Q3	-0.200 - 0.190	-0.270 - 0.230	-0.160 - 0.240	-0.140 - 0.130	-0.200 - 0.210	-0.200 - 0.200
		Min - Max	-0.83 - 0.70	-0.84 - 0.68	-0.83 - 0.77	-1.03 - 0.78	-1.03 - 0.78	-1.03 - 0.78
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	4.092 (0.2986)	4.127 (0.2568)	4.110 (0.2456)	4.113 (0.2446)	4.117 (0.2480)	4.111 (0.2610)
		Median	4.065	4.140	4.090	4.090	4.100	4.095
		Q1 - Q3	3.860 - 4.280	3.950 - 4.290	3.970 - 4.250	3.940 - 4.300	3.950 - 4.290	3.950 - 4.290
		Min - Max	3.45 - 5.24	3.30 - 4.76	3.52 - 4.66	3.70 - 4.77	3.30 - 4.77	3.30 - 5.24

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Potassium (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.029 (0.2997)	-0.078 (0.3444)	0.004 (0.3101)	-0.039 (0.2782)	-0.038 (0.3130)	-0.036 (0.3092)
		Median	-0.020	-0.090	0.020	-0.040	-0.030	-0.030
		Q1 - Q3	-0.210 - 0.150	-0.320 - 0.190	-0.230 - 0.210	-0.150 - 0.140	-0.225 - 0.195	-0.215 - 0.180
		Min - Max	-0.80 - 0.65	-0.86 - 0.58	-0.85 - 0.86	-1.16 - 0.46	-1.16 - 0.86	-1.16 - 0.86
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	4.135 (0.2660)	4.141 (0.2512)	4.217 (0.2652)	4.184 (0.2819)	4.180 (0.2665)	4.169 (0.2666)
		Median	4.125	4.115	4.205	4.160	4.170	4.160
		Q1 - Q3	4.000 - 4.300	3.980 - 4.320	4.000 - 4.380	3.990 - 4.390	4.000 - 4.350	4.000 - 4.340
		Min - Max	3.52 - 4.75	3.50 - 4.65	3.62 - 4.88	3.62 - 4.95	3.50 - 4.95	3.50 - 4.95
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.004 (0.2676)	-0.054 (0.3261)	0.118 (0.3083)	0.029 (0.3264)	0.030 (0.3265)	0.024 (0.3128)
		Median	0.055	-0.075	0.100	0.030	0.030	0.030
		Q1 - Q3	-0.200 - 0.200	-0.200 - 0.175	-0.100 - 0.300	-0.110 - 0.270	-0.150 - 0.230	-0.160 - 0.200
		Min - Max	-0.70 - 0.68	-0.89 - 0.60	-0.62 - 0.84	-1.05 - 0.61	-1.05 - 0.84	-1.05 - 0.84

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sodium (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	141.279 (1.8795)	140.819 (2.7250)	141.219 (2.1932)	141.278 (1.7187)	141.103 (2.2534)	141.147 (2.1641)
		Median	141.000	141.000	141.000	141.000	141.000	141.000
		Q1 - Q3	140.000 - 142.500	140.000 - 142.400	140.090 - 142.200	140.000 - 142.600	140.000 - 142.400	140.000 - 142.415
		Min - Max	136.70 - 146.00	127.00 - 145.00	136.00 - 147.50	138.00 - 145.60	127.00 - 147.50	127.00 - 147.50
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	140.829 (2.2727)	141.040 (1.8957)	141.173 (1.9609)	141.166 (1.7185)	141.125 (1.8535)	141.051 (1.9669)
		Median	141.000	141.000	141.550	141.000	141.000	141.000
		Q1 - Q3	139.680 - 142.000	140.000 - 142.500	139.750 - 142.400	140.050 - 142.000	140.000 - 142.300	140.000 - 142.300
		Min - Max	136.00 - 145.50	136.00 - 144.80	137.00 - 145.00	137.20 - 144.60	136.00 - 145.00	136.00 - 145.50
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.449 (1.6550)	0.221 (2.7326)	-0.081 (2.0356)	-0.112 (1.5706)	0.011 (2.1672)	-0.104 (2.0576)
		Median	-0.400	0	0	0	0	0
		Q1 - Q3	-1.790 - 0.900	-1.200 - 1.000	-1.500 - 1.000	-1.000 - 1.000	-1.100 - 1.000	-1.300 - 1.000
		Min - Max	-5.00 - 2.40	-4.30 - 15.00	-5.20 - 4.30	-5.00 - 3.50	-5.20 - 15.00	-5.20 - 15.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sodium (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	141.373 (1.7903)	141.001 (1.9340)	141.063 (2.0625)	141.033 (1.9913)	141.032 (1.9863)	141.117 (1.9419)
		Median	141.300	140.950	141.010	141.000	141.000	141.005
		Q1 - Q3	140.100 - 142.600	139.600 - 142.000	139.600 - 143.000	139.900 - 142.400	139.600 - 142.300	139.900 - 142.400
		Min - Max	137.00 - 145.00	137.00 - 147.00	136.00 - 145.10	134.90 - 145.40	134.90 - 147.00	134.90 - 147.00
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.047 (1.6043)	0.209 (2.6945)	-0.161 (1.9934)	-0.240 (1.6404)	-0.061 (2.1588)	-0.034 (2.0331)
		Median	0.300	0	0	-0.200	0	0
		Q1 - Q3	-1.000 - 1.000	-1.500 - 1.000	-1.200 - 1.100	-1.100 - 0.900	-1.200 - 1.000	-1.100 - 1.000
		Min - Max	-3.60 - 6.20	-3.90 - 15.00	-5.30 - 4.00	-5.30 - 3.50	-5.30 - 15.00	-5.30 - 15.00
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	141.353 (2.3116)	141.269 (2.3020)	141.214 (2.2849)	141.083 (1.9699)	141.191 (2.1856)	141.231 (2.2142)
		Median	141.300	141.300	141.100	141.000	141.100	141.240
		Q1 - Q3	140.000 - 143.000	140.000 - 142.600	139.600 - 142.800	139.700 - 142.250	139.700 - 142.600	139.900 - 142.800
		Min - Max	136.00 - 146.40	135.90 - 148.80	135.90 - 146.70	136.00 - 145.70	135.90 - 148.80	135.90 - 148.80

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sodium (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.023 (1.5225)	0.478 (3.1281)	-0.011 (1.7081)	-0.196 (1.8400)	0.099 (2.3377)	0.080 (2.1618)
		Median	0.250	0	0	0	0	0
		Q1 - Q3	-1.000 - 1.000	-1.500 - 1.200	-1.000 - 1.500	-0.900 - 0.950	-1.000 - 1.150	-1.000 - 1.000
		Min - Max	-3.70 - 4.40	-7.50 - 18.00	-4.90 - 3.20	-5.10 - 3.90	-7.50 - 18.00	-7.50 - 18.00
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	141.308 (2.0003)	141.328 (1.8418)	141.399 (2.1632)	141.482 (2.0338)	141.401 (2.0060)	141.378 (2.0011)
		Median	141.300	141.000	141.300	141.200	141.200	141.205
		Q1 - Q3	140.000 - 142.900	140.000 - 143.000	140.000 - 142.900	140.000 - 143.000	140.000 - 143.000	140.000 - 143.000
		Min - Max	136.00 - 146.00	137.00 - 144.70	136.60 - 146.90	137.00 - 146.40	136.60 - 146.90	136.00 - 146.90
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.004 (1.9403)	0.537 (2.4550)	0.156 (1.9751)	0.207 (1.5168)	0.304 (2.0275)	0.228 (2.0070)
		Median	0	0.150	0	0.100	0	0
		Q1 - Q3	-1.000 - 1.100	-1.000 - 1.200	-1.000 - 1.300	-0.600 - 1.100	-1.000 - 1.100	-1.000 - 1.100
		Min - Max	-5.00 - 6.30	-2.50 - 17.00	-4.70 - 5.00	-4.00 - 3.40	-4.70 - 17.00	-5.00 - 17.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sodium (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	140.988 (2.2448)	140.999 (2.0985)	141.228 (1.9756)	141.202 (2.1763)	141.140 (2.0762)	141.102 (2.1161)
		Median	141.000	141.000	141.300	141.300	141.170	141.000
		Q1 - Q3	139.000 - 142.500	139.850 - 142.250	140.000 - 142.800	139.800 - 142.600	139.900 - 142.550	139.700 - 142.500
		Min - Max	136.00 - 146.00	135.60 - 145.60	135.30 - 145.00	135.00 - 146.10	135.00 - 146.10	135.00 - 146.10
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.324 (1.7987)	0.208 (2.2520)	-0.065 (1.9479)	-0.073 (1.6601)	0.027 (1.9702)	-0.060 (1.9315)
		Median	-0.390	0	-0.200	-0.300	-0.100	-0.200
		Q1 - Q3	-1.100 - 1.000	-1.000 - 1.050	-1.200 - 1.100	-1.100 - 1.000	-1.150 - 1.090	-1.100 - 1.000
		Min - Max	-5.50 - 4.10	-3.00 - 13.00	-4.80 - 5.90	-3.50 - 4.00	-4.80 - 13.00	-5.50 - 13.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	141.191 (1.8040)	141.326 (2.1370)	141.265 (2.0959)	141.172 (1.8882)	141.256 (2.0365)	141.240 (1.9786)
		Median	141.100	141.200	141.100	141.100	141.150	141.100
		Q1 - Q3	140.000 - 142.050	140.000 - 142.400	140.000 - 143.000	139.900 - 142.600	140.000 - 142.600	140.000 - 142.405
		Min - Max	136.00 - 146.20	135.00 - 147.00	134.00 - 145.00	137.00 - 145.20	134.00 - 147.00	134.00 - 147.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Sodium (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.092 (1.4890)	0.553 (2.7875)	0.022 (1.9000)	-0.103 (1.4826)	0.163 (2.1479)	0.100 (2.0063)
		Median	0	0.400	0.150	0	0.100	0
		Q1 - Q3	-1.000 - 1.000	-1.000 - 1.600	-1.500 - 1.200	-1.000 - 1.000	-1.225 - 1.200	-1.000 - 1.200
		Min - Max	-4.00 - 3.30	-4.00 - 15.00	-4.10 - 4.00	-3.00 - 4.00	-4.10 - 15.00	-4.10 - 15.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	141.212 (1.9444)	141.185 (2.3406)	141.312 (1.7159)	141.363 (1.9093)	141.284 (2.0020)	141.267 (1.9846)
		Median	141.200	141.050	141.350	141.100	141.200	141.200
		Q1 - Q3	139.900 - 142.600	139.545 - 143.000	140.000 - 142.200	140.000 - 142.800	140.000 - 142.600	140.000 - 142.600
		Min - Max	137.00 - 146.80	134.00 - 147.00	138.00 - 145.00	138.00 - 147.00	134.00 - 147.00	134.00 - 147.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.131 (1.6085)	0.411 (2.9016)	0.038 (1.9873)	0.126 (1.4994)	0.195 (2.2192)	0.115 (2.0879)
		Median	0	0	0.100	0	0	0
		Q1 - Q3	-1.000 - 0.900	-1.000 - 1.450	-1.030 - 1.300	-1.000 - 1.000	-1.000 - 1.200	-1.000 - 1.000
		Min - Max	-4.00 - 3.30	-4.00 - 18.00	-6.00 - 5.20	-3.00 - 6.10	-6.00 - 18.00	-6.00 - 18.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Chloride (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	104.947 (2.6038)	104.258 (2.5119)	104.378 (2.5603)	105.163 (1.8318)	104.595 (2.3515)	104.683 (2.4170)
		Median	105.000	104.800	104.000	105.150	104.800	104.850
		Q1 - Q3	103.300 - 106.400	103.000 - 106.000	102.600 - 106.300	103.800 - 106.100	103.000 - 106.100	103.150 - 106.100
		Min - Max	96.00 - 110.10	94.00 - 108.00	96.70 - 110.50	101.20 - 110.20	94.00 - 110.50	94.00 - 110.50
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	104.464 (2.2398)	104.853 (1.8773)	104.597 (2.2326)	105.003 (2.1489)	104.818 (2.0863)	104.729 (2.1272)
		Median	104.500	105.050	104.450	104.950	105.000	104.900
		Q1 - Q3	103.000 - 106.000	103.700 - 106.000	102.900 - 106.150	103.200 - 106.675	103.300 - 106.200	103.100 - 106.100
		Min - Max	99.80 - 109.10	99.60 - 109.00	100.00 - 108.90	100.80 - 108.70	99.60 - 109.00	99.60 - 109.10
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.482 (2.1801)	0.596 (2.5167)	0.183 (2.2030)	-0.160 (1.6780)	0.210 (2.1759)	0.036 (2.1937)
		Median	-0.600	0.150	0.400	-0.150	0	0
		Q1 - Q3	-1.900 - 1.000	-1.000 - 1.800	-1.200 - 1.150	-1.400 - 1.000	-1.100 - 1.100	-1.300 - 1.000
		Min - Max	-7.00 - 5.90	-3.70 - 11.00	-5.10 - 7.80	-4.70 - 3.50	-5.10 - 11.00	-7.00 - 11.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Chloride (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	104.836 (1.9554)	104.987 (2.1025)	104.676 (2.4057)	105.170 (2.0936)	104.945 (2.2028)	104.918 (2.1411)
		Median	105.000	105.000	104.700	105.400	105.000	105.000
		Q1 - Q3	103.200 - 106.100	104.000 - 106.300	103.100 - 106.200	103.900 - 106.700	103.700 - 106.410	103.600 - 106.300
		Min - Max	100.80 - 109.50	99.00 - 111.80	99.00 - 109.00	99.70 - 109.00	99.00 - 111.80	99.00 - 111.80
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.116 (2.3830)	0.730 (2.8259)	0.199 (2.0814)	-0.001 (1.8901)	0.313 (2.3168)	0.207 (2.3363)
		Median	0	0.100	0.400	0.100	0.200	0.100
		Q1 - Q3	-1.400 - 1.200	-0.800 - 2.000	-0.900 - 1.500	-0.900 - 1.200	-0.800 - 1.500	-1.000 - 1.400
		Min - Max	-5.90 - 9.50	-4.70 - 10.00	-5.00 - 4.60	-6.00 - 4.90	-6.00 - 10.00	-6.00 - 10.00
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	104.868 (2.3171)	104.823 (2.4376)	104.443 (2.2842)	104.871 (2.0638)	104.711 (2.2685)	104.750 (2.2773)
		Median	104.700	105.000	104.500	105.300	105.000	105.000
		Q1 - Q3	103.100 - 106.350	103.600 - 106.000	102.600 - 106.500	103.300 - 106.350	103.000 - 106.350	103.000 - 106.350
		Min - Max	99.60 - 110.20	97.00 - 110.40	98.50 - 108.40	100.00 - 109.80	97.00 - 110.40	97.00 - 110.40

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Chloride (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.058 (2.2406)	0.567 (2.9842)	-0.034 (1.8789)	-0.328 (1.7739)	0.079 (2.3131)	0.045 (2.2919)
		Median	0.200	0.100	-0.200	-0.400	0	0
		Q1 - Q3	-1.060 - 1.000	-0.800 - 1.750	-1.100 - 1.000	-1.500 - 1.000	-1.100 - 1.000	-1.100 - 1.000
		Min - Max	-7.00 - 6.90	-6.30 - 14.00	-4.70 - 5.10	-5.00 - 3.10	-6.30 - 14.00	-7.00 - 14.00
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	104.991 (2.0772)	105.136 (2.1478)	104.484 (2.4508)	105.123 (2.3831)	104.913 (2.3364)	104.933 (2.2712)
		Median	105.000	105.500	104.600	105.000	104.900	105.000
		Q1 - Q3	103.600 - 106.200	103.350 - 106.950	102.800 - 106.200	103.400 - 106.800	103.000 - 106.400	103.100 - 106.400
		Min - Max	101.00 - 109.50	101.30 - 109.10	99.50 - 110.50	100.10 - 111.77	99.50 - 111.77	99.50 - 111.77
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.074 (2.3618)	0.877 (2.7574)	0.049 (2.1936)	-0.053 (1.7969)	0.302 (2.3223)	0.246 (2.3297)
		Median	0	0.450	0	0	0	0
		Q1 - Q3	-1.580 - 1.200	-1.000 - 2.000	-1.500 - 1.500	-1.400 - 1.000	-1.200 - 1.690	-1.300 - 1.690
		Min - Max	-4.72 - 7.00	-4.10 - 15.00	-4.00 - 5.50	-4.50 - 3.80	-4.50 - 15.00	-4.72 - 15.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Chloride (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	104.674 (2.2983)	104.728 (1.9877)	104.290 (2.5368)	104.824 (2.4441)	104.614 (2.3287)	104.629 (2.3169)
		Median	104.700	105.000	104.500	105.000	104.950	104.900
		Q1 - Q3	103.200 - 106.200	103.250 - 106.000	103.000 - 105.900	103.800 - 106.100	103.100 - 106.000	103.100 - 106.000
		Min - Max	98.00 - 109.90	100.00 - 108.00	96.80 - 110.00	97.20 - 109.44	96.80 - 110.00	96.80 - 110.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.243 (2.3280)	0.469 (2.4201)	-0.176 (2.1842)	-0.352 (1.8396)	-0.009 (2.1866)	-0.067 (2.2204)
		Median	0	0.250	0	-0.600	0	0
		Q1 - Q3	-1.700 - 1.200	-0.950 - 1.700	-1.900 - 1.100	-1.200 - 1.000	-1.200 - 1.200	-1.500 - 1.200
		Min - Max	-6.24 - 4.80	-4.60 - 10.00	-4.99 - 4.50	-4.80 - 5.00	-4.99 - 10.00	-6.24 - 10.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	104.809 (2.1691)	105.003 (2.2940)	104.322 (2.2974)	104.946 (2.3738)	104.755 (2.3300)	104.769 (2.2874)
		Median	104.350	105.000	104.300	105.000	104.900	104.800
		Q1 - Q3	103.350 - 106.450	103.600 - 106.100	103.000 - 106.000	103.200 - 106.500	103.100 - 106.300	103.150 - 106.350
		Min - Max	100.10 - 109.00	99.20 - 111.00	98.50 - 110.20	100.00 - 110.35	98.50 - 111.00	98.50 - 111.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Chloride (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.106 (2.4267)	0.710 (2.9776)	-0.113 (2.2100)	-0.230 (1.8472)	0.131 (2.4272)	0.073 (2.4245)
		Median	-0.100	0	-0.150	-0.100	0	0
		Q1 - Q3	-1.400 - 1.100	-1.500 - 2.000	-1.500 - 1.600	-1.000 - 1.000	-1.350 - 1.500	-1.400 - 1.500
		Min - Max	-8.00 - 7.00	-4.10 - 10.00	-6.00 - 6.30	-6.00 - 4.40	-6.00 - 10.00	-8.00 - 10.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	104.723 (2.2110)	104.737 (2.3967)	105.113 (2.4591)	105.299 (2.1357)	105.043 (2.3382)	104.964 (2.3076)
		Median	104.400	105.050	105.000	105.200	105.000	105.000
		Q1 - Q3	103.250 - 106.450	103.000 - 106.150	103.400 - 106.900	103.700 - 107.300	103.500 - 106.900	103.500 - 106.830
		Min - Max	100.00 - 109.70	98.00 - 110.00	98.80 - 110.00	100.50 - 109.30	98.00 - 110.00	98.00 - 110.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.205 (2.4207)	0.446 (2.5922)	0.604 (2.1850)	0.161 (1.7200)	0.408 (2.2021)	0.258 (2.2683)
		Median	0	0.100	0.780	0	0.200	0.200
		Q1 - Q3	-1.100 - 1.000	-1.000 - 1.600	-0.900 - 2.000	-0.900 - 1.800	-1.000 - 1.900	-1.000 - 1.800
		Min - Max	-8.00 - 6.00	-4.80 - 14.00	-4.90 - 5.60	-3.50 - 4.00	-4.90 - 14.00	-8.00 - 14.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Calcium (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	2.392 (0.0951)	2.380 (0.0872)	2.396 (0.0848)	2.408 (0.1071)	2.395 (0.0937)	2.394 (0.0939)
		Median	2.400	2.380	2.400	2.395	2.390	2.390
		Q1 - Q3	2.340 - 2.450	2.320 - 2.440	2.340 - 2.440	2.350 - 2.485	2.330 - 2.440	2.330 - 2.445
		Min - Max	2.16 - 2.60	2.16 - 2.65	2.20 - 2.65	2.19 - 2.68	2.16 - 2.68	2.16 - 2.68
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	2.396 (0.1003)	2.382 (0.0964)	2.386 (0.1007)	2.398 (0.0905)	2.389 (0.0957)	2.391 (0.0968)
		Median	2.390	2.400	2.390	2.405	2.400	2.400
		Q1 - Q3	2.330 - 2.480	2.320 - 2.450	2.320 - 2.435	2.335 - 2.450	2.320 - 2.450	2.320 - 2.450
		Min - Max	2.19 - 2.61	2.09 - 2.61	2.18 - 2.65	2.23 - 2.62	2.09 - 2.65	2.09 - 2.65
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.003 (0.0700)	0.002 (0.0990)	-0.010 (0.0803)	-0.009 (0.0730)	-0.005 (0.0847)	-0.003 (0.0813)
		Median	0	0	-0.010	-0.010	-0.010	0
		Q1 - Q3	-0.040 - 0.050	-0.050 - 0.050	-0.070 - 0.040	-0.050 - 0.035	-0.050 - 0.040	-0.050 - 0.040
		Min - Max	-0.22 - 0.15	-0.37 - 0.23	-0.19 - 0.30	-0.22 - 0.15	-0.37 - 0.30	-0.37 - 0.30

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Calcium (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	2.385 (0.0937)	2.383 (0.0944)	2.369 (0.1075)	2.393 (0.1100)	2.381 (0.1041)	2.382 (0.1015)
		Median	2.390	2.380	2.360	2.400	2.380	2.380
		Q1 - Q3	2.310 - 2.440	2.330 - 2.430	2.320 - 2.430	2.320 - 2.450	2.330 - 2.440	2.320 - 2.440
		Min - Max	2.19 - 2.59	2.19 - 2.83	1.95 - 2.61	2.11 - 2.74	1.95 - 2.83	1.95 - 2.83
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.006 (0.0780)	0.001 (0.0870)	-0.025 (0.1103)	-0.014 (0.0876)	-0.013 (0.0956)	-0.011 (0.0915)
		Median	-0.010	0.010	-0.030	-0.010	-0.010	-0.010
		Q1 - Q3	-0.040 - 0.050	-0.050 - 0.060	-0.070 - 0.030	-0.050 - 0.050	-0.060 - 0.040	-0.050 - 0.040
		Min - Max	-0.22 - 0.16	-0.17 - 0.31	-0.48 - 0.40	-0.24 - 0.19	-0.48 - 0.40	-0.48 - 0.40
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	2.387 (0.1035)	2.376 (0.1007)	2.384 (0.1118)	2.377 (0.0968)	2.379 (0.1029)	2.381 (0.1029)
		Median	2.405	2.380	2.380	2.375	2.380	2.390
		Q1 - Q3	2.320 - 2.450	2.300 - 2.440	2.300 - 2.450	2.310 - 2.445	2.300 - 2.440	2.320 - 2.450
		Min - Max	2.10 - 2.58	2.12 - 2.61	2.15 - 2.74	2.16 - 2.61	2.12 - 2.74	2.10 - 2.74

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Calcium (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.004 (0.0785)	-0.006 (0.0971)	-0.010 (0.0955)	-0.031 (0.0973)	-0.015 (0.0967)	-0.012 (0.0925)
		Median	-0.010	-0.010	-0.010	-0.020	-0.010	-0.010
		Q1 - Q3	-0.050 - 0.050	-0.080 - 0.060	-0.070 - 0.050	-0.085 - 0.040	-0.080 - 0.060	-0.070 - 0.050
		Min - Max	-0.19 - 0.18	-0.19 - 0.18	-0.26 - 0.30	-0.32 - 0.13	-0.32 - 0.30	-0.32 - 0.30
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	2.376 (0.0963)	2.378 (0.0908)	2.380 (0.0977)	2.378 (0.1016)	2.379 (0.0961)	2.378 (0.0960)
		Median	2.390	2.380	2.390	2.380	2.380	2.380
		Q1 - Q3	2.300 - 2.450	2.315 - 2.425	2.310 - 2.440	2.320 - 2.440	2.310 - 2.440	2.310 - 2.440
		Min - Max	2.20 - 2.63	2.19 - 2.61	2.19 - 2.69	2.11 - 2.60	2.11 - 2.69	2.11 - 2.69
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.013 (0.0839)	-0.003 (0.0782)	-0.013 (0.0867)	-0.028 (0.0928)	-0.015 (0.0861)	-0.014 (0.0854)
		Median	-0.010	0	-0.025	-0.040	-0.020	-0.020
		Q1 - Q3	-0.060 - 0.040	-0.060 - 0.060	-0.070 - 0.030	-0.090 - 0.060	-0.070 - 0.050	-0.070 - 0.050
		Min - Max	-0.24 - 0.13	-0.19 - 0.17	-0.20 - 0.30	-0.27 - 0.17	-0.27 - 0.30	-0.27 - 0.30

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Calcium (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	2.368 (0.1023)	2.372 (0.0987)	2.374 (0.1898)	2.381 (0.0977)	2.376 (0.1350)	2.374 (0.1275)
		Median	2.390	2.390	2.390	2.380	2.385	2.390
		Q1 - Q3	2.300 - 2.420	2.285 - 2.435	2.340 - 2.450	2.320 - 2.430	2.310 - 2.440	2.310 - 2.430
		Min - Max	2.05 - 2.57	2.19 - 2.61	1.11 - 2.80	2.18 - 2.65	1.11 - 2.80	1.11 - 2.80
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.022 (0.0772)	-0.010 (0.0968)	-0.019 (0.1781)	-0.026 (0.0905)	-0.018 (0.1276)	-0.019 (0.1170)
		Median	-0.010	0	0	-0.020	-0.010	-0.010
		Q1 - Q3	-0.060 - 0.030	-0.090 - 0.065	-0.060 - 0.050	-0.060 - 0.010	-0.070 - 0.050	-0.070 - 0.050
		Min - Max	-0.20 - 0.14	-0.18 - 0.15	-1.21 - 0.30	-0.31 - 0.20	-1.21 - 0.30	-1.21 - 0.30
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	2.374 (0.1221)	2.374 (0.0909)	2.375 (0.0967)	2.373 (0.0987)	2.374 (0.0949)	2.374 (0.1020)
		Median	2.390	2.370	2.365	2.380	2.370	2.380
		Q1 - Q3	2.325 - 2.440	2.320 - 2.430	2.310 - 2.430	2.310 - 2.430	2.315 - 2.430	2.320 - 2.430
		Min - Max	1.80 - 2.63	2.18 - 2.63	2.19 - 2.61	2.10 - 2.61	2.10 - 2.63	1.80 - 2.63

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Calcium (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.013 (0.0921)	-0.007 (0.0885)	-0.018 (0.1009)	-0.034 (0.1063)	-0.019 (0.0988)	-0.018 (0.0970)
		Median	-0.005	-0.010	-0.020	-0.020	-0.010	-0.010
		Q1 - Q3	-0.050 - 0.045	-0.080 - 0.070	-0.070 - 0.030	-0.120 - 0.050	-0.080 - 0.050	-0.075 - 0.050
		Min - Max	-0.43 - 0.15	-0.15 - 0.19	-0.28 - 0.40	-0.38 - 0.14	-0.38 - 0.40	-0.43 - 0.40
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	2.384 (0.0892)	2.371 (0.1040)	2.368 (0.0921)	2.376 (0.0944)	2.371 (0.0966)	2.375 (0.0948)
		Median	2.390	2.370	2.380	2.370	2.380	2.380
		Q1 - Q3	2.340 - 2.435	2.320 - 2.410	2.300 - 2.430	2.300 - 2.430	2.300 - 2.420	2.320 - 2.430
		Min - Max	2.12 - 2.59	2.14 - 2.78	2.17 - 2.59	2.20 - 2.66	2.14 - 2.78	2.12 - 2.78
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.006 (0.0749)	-0.009 (0.0972)	-0.026 (0.0830)	-0.035 (0.0943)	-0.023 (0.0919)	-0.019 (0.0882)
		Median	0	-0.005	-0.020	-0.010	-0.020	-0.010
		Q1 - Q3	-0.055 - 0.035	-0.075 - 0.060	-0.070 - 0.020	-0.090 - 0.040	-0.070 - 0.030	-0.070 - 0.030
		Min - Max	-0.20 - 0.16	-0.25 - 0.21	-0.23 - 0.20	-0.31 - 0.10	-0.31 - 0.21	-0.31 - 0.21

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Phosphate (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	1.2155 (0.17008)	1.2041 (0.14327)	1.1931 (0.13884)	1.2022 (0.14701)	1.1998 (0.14245)	1.2038 (0.14966)
		Median	1.2400	1.2000	1.1900	1.2000	1.2000	1.2000
		Q1 - Q3	1.1000 - 1.3300	1.1300 - 1.3000	1.0900 - 1.2900	1.1050 - 1.3150	1.1100 - 1.3100	1.1100 - 1.3100
		Min - Max	0.760 - 1.760	0.770 - 1.590	0.780 - 1.440	0.890 - 1.510	0.770 - 1.590	0.760 - 1.760
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	1.2223 (0.16949)	1.1942 (0.14673)	1.2156 (0.13176)	1.2243 (0.13522)	1.2112 (0.13805)	1.2140 (0.14633)
		Median	1.2100	1.2050	1.2100	1.2300	1.2200	1.2200
		Q1 - Q3	1.1300 - 1.3200	1.1200 - 1.2800	1.1230 - 1.3100	1.1400 - 1.3050	1.1300 - 1.3000	1.1300 - 1.3000
		Min - Max	0.790 - 1.710	0.800 - 1.510	0.910 - 1.570	0.870 - 1.530	0.800 - 1.570	0.790 - 1.710
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.0068 (0.12024)	-0.0099 (0.08467)	0.0201 (0.09978)	0.0221 (0.11423)	0.0106 (0.10075)	0.0096 (0.10576)
		Median	0.0100	-0.0200	0.0200	0.0130	0.0100	0.0100
		Q1 - Q3	-0.0700 - 0.0700	-0.0800 - 0.0500	-0.0400 - 0.0800	-0.0550 - 0.1150	-0.0600 - 0.0800	-0.0600 - 0.0800
		Min - Max	-0.220 - 0.280	-0.220 - 0.190	-0.200 - 0.330	-0.230 - 0.260	-0.230 - 0.330	-0.230 - 0.330

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Phosphate (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	1.2111 (0.14559)	1.2044 (0.13900)	1.1793 (0.13172)	1.2168 (0.15594)	1.2002 (0.14269)	1.2029 (0.14322)
		Median	1.2200	1.2000	1.1800	1.2100	1.1900	1.2000
		Q1 - Q3	1.1210 - 1.3100	1.1100 - 1.2900	1.0900 - 1.2800	1.1100 - 1.3000	1.1100 - 1.2900	1.1100 - 1.2900
		Min - Max	0.880 - 1.670	0.870 - 1.490	0.900 - 1.500	0.930 - 1.820	0.870 - 1.820	0.870 - 1.820
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.0053 (0.12704)	-0.0011 (0.10164)	-0.0154 (0.10994)	0.0179 (0.13951)	0.0004 (0.11820)	-0.0010 (0.12024)
		Median	-0.0200	-0.0100	-0.0200	0.0100	-0.0100	-0.0100
		Q1 - Q3	-0.0900 - 0.0900	-0.0700 - 0.0500	-0.0900 - 0.0500	-0.0900 - 0.0900	-0.0800 - 0.0700	-0.0800 - 0.0800
		Min - Max	-0.320 - 0.320	-0.180 - 0.340	-0.250 - 0.380	-0.270 - 0.450	-0.270 - 0.450	-0.320 - 0.450
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	1.2263 (0.16355)	1.1888 (0.15398)	1.2188 (0.12721)	1.2013 (0.13838)	1.2029 (0.14031)	1.2087 (0.14645)
		Median	1.2200	1.1800	1.2200	1.2000	1.2000	1.2100
		Q1 - Q3	1.1400 - 1.3300	1.1000 - 1.2900	1.1400 - 1.3100	1.1150 - 1.2800	1.1250 - 1.2900	1.1300 - 1.3000
		Min - Max	0.860 - 1.680	0.840 - 1.490	0.930 - 1.530	0.910 - 1.610	0.840 - 1.610	0.840 - 1.680

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Phosphate (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.0110 (0.14530)	-0.0167 (0.10966)	0.0241 (0.11862)	-0.0038 (0.12495)	0.0011 (0.11838)	0.0035 (0.12538)
		Median	-0.0100	-0.0100	0.0200	0	0.0100	0
		Q1 - Q3	-0.0900 - 0.1000	-0.0700 - 0.0400	-0.0500 - 0.1100	-0.0750 - 0.0900	-0.0700 - 0.0800	-0.0700 - 0.0800
		Min - Max	-0.250 - 0.370	-0.430 - 0.240	-0.300 - 0.310	-0.300 - 0.290	-0.430 - 0.310	-0.430 - 0.370
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	1.2145 (0.17746)	1.1948 (0.14452)	1.2181 (0.13222)	1.2162 (0.13803)	1.2095 (0.13813)	1.2107 (0.14851)
		Median	1.2000	1.1950	1.2200	1.2000	1.2100	1.2100
		Q1 - Q3	1.0900 - 1.3300	1.1100 - 1.2800	1.1200 - 1.3100	1.1300 - 1.3000	1.1200 - 1.2900	1.1200 - 1.3000
		Min - Max	0.820 - 1.720	0.880 - 1.620	0.870 - 1.600	0.840 - 1.510	0.840 - 1.620	0.820 - 1.720
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.0009 (0.12560)	-0.0117 (0.11700)	0.0224 (0.11499)	0.0123 (0.12381)	0.0074 (0.11884)	0.0058 (0.12034)
		Median	0	-0.0150	0.0300	0.0100	0.0100	0.0100
		Q1 - Q3	-0.0700 - 0.0980	-0.0900 - 0.0750	-0.0500 - 0.1100	-0.0600 - 0.0900	-0.0700 - 0.0900	-0.0700 - 0.0900
		Min - Max	-0.300 - 0.310	-0.300 - 0.270	-0.230 - 0.270	-0.350 - 0.250	-0.350 - 0.270	-0.350 - 0.310

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Phosphate (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	1.2362 (0.17757)	1.2083 (0.14134)	1.2731 (0.35880)	1.2227 (0.13174)	1.2344 (0.23541)	1.2349 (0.22209)
		Median	1.2500	1.1950	1.2400	1.2200	1.2300	1.2300
		Q1 - Q3	1.1200 - 1.3400	1.1250 - 1.3200	1.1500 - 1.3200	1.1500 - 1.2900	1.1300 - 1.3050	1.1300 - 1.3200
		Min - Max	0.830 - 1.900	0.850 - 1.490	0.850 - 3.940	0.940 - 1.560	0.850 - 3.940	0.830 - 3.940
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.0226 (0.16763)	0.0018 (0.12598)	0.0798 (0.35984)	0.0187 (0.11639)	0.0331 (0.23107)	0.0305 (0.21675)
		Median	0	-0.0100	0.0500	0.0100	0.0100	0.0100
		Q1 - Q3	-0.0800 - 0.1400	-0.0700 - 0.0850	-0.0500 - 0.1200	-0.0800 - 0.0900	-0.0650 - 0.1100	-0.0700 - 0.1200
		Min - Max	-0.380 - 0.460	-0.300 - 0.340	-0.240 - 2.770	-0.300 - 0.270	-0.300 - 2.770	-0.380 - 2.770
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	1.2370 (0.13553)	1.2083 (0.13849)	1.2298 (0.12953)	1.2090 (0.13677)	1.2158 (0.13466)	1.2210 (0.13492)
		Median	1.2750	1.2100	1.2500	1.1900	1.2200	1.2300
		Q1 - Q3	1.1350 - 1.3300	1.1200 - 1.3000	1.1660 - 1.3100	1.1300 - 1.3000	1.1300 - 1.3000	1.1300 - 1.3150
		Min - Max	0.880 - 1.520	0.860 - 1.470	0.890 - 1.480	0.870 - 1.530	0.860 - 1.530	0.860 - 1.530

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Phosphate (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	0.0238 (0.13265)	0.0027 (0.12004)	0.0341 (0.12323)	0.0050 (0.13127)	0.0141 (0.12500)	0.0165 (0.12674)
		Median	0.0300	0	0.0300	0	0	0.0100
		Q1 - Q3	-0.0850 - 0.1250	-0.1100 - 0.0700	-0.0400 - 0.1100	-0.0800 - 0.1200	-0.0700 - 0.1000	-0.0800 - 0.1100
		Min - Max	-0.240 - 0.300	-0.300 - 0.300	-0.250 - 0.290	-0.250 - 0.260	-0.300 - 0.300	-0.300 - 0.300
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	1.2405 (0.13590)	1.2120 (0.14299)	1.2055 (0.13153)	1.2048 (0.13823)	1.2075 (0.13704)	1.2156 (0.13724)
		Median	1.2500	1.2000	1.1950	1.2100	1.2000	1.2100
		Q1 - Q3	1.1350 - 1.3250	1.1200 - 1.2900	1.1200 - 1.2900	1.1300 - 1.2800	1.1200 - 1.2900	1.1300 - 1.3000
		Min - Max	0.910 - 1.610	0.830 - 1.630	0.890 - 1.520	0.920 - 1.600	0.830 - 1.630	0.830 - 1.630
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.0263 (0.14600)	0.0075 (0.11991)	0.0131 (0.11850)	-0.0001 (0.10947)	0.0069 (0.11572)	0.0117 (0.12381)
		Median	0.0200	-0.0100	0.0150	0	0	0.0100
		Q1 - Q3	-0.0700 - 0.1300	-0.0600 - 0.0800	-0.0800 - 0.0760	-0.0600 - 0.0700	-0.0600 - 0.0700	-0.0700 - 0.0900
		Min - Max	-0.320 - 0.340	-0.260 - 0.300	-0.210 - 0.360	-0.350 - 0.230	-0.350 - 0.360	-0.350 - 0.360

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Magnesium (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.893 (0.0694)	0.888 (0.0667)	0.908 (0.0767)	0.914 (0.0949)	0.903 (0.0805)	0.900 (0.0779)
		Median	0.890	0.890	0.900	0.890	0.900	0.890
		Q1 - Q3	0.840 - 0.920	0.850 - 0.930	0.860 - 0.950	0.855 - 0.975	0.850 - 0.950	0.850 - 0.940
		Min - Max	0.78 - 1.24	0.66 - 1.01	0.79 - 1.26	0.72 - 1.34	0.66 - 1.34	0.66 - 1.34
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	0.893 (0.0681)	0.891 (0.0803)	0.901 (0.0678)	0.913 (0.0703)	0.902 (0.0732)	0.899 (0.0720)
		Median	0.880	0.880	0.880	0.905	0.890	0.880
		Q1 - Q3	0.850 - 0.950	0.850 - 0.940	0.845 - 0.950	0.870 - 0.965	0.850 - 0.950	0.850 - 0.950
		Min - Max	0.76 - 1.06	0.66 - 1.12	0.77 - 1.05	0.76 - 1.08	0.66 - 1.12	0.66 - 1.12
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.000 (0.0540)	0.004 (0.0617)	-0.006 (0.0576)	-0.001 (0.0857)	-0.001 (0.0692)	-0.001 (0.0656)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.030 - 0.030	-0.030 - 0.040	-0.040 - 0.030	-0.040 - 0.040	-0.040 - 0.040	-0.030 - 0.040
		Min - Max	-0.19 - 0.12	-0.13 - 0.18	-0.29 - 0.13	-0.36 - 0.20	-0.36 - 0.20	-0.36 - 0.20

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Magnesium (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	0.892 (0.0571)	0.878 (0.0786)	0.894 (0.0669)	0.907 (0.0727)	0.893 (0.0736)	0.893 (0.0698)
		Median	0.890	0.870	0.890	0.910	0.890	0.890
		Q1 - Q3	0.850 - 0.920	0.830 - 0.920	0.850 - 0.940	0.860 - 0.950	0.840 - 0.940	0.850 - 0.930
		Min - Max	0.76 - 1.06	0.71 - 1.08	0.72 - 1.05	0.73 - 1.12	0.71 - 1.12	0.71 - 1.12
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.000 (0.0596)	-0.009 (0.0644)	-0.014 (0.0682)	-0.005 (0.0857)	-0.009 (0.0729)	-0.007 (0.0699)
		Median	0	-0.010	0	0	-0.010	0
		Q1 - Q3	-0.020 - 0.030	-0.040 - 0.030	-0.050 - 0.020	-0.040 - 0.040	-0.040 - 0.030	-0.040 - 0.030
		Min - Max	-0.34 - 0.11	-0.17 - 0.14	-0.34 - 0.11	-0.35 - 0.17	-0.35 - 0.17	-0.35 - 0.17
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	0.882 (0.0647)	0.887 (0.0777)	0.908 (0.0643)	0.897 (0.0626)	0.897 (0.0689)	0.893 (0.0681)
		Median	0.870	0.870	0.890	0.890	0.880	0.880
		Q1 - Q3	0.830 - 0.930	0.840 - 0.930	0.860 - 0.960	0.860 - 0.930	0.860 - 0.940	0.850 - 0.930
		Min - Max	0.76 - 1.04	0.71 - 1.14	0.80 - 1.10	0.77 - 1.06	0.71 - 1.14	0.71 - 1.14

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Magnesium (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.011 (0.0698)	0 (0.0679)	-0.000 (0.0652)	-0.017 (0.0899)	-0.006 (0.0749)	-0.007 (0.0736)
		Median	-0.010	0	0	-0.005	0	0
		Q1 - Q3	-0.040 - 0.030	-0.030 - 0.030	-0.040 - 0.030	-0.050 - 0.040	-0.040 - 0.030	-0.040 - 0.030
		Min - Max	-0.33 - 0.14	-0.16 - 0.22	-0.30 - 0.16	-0.37 - 0.17	-0.37 - 0.22	-0.37 - 0.22
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	0.884 (0.0661)	0.892 (0.0796)	0.902 (0.0570)	0.895 (0.0682)	0.896 (0.0688)	0.893 (0.0682)
		Median	0.870	0.890	0.900	0.900	0.890	0.890
		Q1 - Q3	0.840 - 0.920	0.845 - 0.940	0.860 - 0.950	0.850 - 0.930	0.850 - 0.940	0.850 - 0.930
		Min - Max	0.76 - 1.07	0.72 - 1.12	0.79 - 1.03	0.74 - 1.08	0.72 - 1.12	0.72 - 1.12
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.009 (0.0592)	0.005 (0.0643)	-0.006 (0.0669)	-0.020 (0.0755)	-0.007 (0.0693)	-0.007 (0.0669)
		Median	-0.010	0	0	-0.020	0	-0.005
		Q1 - Q3	-0.050 - 0.030	-0.035 - 0.045	-0.040 - 0.030	-0.060 - 0.020	-0.040 - 0.030	-0.050 - 0.030
		Min - Max	-0.17 - 0.14	-0.17 - 0.14	-0.30 - 0.11	-0.34 - 0.16	-0.34 - 0.16	-0.34 - 0.16

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Magnesium (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	0.881 (0.0584)	0.884 (0.0764)	0.898 (0.0674)	0.899 (0.0763)	0.893 (0.0735)	0.890 (0.0701)
		Median	0.880	0.880	0.880	0.900	0.880	0.880
		Q1 - Q3	0.850 - 0.920	0.830 - 0.935	0.850 - 0.940	0.850 - 0.960	0.840 - 0.950	0.840 - 0.940
		Min - Max	0.71 - 1.01	0.72 - 1.08	0.73 - 1.04	0.73 - 1.07	0.72 - 1.08	0.71 - 1.08
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.012 (0.0613)	-0.002 (0.0626)	-0.012 (0.0776)	-0.016 (0.0736)	-0.010 (0.0712)	-0.010 (0.0688)
		Median	0	0	-0.020	-0.010	-0.010	-0.010
		Q1 - Q3	-0.040 - 0.030	-0.040 - 0.035	-0.050 - 0.040	-0.040 - 0.030	-0.050 - 0.040	-0.050 - 0.030
		Min - Max	-0.29 - 0.09	-0.16 - 0.15	-0.28 - 0.12	-0.36 - 0.11	-0.36 - 0.15	-0.36 - 0.15
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	0.884 (0.0617)	0.888 (0.0749)	0.894 (0.0690)	0.898 (0.0699)	0.893 (0.0711)	0.891 (0.0689)
		Median	0.880	0.880	0.890	0.900	0.890	0.890
		Q1 - Q3	0.840 - 0.920	0.840 - 0.920	0.840 - 0.940	0.840 - 0.950	0.840 - 0.940	0.840 - 0.940
		Min - Max	0.76 - 1.02	0.71 - 1.08	0.74 - 1.07	0.77 - 1.05	0.71 - 1.08	0.71 - 1.08

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Magnesium (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.010 (0.0625)	0.002 (0.0739)	-0.014 (0.0744)	-0.016 (0.0840)	-0.009 (0.0775)	-0.009 (0.0740)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.050 - 0.030	-0.030 - 0.040	-0.060 - 0.030	-0.040 - 0.040	-0.040 - 0.030	-0.040 - 0.030
		Min - Max	-0.26 - 0.17	-0.21 - 0.18	-0.35 - 0.17	-0.33 - 0.15	-0.35 - 0.18	-0.35 - 0.18
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	0.877 (0.0671)	0.883 (0.0740)	0.888 (0.0647)	0.900 (0.0580)	0.890 (0.0662)	0.887 (0.0665)
		Median	0.880	0.870	0.885	0.890	0.880	0.880
		Q1 - Q3	0.850 - 0.920	0.835 - 0.920	0.850 - 0.930	0.850 - 0.950	0.850 - 0.930	0.850 - 0.930
		Min - Max	0.66 - 1.14	0.74 - 1.15	0.71 - 1.03	0.79 - 1.00	0.71 - 1.15	0.66 - 1.15
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.015 (0.0567)	-0.004 (0.0750)	-0.021 (0.0719)	-0.016 (0.0831)	-0.014 (0.0767)	-0.014 (0.0722)
		Median	0	-0.010	-0.015	0	-0.010	-0.010
		Q1 - Q3	-0.050 - 0.025	-0.045 - 0.045	-0.060 - 0.020	-0.050 - 0.030	-0.050 - 0.030	-0.050 - 0.030
		Min - Max	-0.19 - 0.08	-0.17 - 0.24	-0.41 - 0.07	-0.35 - 0.18	-0.41 - 0.24	-0.41 - 0.24

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glucose (mmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	5.2655 (0.49739)	5.1963 (0.46324)	5.3204 (0.41238)	5.3819 (0.54454)	5.2986 (0.48006)	5.2904 (0.48375)
		Median	5.2000	5.1150	5.3000	5.3550	5.2600	5.2350
		Q1 - Q3	4.9600 - 5.5700	4.8500 - 5.3700	5.1000 - 5.5300	5.1000 - 5.6600	5.0000 - 5.5300	4.9800 - 5.5550
		Min - Max	4.300 - 6.660	4.370 - 6.620	4.420 - 6.680	3.830 - 6.650	3.830 - 6.680	3.830 - 6.680
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	5.2914 (0.52845)	5.2086 (0.54007)	5.2774 (0.47944)	5.3994 (0.63641)	5.2943 (0.55852)	5.2936 (0.55018)
		Median	5.2400	5.0850	5.2550	5.3200	5.2100	5.2200
		Q1 - Q3	4.9100 - 5.6000	4.8500 - 5.4500	4.9300 - 5.5350	4.9950 - 5.7000	4.9100 - 5.5700	4.9100 - 5.5900
		Min - Max	4.400 - 6.810	4.450 - 7.550	4.230 - 6.520	4.070 - 8.230	4.070 - 8.230	4.070 - 8.230
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.0259 (0.33985)	0.0123 (0.32795)	-0.0326 (0.30525)	0.0175 (0.47772)	-0.0008 (0.37649)	0.0059 (0.36722)
		Median	-0.0100	0	-0.0100	0	0	0
		Q1 - Q3	-0.1900 - 0.2600	-0.1900 - 0.2000	-0.2000 - 0.1150	-0.3400 - 0.3100	-0.2300 - 0.2000	-0.2000 - 0.2200
		Min - Max	-0.650 - 0.970	-0.800 - 0.960	-1.000 - 0.870	-0.900 - 1.580	-1.000 - 1.580	-1.000 - 1.580

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glucose (mmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	5.2593 (0.50421)	5.1764 (0.50178)	5.2527 (0.59923)	5.3991 (0.69185)	5.2751 (0.60586)	5.2711 (0.58143)
		Median	5.2400	5.1500	5.1700	5.2900	5.2000	5.2000
		Q1 - Q3	4.8300 - 5.5000	4.8100 - 5.4000	4.9000 - 5.6400	4.9700 - 5.6700	4.9200 - 5.5800	4.9000 - 5.5500
		Min - Max	4.460 - 6.910	4.150 - 6.700	4.140 - 8.070	4.500 - 9.510	4.140 - 9.510	4.140 - 9.510
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.0104 (0.36927)	-0.0052 (0.33723)	-0.0500 (0.37314)	0.0343 (0.52501)	-0.0069 (0.41835)	-0.0078 (0.40606)
		Median	-0.0200	0	-0.1200	0.0300	-0.0200	-0.0200
		Q1 - Q3	-0.2600 - 0.2000	-0.2300 - 0.2200	-0.3000 - 0.1600	-0.2600 - 0.3000	-0.2700 - 0.2400	-0.2600 - 0.2200
		Min - Max	-0.870 - 1.340	-0.750 - 0.730	-1.000 - 1.390	-1.160 - 2.860	-1.160 - 2.860	-1.160 - 2.860
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	5.3244 (0.61340)	5.2426 (0.56417)	5.2943 (0.45913)	5.4984 (0.97187)	5.3418 (0.69983)	5.3375 (0.67833)
		Median	5.2850	5.1000	5.3100	5.2700	5.2000	5.2250
		Q1 - Q3	4.8400 - 5.6600	4.9400 - 5.3900	4.9700 - 5.5400	5.0000 - 5.7500	4.9600 - 5.5800	4.9500 - 5.6000
		Min - Max	4.220 - 6.820	4.390 - 7.360	3.900 - 6.590	4.330 - 11.630	3.900 - 11.630	3.900 - 11.630

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glucose (mmol/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.0548 (0.37908)	0.0610 (0.46674)	-0.0084 (0.36781)	0.1228 (0.77632)	0.0576 (0.55941)	0.0569 (0.51985)
		Median	0.0300	0	-0.0200	0.0150	0	0
		Q1 - Q3	-0.2000 - 0.3000	-0.1900 - 0.2600	-0.2500 - 0.2800	-0.2100 - 0.1750	-0.2200 - 0.2500	-0.2100 - 0.2600
		Min - Max	-0.940 - 0.930	-0.910 - 2.290	-0.840 - 0.880	-0.900 - 4.980	-0.910 - 4.980	-0.940 - 4.980
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	5.3288 (0.64598)	5.2706 (0.57296)	5.3267 (0.53961)	5.5067 (0.96508)	5.3649 (0.71655)	5.3559 (0.69867)
		Median	5.2000	5.1800	5.2650	5.3900	5.2600	5.2550
		Q1 - Q3	4.9100 - 5.6000	4.9300 - 5.4800	5.0100 - 5.6300	5.0000 - 5.7600	5.0000 - 5.5500	4.9500 - 5.5800
		Min - Max	4.450 - 7.980	4.400 - 7.530	4.260 - 7.630	3.990 - 10.950	3.990 - 10.950	3.990 - 10.950
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.0691 (0.42333)	0.0982 (0.42213)	0.0212 (0.39347)	0.1322 (0.74855)	0.0833 (0.54004)	0.0798 (0.51283)
		Median	0.0200	0.0100	0.0100	0.0900	0.0200	0.0200
		Q1 - Q3	-0.2000 - 0.2700	-0.1850 - 0.3650	-0.2300 - 0.2400	-0.3300 - 0.3400	-0.2300 - 0.3000	-0.2000 - 0.3000
		Min - Max	-0.760 - 2.140	-0.740 - 1.920	-0.900 - 1.420	-0.920 - 4.300	-0.920 - 4.300	-0.920 - 4.300

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glucose (mmol/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	5.2672 (0.50373)	5.2665 (0.57309)	5.3837 (0.59389)	5.6381 (1.47355)	5.4248 (0.97107)	5.3856 (0.87998)
		Median	5.2800	5.1700	5.3300	5.4000	5.2800	5.2800
		Q1 - Q3	4.8700 - 5.6000	4.9450 - 5.4600	5.0000 - 5.6000	5.1100 - 5.6900	5.0000 - 5.5600	4.9600 - 5.5700
		Min - Max	4.400 - 6.820	4.370 - 7.860	4.400 - 8.050	4.140 - 14.500	4.140 - 14.500	4.140 - 14.500
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.0075 (0.32349)	0.0941 (0.43025)	0.0817 (0.41948)	0.2637 (1.30236)	0.1445 (0.81696)	0.1104 (0.72791)
		Median	0	0.0300	0.0500	0.0600	0.0400	0.0300
		Q1 - Q3	-0.1600 - 0.1500	-0.2050 - 0.2500	-0.2100 - 0.2000	-0.1700 - 0.2600	-0.2000 - 0.2400	-0.2000 - 0.2200
		Min - Max	-0.850 - 0.980	-0.570 - 1.800	-0.660 - 1.880	-0.960 - 7.850	-0.960 - 7.850	-0.960 - 7.850
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	5.2125 (0.53940)	5.2372 (0.58285)	5.2388 (0.45877)	5.5337 (1.16198)	5.3330 (0.79599)	5.3034 (0.74196)
		Median	5.1600	5.2300	5.1600	5.3200	5.2600	5.2400
		Q1 - Q3	4.8600 - 5.4250	4.9600 - 5.4100	5.0000 - 5.5000	5.1000 - 5.6500	5.0000 - 5.5100	5.0000 - 5.5000
		Min - Max	4.290 - 6.850	3.420 - 7.600	4.500 - 7.340	4.270 - 13.640	3.420 - 13.640	3.420 - 13.640

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glucose (mmol/L)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.0488 (0.35366)	0.0587 (0.45957)	-0.0667 (0.33540)	0.1592 (0.98444)	0.0488 (0.65238)	0.0248 (0.59382)
		Median	-0.0700	0.0600	-0.0750	0.0400	-0.0200	-0.0500
		Q1 - Q3	-0.3000 - 0.2050	-0.2500 - 0.3000	-0.3000 - 0.1200	-0.3000 - 0.2900	-0.2850 - 0.2400	-0.2950 - 0.2350
		Min - Max	-0.870 - 0.820	-1.350 - 1.800	-0.850 - 0.740	-0.640 - 6.990	-1.350 - 6.990	-1.350 - 6.990
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	5.2219 (0.45055)	5.2834 (0.61087)	5.2517 (0.72203)	5.4963 (0.88107)	5.3409 (0.74673)	5.3117 (0.68714)
		Median	5.1250	5.1700	5.1800	5.3000	5.2000	5.1900
		Q1 - Q3	4.8400 - 5.4850	4.9700 - 5.4250	4.9000 - 5.5000	5.0900 - 5.6600	4.9700 - 5.5500	4.9500 - 5.5300
		Min - Max	4.530 - 6.320	4.400 - 8.160	4.180 - 9.490	4.400 - 11.160	4.180 - 11.160	4.180 - 11.160
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.0181 (0.32465)	0.0956 (0.50578)	-0.0476 (0.62802)	0.0994 (0.68038)	0.0488 (0.60777)	0.0324 (0.55212)
		Median	-0.0350	0.0050	-0.1650	0.0300	-0.0100	-0.0100
		Q1 - Q3	-0.2550 - 0.2100	-0.2000 - 0.2900	-0.3600 - 0.1700	-0.2600 - 0.2700	-0.2600 - 0.2400	-0.2600 - 0.2400
		Min - Max	-0.690 - 1.100	-0.840 - 2.450	-1.000 - 3.860	-0.940 - 4.510	-1.000 - 4.510	-1.000 - 4.510

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glomerular Filtration Rate, Estimated	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	114.39 (16.899)	115.04 (19.160)	117.31 (18.732)	115.13 (21.231)	115.82 (19.659)	115.47 (18.987)
		Median	115.50	116.55	115.20	111.65	114.50	114.85
		Q1 - Q3	101.90 - 125.40	97.70 - 126.30	102.50 - 130.30	100.85 - 126.25	100.80 - 127.50	101.50 - 127.40
		Min - Max	79.3 - 157.6	80.3 - 159.7	85.6 - 165.4	80.5 - 180.7	80.3 - 180.7	79.3 - 180.7
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	114.34 (19.115)	115.20 (20.450)	116.78 (20.425)	118.35 (23.992)	116.76 (21.608)	116.15 (21.002)
		Median	113.30	113.10	112.90	115.55	114.05	113.90
		Q1 - Q3	101.70 - 124.30	99.60 - 130.10	103.05 - 128.40	102.65 - 130.40	102.30 - 129.50	102.10 - 128.60
		Min - Max	72.2 - 184.6	65.4 - 184.6	81.6 - 202.0	70.2 - 186.5	65.4 - 202.0	65.4 - 202.0
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.05 (11.710)	0.16 (12.744)	0.06 (13.876)	3.22 (13.061)	1.14 (13.247)	0.84 (12.868)
		Median	0	-0.55	-0.65	1.70	0	0
		Q1 - Q3	-7.90 - 8.80	-7.00 - 8.90	-8.60 - 8.20	-4.90 - 8.30	-6.60 - 8.30	-7.00 - 8.60
		Min - Max	-25.6 - 33.3	-32.3 - 29.9	-34.4 - 43.5	-17.5 - 61.7	-34.4 - 61.7	-34.4 - 61.7

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glomerular Filtration Rate, Estimated	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	113.81 (18.699)	119.39 (20.598)	118.76 (21.345)	118.45 (24.179)	118.87 (21.974)	117.62 (21.288)
		Median	115.30	117.40	115.20	115.60	116.30	115.85
		Q1 - Q3	97.00 - 127.20	104.10 - 128.10	102.50 - 131.20	100.10 - 131.60	103.30 - 131.40	102.60 - 130.70
		Min - Max	73.3 - 155.4	75.3 - 169.5	86.2 - 171.4	76.2 - 205.8	75.3 - 205.8	73.3 - 205.8
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.19 (13.040)	3.86 (11.752)	1.80 (12.210)	3.27 (13.839)	2.98 (12.591)	1.95 (12.808)
		Median	0	5.20	0	3.00	2.80	1.95
		Q1 - Q3	-8.70 - 6.80	-4.10 - 12.60	-6.80 - 11.30	-6.10 - 11.50	-5.10 - 11.90	-6.10 - 11.00
		Min - Max	-41.4 - 23.6	-27.1 - 30.1	-22.9 - 25.0	-25.9 - 67.7	-27.1 - 67.7	-41.4 - 67.7
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	115.22 (17.251)	117.75 (21.148)	120.41 (22.140)	120.32 (26.666)	119.47 (23.282)	118.41 (21.987)
		Median	114.95	114.90	119.30	114.90	116.50	116.00
		Q1 - Q3	102.50 - 128.60	101.50 - 131.20	101.90 - 134.20	101.20 - 133.00	101.70 - 133.10	101.90 - 131.60
		Min - Max	70.1 - 148.4	83.2 - 167.1	85.7 - 187.7	79.3 - 213.1	79.3 - 213.1	70.1 - 213.1

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glomerular Filtration Rate, Estimated	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.26 (13.109)	2.22 (12.772)	3.45 (12.806)	4.89 (15.204)	3.49 (13.583)	2.69 (13.515)
		Median	0.20	2.80	3.30	2.00	2.40	2.25
		Q1 - Q3	-10.80 - 10.70	-3.90 - 10.50	-3.50 - 11.50	-4.70 - 9.85	-4.00 - 11.05	-4.80 - 11.00
		Min - Max	-29.3 - 23.5	-30.2 - 31.0	-27.0 - 45.8	-18.6 - 74.2	-30.2 - 74.2	-30.2 - 74.2
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	115.00 (19.125)	119.88 (22.396)	119.35 (22.526)	118.77 (25.316)	119.35 (23.295)	118.27 (22.377)
		Median	115.60	117.55	115.65	113.10	116.30	116.25
		Q1 - Q3	101.80 - 124.90	105.10 - 131.85	102.60 - 128.60	101.30 - 132.10	103.40 - 129.20	102.50 - 128.60
		Min - Max	68.2 - 155.4	73.4 - 175.3	85.7 - 186.8	79.3 - 199.0	73.4 - 199.0	68.2 - 199.0
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.43 (15.020)	4.31 (13.851)	2.28 (13.534)	3.58 (15.327)	3.40 (14.190)	2.66 (14.428)
		Median	0	2.80	-0.65	3.40	2.10	1.75
		Q1 - Q3	-8.40 - 9.60	-5.00 - 13.00	-7.90 - 10.40	-6.00 - 12.00	-5.80 - 12.00	-6.10 - 11.80
		Min - Max	-59.0 - 36.1	-22.8 - 53.3	-23.2 - 36.5	-38.3 - 61.7	-38.3 - 61.7	-59.0 - 61.7

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glomerular Filtration Rate, Estimated	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	115.86 (18.343)	121.75 (20.655)	118.73 (19.786)	118.13 (24.618)	119.58 (21.687)	118.66 (20.932)
		Median	114.80	118.85	115.50	115.00	116.50	116.20
		Q1 - Q3	102.30 - 127.00	108.30 - 135.05	104.90 - 129.90	101.90 - 132.60	105.45 - 132.85	104.90 - 131.30
		Min - Max	62.0 - 157.6	71.8 - 167.6	85.5 - 177.8	80.5 - 200.3	71.8 - 200.3	62.0 - 200.3
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.28 (15.233)	6.18 (12.411)	1.64 (12.044)	2.94 (16.959)	3.63 (13.990)	3.05 (14.316)
		Median	0	6.80	0	1.80	2.15	2.00
		Q1 - Q3	-5.00 - 10.00	-2.75 - 14.10	-5.70 - 8.90	-6.00 - 9.90	-4.90 - 10.70	-4.90 - 10.30
		Min - Max	-53.9 - 41.1	-20.9 - 34.5	-20.9 - 30.1	-36.3 - 77.5	-36.3 - 77.5	-53.9 - 77.5
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	116.19 (18.873)	118.87 (20.655)	119.76 (20.446)	121.73 (26.391)	120.09 (22.508)	119.13 (21.700)
		Median	118.15	116.30	115.85	116.20	116.25	116.40
		Q1 - Q3	102.15 - 129.45	106.30 - 127.70	103.70 - 133.90	102.80 - 135.90	103.95 - 131.95	103.55 - 131.85
		Min - Max	64.5 - 154.7	75.7 - 181.3	88.7 - 204.6	75.3 - 205.8	75.3 - 205.8	64.5 - 205.8

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Glomerular Filtration Rate, Estimated	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	1.30 (14.154)	3.96 (12.698)	2.69 (13.574)	6.53 (17.235)	4.36 (14.593)	3.61 (14.519)
		Median	-0.25	3.60	1.15	4.10	3.65	2.65
		Q1 - Q3	-8.20 - 10.85	-3.60 - 11.80	-7.00 - 10.40	-5.20 - 14.60	-4.95 - 12.45	-5.40 - 12.05
		Min - Max	-34.2 - 41.1	-26.0 - 36.5	-24.5 - 39.2	-31.6 - 64.9	-31.6 - 64.9	-34.2 - 64.9
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	114.30 (17.726)	117.47 (22.558)	119.90 (19.040)	117.96 (24.827)	118.44 (22.142)	117.42 (21.187)
		Median	114.00	116.50	117.90	111.20	116.30	115.20
		Q1 - Q3	101.75 - 120.80	104.00 - 127.85	106.70 - 130.30	101.20 - 130.20	103.10 - 129.30	102.80 - 128.40
		Min - Max	79.3 - 157.6	73.1 - 175.3	80.1 - 167.3	81.1 - 187.1	73.1 - 187.1	73.1 - 187.1
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.44 (13.070)	2.58 (14.688)	2.93 (13.940)	2.76 (12.783)	2.75 (13.781)	1.97 (13.654)
		Median	-2.15	2.40	0.95	0.90	1.70	0
		Q1 - Q3	-9.20 - 9.65	-6.30 - 10.65	-7.30 - 9.60	-6.00 - 9.90	-6.50 - 10.00	-7.30 - 10.00
		Min - Max	-29.2 - 34.0	-30.0 - 53.3	-21.2 - 52.2	-22.2 - 55.9	-30.0 - 55.9	-30.0 - 55.9

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase Increased	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	20.325 (8.2113)	19.785 (8.6983)	20.956 (9.3039)	19.965 (7.9273)	20.234 (8.6384)	20.257 (8.5190)
		Median	18.600	18.000	17.600	17.000	17.830	18.000
		Q1 - Q3	14.400 - 24.000	14.000 - 23.000	14.400 - 27.000	14.100 - 24.500	14.000 - 25.000	14.000 - 25.000
		Min - Max	6.00 - 46.00	9.30 - 53.00	4.00 - 45.00	10.00 - 47.81	4.00 - 53.00	4.00 - 53.00
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	20.250 (9.0918)	20.607 (13.8058)	20.471 (10.3324)	20.741 (11.8085)	20.606 (12.0263)	20.517 (11.3467)
		Median	17.920	17.350	18.500	17.000	17.650	17.700
		Q1 - Q3	14.300 - 24.000	14.000 - 21.000	13.000 - 25.400	14.000 - 23.400	14.000 - 23.900	14.000 - 24.000
		Min - Max	6.00 - 61.00	8.00 - 103.00	4.00 - 67.00	10.00 - 82.90	4.00 - 103.00	4.00 - 103.00
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.075 (7.7012)	0.822 (12.8244)	-0.175 (7.5975)	0.776 (8.7359)	0.478 (9.9687)	0.339 (9.4407)
		Median	0	0	-1.065	0	-0.300	-0.100
		Q1 - Q3	-3.600 - 2.100	-3.000 - 2.000	-3.950 - 2.500	-2.635 - 2.300	-3.180 - 2.000	-3.400 - 2.000
		Min - Max	-20.00 - 37.00	-24.00 - 93.70	-22.00 - 37.00	-26.35 - 43.20	-26.35 - 93.70	-26.35 - 93.70

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase Increased	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	20.139 (9.2864)	19.600 (10.4109)	21.150 (10.5130)	26.003 (55.9993)	22.224 (33.2367)	21.707 (29.1806)
		Median	19.000	17.000	18.000	17.000	17.000	18.000
		Q1 - Q3	15.000 - 22.300	14.000 - 23.000	13.000 - 27.000	13.100 - 23.000	14.000 - 23.100	14.000 - 23.000
		Min - Max	5.00 - 63.00	2.33 - 73.00	4.00 - 60.00	7.00 - 472.10	2.33 - 472.10	2.33 - 472.10
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.319 (6.9719)	-0.338 (6.6262)	0.434 (8.1611)	6.097 (53.3224)	2.041 (31.2055)	1.455 (27.2802)
		Median	-1.000	-0.700	0	-1.000	-0.500	-0.600
		Q1 - Q3	-3.000 - 3.200	-4.000 - 3.000	-3.800 - 2.900	-3.800 - 2.000	-3.800 - 2.200	-3.380 - 2.800
		Min - Max	-21.00 - 30.00	-18.00 - 20.00	-23.00 - 27.00	-18.65 - 432.40	-23.00 - 432.40	-23.00 - 432.40
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	19.228 (8.1012)	18.523 (7.5680)	20.039 (9.8392)	22.629 (29.4810)	20.345 (18.1574)	20.068 (16.2453)
		Median	18.000	17.000	17.600	17.150	17.000	17.000
		Q1 - Q3	14.000 - 22.000	14.000 - 21.000	13.000 - 26.000	13.950 - 23.000	13.200 - 23.000	13.700 - 22.700
		Min - Max	3.00 - 49.00	8.00 - 51.00	5.00 - 50.00	8.00 - 247.20	5.00 - 247.20	3.00 - 247.20

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase Increased	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.268 (6.5978)	-1.414 (5.7452)	-0.676 (7.5996)	3.352 (26.8276)	0.358 (16.2054)	-0.045 (14.4355)
		Median	-1.000	-1.000	-1.000	-0.050	-1.000	-1.000
		Q1 - Q3	-4.000 - 2.000	-4.000 - 2.000	-4.000 - 2.700	-2.000 - 1.900	-3.500 - 2.000	-3.600 - 2.000
		Min - Max	-24.00 - 24.00	-21.00 - 12.00	-25.00 - 20.30	-26.74 - 207.50	-26.74 - 207.50	-26.74 - 207.50
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	19.786 (9.8940)	19.650 (9.5549)	21.850 (20.8977)	18.678 (7.6550)	20.076 (14.0116)	20.004 (13.0940)
		Median	17.000	16.900	17.500	18.000	17.000	17.000
		Q1 - Q3	14.200 - 20.300	13.000 - 22.500	12.300 - 24.900	13.000 - 22.800	13.000 - 23.000	13.000 - 23.000
		Min - Max	6.00 - 65.00	10.00 - 56.00	3.00 - 171.00	8.00 - 51.18	3.00 - 171.00	3.00 - 171.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.802 (9.7453)	-0.316 (8.2667)	1.018 (19.9215)	-0.275 (5.3378)	0.144 (12.8208)	-0.091 (12.1199)
		Median	-2.000	-1.000	-0.950	-0.100	-1.000	-1.000
		Q1 - Q3	-5.000 - 2.900	-4.000 - 1.510	-4.300 - 2.700	-3.000 - 2.000	-4.000 - 2.000	-4.000 - 2.250
		Min - Max	-29.00 - 37.00	-25.00 - 28.00	-32.00 - 145.00	-15.00 - 19.00	-32.00 - 145.00	-32.00 - 145.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase Increased	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	35.546 (122.0404)	19.735 (9.3986)	19.192 (8.0336)	18.393 (8.1063)	19.124 (8.5281)	23.214 (61.4114)
		Median	17.000	18.500	17.400	17.000	17.450	17.200
		Q1 - Q3	14.000 - 23.000	13.000 - 22.450	13.200 - 23.200	13.000 - 20.900	13.000 - 22.750	13.000 - 23.000
		Min - Max	1.40 - 999.00	8.00 - 62.00	7.00 - 46.00	9.00 - 61.70	7.00 - 62.00	1.40 - 999.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	14.958 (120.7617)	-0.231 (7.6709)	-1.468 (8.2434)	-0.560 (6.5794)	-0.747 (7.5208)	3.164 (60.6505)
		Median	0	-0.250	-0.700	-1.000	-0.500	-0.200
		Q1 - Q3	-4.000 - 3.300	-4.000 - 2.950	-4.500 - 2.400	-3.000 - 1.600	-4.000 - 2.000	-4.000 - 2.600
		Min - Max	-34.00 - 969.00	-23.00 - 24.00	-30.00 - 19.00	-27.39 - 28.10	-30.00 - 28.10	-34.00 - 969.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	18.196 (7.2845)	19.934 (10.8038)	22.201 (15.9671)	18.169 (6.3585)	20.130 (11.8343)	19.654 (10.9109)
		Median	17.000	17.000	17.450	16.300	17.000	17.000
		Q1 - Q3	14.000 - 22.050	13.000 - 21.000	14.000 - 25.500	14.000 - 21.000	13.950 - 22.500	14.000 - 22.050
		Min - Max	6.00 - 47.00	8.00 - 74.00	5.00 - 96.00	8.00 - 42.70	5.00 - 96.00	5.00 - 96.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alanine Aminotransferase Increased	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-2.245 (7.5224)	0.371 (8.0372)	1.369 (12.5269)	-0.784 (6.5228)	0.336 (9.4057)	-0.300 (9.0339)
		Median	-1.000	-1.000	-0.250	0	-0.650	-0.855
		Q1 - Q3	-4.500 - 1.050	-3.900 - 3.000	-2.000 - 3.900	-3.000 - 2.000	-3.000 - 3.000	-3.650 - 2.200
		Min - Max	-34.00 - 12.00	-16.00 - 30.00	-27.00 - 55.00	-28.38 - 25.80	-28.38 - 55.00	-34.00 - 55.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	19.152 (8.9062)	19.595 (9.1560)	19.243 (11.5851)	19.215 (7.3147)	19.356 (9.4933)	19.306 (9.3363)
		Median	17.000	17.000	17.000	18.000	17.000	17.000
		Q1 - Q3	13.000 - 21.500	14.000 - 21.850	12.000 - 22.800	15.000 - 23.000	14.000 - 22.200	13.110 - 22.000
		Min - Max	6.00 - 50.00	9.00 - 66.00	5.00 - 71.00	9.00 - 41.50	5.00 - 71.00	5.00 - 71.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.575 (10.1153)	0.055 (6.5026)	-1.301 (10.8598)	0.246 (7.0814)	-0.338 (8.3609)	-0.641 (8.8189)
		Median	-1.850	-0.100	-2.450	0	-0.800	-1.000
		Q1 - Q3	-5.150 - 1.385	-2.900 - 2.050	-5.500 - 1.000	-2.000 - 2.000	-3.200 - 2.000	-4.000 - 2.000
		Min - Max	-36.00 - 29.00	-16.60 - 17.00	-28.00 - 48.00	-24.28 - 24.10	-28.00 - 48.00	-36.00 - 48.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase Increased	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	22.965 (5.5040)	22.513 (5.7478)	22.741 (5.5797)	21.980 (4.5527)	22.414 (5.3090)	22.552 (5.3536)
		Median	22.700	21.000	22.000	22.000	21.400	22.000
		Q1 - Q3	19.000 - 26.000	19.000 - 24.700	19.000 - 25.000	18.000 - 25.550	19.000 - 25.000	19.000 - 25.000
		Min - Max	11.00 - 43.00	13.70 - 43.00	12.80 - 42.00	13.11 - 33.00	12.80 - 43.00	11.00 - 43.00
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	23.132 (6.6195)	23.887 (10.2143)	23.238 (7.1171)	22.001 (6.0917)	23.050 (8.0259)	23.071 (7.6857)
		Median	22.000	21.050	22.000	20.500	21.000	21.200
		Q1 - Q3	19.000 - 25.000	19.000 - 25.000	18.450 - 25.750	18.000 - 23.200	19.000 - 25.000	19.000 - 25.000
		Min - Max	13.90 - 46.00	14.00 - 92.60	12.60 - 54.00	14.00 - 52.10	12.60 - 92.60	12.60 - 92.60
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.167 (5.3089)	1.374 (10.4372)	0.634 (4.7975)	0.022 (4.6856)	0.683 (7.1883)	0.554 (6.7605)
		Median	-0.500	0.215	0.170	0	0	0
		Q1 - Q3	-2.600 - 2.000	-2.000 - 3.100	-2.150 - 2.800	-2.000 - 1.000	-2.000 - 2.000	-2.000 - 2.000
		Min - Max	-15.00 - 24.00	-16.00 - 78.90	-11.60 - 17.00	-7.80 - 27.30	-16.00 - 78.90	-16.00 - 78.90

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase Increased	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	22.209 (4.8191)	22.502 (6.4307)	23.392 (6.1884)	33.422 (88.1351)	26.400 (50.8819)	25.360 (44.1941)
		Median	22.000	21.000	22.860	21.000	22.000	22.000
		Q1 - Q3	19.000 - 25.000	19.000 - 25.000	18.600 - 26.600	18.000 - 26.000	18.600 - 26.000	18.700 - 25.700
		Min - Max	13.00 - 37.00	15.00 - 57.00	12.70 - 43.00	13.00 - 741.60	12.70 - 741.60	12.70 - 741.60
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.835 (4.5120)	-0.138 (4.6031)	0.808 (4.5812)	11.487 (87.3434)	4.011 (50.3430)	2.809 (43.7328)
		Median	0	0	0.400	0	0	0
		Q1 - Q3	-3.000 - 1.800	-2.100 - 2.000	-2.000 - 3.000	-2.000 - 1.800	-2.000 - 2.000	-2.100 - 2.000
		Min - Max	-14.40 - 15.00	-16.00 - 14.00	-14.00 - 13.00	-7.00 - 713.90	-16.00 - 713.90	-16.00 - 713.90
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	21.849 (6.5814)	22.432 (5.5145)	22.309 (6.6577)	22.069 (5.8259)	22.275 (5.9883)	22.169 (6.1308)
		Median	21.000	21.300	20.700	20.900	21.000	21.000
		Q1 - Q3	17.700 - 24.000	19.000 - 25.000	18.000 - 24.700	18.800 - 25.500	18.800 - 25.000	18.000 - 25.000
		Min - Max	4.80 - 46.00	15.00 - 42.00	13.00 - 48.00	12.00 - 43.60	12.00 - 48.00	4.80 - 48.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase Increased	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.242 (4.9710)	-0.208 (4.7005)	-0.275 (4.9785)	0.449 (4.6415)	-0.020 (4.7639)	-0.323 (4.8356)
		Median	-0.400	-1.000	-0.700	-0.050	-0.750	-0.700
		Q1 - Q3	-3.100 - 1.500	-2.100 - 1.500	-3.000 - 1.200	-2.350 - 2.300	-2.750 - 2.000	-3.000 - 2.000
		Min - Max	-18.80 - 11.00	-16.00 - 15.00	-11.60 - 18.40	-8.00 - 15.90	-16.00 - 18.40	-18.80 - 18.40
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	22.959 (6.6128)	22.543 (6.7436)	22.595 (9.6329)	21.380 (4.4469)	22.189 (7.2720)	22.380 (7.1096)
		Median	22.000	20.950	20.000	20.000	20.100	21.000
		Q1 - Q3	18.200 - 25.000	18.500 - 24.950	18.300 - 24.000	18.000 - 24.300	18.000 - 24.800	18.000 - 25.000
		Min - Max	14.00 - 49.00	14.00 - 48.00	11.40 - 83.00	14.28 - 34.00	11.40 - 83.00	11.40 - 83.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.205 (6.0179)	-0.138 (6.1212)	0.018 (9.6819)	-0.144 (3.4582)	-0.088 (6.9054)	-0.117 (6.6852)
		Median	0	-0.440	-1.000	0	-0.070	0
		Q1 - Q3	-4.000 - 2.300	-3.000 - 2.300	-4.000 - 1.900	-1.700 - 2.500	-3.000 - 2.000	-3.000 - 2.000
		Min - Max	-19.00 - 20.00	-18.00 - 25.30	-12.00 - 65.00	-8.00 - 7.80	-18.00 - 65.00	-19.00 - 65.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase Increased	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	28.848 (51.4097)	22.605 (6.7516)	22.144 (5.0670)	21.817 (5.4929)	22.199 (5.8127)	23.855 (26.1575)
		Median	21.000	20.250	21.000	21.000	21.000	21.000
		Q1 - Q3	19.000 - 25.000	18.850 - 24.450	19.000 - 25.000	17.000 - 25.000	18.050 - 25.000	18.600 - 25.000
		Min - Max	6.40 - 433.00	15.00 - 51.00	12.80 - 36.00	14.80 - 40.70	12.80 - 51.00	6.40 - 433.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	5.684 (50.8922)	-0.076 (5.6035)	-0.396 (5.2412)	0.293 (3.7680)	-0.063 (4.9393)	1.368 (25.7301)
		Median	-1.000	-1.000	0	0	0	0
		Q1 - Q3	-4.000 - 3.000	-3.000 - 3.000	-2.700 - 2.000	-1.700 - 2.000	-2.000 - 2.000	-3.000 - 2.100
		Min - Max	-23.00 - 405.00	-16.00 - 16.00	-16.00 - 15.00	-10.00 - 16.60	-16.00 - 16.60	-23.00 - 405.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	21.908 (5.6302)	22.665 (7.9522)	22.976 (7.4795)	20.592 (4.2804)	22.103 (6.8542)	22.055 (6.5642)
		Median	21.350	21.000	21.745	19.300	21.000	21.000
		Q1 - Q3	19.000 - 24.450	18.000 - 26.000	18.100 - 24.400	18.000 - 22.900	18.000 - 24.000	18.010 - 24.000
		Min - Max	9.90 - 49.00	12.00 - 68.00	11.60 - 54.00	13.00 - 39.00	11.60 - 68.00	9.90 - 68.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Aspartate Aminotransferase Increased	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-1.181 (5.1321)	0.168 (5.3836)	0.398 (5.9702)	-0.932 (3.6188)	-0.108 (5.1173)	-0.372 (5.1320)
		Median	-1.000	-0.500	0	-1.000	-0.550	-0.990
		Q1 - Q3	-4.300 - 1.000	-3.000 - 3.000	-3.000 - 2.700	-3.000 - 1.500	-3.000 - 2.000	-3.000 - 2.000
		Min - Max	-20.00 - 14.00	-12.00 - 25.00	-18.00 - 22.00	-10.00 - 8.00	-18.00 - 25.00	-20.00 - 25.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	22.334 (5.4425)	22.285 (6.0089)	21.618 (5.7450)	20.874 (4.2654)	21.610 (5.4199)	21.788 (5.4239)
		Median	22.000	21.000	20.350	20.100	20.800	21.000
		Q1 - Q3	18.000 - 26.000	18.900 - 24.000	18.000 - 23.400	17.300 - 23.000	18.000 - 23.300	18.000 - 24.000
		Min - Max	13.00 - 38.00	14.00 - 50.00	13.20 - 45.00	15.00 - 33.30	13.20 - 50.00	13.00 - 50.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.946 (5.9425)	-0.174 (4.7780)	-0.929 (5.6398)	-0.634 (3.7617)	-0.574 (4.7883)	-0.665 (5.0859)
		Median	-0.700	0	-1.000	-1.000	-1.000	-1.000
		Q1 - Q3	-4.000 - 2.500	-3.200 - 3.000	-3.700 - 1.200	-3.000 - 1.500	-3.000 - 2.000	-3.400 - 2.000
		Min - Max	-23.00 - 18.00	-13.00 - 12.00	-20.00 - 20.00	-10.00 - 13.20	-20.00 - 20.00	-23.00 - 20.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Blood Bilirubin Increased	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	12.193 (4.1586)	10.678 (3.1144)	12.170 (4.0036)	12.208 (4.5724)	11.678 (3.9816)	11.807 (4.0251)
		Median	11.340	10.350	11.900	11.150	11.100	11.190
		Q1 - Q3	9.700 - 13.900	8.870 - 12.400	9.600 - 14.070	8.650 - 15.720	8.900 - 13.900	9.000 - 13.900
		Min - Max	4.30 - 27.90	5.30 - 19.00	4.80 - 26.60	5.18 - 27.20	4.80 - 27.20	4.30 - 27.90
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	12.041 (4.3815)	10.336 (3.6691)	11.860 (4.2166)	11.898 (3.5383)	11.355 (3.8692)	11.527 (4.0067)
		Median	11.000	9.700	11.100	11.400	10.900	10.900
		Q1 - Q3	9.200 - 14.400	7.700 - 13.000	9.000 - 13.750	9.100 - 14.750	8.400 - 13.700	8.500 - 13.700
		Min - Max	5.50 - 31.70	3.90 - 22.10	5.20 - 27.20	5.20 - 21.00	3.90 - 27.20	3.90 - 31.70
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.152 (3.3347)	-0.342 (2.4750)	-0.314 (2.7573)	-0.310 (3.0987)	-0.322 (2.7722)	-0.280 (2.9181)
		Median	-0.600	-0.350	-0.150	-0.200	-0.200	-0.200
		Q1 - Q3	-1.900 - 1.700	-2.050 - 1.300	-1.900 - 1.550	-2.400 - 1.600	-2.100 - 1.400	-2.100 - 1.600
		Min - Max	-7.90 - 8.30	-5.80 - 6.40	-7.60 - 6.30	-8.20 - 7.20	-8.20 - 7.20	-8.20 - 8.30

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Blood Bilirubin Increased	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	11.095 (3.1532)	10.394 (3.5831)	12.058 (4.3917)	12.563 (5.4574)	11.659 (4.6070)	11.519 (4.2939)
		Median	11.200	9.700	11.300	11.100	10.910	11.000
		Q1 - Q3	8.900 - 12.600	7.700 - 12.900	8.500 - 14.600	9.200 - 15.100	8.300 - 14.400	8.500 - 13.900
		Min - Max	5.10 - 19.00	4.20 - 18.90	4.90 - 27.70	5.10 - 42.00	4.20 - 42.00	4.20 - 42.00
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.044 (3.6234)	-0.310 (2.3396)	-0.110 (3.2433)	0.307 (4.9005)	-0.040 (3.6321)	-0.289 (3.6492)
		Median	-0.800	-0.300	-0.200	-0.200	-0.200	-0.200
		Q1 - Q3	-2.600 - 1.400	-1.600 - 1.100	-2.100 - 2.000	-1.600 - 1.540	-1.600 - 1.540	-1.900 - 1.500
		Min - Max	-10.60 - 5.87	-7.40 - 5.00	-7.08 - 8.70	-8.70 - 31.60	-8.70 - 31.60	-10.60 - 31.60
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	11.240 (3.7714)	10.282 (3.4454)	11.227 (3.3487)	11.801 (3.9315)	11.085 (3.6144)	11.123 (3.6474)
		Median	10.350	10.100	11.100	11.950	10.950	10.800
		Q1 - Q3	8.900 - 12.800	7.800 - 12.400	8.900 - 13.100	8.550 - 14.050	8.400 - 13.230	8.500 - 13.100
		Min - Max	3.00 - 23.00	4.60 - 19.20	3.10 - 21.80	4.00 - 22.80	3.10 - 22.80	3.00 - 23.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Blood Bilirubin Increased	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.954 (3.7233)	-0.422 (2.5207)	-0.941 (3.5049)	-0.596 (3.1782)	-0.651 (3.0807)	-0.726 (3.2472)
		Median	-0.850	-0.100	-0.600	-0.100	-0.250	-0.450
		Q1 - Q3	-3.600 - 1.200	-1.800 - 1.100	-3.300 - 1.200	-2.350 - 1.330	-2.370 - 1.200	-2.600 - 1.200
		Min - Max	-11.90 - 7.90	-7.80 - 5.50	-16.90 - 8.20	-12.70 - 6.20	-16.90 - 8.20	-16.90 - 8.20
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	11.024 (4.3075)	9.936 (3.7377)	10.861 (3.7980)	11.819 (3.7089)	10.848 (3.8082)	10.892 (3.9302)
		Median	10.400	9.600	10.300	11.000	10.300	10.300
		Q1 - Q3	8.200 - 12.500	7.150 - 12.050	8.500 - 12.400	9.300 - 14.300	8.200 - 12.900	8.200 - 12.900
		Min - Max	4.80 - 27.50	2.60 - 22.20	4.70 - 28.90	5.20 - 21.00	2.60 - 28.90	2.60 - 28.90
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-1.131 (3.5709)	-0.719 (2.7086)	-1.324 (3.0772)	-0.610 (3.0584)	-0.887 (2.9506)	-0.948 (3.1106)
		Median	-1.100	-0.850	-1.450	-0.400	-0.800	-0.850
		Q1 - Q3	-3.300 - 0.900	-2.520 - 1.050	-3.300 - 0.600	-2.400 - 1.400	-2.600 - 1.000	-3.000 - 1.000
		Min - Max	-9.70 - 7.30	-7.90 - 5.80	-7.30 - 8.00	-10.70 - 5.59	-10.70 - 8.00	-10.70 - 8.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Blood Bilirubin Increased	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	10.766 (3.0815)	9.838 (2.9971)	10.889 (4.1320)	11.198 (3.9021)	10.624 (3.7251)	10.659 (3.5705)
		Median	10.900	9.700	10.600	10.600	10.150	10.300
		Q1 - Q3	8.600 - 12.600	7.750 - 11.950	8.500 - 12.200	8.400 - 13.300	8.100 - 12.450	8.200 - 12.500
		Min - Max	3.60 - 20.10	3.10 - 18.10	1.20 - 26.60	4.60 - 20.90	1.20 - 26.60	1.20 - 26.60
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.389 (3.3713)	-0.818 (2.6144)	-1.163 (3.5188)	-1.231 (3.4731)	-1.065 (3.2064)	-1.146 (3.2447)
		Median	-1.000	-0.550	-1.300	-1.100	-1.100	-1.100
		Q1 - Q3	-3.100 - 1.200	-2.100 - 1.000	-3.700 - 0.600	-3.200 - 0.900	-2.800 - 0.900	-3.000 - 0.900
		Min - Max	-11.20 - 3.60	-7.90 - 4.60	-8.80 - 7.60	-12.20 - 6.00	-12.20 - 7.60	-12.20 - 7.60
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	11.598 (5.0394)	9.935 (3.5786)	11.065 (3.6415)	11.871 (3.4617)	10.938 (3.6328)	11.100 (4.0243)
		Median	10.600	9.600	10.750	11.400	10.450	10.500
		Q1 - Q3	8.650 - 12.950	7.800 - 11.400	8.600 - 12.500	9.500 - 14.900	8.450 - 12.800	8.550 - 12.880
		Min - Max	3.80 - 36.00	3.50 - 20.10	4.70 - 23.70	5.90 - 20.50	3.50 - 23.70	3.50 - 36.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Blood Bilirubin Increased	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.557 (3.4739)	-0.640 (2.8811)	-1.120 (3.4459)	-0.558 (3.1525)	-0.775 (3.1605)	-0.721 (3.2350)
		Median	-0.900	-1.000	-1.750	-0.200	-1.000	-1.000
		Q1 - Q3	-2.950 - 1.510	-2.350 - 0.700	-3.000 - 0.900	-2.400 - 1.400	-2.500 - 1.100	-2.600 - 1.200
		Min - Max	-8.20 - 9.10	-8.90 - 6.90	-8.60 - 9.80	-10.30 - 10.15	-10.30 - 10.15	-10.30 - 10.15
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	10.992 (3.0688)	9.925 (3.4854)	10.352 (3.3955)	11.593 (3.6948)	10.602 (3.5764)	10.697 (3.4572)
		Median	10.650	9.500	9.800	11.600	10.200	10.200
		Q1 - Q3	9.100 - 12.450	7.700 - 11.550	7.700 - 12.800	8.400 - 13.700	7.900 - 12.900	8.100 - 12.800
		Min - Max	5.20 - 22.10	5.10 - 18.90	2.80 - 22.70	5.90 - 21.20	2.80 - 22.70	2.80 - 22.70
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.085 (3.5528)	-0.700 (2.7404)	-1.683 (2.8689)	-0.840 (3.1524)	-1.074 (2.9379)	-1.077 (3.0928)
		Median	-0.700	-0.700	-1.700	-0.400	-1.000	-0.900
		Q1 - Q3	-2.700 - 1.050	-2.600 - 1.000	-3.900 - 0.500	-2.400 - 1.100	-3.100 - 0.900	-3.000 - 0.900
		Min - Max	-15.30 - 6.80	-6.50 - 6.20	-7.30 - 7.00	-12.70 - 6.80	-12.70 - 7.00	-15.30 - 7.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
GGT Increased	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	20.242 (11.4106)	20.138 (10.4014)	24.387 (13.3406)	22.735 (20.3916)	22.407 (15.2750)	21.866 (14.4173)
		Median	17.000	17.100	21.000	16.535	18.000	17.380
		Q1 - Q3	12.000 - 24.000	13.000 - 23.000	15.100 - 30.300	12.650 - 23.000	14.000 - 26.000	13.200 - 25.350
		Min - Max	7.16 - 69.00	6.00 - 52.00	9.00 - 71.50	9.00 - 124.20	6.00 - 124.20	6.00 - 124.20
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	19.400 (10.7453)	23.614 (35.1430)	23.595 (14.5017)	25.969 (40.7604)	24.385 (32.0728)	23.134 (28.3366)
		Median	17.000	17.400	18.300	18.000	18.000	18.000
		Q1 - Q3	12.000 - 22.000	12.000 - 24.000	15.000 - 29.000	12.800 - 25.450	13.000 - 25.400	13.000 - 25.000
		Min - Max	7.74 - 63.00	6.00 - 302.00	9.00 - 72.00	7.00 - 334.30	6.00 - 334.30	6.00 - 334.30
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.842 (6.8911)	3.476 (33.0069)	-0.563 (7.4694)	3.235 (28.5072)	2.063 (25.5725)	1.334 (22.4199)
		Median	0	0	-1.000	0	0	0
		Q1 - Q3	-3.000 - 1.300	-2.000 - 1.000	-3.000 - 1.000	-1.100 - 1.850	-2.000 - 1.100	-2.300 - 1.300
		Min - Max	-36.00 - 23.00	-16.00 - 274.00	-20.00 - 34.00	-32.50 - 228.20	-32.50 - 274.00	-36.00 - 274.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
GGT Increased	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	18.397 (8.3020)	19.198 (9.1838)	23.583 (15.3141)	27.562 (54.9310)	23.406 (33.2069)	22.163 (29.1488)
		Median	16.000	17.000	19.000	16.000	17.000	17.000
		Q1 - Q3	12.000 - 23.700	13.000 - 23.740	14.600 - 28.000	12.000 - 24.000	13.000 - 24.000	13.000 - 24.000
		Min - Max	6.00 - 46.00	7.00 - 54.00	10.00 - 92.00	8.00 - 454.50	7.00 - 454.50	6.00 - 454.50
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.712 (6.7155)	-0.826 (4.6288)	-0.054 (9.7456)	4.816 (43.5034)	1.291 (25.7460)	0.546 (22.5945)
		Median	-0.200	0	-0.900	0	0	0
		Q1 - Q3	-3.000 - 1.060	-2.000 - 1.400	-3.000 - 1.100	-2.600 - 2.000	-2.700 - 2.000	-2.900 - 1.500
		Min - Max	-35.00 - 10.00	-23.00 - 6.60	-29.00 - 42.00	-37.00 - 348.40	-37.00 - 348.40	-37.00 - 348.40
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	18.707 (8.9694)	19.099 (11.1986)	23.249 (13.2793)	26.855 (50.7341)	22.971 (30.4349)	21.913 (26.8090)
		Median	15.700	16.000	19.000	15.950	17.000	17.000
		Q1 - Q3	12.000 - 23.000	13.000 - 22.000	14.790 - 28.000	11.900 - 23.000	13.000 - 23.000	13.000 - 23.000
		Min - Max	8.00 - 50.00	6.00 - 67.00	9.00 - 79.70	6.00 - 404.80	6.00 - 404.80	6.00 - 404.80

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
GGT Increased	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.495 (7.5829)	-0.925 (6.2113)	-0.388 (6.6308)	4.578 (39.0105)	1.016 (22.7068)	0.393 (20.0616)
		Median	-1.000	-1.000	-0.690	-0.200	-0.600	-0.745
		Q1 - Q3	-3.000 - 1.360	-3.000 - 1.100	-2.900 - 2.000	-2.950 - 1.150	-2.900 - 1.800	-3.000 - 1.680
		Min - Max	-35.00 - 22.80	-20.00 - 27.00	-24.00 - 19.00	-43.10 - 298.70	-43.10 - 298.70	-43.10 - 298.70
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	19.072 (11.8642)	19.485 (11.3967)	23.055 (13.5902)	20.252 (14.7602)	20.926 (13.3026)	20.466 (12.9633)
		Median	15.000	16.750	19.510	15.000	17.000	17.000
		Q1 - Q3	12.000 - 21.400	12.000 - 25.000	14.000 - 25.900	11.200 - 23.000	12.600 - 25.000	12.000 - 24.000
		Min - Max	7.21 - 75.00	5.00 - 81.00	8.00 - 78.00	8.00 - 82.00	5.00 - 82.00	5.00 - 82.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-1.135 (10.0306)	-0.532 (7.4051)	-0.622 (9.6540)	-0.695 (12.4829)	-0.614 (9.9473)	-0.743 (9.9513)
		Median	-1.000	0	-0.015	-1.000	-0.100	-0.650
		Q1 - Q3	-3.000 - 2.000	-2.500 - 2.000	-3.000 - 2.800	-2.000 - 1.000	-3.000 - 2.000	-3.000 - 2.000
		Min - Max	-42.00 - 36.90	-22.00 - 41.00	-25.00 - 34.00	-53.60 - 62.00	-53.60 - 62.00	-53.60 - 62.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
GGT Increased	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	21.834 (19.1019)	20.080 (12.2798)	23.121 (13.4701)	20.860 (19.0357)	21.339 (15.1082)	21.463 (16.1573)
		Median	15.700	17.000	19.000	16.000	17.000	17.000
		Q1 - Q3	12.000 - 22.000	13.000 - 25.100	15.000 - 26.700	11.700 - 22.000	13.000 - 24.350	12.400 - 24.000
		Min - Max	7.00 - 116.00	7.00 - 85.00	9.00 - 71.00	7.00 - 139.00	7.00 - 139.00	7.00 - 139.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.628 (14.5038)	0.063 (7.8833)	-0.397 (8.5049)	-0.087 (7.4583)	-0.138 (7.9257)	0.302 (9.9739)
		Median	-0.600	0	0	0	0	0
		Q1 - Q3	-3.000 - 2.300	-2.000 - 2.000	-2.000 - 2.300	-2.000 - 1.200	-2.000 - 2.000	-2.000 - 2.000
		Min - Max	-20.00 - 94.00	-21.00 - 45.00	-26.00 - 38.00	-25.00 - 33.00	-26.00 - 45.00	-26.00 - 94.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	19.531 (11.8614)	20.603 (14.4146)	25.251 (24.3588)	20.466 (15.7014)	22.124 (18.7480)	21.486 (17.3236)
		Median	15.900	17.000	19.490	15.000	17.000	17.000
		Q1 - Q3	11.000 - 22.000	12.000 - 24.800	13.400 - 24.300	12.000 - 23.900	12.620 - 24.000	12.000 - 24.000
		Min - Max	8.00 - 60.00	7.00 - 78.00	8.00 - 156.00	7.00 - 105.70	7.00 - 156.00	7.00 - 156.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
GGT Increased	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.647 (6.7003)	0.764 (8.0298)	1.574 (18.4541)	-0.481 (6.2947)	0.637 (12.1920)	0.321 (11.0969)
		Median	0	-0.380	0	0	0	0
		Q1 - Q3	-3.000 - 2.000	-3.000 - 3.000	-4.000 - 2.000	-2.000 - 1.400	-2.895 - 2.000	-3.000 - 2.000
		Min - Max	-20.00 - 20.00	-15.00 - 33.00	-32.00 - 118.00	-22.71 - 16.00	-32.00 - 118.00	-32.00 - 118.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	19.840 (15.8983)	19.057 (10.1706)	23.702 (20.5768)	20.373 (15.0738)	21.034 (15.8601)	20.741 (15.8472)
		Median	15.100	16.380	18.000	16.000	17.000	17.000
		Q1 - Q3	11.500 - 22.000	12.000 - 22.500	13.100 - 24.400	12.000 - 22.000	12.200 - 22.500	12.000 - 22.000
		Min - Max	8.00 - 118.00	6.00 - 54.00	6.40 - 132.00	7.00 - 91.00	6.00 - 132.00	6.00 - 132.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.326 (14.6226)	-0.791 (5.2750)	0.222 (15.9230)	-0.573 (6.9794)	-0.382 (10.4497)	-0.368 (11.5814)
		Median	-1.000	-0.500	-1.000	0	-0.600	-0.900
		Q1 - Q3	-4.000 - 1.355	-4.000 - 1.415	-4.000 - 1.000	-2.000 - 2.000	-3.000 - 1.100	-3.000 - 1.200
		Min - Max	-37.00 - 96.00	-17.00 - 22.00	-27.00 - 99.00	-33.20 - 22.00	-33.20 - 99.00	-37.00 - 99.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase Increased	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	82.417 (19.0461)	82.613 (18.6017)	80.994 (18.8175)	79.967 (18.2839)	81.204 (18.5124)	81.507 (18.6198)
		Median	82.000	83.000	79.000	80.000	80.000	80.450
		Q1 - Q3	70.000 - 93.000	70.000 - 90.000	68.000 - 89.000	66.750 - 94.000	67.000 - 91.000	68.000 - 91.500
		Min - Max	34.00 - 141.80	50.00 - 139.00	43.00 - 130.30	42.00 - 130.00	42.00 - 139.00	34.00 - 141.80
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	81.765 (17.3978)	84.813 (23.8523)	79.502 (17.8197)	79.273 (19.0025)	81.231 (20.4924)	81.365 (19.7322)
		Median	83.000	81.500	77.700	77.000	79.200	80.000
		Q1 - Q3	70.000 - 93.000	68.000 - 96.000	68.000 - 91.250	65.000 - 93.350	67.000 - 92.100	67.310 - 92.700
		Min - Max	36.00 - 120.80	54.00 - 206.00	41.00 - 119.00	42.00 - 140.10	41.00 - 206.00	36.00 - 206.00
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.652 (8.1657)	2.201 (15.9600)	-1.316 (7.3523)	-0.694 (9.4105)	0.084 (11.6072)	-0.100 (10.8374)
		Median	0.900	0.500	-2.000	-1.000	-0.600	-0.200
		Q1 - Q3	-4.000 - 4.000	-4.000 - 4.000	-5.300 - 2.220	-6.000 - 3.900	-5.000 - 4.000	-5.000 - 4.000
		Min - Max	-29.00 - 15.00	-23.00 - 114.00	-21.80 - 18.00	-27.00 - 46.10	-27.00 - 114.00	-29.00 - 114.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase Increased	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	79.985 (17.9342)	81.267 (19.1097)	79.996 (18.3492)	79.030 (18.9438)	80.109 (18.7361)	80.078 (18.5075)
		Median	77.000	79.000	78.000	77.400	78.000	78.000
		Q1 - Q3	68.700 - 91.000	69.000 - 91.000	65.000 - 95.500	67.000 - 92.000	67.000 - 92.000	67.000 - 91.000
		Min - Max	36.00 - 123.00	48.00 - 143.00	46.00 - 119.00	35.00 - 160.60	35.00 - 160.60	35.00 - 160.60
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-2.287 (8.4205)	-1.210 (8.3267)	-0.729 (7.7229)	-0.728 (12.0352)	-0.892 (9.4977)	-1.238 (9.2466)
		Median	-1.000	-1.000	0	-1.000	-0.770	-1.000
		Q1 - Q3	-8.000 - 2.000	-5.600 - 4.000	-6.000 - 3.000	-7.500 - 3.000	-6.000 - 4.000	-6.500 - 3.000
		Min - Max	-25.70 - 17.00	-29.00 - 18.00	-15.10 - 24.00	-38.00 - 66.60	-38.00 - 66.60	-38.00 - 66.60
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	80.765 (18.4102)	81.873 (19.6485)	79.945 (18.9327)	79.448 (18.7669)	80.451 (19.0634)	80.529 (18.8695)
		Median	81.850	79.000	79.000	79.900	79.000	79.900
		Q1 - Q3	68.000 - 92.000	69.000 - 93.000	65.000 - 93.000	66.000 - 91.500	66.350 - 92.000	67.000 - 92.000
		Min - Max	31.00 - 123.00	51.00 - 154.00	48.00 - 128.92	38.00 - 147.20	38.00 - 154.00	31.00 - 154.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase Increased	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.587 (9.2386)	-0.603 (10.1935)	-0.781 (8.9513)	-0.009 (11.9833)	-0.472 (10.3754)	-0.749 (10.0998)
		Median	-1.000	-1.000	0	-1.500	-1.000	-1.000
		Q1 - Q3	-6.000 - 2.000	-6.000 - 5.200	-5.000 - 5.000	-6.600 - 8.000	-6.000 - 6.000	-6.000 - 5.200
		Min - Max	-28.60 - 21.30	-36.00 - 20.00	-23.90 - 30.10	-31.00 - 53.20	-36.00 - 53.20	-36.00 - 53.20
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	81.084 (20.1746)	82.120 (19.8169)	79.723 (17.1107)	76.894 (17.7763)	79.646 (18.3263)	80.002 (18.7724)
		Median	80.000	81.000	79.500	76.900	79.000	79.050
		Q1 - Q3	68.000 - 93.580	68.000 - 89.500	66.000 - 90.400	65.000 - 87.040	66.000 - 89.000	67.000 - 90.000
		Min - Max	32.00 - 133.00	52.00 - 151.00	49.00 - 119.00	36.00 - 132.00	36.00 - 151.00	32.00 - 151.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-1.410 (11.9499)	-0.064 (11.4244)	-1.029 (8.3380)	-2.332 (9.4574)	-1.113 (9.8401)	-1.186 (10.3801)
		Median	0	0.920	-1.500	-1.000	-0.760	-0.250
		Q1 - Q3	-8.000 - 6.000	-5.000 - 5.650	-6.000 - 5.000	-8.000 - 3.000	-6.000 - 4.000	-6.000 - 5.000
		Min - Max	-31.00 - 34.00	-33.00 - 37.00	-21.70 - 16.00	-31.00 - 25.00	-33.00 - 37.00	-33.00 - 37.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase Increased	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	80.607 (19.3934)	82.883 (20.0332)	79.640 (17.5297)	77.667 (16.4023)	80.131 (18.1375)	80.250 (18.4215)
		Median	79.000	82.000	77.000	75.400	78.600	78.700
		Q1 - Q3	68.000 - 93.000	67.500 - 91.500	67.000 - 91.000	67.000 - 91.200	67.000 - 91.100	67.000 - 91.900
		Min - Max	35.00 - 137.00	51.00 - 156.00	49.00 - 121.00	45.00 - 114.10	45.00 - 156.00	35.00 - 156.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.888 (12.4404)	0.700 (11.1766)	-0.569 (8.5844)	-1.559 (9.5679)	-0.447 (9.8527)	-0.806 (10.5495)
		Median	-2.000	0.765	-1.000	-1.000	-0.100	-1.000
		Q1 - Q3	-8.000 - 4.100	-4.000 - 8.000	-6.000 - 3.300	-9.600 - 4.800	-6.350 - 6.000	-7.000 - 5.200
		Min - Max	-35.00 - 26.00	-46.00 - 22.80	-23.00 - 23.00	-34.00 - 23.50	-46.00 - 23.50	-46.00 - 26.00
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	80.636 (17.0632)	84.336 (21.3370)	79.553 (18.7256)	78.345 (16.3942)	80.800 (19.0578)	80.760 (18.5547)
		Median	80.500	83.000	73.000	79.600	80.000	80.000
		Q1 - Q3	70.000 - 92.250	68.000 - 95.600	68.000 - 90.000	65.000 - 91.000	67.500 - 91.650	68.000 - 92.000
		Min - Max	30.00 - 119.00	48.00 - 164.00	47.00 - 128.00	38.00 - 111.00	38.00 - 164.00	30.00 - 164.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.1
Summary of Chemistry
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Alkaline Phosphatase Increased	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-1.382 (9.2459)	1.837 (11.7402)	-1.198 (9.4100)	-0.881 (8.9312)	-0.059 (10.1696)	-0.385 (9.9491)
		Median	0	3.000	-1.000	-2.000	-0.545	-0.165
		Q1 - Q3	-5.500 - 4.000	-4.000 - 7.000	-5.000 - 2.000	-6.700 - 4.000	-6.000 - 6.000	-6.000 - 5.000
		Min - Max	-29.90 - 21.90	-31.00 - 36.20	-26.00 - 40.00	-19.19 - 28.00	-31.00 - 40.00	-31.00 - 40.00
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	80.651 (18.2064)	82.115 (20.7030)	78.652 (17.2627)	77.749 (16.0676)	79.559 (18.1825)	79.826 (18.1594)
		Median	79.000	81.000	76.000	78.000	78.000	78.000
		Q1 - Q3	70.720 - 91.000	68.500 - 89.550	68.300 - 92.000	66.000 - 87.000	67.620 - 89.100	69.000 - 90.000
		Min - Max	32.00 - 130.00	48.00 - 162.00	45.00 - 114.45	43.00 - 127.00	43.00 - 162.00	32.00 - 162.00
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.950 (9.3982)	-0.678 (11.8018)	-1.539 (10.2463)	-2.017 (10.2444)	-1.394 (10.7674)	-1.531 (10.4335)
		Median	-2.000	-0.500	-3.000	-2.000	-1.600	-2.000
		Q1 - Q3	-8.900 - 3.500	-5.890 - 4.500	-6.000 - 2.900	-8.000 - 3.000	-7.000 - 4.000	-7.000 - 4.000
		Min - Max	-25.00 - 19.00	-42.00 - 28.00	-34.80 - 40.00	-22.16 - 49.00	-42.00 - 49.00	-42.00 - 49.00

Data Source: Listing 16.2.8.1.3
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	D15	Placebo (N=69)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	1 (1.4)	0	1 (1.4)	2 (2.9)
			Total	66 (95.7)	2 (2.9)	1 (1.4)	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (90.0)	1 (1.4)	1 (1.4)	65 (92.9)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Total	66 (94.3)	3 (4.3)	1 (1.4)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	2 (2.9)	1 (1.5)	63 (92.6)
			Abnormal NCS	4 (5.9)	1 (1.5)	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	3 (4.4)	1 (1.5)	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	2 (2.9)	0	0	2 (2.9)
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	D15	Combined GS1-144 (N=207)	Normal	186 (90.3)	4 (1.9)	2 (1.0)	192 (93.2)
			Abnormal NCS	8 (3.9)	1 (0.5)	0	9 (4.4)
			Abnormal CS	3 (1.5)	2 (1.0)	0	5 (2.4)
			Total	197 (95.6)	7 (3.4)	2 (1.0)	206 (100)
	D29	Placebo (N=69)	Normal	63 (94.0)	0	0	63 (94.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.0)
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	1 (1.4)	1 (1.4)	67 (97.1)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	2 (2.9)	0	2 (2.9)
			Total	65 (94.2)	3 (4.3)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (88.1)	2 (3.0)	1 (1.5)	62 (92.5)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (94.0)	3 (4.5)	1 (1.5)	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	D29	GS1-144 30 mg BID (N=68)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	185 (91.1)	4 (2.0)	2 (1.0)	191 (94.1)
			Abnormal NCS	6 (3.0)	1 (0.5)	0	7 (3.4)
			Abnormal CS	3 (1.5)	2 (1.0)	0	5 (2.5)
			Total	194 (95.6)	7 (3.4)	2 (1.0)	203 (100)
	D43	Placebo (N=69)	Normal	61 (92.4)	1 (1.5)	0	62 (93.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	1 (1.4)	1 (1.4)	67 (97.1)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	65 (94.2)	3 (4.3)	1 (1.4)	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Alanine Aminotransferase (U/L)	D43	GS1-144 60 mg QD (N=69)	Normal	59 (88.1)	2 (3.0)	1 (1.5)	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	3 (4.5)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	184 (92.0)	4 (2.0)	2 (1.0)	190 (95.0)
			Abnormal NCS	6 (3.0)	2 (1.0)	0	8 (4.0)
			Abnormal CS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Total	191 (95.5)	7 (3.5)	2 (1.0)	200 (100)
	D57	Placebo (N=69)	Normal	60 (92.3)	1 (1.5)	0	61 (93.8)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.1)
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	D57	GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	1 (1.5)	1 (1.5)	63 (92.6)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	2 (2.9)	0	2 (2.9)
			Total	64 (94.1)	3 (4.4)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	2 (3.0)	1 (1.5)	61 (92.4)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	180 (91.4)	3 (1.5)	2 (1.0)	185 (93.9)
			Abnormal NCS	6 (3.0)	2 (1.0)	0	8 (4.1)
			Abnormal CS	2 (1.0)	2 (1.0)	0	4 (2.0)
			Total	188 (95.4)	7 (3.6)	2 (1.0)	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	D71	Placebo (N=69)	Normal	56 (86.2)	1 (1.5)	0	57 (87.7)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	3 (4.6)	0	1 (1.5)	4 (6.2)
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	1 (1.5)	66 (97.1)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	64 (94.1)	3 (4.4)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (92.3)	3 (4.6)	1 (1.5)	64 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (93.8)	3 (4.6)	1 (1.5)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	D71	Combined GS1-144 (N=207)	Normal	183 (93.4)	6 (3.1)	2 (1.0)	191 (97.4)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Total	187 (95.4)	7 (3.6)	2 (1.0)	196 (100)
	D85	Placebo (N=69)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	61 (95.3)	2 (3.1)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	2 (3.0)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	0	0	4 (6.0)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (86.4)	1 (1.5)	0	58 (87.9)
			Abnormal NCS	5 (7.6)	1 (1.5)	0	6 (9.1)
			Abnormal CS	0	1 (1.5)	1 (1.5)	2 (3.0)
			Total	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	D85	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.8)	4 (2.0)	0	182 (92.9)
			Abnormal NCS	10 (5.1)	1 (0.5)	0	11 (5.6)
			Abnormal CS	0	2 (1.0)	1 (0.5)	3 (1.5)
			Total	188 (95.9)	7 (3.6)	1 (0.5)	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	60 (93.8)	1 (1.6)	1 (1.6)	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	2 (3.1)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alanine Aminotransferase (U/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	2 (3.0)	1 (1.5)	61 (92.4)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (92.9)	5 (2.5)	1 (0.5)	189 (95.9)
			Abnormal NCS	4 (2.0)	1 (0.5)	0	5 (2.5)
			Abnormal CS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Total	189 (95.9)	7 (3.6)	1 (0.5)	197 (100)
Aspartate Aminotransferase (U/L)	D15	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	2 (2.9)	0	1 (1.4)	3 (4.3)
			Total	66 (95.7)	2 (2.9)	1 (1.4)	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	D15	GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	1 (1.4)	0	65 (92.9)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	3 (4.3)	1 (1.4)	0	4 (5.7)
			Total	68 (97.1)	2 (2.9)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	193 (93.7)	2 (1.0)	0	195 (94.7)
			Abnormal NCS	4 (1.9)	2 (1.0)	0	6 (2.9)
			Abnormal CS	4 (1.9)	1 (0.5)	0	5 (2.4)
			Total	201 (97.6)	5 (2.4)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	D29	Placebo (N=69)	Normal	63 (94.0)	2 (3.0)	1 (1.5)	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	1 (1.4)	0	67 (97.1)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	2 (3.0)	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (92.5)	0	0	62 (92.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	D29	Combined GS1-144 (N=207)	Normal	189 (93.1)	3 (1.5)	0	192 (94.6)
			Abnormal NCS	6 (3.0)	1 (0.5)	0	7 (3.4)
			Abnormal CS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Total	198 (97.5)	5 (2.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	61 (92.4)	1 (1.5)	0	62 (93.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	1 (1.4)	0	67 (97.1)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	D43	GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	0	0	60 (93.8)
			Abnormal NCS	3 (4.7)	0	0	3 (4.7)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	64 (100)	0	0	64 (100)
		Combined GS1-144 (N=207)	Normal	190 (95.0)	2 (1.0)	0	192 (96.0)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.0)
			Abnormal CS	2 (1.0)	0	0	2 (1.0)
			Total	195 (97.5)	5 (2.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	61 (93.8)	1 (1.5)	0	62 (95.4)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.1)
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	1 (1.5)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	D57	GS1-144 60 mg QD (N=69)	Normal	60 (90.9)	3 (4.5)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	187 (94.9)	4 (2.0)	0	191 (97.0)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Total	192 (97.5)	5 (2.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	57 (87.7)	2 (3.1)	1 (1.5)	60 (92.3)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	3 (4.6)	0	0	3 (4.6)
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Aspartate Aminotransferase (U/L)	D71	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	0	2 (3.1)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.9)	2 (1.0)	0	188 (95.9)
			Abnormal NCS	3 (1.5)	2 (1.0)	0	5 (2.6)
			Abnormal CS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Total	191 (97.4)	5 (2.6)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	D85	Placebo (N=69)	Normal	59 (92.2)	2 (3.1)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	61 (95.3)	2 (3.1)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (94.0)	0	0	63 (94.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	2 (3.0)	0	60 (90.9)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	D85	Combined GS1-144 (N=207)	Normal	182 (92.9)	2 (1.0)	0	184 (93.9)
			Abnormal NCS	6 (3.1)	2 (1.0)	0	8 (4.1)
			Abnormal CS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Total	191 (97.4)	5 (2.6)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	60 (93.8)	2 (3.1)	1 (1.6)	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	2 (3.1)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	3 (4.5)	0	65 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Aspartate Aminotransferase (U/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (96.4)	4 (2.0)	0	194 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Total	192 (97.5)	5 (2.5)	0	197 (100)
Gamma Glutamyl Transferase (U/L)	D15	Placebo (N=69)	Normal	65 (94.2)	2 (2.9)	0	67 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	2 (2.9)	0	66 (94.3)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Gamma Glutamyl Transferase (U/L)	D15	GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	2 (2.9)	0	62 (91.2)
			Abnormal NCS	2 (2.9)	4 (5.9)	0	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	62 (91.2)	6 (8.8)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	1 (1.5)	1 (1.5)	2 (2.9)
			Total	63 (92.6)	4 (5.9)	1 (1.5)	68 (100)
		Combined GS1-144 (N=207)	Normal	187 (90.8)	5 (2.4)	0	192 (93.2)
			Abnormal NCS	4 (1.9)	7 (3.4)	0	11 (5.3)
			Abnormal CS	1 (0.5)	1 (0.5)	1 (0.5)	3 (1.5)
			Total	192 (93.2)	13 (6.3)	1 (0.5)	206 (100)
	D29	Placebo (N=69)	Normal	62 (92.5)	3 (4.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Gamma Glutamyl Transferase (U/L)	D29	GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	2 (2.9)	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (85.1)	2 (3.0)	0	59 (88.1)
			Abnormal NCS	4 (6.0)	2 (3.0)	0	6 (9.0)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (92.5)	1 (1.5)	0	63 (94.0)
			Abnormal NCS	0	2 (3.0)	1 (1.5)	3 (4.5)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	62 (92.5)	4 (6.0)	1 (1.5)	67 (100)
		Combined GS1-144 (N=207)	Normal	185 (91.1)	5 (2.5)	0	190 (93.6)
			Abnormal NCS	4 (2.0)	5 (2.5)	1 (0.5)	10 (4.9)
			Abnormal CS	1 (0.5)	2 (1.0)	0	3 (1.5)
			Total	190 (93.6)	12 (5.9)	1 (0.5)	203 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Gamma Glutamyl Transferase (U/L)	D43	Placebo (N=69)	Normal	62 (93.9)	3 (4.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (88.1)	3 (4.5)	0	62 (92.5)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (87.5)	1 (1.6)	1 (1.6)	58 (90.6)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Total	59 (92.2)	4 (6.3)	1 (1.6)	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Gamma Glutamyl Transferase (U/L)	D43	Combined GS1-144 (N=207)	Normal	179 (89.5)	6 (3.0)	1 (0.5)	186 (93.0)
			Abnormal NCS	7 (3.5)	5 (2.5)	0	12 (6.0)
			Abnormal CS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Total	187 (93.5)	12 (6.0)	1 (0.5)	200 (100)
	D57	Placebo (N=69)	Normal	60 (92.3)	3 (4.6)	0	63 (96.9)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	3 (4.5)	0	61 (92.4)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.1)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (92.4)	5 (7.6)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Gamma Glutamyl Transferase (U/L)	D57	GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	0	0	57 (90.5)
			Abnormal NCS	1 (1.6)	3 (4.8)	1 (1.6)	5 (7.9)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	59 (93.7)	3 (4.8)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.4)	5 (2.5)	0	183 (92.9)
			Abnormal NCS	5 (2.5)	6 (3.0)	1 (0.5)	12 (6.1)
			Abnormal CS	2 (1.0)	0	0	2 (1.0)
			Total	185 (93.9)	11 (5.6)	1 (0.5)	197 (100)
	D71	Placebo (N=69)	Normal	59 (90.8)	1 (1.5)	0	60 (92.3)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	2 (3.1)	1 (1.5)	0	3 (4.6)
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Gamma Glutamyl Transferase (U/L)	D71	GS1-144 60 mg QD (N=69)	Normal	57 (87.7)	3 (4.6)	0	60 (92.3)
			Abnormal NCS	3 (4.6)	2 (3.1)	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	1 (1.6)	0	58 (92.1)
			Abnormal NCS	1 (1.6)	2 (3.2)	1 (1.6)	4 (6.3)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	59 (93.7)	3 (4.8)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.8)	6 (3.1)	0	184 (93.9)
			Abnormal NCS	5 (2.6)	5 (2.6)	1 (0.5)	11 (5.6)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	184 (93.9)	11 (5.6)	1 (0.5)	196 (100)
	D85	Placebo (N=69)	Normal	60 (93.8)	0	0	60 (93.8)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	1 (1.6)	0	1 (1.6)
			Total	61 (95.3)	3 (4.7)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Gamma Glutamyl Transferase (U/L)	D85	GS1-144 30 mg QD (N=70)	Normal	62 (92.5)	1 (1.5)	0	63 (94.0)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	3 (4.5)	0	61 (92.4)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	1 (1.6)	0	59 (93.7)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	59 (93.7)	3 (4.8)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.8)	5 (2.6)	0	183 (93.4)
			Abnormal NCS	6 (3.1)	6 (3.1)	0	12 (6.1)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	184 (93.9)	11 (5.6)	1 (0.5)	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Gamma Glutamyl Transferase (U/L)	Safety Follow-up	Placebo (N=69)	Normal	58 (90.6)	2 (3.1)	0	60 (93.8)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	3 (4.5)	0	62 (93.9)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	1 (1.6)	0	59 (93.7)
			Abnormal NCS	1 (1.6)	2 (3.2)	1 (1.6)	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	3 (4.8)	1 (1.6)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Gamma Glutamyl Transferase (U/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	180 (91.4)	5 (2.5)	0	185 (93.9)
			Abnormal NCS	4 (2.0)	6 (3.0)	1 (0.5)	11 (5.6)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	185 (93.9)	11 (5.6)	1 (0.5)	197 (100)
Alkaline Phosphatase (U/L)	D15	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
			Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (97.1)	0	0	68 (97.1)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	69 (98.6)	1 (1.4)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	0	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alkaline Phosphatase (U/L)	D15	GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	197 (95.6)	1 (0.5)	0	198 (96.1)
			Abnormal NCS	3 (1.5)	4 (1.9)	0	7 (3.4)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	201 (97.6)	5 (2.4)	0	206 (100)
	D29	Placebo (N=69)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alkaline Phosphatase (U/L)	D29	GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	195 (96.1)	2 (1.0)	0	197 (97.0)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	198 (97.5)	5 (2.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	0	3 (4.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Alkaline Phosphatase (U/L)	D43	GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	193 (96.5)	2 (1.0)	0	195 (97.5)
			Abnormal NCS	1 (0.5)	3 (1.5)	0	4 (2.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	195 (97.5)	5 (2.5)	0	200 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alkaline Phosphatase (U/L)	D57	Placebo (N=69)	Normal	59 (90.8)	1 (1.5)	0	60 (92.3)
			Abnormal NCS	2 (3.1)	3 (4.6)	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alkaline Phosphatase (U/L)	D57	Combined GS1-144 (N=207)	Normal	191 (97.0)	1 (0.5)	0	192 (97.5)
			Abnormal NCS	0	4 (2.0)	0	4 (2.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	192 (97.5)	5 (2.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	58 (89.2)	2 (3.1)	0	60 (92.3)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Alkaline Phosphatase (U/L)	D71	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (96.9)	1 (0.5)	0	191 (97.4)
			Abnormal NCS	1 (0.5)	4 (2.0)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	191 (97.4)	5 (2.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	59 (92.2)	1 (1.6)	0	60 (93.8)
			Abnormal NCS	1 (1.6)	3 (4.7)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Alkaline Phosphatase (U/L)	D85	GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	0	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (96.4)	1 (0.5)	0	190 (96.9)
			Abnormal NCS	2 (1.0)	4 (2.0)	0	6 (3.1)
			Abnormal CS	0	0	0	0
			Total	191 (97.4)	5 (2.6)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	2 (3.1)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Alkaline Phosphatase (U/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	0	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (96.4)	1 (0.5)	0	191 (97.0)
			Abnormal NCS	2 (1.0)	4 (2.0)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	192 (97.5)	5 (2.5)	0	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lactate Dehydrogenase (U/L)	D15	Placebo (N=69)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	2 (2.9)	0	67 (95.7)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	67 (95.7)	3 (4.3)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	3 (4.4)	0	65 (95.6)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	0	0	64 (94.1)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lactate Dehydrogenase (U/L)	D15	Combined GS1-144 (N=207)	Normal	191 (92.7)	5 (2.4)	0	196 (95.1)
			Abnormal NCS	7 (3.4)	2 (1.0)	0	9 (4.4)
			Abnormal CS	0	1 (0.5)	0	1 (0.5)
			Total	198 (96.1)	8 (3.9)	0	206 (100)
	D29	Placebo (N=69)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	3 (4.3)	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (89.6)	2 (3.0)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lactate Dehydrogenase (U/L)	D29	GS1-144 30 mg BID (N=68)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	187 (92.1)	7 (3.4)	0	194 (95.6)
			Abnormal NCS	7 (3.4)	1 (0.5)	0	8 (3.9)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	195 (96.1)	8 (3.9)	0	203 (100)
	D43	Placebo (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	3 (4.3)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lactate Dehydrogenase (U/L)	D43	GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	2 (3.0)	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	186 (93.0)	6 (3.0)	0	192 (96.0)
			Abnormal NCS	6 (3.0)	2 (1.0)	0	8 (4.0)
			Abnormal CS	0	0	0	0
			Total	192 (96.0)	8 (4.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	61 (93.8)	0	0	61 (93.8)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lactate Dehydrogenase (U/L)	D57	GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	3 (4.4)	0	65 (95.6)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	3 (4.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	0	0	60 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	184 (93.4)	6 (3.0)	0	190 (96.4)
			Abnormal NCS	5 (2.5)	2 (1.0)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	189 (95.9)	8 (4.1)	0	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lactate Dehydrogenase (U/L)	D71	Placebo (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	3 (4.4)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (92.3)	3 (4.6)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	0	60 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lactate Dehydrogenase (U/L)	D71	Combined GS1-144 (N=207)	Normal	182 (92.9)	8 (4.1)	0	190 (96.9)
			Abnormal NCS	6 (3.1)	0	0	6 (3.1)
			Abnormal CS	0	0	0	0
			Total	188 (95.9)	8 (4.1)	0	196 (100)
	D85	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (94.0)	3 (4.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (90.9)	2 (3.0)	0	62 (93.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Lactate Dehydrogenase (U/L)	D85	GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (93.4)	6 (3.1)	0	189 (96.4)
			Abnormal NCS	4 (2.0)	2 (1.0)	0	6 (3.1)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	188 (95.9)	8 (4.1)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	3 (4.4)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lactate Dehydrogenase (U/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	3 (4.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	185 (93.9)	7 (3.6)	0	192 (97.5)
			Abnormal NCS	4 (2.0)	1 (0.5)	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	189 (95.9)	8 (4.1)	0	197 (100)
Bilirubin (umol/L)	D15	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
			Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Bilirubin (umol/L)	D15	GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	0	0	69 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	202 (98.1)	1 (0.5)	0	203 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	204 (99.0)	2 (1.0)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Bilirubin (umol/L)	D29	Placebo (N=69)	Normal	63 (94.0)	4 (6.0)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Bilirubin (umol/L)	D29	Combined GS1-144 (N=207)	Normal	199 (98.0)	1 (0.5)	0	200 (98.5)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	201 (99.0)	2 (1.0)	0	203 (100)
	D43	Placebo (N=69)	Normal	62 (93.9)	3 (4.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Bilirubin (umol/L)	D43	GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	198 (99.0)	2 (1.0)	0	200 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	198 (99.0)	2 (1.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	60 (92.3)	2 (3.1)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Bilirubin (umol/L)	D57	GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.0)	2 (1.0)	0	195 (99.0)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	195 (99.0)	2 (1.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	61 (93.8)	4 (6.2)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Bilirubin (umol/L)	D71	GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.5)	1 (0.5)	0	194 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	194 (99.0)	2 (1.0)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Bilirubin (umol/L)	D85	Placebo (N=69)	Normal	59 (92.2)	2 (3.1)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Bilirubin (umol/L)	D85	Combined GS1-144 (N=207)	Normal	192 (98.0)	1 (0.5)	0	193 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	194 (99.0)	2 (1.0)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	4 (6.3)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Bilirubin (umol/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	195 (99.0)	1 (0.5)	0	196 (99.5)
			Abnormal NCS	0	1 (0.5)	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	195 (99.0)	2 (1.0)	0	197 (100)
Direct Bilirubin (umol/L)	D15	Placebo (N=69)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	70 (100)	0	0	70 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Direct Bilirubin (umol/L)	D15	GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	202 (98.1)	2 (1.0)	0	204 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	203 (98.5)	3 (1.5)	0	206 (100)
	D29	Placebo (N=69)	Normal	62 (92.5)	4 (6.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Direct Bilirubin (umol/L)	D29	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (92.5)	1 (1.5)	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	196 (96.6)	2 (1.0)	0	198 (97.5)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	200 (98.5)	3 (1.5)	0	203 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Direct Bilirubin (umol/L)	D43	Placebo (N=69)	Normal	62 (93.9)	3 (4.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Direct Bilirubin (umol/L)	D43	Combined GS1-144 (N=207)	Normal	194 (97.0)	3 (1.5)	0	197 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	197 (98.5)	3 (1.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	60 (92.3)	3 (4.6)	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Direct Bilirubin (umol/L)	D57	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (97.5)	2 (1.0)	0	194 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	61 (93.8)	4 (6.2)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Direct Bilirubin (umol/L)	D71	GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (98.0)	2 (1.0)	0	194 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	193 (98.5)	3 (1.5)	0	196 (100)
	D85	Placebo (N=69)	Normal	58 (90.6)	2 (3.1)	0	60 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Direct Bilirubin (umol/L)	D85	GS1-144 30 mg QD (N=70)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.5)	2 (1.0)	0	195 (99.5)
			Abnormal NCS	0	1 (0.5)	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	193 (98.5)	3 (1.5)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Direct Bilirubin (umol/L)	Safety Follow-up	Placebo (N=69)	Normal	60 (93.8)	4 (6.3)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Direct Bilirubin (umol/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	193 (98.0)	2 (1.0)	0	195 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)
Protein (g/L)	D15	Placebo (N=69)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	1 (1.4)	0	70 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (98.6)	1 (1.4)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Protein (g/L)	D15	GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	201 (97.6)	2 (1.0)	0	203 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	203 (98.5)	3 (1.5)	0	206 (100)
	D29	Placebo (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Protein (g/L)	D29	GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	198 (97.5)	3 (1.5)	0	201 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	200 (98.5)	3 (1.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Protein (g/L)	D43	GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	194 (97.0)	3 (1.5)	0	197 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	197 (98.5)	3 (1.5)	0	200 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Protein (g/L)	D57	Placebo (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Protein (g/L)	D57	Combined GS1-144 (N=207)	Normal	189 (95.9)	3 (1.5)	0	192 (97.5)
			Abnormal NCS	5 (2.5)	0	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Protein (g/L)	D71	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (98.0)	3 (1.5)	0	195 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	193 (98.5)	3 (1.5)	0	196 (100)
	D85	Placebo (N=69)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Protein (g/L)	D85	GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.4)	3 (1.5)	0	194 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	193 (98.5)	3 (1.5)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Protein (g/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.0)	3 (1.5)	0	196 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Albumin (g/L)	D15	Placebo (N=69)	Normal	66 (95.7)	0	0	66 (95.7)
			Abnormal NCS	3 (4.3)	0	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	70 (100)	0	0	70 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Albumin (g/L)	D15	Combined GS1-144 (N=207)	Normal	206 (100)	0	0	206 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	206 (100)	0	0	206 (100)
	D29	Placebo (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Albumin (g/L)	D29	GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	200 (98.5)	0	0	200 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	203 (100)	0	0	203 (100)
	D43	Placebo (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Albumin (g/L)	D43	GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		Combined GS1-144 (N=207)	Normal	199 (99.5)	0	0	199 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	200 (100)	0	0	200 (100)
	D57	Placebo (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Albumin (g/L)	D57	GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	196 (99.5)	0	0	196 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	197 (100)	0	0	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Albumin (g/L)	D71	Placebo (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Albumin (g/L)	D71	Combined GS1-144 (N=207)	Normal	195 (99.5)	0	0	195 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	196 (100)	0	0	196 (100)
	D85	Placebo (N=69)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Albumin (g/L)	D85	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.5)	0	0	193 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	196 (100)	0	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Albumin (g/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	197 (100)	0	0	197 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	197 (100)	0	0	197 (100)
Globulin (g/L)	D15	Placebo (N=69)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	D15	GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	1 (1.4)	0	66 (94.3)
			Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.7)
			Abnormal CS	0	0	0	0
			Total	66 (94.3)	4 (5.7)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	0	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	0	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	193 (93.7)	1 (0.5)	0	194 (94.2)
			Abnormal NCS	5 (2.4)	7 (3.4)	0	12 (5.8)
			Abnormal CS	0	0	0	0
			Total	198 (96.1)	8 (3.9)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	D29	Placebo (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	D29	Combined GS1-144 (N=207)	Normal	192 (94.6)	3 (1.5)	0	195 (96.1)
			Abnormal NCS	3 (1.5)	5 (2.5)	0	8 (3.9)
			Abnormal CS	0	0	0	0
			Total	195 (96.1)	8 (3.9)	0	203 (100)
	D43	Placebo (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Globulin (g/L)	D43	GS1-144 30 mg BID (N=68)	Normal	61 (95.3)	0	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	189 (94.5)	3 (1.5)	0	192 (96.0)
			Abnormal NCS	3 (1.5)	5 (2.5)	0	8 (4.0)
			Abnormal CS	0	0	0	0
			Total	192 (96.0)	8 (4.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	D57	GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	0	0	60 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.4)	3 (1.5)	0	189 (95.9)
			Abnormal NCS	3 (1.5)	5 (2.5)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	189 (95.9)	8 (4.1)	0	197 (100)
	D71	Placebo (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	D71	GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	0	0	62 (95.4)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	0	0	60 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.9)	2 (1.0)	0	188 (95.9)
			Abnormal NCS	2 (1.0)	6 (3.1)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	188 (95.9)	8 (4.1)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	D85	Placebo (N=69)	Normal	61 (95.3)	1 (1.6)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (92.5)	2 (3.0)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	1 (1.5)	0	62 (93.9)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	D85	Combined GS1-144 (N=207)	Normal	184 (93.9)	3 (1.5)	0	187 (95.4)
			Abnormal NCS	4 (2.0)	5 (2.6)	0	9 (4.6)
			Abnormal CS	0	0	0	0
			Total	188 (95.9)	8 (4.1)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	0	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Globulin (g/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	187 (94.9)	3 (1.5)	0	190 (96.4)
			Abnormal NCS	2 (1.0)	5 (2.5)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	189 (95.9)	8 (4.1)	0	197 (100)
Creatinine (umol/L)	D15	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	1 (1.4)	0	65 (92.9)
			Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.1)
			Abnormal CS	0	0	0	0
			Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Creatinine (umol/L)	D15	GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	2 (2.9)	0	62 (91.2)
			Abnormal NCS	3 (4.4)	3 (4.4)	0	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (89.7)	0	0	61 (89.7)
			Abnormal NCS	4 (5.9)	3 (4.4)	0	7 (10.3)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	185 (89.8)	3 (1.5)	0	188 (91.3)
			Abnormal NCS	10 (4.9)	8 (3.9)	0	18 (8.7)
			Abnormal CS	0	0	0	0
			Total	195 (94.7)	11 (5.3)	0	206 (100)
	D29	Placebo (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Creatinine (umol/L)	D29	GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	1 (1.5)	4 (6.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (89.6)	1 (1.5)	0	61 (91.0)
			Abnormal NCS	4 (6.0)	2 (3.0)	0	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	186 (91.6)	3 (1.5)	0	189 (93.1)
			Abnormal NCS	6 (3.0)	8 (3.9)	0	14 (6.9)
			Abnormal CS	0	0	0	0
			Total	192 (94.6)	11 (5.4)	0	203 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Creatinine (umol/L)	D43	Placebo (N=69)	Normal	63 (95.5)	2 (3.0)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	0	0	65 (94.2)
			Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (88.1)	1 (1.5)	0	60 (89.6)
			Abnormal NCS	3 (4.5)	4 (6.0)	0	7 (10.4)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (87.5)	0	0	56 (87.5)
			Abnormal NCS	5 (7.8)	3 (4.7)	0	8 (12.5)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Creatinine (umol/L)	D43	Combined GS1-144 (N=207)	Normal	180 (90.0)	1 (0.5)	0	181 (90.5)
			Abnormal NCS	9 (4.5)	10 (5.0)	0	19 (9.5)
			Abnormal CS	0	0	0	0
			Total	189 (94.5)	11 (5.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	63 (96.9)	2 (3.1)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	2 (3.0)	0	61 (92.4)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Creatinine (umol/L)	D57	GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	0	0	57 (90.5)
			Abnormal NCS	3 (4.8)	3 (4.8)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	181 (91.9)	4 (2.0)	0	185 (93.9)
			Abnormal NCS	5 (2.5)	7 (3.6)	0	12 (6.1)
			Abnormal CS	0	0	0	0
			Total	186 (94.4)	11 (5.6)	0	197 (100)
	D71	Placebo (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	1 (1.5)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Creatinine (umol/L)	D71	GS1-144 60 mg QD (N=69)	Normal	59 (90.8)	1 (1.5)	0	60 (92.3)
			Abnormal NCS	1 (1.5)	4 (6.2)	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	1 (1.6)	0	57 (90.5)
			Abnormal NCS	4 (6.3)	2 (3.2)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	179 (91.3)	3 (1.5)	0	182 (92.9)
			Abnormal NCS	6 (3.1)	8 (4.1)	0	14 (7.1)
			Abnormal CS	0	0	0	0
			Total	185 (94.4)	11 (5.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	61 (95.3)	1 (1.6)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Creatinine (umol/L)	D85	GS1-144 30 mg QD (N=70)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	2 (3.0)	0	61 (92.4)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	1 (1.6)	0	56 (88.9)
			Abnormal NCS	5 (7.9)	2 (3.2)	0	7 (11.1)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	177 (90.3)	4 (2.0)	0	181 (92.3)
			Abnormal NCS	8 (4.1)	7 (3.6)	0	15 (7.7)
			Abnormal CS	0	0	0	0
			Total	185 (94.4)	11 (5.6)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Creatinine (umol/L)	Safety Follow-up	Placebo (N=69)	Normal	61 (95.3)	0	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (90.9)	2 (3.0)	0	62 (93.9)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	1 (1.6)	0	57 (90.5)
			Abnormal NCS	4 (6.3)	2 (3.2)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Creatinine (umol/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	180 (91.4)	5 (2.5)	0	185 (93.9)
			Abnormal NCS	6 (3.0)	6 (3.0)	0	12 (6.1)
			Abnormal CS	0	0	0	0
			Total	186 (94.4)	11 (5.6)	0	197 (100)
Urea (mmol/L)	D15	Placebo (N=69)	Normal	62 (89.9)	3 (4.3)	0	65 (94.2)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	3 (4.3)	0	63 (91.3)
			Abnormal NCS	5 (7.2)	1 (1.4)	0	6 (8.7)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	3 (4.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	D15	GS1-144 30 mg BID (N=68)	Normal	61 (92.4)	3 (4.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		Combined GS1-144 (N=207)	Normal	183 (91.0)	9 (4.5)	0	192 (95.5)
			Abnormal NCS	8 (4.0)	1 (0.5)	0	9 (4.5)
			Abnormal CS	0	0	0	0
			Total	191 (95.0)	10 (5.0)	0	201 (100)
	D29	Placebo (N=69)	Normal	61 (91.0)	3 (4.5)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	3 (4.4)	0	64 (94.1)
			Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	D29	GS1-144 60 mg QD (N=69)	Normal	57 (87.7)	3 (4.6)	0	60 (92.3)
			Abnormal NCS	5 (7.7)	0	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (92.3)	2 (3.1)	0	62 (95.4)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		Combined GS1-144 (N=207)	Normal	178 (89.9)	8 (4.0)	0	186 (93.9)
			Abnormal NCS	11 (5.6)	1 (0.5)	0	12 (6.1)
			Abnormal CS	0	0	0	0
			Total	189 (95.5)	9 (4.5)	0	198 (100)
	D43	Placebo (N=69)	Normal	60 (90.9)	2 (3.0)	0	62 (93.9)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	D43	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	4 (5.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	2 (3.1)	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (91.9)	2 (3.2)	0	59 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	60 (96.8)	2 (3.2)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	182 (93.3)	8 (4.1)	0	190 (97.4)
			Abnormal NCS	4 (2.1)	1 (0.5)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	186 (95.4)	9 (4.6)	0	195 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	D57	Placebo (N=69)	Normal	60 (92.3)	2 (3.1)	0	62 (95.4)
			Abnormal NCS	2 (3.1)	1 (1.5)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (91.0)	4 (6.0)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (95.3)	3 (4.7)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (95.1)	1 (1.6)	0	59 (96.7)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.3)
			Abnormal CS	0	0	0	0
			Total	59 (96.7)	2 (3.3)	0	61 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	D57	Combined GS1-144 (N=207)	Normal	180 (93.8)	8 (4.2)	0	188 (97.9)
			Abnormal NCS	3 (1.6)	1 (0.5)	0	4 (2.1)
			Abnormal CS	0	0	0	0
			Total	183 (95.3)	9 (4.7)	0	192 (100)
	D71	Placebo (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	4 (6.2)	0	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (92.5)	4 (6.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (88.9)	3 (4.8)	0	59 (93.7)
			Abnormal NCS	4 (6.3)	0	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	D71	GS1-144 30 mg BID (N=68)	Normal	57 (93.4)	2 (3.3)	0	59 (96.7)
			Abnormal NCS	2 (3.3)	0	0	2 (3.3)
			Abnormal CS	0	0	0	0
			Total	59 (96.7)	2 (3.3)	0	61 (100)
		Combined GS1-144 (N=207)	Normal	175 (91.6)	9 (4.7)	0	184 (96.3)
			Abnormal NCS	7 (3.7)	0	0	7 (3.7)
			Abnormal CS	0	0	0	0
			Total	182 (95.3)	9 (4.7)	0	191 (100)
	D85	Placebo (N=69)	Normal	58 (90.6)	3 (4.7)	0	61 (95.3)
			Abnormal NCS	3 (4.7)	0	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	58 (87.9)	4 (6.1)	0	62 (93.9)
			Abnormal NCS	4 (6.1)	0	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	D85	GS1-144 60 mg QD (N=69)	Normal	59 (92.2)	3 (4.7)	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (96.7)	2 (3.3)	0	61 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	59 (96.7)	2 (3.3)	0	61 (100)
		Combined GS1-144 (N=207)	Normal	176 (92.1)	9 (4.7)	0	185 (96.9)
			Abnormal NCS	6 (3.1)	0	0	6 (3.1)
			Abnormal CS	0	0	0	0
			Total	182 (95.3)	9 (4.7)	0	191 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	3 (4.7)	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea (mmol/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	2 (3.0)	0	62 (92.5)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (92.2)	2 (3.1)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (93.4)	1 (1.6)	0	58 (95.1)
			Abnormal NCS	1 (1.6)	2 (3.3)	0	3 (4.9)
			Abnormal CS	0	0	0	0
			Total	58 (95.1)	3 (4.9)	0	61 (100)
		Combined GS1-144 (N=207)	Normal	176 (91.7)	5 (2.6)	0	181 (94.3)
			Abnormal NCS	6 (3.1)	5 (2.6)	0	11 (5.7)
			Abnormal CS	0	0	0	0
			Total	182 (94.8)	10 (5.2)	0	192 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urea Nitrogen (mmol/L)	D15	Placebo (N=69)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		GS1-144 30 mg BID (N=68)	Normal	1 (50.0)	0	0	1 (50.0)
			Abnormal NCS	1 (50.0)	0	0	1 (50.0)
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea Nitrogen (mmol/L)	D15	Combined GS1-144 (N=207)	Normal	3 (75.0)	0	0	3 (75.0)
			Abnormal NCS	1 (25.0)	0	0	1 (25.0)
			Abnormal CS	0	0	0	0
			Total	4 (100)	0	0	4 (100)
	D29	Placebo (N=69)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urea Nitrogen (mmol/L)	D29	GS1-144 30 mg BID (N=68)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		Combined GS1-144 (N=207)	Normal	4 (100)	0	0	4 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	4 (100)	0	0	4 (100)
	D43	Placebo (N=69)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urea Nitrogen (mmol/L)	D43	GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		GS1-144 30 mg BID (N=68)	Normal	0	0	0	0
			Abnormal NCS	2 (100)	0	0	2 (100)
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		Combined GS1-144 (N=207)	Normal	2 (50.0)	0	0	2 (50.0)
			Abnormal NCS	2 (50.0)	0	0	2 (50.0)
			Abnormal CS	0	0	0	0
			Total	4 (100)	0	0	4 (100)
	D57	Placebo (N=69)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea Nitrogen (mmol/L)	D57	GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		GS1-144 30 mg BID (N=68)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		Combined GS1-144 (N=207)	Normal	4 (100)	0	0	4 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	4 (100)	0	0	4 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urea Nitrogen (mmol/L)	D71	Placebo (N=69)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		GS1-144 30 mg BID (N=68)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urea Nitrogen (mmol/L)	D71	Combined GS1-144 (N=207)	Normal	4 (100)	0	0	4 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	4 (100)	0	0	4 (100)
	D85	Placebo (N=69)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urea Nitrogen (mmol/L)	D85	GS1-144 30 mg BID (N=68)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		Combined GS1-144 (N=207)	Normal	4 (100)	0	0	4 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	4 (100)	0	0	4 (100)
	Safety Follow-up	Placebo (N=69)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0
		GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	0	0	0	0

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urea Nitrogen (mmol/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		GS1-144 30 mg BID (N=68)	Normal	2 (100)	0	0	2 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	2 (100)	0	0	2 (100)
		Combined GS1-144 (N=207)	Normal	4 (100)	0	0	4 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	4 (100)	0	0	4 (100)
Urate (mmol/L)	D15	Placebo (N=69)	Normal	53 (76.8)	2 (2.9)	2 (2.9)	57 (82.6)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	3 (4.3)	1 (1.4)	5 (7.2)	9 (13.0)
			Total	58 (84.1)	4 (5.8)	7 (10.1)	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urate (mmol/L)	D15	GS1-144 30 mg QD (N=70)	Normal	60 (85.7)	4 (5.7)	0	64 (91.4)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	1 (1.4)	0	2 (2.9)	3 (4.3)
			Total	62 (88.6)	6 (8.6)	2 (2.9)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (85.1)	1 (1.5)	2 (3.0)	60 (89.6)
			Abnormal NCS	5 (7.5)	1 (1.5)	0	6 (9.0)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	62 (92.5)	2 (3.0)	3 (4.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (82.4)	1 (1.5)	2 (2.9)	59 (86.8)
			Abnormal NCS	5 (7.4)	1 (1.5)	0	6 (8.8)
			Abnormal CS	0	0	3 (4.4)	3 (4.4)
			Total	61 (89.7)	2 (2.9)	5 (7.4)	68 (100)
		Combined GS1-144 (N=207)	Normal	173 (84.4)	6 (2.9)	4 (2.0)	183 (89.3)
			Abnormal NCS	11 (5.4)	4 (2.0)	0	15 (7.3)
			Abnormal CS	1 (0.5)	0	6 (2.9)	7 (3.4)
			Total	185 (90.2)	10 (4.9)	10 (4.9)	205 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urate (mmol/L)	D29	Placebo (N=69)	Normal	53 (79.1)	2 (3.0)	1 (1.5)	56 (83.6)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	1 (1.5)	1 (1.5)	6 (9.0)	8 (11.9)
			Total	56 (83.6)	4 (6.0)	7 (10.4)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	57 (82.6)	5 (7.2)	1 (1.4)	63 (91.3)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	1 (1.4)	0	1 (1.4)	2 (2.9)
			Total	61 (88.4)	6 (8.7)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (85.1)	2 (3.0)	1 (1.5)	60 (89.6)
			Abnormal NCS	3 (4.5)	0	1 (1.5)	4 (6.0)
			Abnormal CS	2 (3.0)	0	1 (1.5)	3 (4.5)
			Total	62 (92.5)	2 (3.0)	3 (4.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (86.4)	1 (1.5)	2 (3.0)	60 (90.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	3 (4.5)	3 (4.5)
			Total	59 (89.4)	2 (3.0)	5 (7.6)	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urate (mmol/L)	D29	Combined GS1-144 (N=207)	Normal	171 (84.7)	8 (4.0)	4 (2.0)	183 (90.6)
			Abnormal NCS	8 (4.0)	2 (1.0)	1 (0.5)	11 (5.4)
			Abnormal CS	3 (1.5)	0	5 (2.5)	8 (4.0)
			Total	182 (90.1)	10 (5.0)	10 (5.0)	202 (100)
	D43	Placebo (N=69)	Normal	53 (80.3)	2 (3.0)	0	55 (83.3)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	1 (1.5)	1 (1.5)	7 (10.6)	9 (13.6)
			Total	55 (83.3)	4 (6.1)	7 (10.6)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (85.5)	5 (7.2)	0	64 (92.8)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	61 (88.4)	6 (8.7)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (86.6)	1 (1.5)	1 (1.5)	60 (89.6)
			Abnormal NCS	3 (4.5)	1 (1.5)	1 (1.5)	5 (7.5)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.0)
			Total	62 (92.5)	2 (3.0)	3 (4.5)	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urate (mmol/L)	D43	GS1-144 30 mg BID (N=68)	Normal	53 (82.8)	1 (1.6)	2 (3.1)	56 (87.5)
			Abnormal NCS	3 (4.7)	1 (1.6)	0	4 (6.3)
			Abnormal CS	1 (1.6)	0	3 (4.7)	4 (6.3)
			Total	57 (89.1)	2 (3.1)	5 (7.8)	64 (100)
		Combined GS1-144 (N=207)	Normal	170 (85.0)	7 (3.5)	3 (1.5)	180 (90.0)
			Abnormal NCS	8 (4.0)	3 (1.5)	1 (0.5)	12 (6.0)
			Abnormal CS	2 (1.0)	0	6 (3.0)	8 (4.0)
			Total	180 (90.0)	10 (5.0)	10 (5.0)	200 (100)
	D57	Placebo (N=69)	Normal	50 (76.9)	2 (3.1)	2 (3.1)	54 (83.1)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	1 (1.5)	1 (1.5)	5 (7.7)	7 (10.8)
			Total	54 (83.1)	4 (6.2)	7 (10.8)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	57 (83.8)	6 (8.8)	0	63 (92.6)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	60 (88.2)	6 (8.8)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urate (mmol/L)	D57	GS1-144 60 mg QD (N=69)	Normal	57 (86.4)	1 (1.5)	2 (3.0)	60 (90.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	1 (1.5)	3 (4.5)
			Total	61 (92.4)	2 (3.0)	3 (4.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	1 (1.6)	1 (1.6)	56 (88.9)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	4 (6.3)	4 (6.3)
			Total	56 (88.9)	2 (3.2)	5 (7.9)	63 (100)
		Combined GS1-144 (N=207)	Normal	168 (85.3)	8 (4.1)	3 (1.5)	179 (90.9)
			Abnormal NCS	7 (3.6)	2 (1.0)	0	9 (4.6)
			Abnormal CS	2 (1.0)	0	7 (3.6)	9 (4.6)
			Total	177 (89.8)	10 (5.1)	10 (5.1)	197 (100)
	D71	Placebo (N=69)	Normal	50 (76.9)	3 (4.6)	2 (3.1)	55 (84.6)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	1 (1.5)	1 (1.5)	5 (7.7)	7 (10.8)
			Total	54 (83.1)	4 (6.2)	7 (10.8)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urate (mmol/L)	D71	GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	5 (7.4)	0	64 (94.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	60 (88.2)	6 (8.8)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	55 (84.6)	2 (3.1)	3 (4.6)	60 (92.3)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	2 (3.1)	0	0	2 (3.1)
			Total	60 (92.3)	2 (3.1)	3 (4.6)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	1 (1.6)	0	55 (87.3)
			Abnormal NCS	2 (3.2)	1 (1.6)	1 (1.6)	4 (6.3)
			Abnormal CS	0	0	4 (6.3)	4 (6.3)
			Total	56 (88.9)	2 (3.2)	5 (7.9)	63 (100)
		Combined GS1-144 (N=207)	Normal	168 (85.7)	8 (4.1)	3 (1.5)	179 (91.3)
			Abnormal NCS	6 (3.1)	2 (1.0)	1 (0.5)	9 (4.6)
			Abnormal CS	2 (1.0)	0	6 (3.1)	8 (4.1)
			Total	176 (89.8)	10 (5.1)	10 (5.1)	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urate (mmol/L)	D85	Placebo (N=69)	Normal	50 (78.1)	3 (4.7)	2 (3.1)	55 (85.9)
			Abnormal NCS	3 (4.7)	1 (1.6)	0	4 (6.3)
			Abnormal CS	1 (1.6)	0	4 (6.3)	5 (7.8)
			Total	54 (84.4)	4 (6.3)	6 (9.4)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	55 (82.1)	5 (7.5)	1 (1.5)	61 (91.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.0)
			Total	59 (88.1)	6 (9.0)	2 (3.0)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (86.4)	1 (1.5)	2 (3.0)	60 (90.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	1 (1.5)	3 (4.5)
			Total	61 (92.4)	2 (3.0)	3 (4.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	1 (1.6)	1 (1.6)	57 (90.5)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	4 (6.3)	4 (6.3)
			Total	56 (88.9)	2 (3.2)	5 (7.9)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urate (mmol/L)	D85	Combined GS1-144 (N=207)	Normal	167 (85.2)	7 (3.6)	4 (2.0)	178 (90.8)
			Abnormal NCS	6 (3.1)	3 (1.5)	0	9 (4.6)
			Abnormal CS	3 (1.5)	0	6 (3.1)	9 (4.6)
			Total	176 (89.8)	10 (5.1)	10 (5.1)	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	51 (79.7)	2 (3.1)	3 (4.7)	56 (87.5)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	1 (1.6)	1 (1.6)	4 (6.3)	6 (9.4)
			Total	54 (84.4)	3 (4.7)	7 (10.9)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	58 (85.3)	4 (5.9)	1 (1.5)	63 (92.6)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	60 (88.2)	6 (8.8)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	54 (81.8)	1 (1.5)	2 (3.0)	57 (86.4)
			Abnormal NCS	5 (7.6)	1 (1.5)	1 (1.5)	7 (10.6)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	61 (92.4)	2 (3.0)	3 (4.5)	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urate (mmol/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	53 (84.1)	1 (1.6)	1 (1.6)	55 (87.3)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	4 (6.3)	4 (6.3)
			Total	56 (88.9)	2 (3.2)	5 (7.9)	63 (100)
		Combined GS1-144 (N=207)	Normal	165 (83.8)	6 (3.0)	4 (2.0)	175 (88.8)
			Abnormal NCS	10 (5.1)	4 (2.0)	1 (0.5)	15 (7.6)
			Abnormal CS	2 (1.0)	0	5 (2.5)	7 (3.6)
			Total	177 (89.8)	10 (5.1)	10 (5.1)	197 (100)
Cholesterol (mmol/L)	D15	Placebo (N=69)	Normal	24 (35.3)	5 (7.4)	1 (1.5)	30 (44.1)
			Abnormal NCS	2 (2.9)	19 (27.9)	0	21 (30.9)
			Abnormal CS	0	1 (1.5)	16 (23.5)	17 (25.0)
			Total	26 (38.2)	25 (36.8)	17 (25.0)	68 (100)
		GS1-144 30 mg QD (N=70)	Normal	27 (38.6)	3 (4.3)	2 (2.9)	32 (45.7)
			Abnormal NCS	5 (7.1)	16 (22.9)	0	21 (30.0)
			Abnormal CS	5 (7.1)	3 (4.3)	9 (12.9)	17 (24.3)
			Total	37 (52.9)	22 (31.4)	11 (15.7)	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Cholesterol (mmol/L)	D15	GS1-144 60 mg QD (N=69)	Normal	25 (37.3)	8 (11.9)	2 (3.0)	35 (52.2)
			Abnormal NCS	4 (6.0)	10 (14.9)	1 (1.5)	15 (22.4)
			Abnormal CS	2 (3.0)	0	15 (22.4)	17 (25.4)
			Total	31 (46.3)	18 (26.9)	18 (26.9)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	25 (36.8)	5 (7.4)	1 (1.5)	31 (45.6)
			Abnormal NCS	7 (10.3)	14 (20.6)	0	21 (30.9)
			Abnormal CS	3 (4.4)	1 (1.5)	12 (17.6)	16 (23.5)
			Total	35 (51.5)	20 (29.4)	13 (19.1)	68 (100)
		Combined GS1-144 (N=207)	Normal	77 (37.6)	16 (7.8)	5 (2.4)	98 (47.8)
			Abnormal NCS	16 (7.8)	40 (19.5)	1 (0.5)	57 (27.8)
			Abnormal CS	10 (4.9)	4 (2.0)	36 (17.6)	50 (24.4)
			Total	103 (50.2)	60 (29.3)	42 (20.5)	205 (100)
	D29	Placebo (N=69)	Normal	24 (36.4)	2 (3.0)	4 (6.1)	30 (45.5)
			Abnormal NCS	2 (3.0)	21 (31.8)	0	23 (34.8)
			Abnormal CS	0	0	13 (19.7)	13 (19.7)
			Total	26 (39.4)	23 (34.8)	17 (25.8)	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Cholesterol (mmol/L)	D29	GS1-144 30 mg QD (N=70)	Normal	31 (44.9)	7 (10.1)	2 (2.9)	40 (58.0)
			Abnormal NCS	3 (4.3)	14 (20.3)	0	17 (24.6)
			Abnormal CS	3 (4.3)	0	9 (13.0)	12 (17.4)
			Total	37 (53.6)	21 (30.4)	11 (15.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	23 (34.8)	7 (10.6)	8 (12.1)	38 (57.6)
			Abnormal NCS	6 (9.1)	10 (15.2)	0	16 (24.2)
			Abnormal CS	2 (3.0)	1 (1.5)	9 (13.6)	12 (18.2)
			Total	31 (47.0)	18 (27.3)	17 (25.8)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	29 (43.3)	5 (7.5)	0	34 (50.7)
			Abnormal NCS	4 (6.0)	15 (22.4)	0	19 (28.4)
			Abnormal CS	2 (3.0)	0	12 (17.9)	14 (20.9)
			Total	35 (52.2)	20 (29.9)	12 (17.9)	67 (100)
		Combined GS1-144 (N=207)	Normal	83 (41.1)	19 (9.4)	10 (5.0)	112 (55.4)
			Abnormal NCS	13 (6.4)	39 (19.3)	0	52 (25.7)
			Abnormal CS	7 (3.5)	1 (0.5)	30 (14.9)	38 (18.8)
			Total	103 (51.0)	59 (29.2)	40 (19.8)	202 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Cholesterol (mmol/L)	D43	Placebo (N=69)	Normal	21 (32.3)	9 (13.8)	1 (1.5)	31 (47.7)
			Abnormal NCS	3 (4.6)	13 (20.0)	0	16 (24.6)
			Abnormal CS	2 (3.1)	1 (1.5)	15 (23.1)	18 (27.7)
			Total	26 (40.0)	23 (35.4)	16 (24.6)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	29 (42.0)	4 (5.8)	2 (2.9)	35 (50.7)
			Abnormal NCS	6 (8.7)	14 (20.3)	0	20 (29.0)
			Abnormal CS	2 (2.9)	3 (4.3)	9 (13.0)	14 (20.3)
			Total	37 (53.6)	21 (30.4)	11 (15.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	22 (33.3)	4 (6.1)	7 (10.6)	33 (50.0)
			Abnormal NCS	6 (9.1)	13 (19.7)	0	19 (28.8)
			Abnormal CS	3 (4.5)	1 (1.5)	10 (15.2)	14 (21.2)
			Total	31 (47.0)	18 (27.3)	17 (25.8)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	28 (43.8)	5 (7.8)	1 (1.6)	34 (53.1)
			Abnormal NCS	4 (6.3)	10 (15.6)	0	14 (21.9)
			Abnormal CS	3 (4.7)	2 (3.1)	11 (17.2)	16 (25.0)
			Total	35 (54.7)	17 (26.6)	12 (18.8)	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Cholesterol (mmol/L)	D43	Combined GS1-144 (N=207)	Normal	79 (39.7)	13 (6.5)	10 (5.0)	102 (51.3)
			Abnormal NCS	16 (8.0)	37 (18.6)	0	53 (26.6)
			Abnormal CS	8 (4.0)	6 (3.0)	30 (15.1)	44 (22.1)
			Total	103 (51.8)	56 (28.1)	40 (20.1)	199 (100)
	D57	Placebo (N=69)	Normal	20 (31.3)	9 (14.1)	3 (4.7)	32 (50.0)
			Abnormal NCS	4 (6.3)	14 (21.9)	0	18 (28.1)
			Abnormal CS	1 (1.6)	0	13 (20.3)	14 (21.9)
			Total	25 (39.1)	23 (35.9)	16 (25.0)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	27 (39.7)	7 (10.3)	2 (2.9)	36 (52.9)
			Abnormal NCS	6 (8.8)	13 (19.1)	2 (2.9)	21 (30.9)
			Abnormal CS	3 (4.4)	1 (1.5)	7 (10.3)	11 (16.2)
			Total	36 (52.9)	21 (30.9)	11 (16.2)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	22 (33.8)	6 (9.2)	7 (10.8)	35 (53.8)
			Abnormal NCS	5 (7.7)	11 (16.9)	0	16 (24.6)
			Abnormal CS	3 (4.6)	1 (1.5)	10 (15.4)	14 (21.5)
			Total	30 (46.2)	18 (27.7)	17 (26.2)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Cholesterol (mmol/L)	D57	GS1-144 30 mg BID (N=68)	Normal	26 (41.3)	1 (1.6)	4 (6.3)	31 (49.2)
			Abnormal NCS	6 (9.5)	13 (20.6)	0	19 (30.2)
			Abnormal CS	3 (4.8)	2 (3.2)	8 (12.7)	13 (20.6)
			Total	35 (55.6)	16 (25.4)	12 (19.0)	63 (100)
		Combined GS1-144 (N=207)	Normal	75 (38.3)	14 (7.1)	13 (6.6)	102 (52.0)
			Abnormal NCS	17 (8.7)	37 (18.9)	2 (1.0)	56 (28.6)
			Abnormal CS	9 (4.6)	4 (2.0)	25 (12.8)	38 (19.4)
			Total	101 (51.5)	55 (28.1)	40 (20.4)	196 (100)
	D71	Placebo (N=69)	Normal	21 (32.8)	12 (18.8)	3 (4.7)	36 (56.3)
			Abnormal NCS	2 (3.1)	10 (15.6)	0	12 (18.8)
			Abnormal CS	2 (3.1)	1 (1.6)	13 (20.3)	16 (25.0)
			Total	25 (39.1)	23 (35.9)	16 (25.0)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	27 (39.7)	7 (10.3)	0	34 (50.0)
			Abnormal NCS	6 (8.8)	11 (16.2)	0	17 (25.0)
			Abnormal CS	3 (4.4)	3 (4.4)	11 (16.2)	17 (25.0)
			Total	36 (52.9)	21 (30.9)	11 (16.2)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Cholesterol (mmol/L)	D71	GS1-144 60 mg QD (N=69)	Normal	21 (32.8)	6 (9.4)	5 (7.8)	32 (50.0)
			Abnormal NCS	6 (9.4)	11 (17.2)	1 (1.6)	18 (28.1)
			Abnormal CS	3 (4.7)	1 (1.6)	10 (15.6)	14 (21.9)
			Total	30 (46.9)	18 (28.1)	16 (25.0)	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	23 (36.5)	6 (9.5)	4 (6.3)	33 (52.4)
			Abnormal NCS	7 (11.1)	9 (14.3)	2 (3.2)	18 (28.6)
			Abnormal CS	5 (7.9)	1 (1.6)	6 (9.5)	12 (19.0)
			Total	35 (55.6)	16 (25.4)	12 (19.0)	63 (100)
		Combined GS1-144 (N=207)	Normal	71 (36.4)	19 (9.7)	9 (4.6)	99 (50.8)
			Abnormal NCS	19 (9.7)	31 (15.9)	3 (1.5)	53 (27.2)
			Abnormal CS	11 (5.6)	5 (2.6)	27 (13.8)	43 (22.1)
			Total	101 (51.8)	55 (28.2)	39 (20.0)	195 (100)
	D85	Placebo (N=69)	Normal	21 (33.3)	7 (11.1)	1 (1.6)	29 (46.0)
			Abnormal NCS	2 (3.2)	16 (25.4)	0	18 (28.6)
			Abnormal CS	2 (3.2)	0	14 (22.2)	16 (25.4)
			Total	25 (39.7)	23 (36.5)	15 (23.8)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Cholesterol (mmol/L)	D85	GS1-144 30 mg QD (N=70)	Normal	23 (34.3)	6 (9.0)	0	29 (43.3)
			Abnormal NCS	10 (14.9)	13 (19.4)	0	23 (34.3)
			Abnormal CS	3 (4.5)	2 (3.0)	10 (14.9)	15 (22.4)
			Total	36 (53.7)	21 (31.3)	10 (14.9)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	21 (32.3)	6 (9.2)	8 (12.3)	35 (53.8)
			Abnormal NCS	6 (9.2)	10 (15.4)	0	16 (24.6)
			Abnormal CS	3 (4.6)	2 (3.1)	9 (13.8)	14 (21.5)
			Total	30 (46.2)	18 (27.7)	17 (26.2)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	24 (38.1)	5 (7.9)	4 (6.3)	33 (52.4)
			Abnormal NCS	6 (9.5)	9 (14.3)	0	15 (23.8)
			Abnormal CS	5 (7.9)	2 (3.2)	8 (12.7)	15 (23.8)
			Total	35 (55.6)	16 (25.4)	12 (19.0)	63 (100)
		Combined GS1-144 (N=207)	Normal	68 (34.9)	17 (8.7)	12 (6.2)	97 (49.7)
			Abnormal NCS	22 (11.3)	32 (16.4)	0	54 (27.7)
			Abnormal CS	11 (5.6)	6 (3.1)	27 (13.8)	44 (22.6)
			Total	101 (51.8)	55 (28.2)	39 (20.0)	195 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Cholesterol (mmol/L)	Safety Follow-up	Placebo (N=69)	Normal	22 (34.9)	6 (9.5)	1 (1.6)	29 (46.0)
			Abnormal NCS	1 (1.6)	17 (27.0)	0	18 (28.6)
			Abnormal CS	1 (1.6)	0	15 (23.8)	16 (25.4)
			Total	24 (38.1)	23 (36.5)	16 (25.4)	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	29 (42.6)	7 (10.3)	2 (2.9)	38 (55.9)
			Abnormal NCS	6 (8.8)	11 (16.2)	0	17 (25.0)
			Abnormal CS	2 (2.9)	3 (4.4)	8 (11.8)	13 (19.1)
			Total	37 (54.4)	21 (30.9)	10 (14.7)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	19 (29.2)	6 (9.2)	6 (9.2)	31 (47.7)
			Abnormal NCS	9 (13.8)	11 (16.9)	0	20 (30.8)
			Abnormal CS	3 (4.6)	1 (1.5)	10 (15.4)	14 (21.5)
			Total	31 (47.7)	18 (27.7)	16 (24.6)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	27 (42.9)	4 (6.3)	1 (1.6)	32 (50.8)
			Abnormal NCS	6 (9.5)	11 (17.5)	2 (3.2)	19 (30.2)
			Abnormal CS	1 (1.6)	1 (1.6)	10 (15.9)	12 (19.0)
			Total	34 (54.0)	16 (25.4)	13 (20.6)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Cholesterol (mmol/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	75 (38.3)	17 (8.7)	9 (4.6)	101 (51.5)
			Abnormal NCS	21 (10.7)	33 (16.8)	2 (1.0)	56 (28.6)
			Abnormal CS	6 (3.1)	5 (2.6)	28 (14.3)	39 (19.9)
			Total	102 (52.0)	55 (28.1)	39 (19.9)	196 (100)
Triglycerides (mmol/L)	D15	Placebo (N=69)	Normal	50 (73.5)	6 (8.8)	3 (4.4)	59 (86.8)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	2 (2.9)	0	5 (7.4)	7 (10.3)
			Total	54 (79.4)	6 (8.8)	8 (11.8)	68 (100)
		GS1-144 30 mg QD (N=70)	Normal	44 (62.9)	2 (2.9)	5 (7.1)	51 (72.9)
			Abnormal NCS	7 (10.0)	3 (4.3)	0	10 (14.3)
			Abnormal CS	2 (2.9)	2 (2.9)	5 (7.1)	9 (12.9)
			Total	53 (75.7)	7 (10.0)	10 (14.3)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	46 (68.7)	5 (7.5)	5 (7.5)	56 (83.6)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	6 (9.0)	8 (11.9)
			Total	49 (73.1)	7 (10.4)	11 (16.4)	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triglycerides (mmol/L)	D15	GS1-144 30 mg BID (N=68)	Normal	58 (85.3)	1 (1.5)	2 (2.9)	61 (89.7)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	3 (4.4)	0	1 (1.5)	4 (5.9)
			Total	63 (92.6)	2 (2.9)	3 (4.4)	68 (100)
		Combined GS1-144 (N=207)	Normal	148 (72.2)	8 (3.9)	12 (5.9)	168 (82.0)
			Abnormal NCS	10 (4.9)	6 (2.9)	0	16 (7.8)
			Abnormal CS	7 (3.4)	2 (1.0)	12 (5.9)	21 (10.2)
			Total	165 (80.5)	16 (7.8)	24 (11.7)	205 (100)
	D29	Placebo (N=69)	Normal	49 (74.2)	2 (3.0)	3 (4.5)	54 (81.8)
			Abnormal NCS	1 (1.5)	4 (6.1)	0	5 (7.6)
			Abnormal CS	2 (3.0)	0	5 (7.6)	7 (10.6)
			Total	52 (78.8)	6 (9.1)	8 (12.1)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	46 (66.7)	3 (4.3)	6 (8.7)	55 (79.7)
			Abnormal NCS	6 (8.7)	2 (2.9)	0	8 (11.6)
			Abnormal CS	1 (1.4)	1 (1.4)	4 (5.8)	6 (8.7)
			Total	53 (76.8)	6 (8.7)	10 (14.5)	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Triglycerides (mmol/L)	D29	GS1-144 60 mg QD (N=69)	Normal	45 (68.2)	4 (6.1)	4 (6.1)	53 (80.3)
			Abnormal NCS	3 (4.5)	3 (4.5)	0	6 (9.1)
			Abnormal CS	0	0	7 (10.6)	7 (10.6)
			Total	48 (72.7)	7 (10.6)	11 (16.7)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (85.1)	1 (1.5)	1 (1.5)	59 (88.1)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	3 (4.5)	0	2 (3.0)	5 (7.5)
			Total	62 (92.5)	2 (3.0)	3 (4.5)	67 (100)
		Combined GS1-144 (N=207)	Normal	148 (73.3)	8 (4.0)	11 (5.4)	167 (82.7)
			Abnormal NCS	11 (5.4)	6 (3.0)	0	17 (8.4)
			Abnormal CS	4 (2.0)	1 (0.5)	13 (6.4)	18 (8.9)
			Total	163 (80.7)	15 (7.4)	24 (11.9)	202 (100)
	D43	Placebo (N=69)	Normal	49 (75.4)	5 (7.7)	3 (4.6)	57 (87.7)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	2 (3.1)	0	4 (6.2)	6 (9.2)
			Total	52 (80.0)	6 (9.2)	7 (10.8)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Triglycerides (mmol/L)	D43	GS1-144 30 mg QD (N=70)	Normal	44 (63.8)	1 (1.4)	5 (7.2)	50 (72.5)
			Abnormal NCS	6 (8.7)	3 (4.3)	0	9 (13.0)
			Abnormal CS	3 (4.3)	2 (2.9)	5 (7.2)	10 (14.5)
			Total	53 (76.8)	6 (8.7)	10 (14.5)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	45 (68.2)	2 (3.0)	4 (6.1)	51 (77.3)
			Abnormal NCS	2 (3.0)	5 (7.6)	0	7 (10.6)
			Abnormal CS	1 (1.5)	0	7 (10.6)	8 (12.1)
			Total	48 (72.7)	7 (10.6)	11 (16.7)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (89.1)	0	1 (1.6)	58 (90.6)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	1 (1.6)	1 (1.6)	2 (3.1)	4 (6.3)
			Total	60 (93.8)	1 (1.6)	3 (4.7)	64 (100)
		Combined GS1-144 (N=207)	Normal	146 (73.4)	3 (1.5)	10 (5.0)	159 (79.9)
			Abnormal NCS	10 (5.0)	8 (4.0)	0	18 (9.0)
			Abnormal CS	5 (2.5)	3 (1.5)	14 (7.0)	22 (11.1)
			Total	161 (80.9)	14 (7.0)	24 (12.1)	199 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Triglycerides (mmol/L)	D57	Placebo (N=69)	Normal	49 (76.6)	3 (4.7)	5 (7.8)	57 (89.1)
			Abnormal NCS	1 (1.6)	3 (4.7)	0	4 (6.3)
			Abnormal CS	1 (1.6)	0	2 (3.1)	3 (4.7)
			Total	51 (79.7)	6 (9.4)	7 (10.9)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	45 (66.2)	2 (2.9)	5 (7.4)	52 (76.5)
			Abnormal NCS	6 (8.8)	2 (2.9)	0	8 (11.8)
			Abnormal CS	1 (1.5)	2 (2.9)	5 (7.4)	8 (11.8)
			Total	52 (76.5)	6 (8.8)	10 (14.7)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	44 (67.7)	1 (1.5)	3 (4.6)	48 (73.8)
			Abnormal NCS	2 (3.1)	6 (9.2)	1 (1.5)	9 (13.8)
			Abnormal CS	1 (1.5)	0	7 (10.8)	8 (12.3)
			Total	47 (72.3)	7 (10.8)	11 (16.9)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	0	1 (1.6)	55 (87.3)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	2 (3.2)	0	2 (3.2)	4 (6.3)
			Total	59 (93.7)	1 (1.6)	3 (4.8)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triglycerides (mmol/L)	D57	Combined GS1-144 (N=207)	Normal	143 (73.0)	3 (1.5)	9 (4.6)	155 (79.1)
			Abnormal NCS	11 (5.6)	9 (4.6)	1 (0.5)	21 (10.7)
			Abnormal CS	4 (2.0)	2 (1.0)	14 (7.1)	20 (10.2)
			Total	158 (80.6)	14 (7.1)	24 (12.2)	196 (100)
	D71	Placebo (N=69)	Normal	45 (70.3)	3 (4.7)	3 (4.7)	51 (79.7)
			Abnormal NCS	3 (4.7)	3 (4.7)	0	6 (9.4)
			Abnormal CS	3 (4.7)	0	4 (6.3)	7 (10.9)
			Total	51 (79.7)	6 (9.4)	7 (10.9)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	41 (60.3)	3 (4.4)	4 (5.9)	48 (70.6)
			Abnormal NCS	9 (13.2)	1 (1.5)	0	10 (14.7)
			Abnormal CS	2 (2.9)	2 (2.9)	6 (8.8)	10 (14.7)
			Total	52 (76.5)	6 (8.8)	10 (14.7)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	42 (65.6)	4 (6.3)	4 (6.3)	50 (78.1)
			Abnormal NCS	4 (6.3)	3 (4.7)	0	7 (10.9)
			Abnormal CS	1 (1.6)	0	6 (9.4)	7 (10.9)
			Total	47 (73.4)	7 (10.9)	10 (15.6)	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triglycerides (mmol/L)	D71	GS1-144 30 mg BID (N=68)	Normal	49 (77.8)	0	0	49 (77.8)
			Abnormal NCS	6 (9.5)	0	0	6 (9.5)
			Abnormal CS	4 (6.3)	1 (1.6)	3 (4.8)	8 (12.7)
			Total	59 (93.7)	1 (1.6)	3 (4.8)	63 (100)
		Combined GS1-144 (N=207)	Normal	132 (67.7)	7 (3.6)	8 (4.1)	147 (75.4)
			Abnormal NCS	19 (9.7)	4 (2.1)	0	23 (11.8)
			Abnormal CS	7 (3.6)	3 (1.5)	15 (7.7)	25 (12.8)
			Total	158 (81.0)	14 (7.2)	23 (11.8)	195 (100)
	D85	Placebo (N=69)	Normal	46 (73.0)	4 (6.3)	3 (4.8)	53 (84.1)
			Abnormal NCS	3 (4.8)	2 (3.2)	0	5 (7.9)
			Abnormal CS	1 (1.6)	0	4 (6.3)	5 (7.9)
			Total	50 (79.4)	6 (9.5)	7 (11.1)	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	45 (67.2)	1 (1.5)	4 (6.0)	50 (74.6)
			Abnormal NCS	5 (7.5)	4 (6.0)	0	9 (13.4)
			Abnormal CS	2 (3.0)	1 (1.5)	5 (7.5)	8 (11.9)
			Total	52 (77.6)	6 (9.0)	9 (13.4)	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triglycerides (mmol/L)	D85	GS1-144 60 mg QD (N=69)	Normal	44 (67.7)	5 (7.7)	6 (9.2)	55 (84.6)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	1 (1.5)	0	5 (7.7)	6 (9.2)
			Total	47 (72.3)	7 (10.8)	11 (16.9)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	0	1 (1.6)	56 (88.9)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	3 (4.8)	1 (1.6)	2 (3.2)	6 (9.5)
			Total	59 (93.7)	1 (1.6)	3 (4.8)	63 (100)
		Combined GS1-144 (N=207)	Normal	144 (73.8)	6 (3.1)	11 (5.6)	161 (82.6)
			Abnormal NCS	8 (4.1)	6 (3.1)	0	14 (7.2)
			Abnormal CS	6 (3.1)	2 (1.0)	12 (6.2)	20 (10.3)
			Total	158 (81.0)	14 (7.2)	23 (11.8)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	48 (76.2)	4 (6.3)	4 (6.3)	56 (88.9)
			Abnormal NCS	2 (3.2)	2 (3.2)	1 (1.6)	5 (7.9)
			Abnormal CS	0	0	2 (3.2)	2 (3.2)
			Total	50 (79.4)	6 (9.5)	7 (11.1)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triglycerides (mmol/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	46 (67.6)	2 (2.9)	5 (7.4)	53 (77.9)
			Abnormal NCS	5 (7.4)	2 (2.9)	0	7 (10.3)
			Abnormal CS	2 (2.9)	2 (2.9)	4 (5.9)	8 (11.8)
			Total	53 (77.9)	6 (8.8)	9 (13.2)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	42 (64.6)	5 (7.7)	6 (9.2)	53 (81.5)
			Abnormal NCS	4 (6.2)	2 (3.1)	0	6 (9.2)
			Abnormal CS	2 (3.1)	0	4 (6.2)	6 (9.2)
			Total	48 (73.8)	7 (10.8)	10 (15.4)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	0	1 (1.6)	56 (88.9)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	1 (1.6)	1 (1.6)	2 (3.2)	4 (6.3)
			Total	59 (93.7)	1 (1.6)	3 (4.8)	63 (100)
		Combined GS1-144 (N=207)	Normal	143 (73.0)	7 (3.6)	12 (6.1)	162 (82.7)
			Abnormal NCS	12 (6.1)	4 (2.0)	0	16 (8.2)
			Abnormal CS	5 (2.6)	3 (1.5)	10 (5.1)	18 (9.2)
			Total	160 (81.6)	14 (7.1)	22 (11.2)	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
LDL Cholesterol (mmol/L)	D15	Placebo (N=69)	Normal	36 (52.9)	4 (5.9)	1 (1.5)	41 (60.3)
			Abnormal NCS	5 (7.4)	9 (13.2)	0	14 (20.6)
			Abnormal CS	1 (1.5)	1 (1.5)	11 (16.2)	13 (19.1)
			Total	42 (61.8)	14 (20.6)	12 (17.6)	68 (100)
		GS1-144 30 mg QD (N=70)	Normal	34 (48.6)	2 (2.9)	1 (1.4)	37 (52.9)
			Abnormal NCS	4 (5.7)	15 (21.4)	0	19 (27.1)
			Abnormal CS	4 (5.7)	1 (1.4)	9 (12.9)	14 (20.0)
			Total	42 (60.0)	18 (25.7)	10 (14.3)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	26 (38.8)	5 (7.5)	3 (4.5)	34 (50.7)
			Abnormal NCS	7 (10.4)	14 (20.9)	1 (1.5)	22 (32.8)
			Abnormal CS	1 (1.5)	0	10 (14.9)	11 (16.4)
			Total	34 (50.7)	19 (28.4)	14 (20.9)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	32 (47.1)	2 (2.9)	2 (2.9)	36 (52.9)
			Abnormal NCS	7 (10.3)	14 (20.6)	0	21 (30.9)
			Abnormal CS	1 (1.5)	2 (2.9)	8 (11.8)	11 (16.2)
			Total	40 (58.8)	18 (26.5)	10 (14.7)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
LDL Cholesterol (mmol/L)	D15	Combined GS1-144 (N=207)	Normal	92 (44.9)	9 (4.4)	6 (2.9)	107 (52.2)
			Abnormal NCS	18 (8.8)	43 (21.0)	1 (0.5)	62 (30.2)
			Abnormal CS	6 (2.9)	3 (1.5)	27 (13.2)	36 (17.6)
			Total	116 (56.6)	55 (26.8)	34 (16.6)	205 (100)
	D29	Placebo (N=69)	Normal	35 (53.0)	1 (1.5)	3 (4.5)	39 (59.1)
			Abnormal NCS	4 (6.1)	12 (18.2)	0	16 (24.2)
			Abnormal CS	2 (3.0)	0	9 (13.6)	11 (16.7)
			Total	41 (62.1)	13 (19.7)	12 (18.2)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	33 (47.8)	4 (5.8)	5 (7.2)	42 (60.9)
			Abnormal NCS	5 (7.2)	14 (20.3)	0	19 (27.5)
			Abnormal CS	3 (4.3)	0	5 (7.2)	8 (11.6)
			Total	41 (59.4)	18 (26.1)	10 (14.5)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	24 (36.4)	6 (9.1)	6 (9.1)	36 (54.5)
			Abnormal NCS	9 (13.6)	12 (18.2)	0	21 (31.8)
			Abnormal CS	1 (1.5)	1 (1.5)	7 (10.6)	9 (13.6)
			Total	34 (51.5)	19 (28.8)	13 (19.7)	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
LDL Cholesterol (mmol/L)	D29	GS1-144 30 mg BID (N=68)	Normal	34 (50.7)	3 (4.5)	3 (4.5)	40 (59.7)
			Abnormal NCS	5 (7.5)	14 (20.9)	0	19 (28.4)
			Abnormal CS	1 (1.5)	1 (1.5)	6 (9.0)	8 (11.9)
			Total	40 (59.7)	18 (26.9)	9 (13.4)	67 (100)
		Combined GS1-144 (N=207)	Normal	91 (45.0)	13 (6.4)	14 (6.9)	118 (58.4)
			Abnormal NCS	19 (9.4)	40 (19.8)	0	59 (29.2)
			Abnormal CS	5 (2.5)	2 (1.0)	18 (8.9)	25 (12.4)
			Total	115 (56.9)	55 (27.2)	32 (15.8)	202 (100)
	D43	Placebo (N=69)	Normal	33 (50.8)	5 (7.7)	2 (3.1)	40 (61.5)
			Abnormal NCS	5 (7.7)	8 (12.3)	0	13 (20.0)
			Abnormal CS	3 (4.6)	0	9 (13.8)	12 (18.5)
			Total	41 (63.1)	13 (20.0)	11 (16.9)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	31 (44.9)	4 (5.8)	3 (4.3)	38 (55.1)
			Abnormal NCS	6 (8.7)	14 (20.3)	0	20 (29.0)
			Abnormal CS	4 (5.8)	0	7 (10.1)	11 (15.9)
			Total	41 (59.4)	18 (26.1)	10 (14.5)	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
LDL Cholesterol (mmol/L)	D43	GS1-144 60 mg QD (N=69)	Normal	27 (40.9)	6 (9.1)	5 (7.6)	38 (57.6)
			Abnormal NCS	5 (7.6)	12 (18.2)	0	17 (25.8)
			Abnormal CS	2 (3.0)	1 (1.5)	8 (12.1)	11 (16.7)
			Total	34 (51.5)	19 (28.8)	13 (19.7)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	32 (50.0)	8 (12.5)	1 (1.6)	41 (64.1)
			Abnormal NCS	4 (6.3)	7 (10.9)	0	11 (17.2)
			Abnormal CS	3 (4.7)	1 (1.6)	8 (12.5)	12 (18.8)
			Total	39 (60.9)	16 (25.0)	9 (14.1)	64 (100)
		Combined GS1-144 (N=207)	Normal	90 (45.2)	18 (9.0)	9 (4.5)	117 (58.8)
			Abnormal NCS	15 (7.5)	33 (16.6)	0	48 (24.1)
			Abnormal CS	9 (4.5)	2 (1.0)	23 (11.6)	34 (17.1)
			Total	114 (57.3)	53 (26.6)	32 (16.1)	199 (100)
	D57	Placebo (N=69)	Normal	33 (51.6)	3 (4.7)	1 (1.6)	37 (57.8)
			Abnormal NCS	5 (7.8)	10 (15.6)	0	15 (23.4)
			Abnormal CS	2 (3.1)	0	10 (15.6)	12 (18.8)
			Total	40 (62.5)	13 (20.3)	11 (17.2)	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
LDL Cholesterol (mmol/L)	D57	GS1-144 30 mg QD (N=70)	Normal	29 (42.6)	4 (5.9)	3 (4.4)	36 (52.9)
			Abnormal NCS	9 (13.2)	12 (17.6)	1 (1.5)	22 (32.4)
			Abnormal CS	3 (4.4)	1 (1.5)	6 (8.8)	10 (14.7)
			Total	41 (60.3)	17 (25.0)	10 (14.7)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	26 (40.0)	8 (12.3)	6 (9.2)	40 (61.5)
			Abnormal NCS	5 (7.7)	10 (15.4)	0	15 (23.1)
			Abnormal CS	2 (3.1)	1 (1.5)	7 (10.8)	10 (15.4)
			Total	33 (50.8)	19 (29.2)	13 (20.0)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	31 (49.2)	4 (6.3)	3 (4.8)	38 (60.3)
			Abnormal NCS	5 (7.9)	9 (14.3)	0	14 (22.2)
			Abnormal CS	3 (4.8)	2 (3.2)	6 (9.5)	11 (17.5)
			Total	39 (61.9)	15 (23.8)	9 (14.3)	63 (100)
		Combined GS1-144 (N=207)	Normal	86 (43.9)	16 (8.2)	12 (6.1)	114 (58.2)
			Abnormal NCS	19 (9.7)	31 (15.8)	1 (0.5)	51 (26.0)
			Abnormal CS	8 (4.1)	4 (2.0)	19 (9.7)	31 (15.8)
			Total	113 (57.7)	51 (26.0)	32 (16.3)	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
LDL Cholesterol (mmol/L)	D71	Placebo (N=69)	Normal	33 (51.6)	5 (7.8)	3 (4.7)	41 (64.1)
			Abnormal NCS	5 (7.8)	7 (10.9)	0	12 (18.8)
			Abnormal CS	2 (3.1)	1 (1.6)	8 (12.5)	11 (17.2)
			Total	40 (62.5)	13 (20.3)	11 (17.2)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	31 (45.6)	5 (7.4)	1 (1.5)	37 (54.4)
			Abnormal NCS	6 (8.8)	11 (16.2)	0	17 (25.0)
			Abnormal CS	4 (5.9)	1 (1.5)	9 (13.2)	14 (20.6)
			Total	41 (60.3)	17 (25.0)	10 (14.7)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	24 (37.5)	7 (10.9)	6 (9.4)	37 (57.8)
			Abnormal NCS	7 (10.9)	11 (17.2)	0	18 (28.1)
			Abnormal CS	1 (1.6)	1 (1.6)	7 (10.9)	9 (14.1)
			Total	32 (50.0)	19 (29.7)	13 (20.3)	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	32 (50.8)	4 (6.3)	4 (6.3)	40 (63.5)
			Abnormal NCS	3 (4.8)	8 (12.7)	0	11 (17.5)
			Abnormal CS	4 (6.3)	3 (4.8)	5 (7.9)	12 (19.0)
			Total	39 (61.9)	15 (23.8)	9 (14.3)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
LDL Cholesterol (mmol/L)	D71	Combined GS1-144 (N=207)	Normal	87 (44.6)	16 (8.2)	11 (5.6)	114 (58.5)
			Abnormal NCS	16 (8.2)	30 (15.4)	0	46 (23.6)
			Abnormal CS	9 (4.6)	5 (2.6)	21 (10.8)	35 (17.9)
			Total	112 (57.4)	51 (26.2)	32 (16.4)	195 (100)
	D85	Placebo (N=69)	Normal	32 (50.8)	2 (3.2)	0	34 (54.0)
			Abnormal NCS	5 (7.9)	11 (17.5)	0	16 (25.4)
			Abnormal CS	3 (4.8)	0	10 (15.9)	13 (20.6)
			Total	40 (63.5)	13 (20.6)	10 (15.9)	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	33 (49.3)	5 (7.5)	0	38 (56.7)
			Abnormal NCS	5 (7.5)	12 (17.9)	0	17 (25.4)
			Abnormal CS	3 (4.5)	0	9 (13.4)	12 (17.9)
			Total	41 (61.2)	17 (25.4)	9 (13.4)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	24 (36.9)	5 (7.7)	5 (7.7)	34 (52.3)
			Abnormal NCS	7 (10.8)	13 (20.0)	0	20 (30.8)
			Abnormal CS	2 (3.1)	1 (1.5)	8 (12.3)	11 (16.9)
			Total	33 (50.8)	19 (29.2)	13 (20.0)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
LDL Cholesterol (mmol/L)	D85	GS1-144 30 mg BID (N=68)	Normal	27 (42.9)	5 (7.9)	2 (3.2)	34 (54.0)
			Abnormal NCS	8 (12.7)	7 (11.1)	1 (1.6)	16 (25.4)
			Abnormal CS	4 (6.3)	3 (4.8)	6 (9.5)	13 (20.6)
			Total	39 (61.9)	15 (23.8)	9 (14.3)	63 (100)
		Combined GS1-144 (N=207)	Normal	84 (43.1)	15 (7.7)	7 (3.6)	106 (54.4)
			Abnormal NCS	20 (10.3)	32 (16.4)	1 (0.5)	53 (27.2)
			Abnormal CS	9 (4.6)	4 (2.1)	23 (11.8)	36 (18.5)
			Total	113 (57.9)	51 (26.2)	31 (15.9)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	34 (54.0)	6 (9.5)	3 (4.8)	43 (68.3)
			Abnormal NCS	3 (4.8)	7 (11.1)	0	10 (15.9)
			Abnormal CS	2 (3.2)	0	8 (12.7)	10 (15.9)
			Total	39 (61.9)	13 (20.6)	11 (17.5)	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	33 (48.5)	3 (4.4)	3 (4.4)	39 (57.4)
			Abnormal NCS	7 (10.3)	15 (22.1)	0	22 (32.4)
			Abnormal CS	1 (1.5)	0	6 (8.8)	7 (10.3)
			Total	41 (60.3)	18 (26.5)	9 (13.2)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
LDL Cholesterol (mmol/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	22 (33.8)	6 (9.2)	5 (7.7)	33 (50.8)
			Abnormal NCS	10 (15.4)	12 (18.5)	0	22 (33.8)
			Abnormal CS	1 (1.5)	1 (1.5)	8 (12.3)	10 (15.4)
			Total	33 (50.8)	19 (29.2)	13 (20.0)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	29 (46.0)	3 (4.8)	1 (1.6)	33 (52.4)
			Abnormal NCS	8 (12.7)	10 (15.9)	1 (1.6)	19 (30.2)
			Abnormal CS	1 (1.6)	2 (3.2)	8 (12.7)	11 (17.5)
			Total	38 (60.3)	15 (23.8)	10 (15.9)	63 (100)
		Combined GS1-144 (N=207)	Normal	84 (42.9)	12 (6.1)	9 (4.6)	105 (53.6)
			Abnormal NCS	25 (12.8)	37 (18.9)	1 (0.5)	63 (32.1)
			Abnormal CS	3 (1.5)	3 (1.5)	22 (11.2)	28 (14.3)
			Total	112 (57.1)	52 (26.5)	32 (16.3)	196 (100)
HDL Cholesterol (mmol/L)	D15	Placebo (N=69)	Normal	43 (63.2)	3 (4.4)	1 (1.5)	47 (69.1)
			Abnormal NCS	2 (2.9)	15 (22.1)	0	17 (25.0)
			Abnormal CS	0	0	4 (5.9)	4 (5.9)
			Total	45 (66.2)	18 (26.5)	5 (7.4)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
HDL Cholesterol (mmol/L)	D15	GS1-144 30 mg QD (N=70)	Normal	50 (71.4)	2 (2.9)	0	52 (74.3)
			Abnormal NCS	3 (4.3)	10 (14.3)	0	13 (18.6)
			Abnormal CS	2 (2.9)	1 (1.4)	2 (2.9)	5 (7.1)
			Total	55 (78.6)	13 (18.6)	2 (2.9)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	43 (64.2)	1 (1.5)	0	44 (65.7)
			Abnormal NCS	2 (3.0)	13 (19.4)	0	15 (22.4)
			Abnormal CS	2 (3.0)	0	6 (9.0)	8 (11.9)
			Total	47 (70.1)	14 (20.9)	6 (9.0)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	47 (69.1)	4 (5.9)	0	51 (75.0)
			Abnormal NCS	2 (2.9)	10 (14.7)	0	12 (17.6)
			Abnormal CS	0	1 (1.5)	4 (5.9)	5 (7.4)
			Total	49 (72.1)	15 (22.1)	4 (5.9)	68 (100)
		Combined GS1-144 (N=207)	Normal	140 (68.3)	7 (3.4)	0	147 (71.7)
			Abnormal NCS	7 (3.4)	33 (16.1)	0	40 (19.5)
			Abnormal CS	4 (2.0)	2 (1.0)	12 (5.9)	18 (8.8)
			Total	151 (73.7)	42 (20.5)	12 (5.9)	205 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
HDL Cholesterol (mmol/L)	D29	Placebo (N=69)	Normal	39 (59.1)	3 (4.5)	2 (3.0)	44 (66.7)
			Abnormal NCS	4 (6.1)	15 (22.7)	0	19 (28.8)
			Abnormal CS	0	0	3 (4.5)	3 (4.5)
			Total	43 (65.2)	18 (27.3)	5 (7.6)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	53 (76.8)	5 (7.2)	0	58 (84.1)
			Abnormal NCS	2 (2.9)	7 (10.1)	0	9 (13.0)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	55 (79.7)	12 (17.4)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	44 (66.7)	3 (4.5)	0	47 (71.2)
			Abnormal NCS	2 (3.0)	10 (15.2)	0	12 (18.2)
			Abnormal CS	1 (1.5)	1 (1.5)	5 (7.6)	7 (10.6)
			Total	47 (71.2)	14 (21.2)	5 (7.6)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	44 (65.7)	2 (3.0)	0	46 (68.7)
			Abnormal NCS	3 (4.5)	12 (17.9)	0	15 (22.4)
			Abnormal CS	1 (1.5)	1 (1.5)	4 (6.0)	6 (9.0)
			Total	48 (71.6)	15 (22.4)	4 (6.0)	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
HDL Cholesterol (mmol/L)	D29	Combined GS1-144 (N=207)	Normal	141 (69.8)	10 (5.0)	0	151 (74.8)
			Abnormal NCS	7 (3.5)	29 (14.4)	0	36 (17.8)
			Abnormal CS	2 (1.0)	2 (1.0)	11 (5.4)	15 (7.4)
			Total	150 (74.3)	41 (20.3)	11 (5.4)	202 (100)
	D43	Placebo (N=69)	Normal	39 (60.0)	3 (4.6)	2 (3.1)	44 (67.7)
			Abnormal NCS	3 (4.6)	14 (21.5)	1 (1.5)	18 (27.7)
			Abnormal CS	0	1 (1.5)	2 (3.1)	3 (4.6)
			Total	42 (64.6)	18 (27.7)	5 (7.7)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	52 (75.4)	3 (4.3)	0	55 (79.7)
			Abnormal NCS	2 (2.9)	9 (13.0)	0	11 (15.9)
			Abnormal CS	1 (1.4)	0	2 (2.9)	3 (4.3)
			Total	55 (79.7)	12 (17.4)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	44 (66.7)	3 (4.5)	0	47 (71.2)
			Abnormal NCS	1 (1.5)	10 (15.2)	0	11 (16.7)
			Abnormal CS	2 (3.0)	1 (1.5)	5 (7.6)	8 (12.1)
			Total	47 (71.2)	14 (21.2)	5 (7.6)	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
HDL Cholesterol (mmol/L)	D43	GS1-144 30 mg BID (N=68)	Normal	41 (64.1)	5 (7.8)	0	46 (71.9)
			Abnormal NCS	4 (6.3)	10 (15.6)	0	14 (21.9)
			Abnormal CS	0	0	4 (6.3)	4 (6.3)
			Total	45 (70.3)	15 (23.4)	4 (6.3)	64 (100)
		Combined GS1-144 (N=207)	Normal	137 (68.8)	11 (5.5)	0	148 (74.4)
			Abnormal NCS	7 (3.5)	29 (14.6)	0	36 (18.1)
			Abnormal CS	3 (1.5)	1 (0.5)	11 (5.5)	15 (7.5)
			Total	147 (73.9)	41 (20.6)	11 (5.5)	199 (100)
	D57	Placebo (N=69)	Normal	36 (56.3)	3 (4.7)	2 (3.1)	41 (64.1)
			Abnormal NCS	5 (7.8)	15 (23.4)	0	20 (31.3)
			Abnormal CS	0	0	3 (4.7)	3 (4.7)
			Total	41 (64.1)	18 (28.1)	5 (7.8)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	52 (76.5)	4 (5.9)	0	56 (82.4)
			Abnormal NCS	2 (2.9)	7 (10.3)	0	9 (13.2)
			Abnormal CS	1 (1.5)	0	2 (2.9)	3 (4.4)
			Total	55 (80.9)	11 (16.2)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
HDL Cholesterol (mmol/L)	D57	GS1-144 60 mg QD (N=69)	Normal	40 (61.5)	3 (4.6)	0	43 (66.2)
			Abnormal NCS	3 (4.6)	10 (15.4)	0	13 (20.0)
			Abnormal CS	3 (4.6)	1 (1.5)	5 (7.7)	9 (13.8)
			Total	46 (70.8)	14 (21.5)	5 (7.7)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	40 (63.5)	4 (6.3)	0	44 (69.8)
			Abnormal NCS	3 (4.8)	10 (15.9)	0	13 (20.6)
			Abnormal CS	1 (1.6)	1 (1.6)	4 (6.3)	6 (9.5)
			Total	44 (69.8)	15 (23.8)	4 (6.3)	63 (100)
		Combined GS1-144 (N=207)	Normal	132 (67.3)	11 (5.6)	0	143 (73.0)
			Abnormal NCS	8 (4.1)	27 (13.8)	0	35 (17.9)
			Abnormal CS	5 (2.6)	2 (1.0)	11 (5.6)	18 (9.2)
			Total	145 (74.0)	40 (20.4)	11 (5.6)	196 (100)
	D71	Placebo (N=69)	Normal	37 (57.8)	4 (6.3)	2 (3.1)	43 (67.2)
			Abnormal NCS	4 (6.3)	13 (20.3)	0	17 (26.6)
			Abnormal CS	0	1 (1.6)	3 (4.7)	4 (6.3)
			Total	41 (64.1)	18 (28.1)	5 (7.8)	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
HDL Cholesterol (mmol/L)	D71	GS1-144 30 mg QD (N=70)	Normal	50 (73.5)	3 (4.4)	0	53 (77.9)
			Abnormal NCS	4 (5.9)	8 (11.8)	0	12 (17.6)
			Abnormal CS	1 (1.5)	0	2 (2.9)	3 (4.4)
			Total	55 (80.9)	11 (16.2)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	42 (65.6)	2 (3.1)	0	44 (68.8)
			Abnormal NCS	2 (3.1)	11 (17.2)	0	13 (20.3)
			Abnormal CS	1 (1.6)	1 (1.6)	5 (7.8)	7 (10.9)
			Total	45 (70.3)	14 (21.9)	5 (7.8)	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	38 (60.3)	4 (6.3)	0	42 (66.7)
			Abnormal NCS	3 (4.8)	10 (15.9)	0	13 (20.6)
			Abnormal CS	3 (4.8)	1 (1.6)	4 (6.3)	8 (12.7)
			Total	44 (69.8)	15 (23.8)	4 (6.3)	63 (100)
		Combined GS1-144 (N=207)	Normal	130 (66.7)	9 (4.6)	0	139 (71.3)
			Abnormal NCS	9 (4.6)	29 (14.9)	0	38 (19.5)
			Abnormal CS	5 (2.6)	2 (1.0)	11 (5.6)	18 (9.2)
			Total	144 (73.8)	40 (20.5)	11 (5.6)	195 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
HDL Cholesterol (mmol/L)	D85	Placebo (N=69)	Normal	36 (57.1)	3 (4.8)	2 (3.2)	41 (65.1)
			Abnormal NCS	4 (6.3)	14 (22.2)	0	18 (28.6)
			Abnormal CS	0	1 (1.6)	3 (4.8)	4 (6.3)
			Total	40 (63.5)	18 (28.6)	5 (7.9)	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	51 (76.1)	2 (3.0)	0	53 (79.1)
			Abnormal NCS	2 (3.0)	9 (13.4)	0	11 (16.4)
			Abnormal CS	1 (1.5)	0	2 (3.0)	3 (4.5)
			Total	54 (80.6)	11 (16.4)	2 (3.0)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	38 (58.5)	5 (7.7)	0	43 (66.2)
			Abnormal NCS	6 (9.2)	9 (13.8)	2 (3.1)	17 (26.2)
			Abnormal CS	2 (3.1)	0	3 (4.6)	5 (7.7)
			Total	46 (70.8)	14 (21.5)	5 (7.7)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	40 (63.5)	3 (4.8)	0	43 (68.3)
			Abnormal NCS	4 (6.3)	11 (17.5)	0	15 (23.8)
			Abnormal CS	0	1 (1.6)	4 (6.3)	5 (7.9)
			Total	44 (69.8)	15 (23.8)	4 (6.3)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
HDL Cholesterol (mmol/L)	D85	Combined GS1-144 (N=207)	Normal	129 (66.2)	10 (5.1)	0	139 (71.3)
			Abnormal NCS	12 (6.2)	29 (14.9)	2 (1.0)	43 (22.1)
			Abnormal CS	3 (1.5)	1 (0.5)	9 (4.6)	13 (6.7)
			Total	144 (73.8)	40 (20.5)	11 (5.6)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	39 (61.9)	3 (4.8)	2 (3.2)	44 (69.8)
			Abnormal NCS	0	14 (22.2)	0	14 (22.2)
			Abnormal CS	1 (1.6)	1 (1.6)	3 (4.8)	5 (7.9)
			Total	40 (63.5)	18 (28.6)	5 (7.9)	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	50 (73.5)	2 (2.9)	0	52 (76.5)
			Abnormal NCS	3 (4.4)	10 (14.7)	0	13 (19.1)
			Abnormal CS	1 (1.5)	0	2 (2.9)	3 (4.4)
			Total	54 (79.4)	12 (17.6)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	40 (61.5)	5 (7.7)	0	45 (69.2)
			Abnormal NCS	4 (6.2)	9 (13.8)	2 (3.1)	15 (23.1)
			Abnormal CS	2 (3.1)	0	3 (4.6)	5 (7.7)
			Total	46 (70.8)	14 (21.5)	5 (7.7)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
HDL Cholesterol (mmol/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	38 (60.3)	5 (7.9)	0	43 (68.3)
			Abnormal NCS	6 (9.5)	9 (14.3)	0	15 (23.8)
			Abnormal CS	1 (1.6)	0	4 (6.3)	5 (7.9)
			Total	45 (71.4)	14 (22.2)	4 (6.3)	63 (100)
		Combined GS1-144 (N=207)	Normal	128 (65.3)	12 (6.1)	0	140 (71.4)
			Abnormal NCS	13 (6.6)	28 (14.3)	2 (1.0)	43 (21.9)
			Abnormal CS	4 (2.0)	0	9 (4.6)	13 (6.6)
			Total	145 (74.0)	40 (20.4)	11 (5.6)	196 (100)
Potassium (mmol/L)	D15	Placebo (N=69)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	0	0	69 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Potassium (mmol/L)	D15	GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	202 (98.1)	2 (1.0)	0	204 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	204 (99.0)	2 (1.0)	0	206 (100)
	D29	Placebo (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Potassium (mmol/L)	D29	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	2 (3.0)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	201 (99.0)	2 (1.0)	0	203 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	201 (99.0)	2 (1.0)	0	203 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Potassium (mmol/L)	D43	Placebo (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Potassium (mmol/L)	D43	Combined GS1-144 (N=207)	Normal	196 (98.0)	2 (1.0)	0	198 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	198 (99.0)	2 (1.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	2 (3.0)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Potassium (mmol/L)	D57	GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.0)	2 (1.0)	0	195 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	195 (99.0)	2 (1.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Potassium (mmol/L)	D71	GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	2 (3.1)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (99.0)	2 (1.0)	0	196 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	194 (99.0)	2 (1.0)	0	196 (100)
	D85	Placebo (N=69)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Potassium (mmol/L)	D85	GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	2 (3.0)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (98.0)	2 (1.0)	0	194 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	194 (99.0)	2 (1.0)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Potassium (mmol/L)	Safety Follow-up	Placebo (N=69)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	2 (3.0)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Potassium (mmol/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	195 (99.0)	2 (1.0)	0	197 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	195 (99.0)	2 (1.0)	0	197 (100)
Sodium (mmol/L)	D15	Placebo (N=69)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	3 (4.3)	0	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	4 (5.7)	0	68 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (94.3)	4 (5.7)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	2 (2.9)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Sodium (mmol/L)	D15	GS1-144 30 mg BID (N=68)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	198 (96.1)	6 (2.9)	0	204 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	200 (97.1)	6 (2.9)	0	206 (100)
	D29	Placebo (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	4 (5.8)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Sodium (mmol/L)	D29	GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	196 (96.6)	5 (2.5)	0	201 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	197 (97.0)	6 (3.0)	0	203 (100)
	D43	Placebo (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Sodium (mmol/L)	D43	GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	4 (5.8)	0	64 (92.8)
			Abnormal NCS	5 (7.2)	0	0	5 (7.2)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		Combined GS1-144 (N=207)	Normal	186 (93.0)	5 (2.5)	0	191 (95.5)
			Abnormal NCS	8 (4.0)	1 (0.5)	0	9 (4.5)
			Abnormal CS	0	0	0	0
			Total	194 (97.0)	6 (3.0)	0	200 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Sodium (mmol/L)	D57	Placebo (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	4 (5.9)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Sodium (mmol/L)	D57	Combined GS1-144 (N=207)	Normal	190 (96.4)	5 (2.5)	0	195 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	191 (97.0)	6 (3.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	4 (5.9)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	2 (3.1)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Sodium (mmol/L)	D71	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.9)	6 (3.1)	0	192 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	190 (96.9)	6 (3.1)	0	196 (100)
	D85	Placebo (N=69)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	4 (6.0)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Sodium (mmol/L)	D85	GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	2 (3.0)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	185 (94.4)	6 (3.1)	0	191 (97.4)
			Abnormal NCS	5 (2.6)	0	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	190 (96.9)	6 (3.1)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Sodium (mmol/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	3 (4.4)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	2 (3.0)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (96.4)	5 (2.5)	0	195 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	191 (97.0)	6 (3.0)	0	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Chloride (mmol/L)	D15	Placebo (N=69)	Normal	65 (94.2)	3 (4.3)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	3 (4.3)	0	69 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (95.7)	3 (4.3)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Chloride (mmol/L)	D15	Combined GS1-144 (N=207)	Normal	199 (96.6)	5 (2.4)	0	204 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	201 (97.6)	5 (2.4)	0	206 (100)
	D29	Placebo (N=69)	Normal	62 (92.5)	3 (4.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	3 (4.3)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Chloride (mmol/L)	D29	GS1-144 30 mg BID (N=68)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	195 (96.1)	5 (2.5)	0	200 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	198 (97.5)	5 (2.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	61 (92.4)	3 (4.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	2 (2.9)	0	65 (94.2)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Chloride (mmol/L)	D43	GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (95.3)	1 (1.6)	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	190 (95.0)	4 (2.0)	0	194 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	195 (97.5)	5 (2.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	60 (92.3)	3 (4.6)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Chloride (mmol/L)	D57	GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.4)	3 (1.5)	0	191 (97.0)
			Abnormal NCS	4 (2.0)	2 (1.0)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	192 (97.5)	5 (2.5)	0	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Chloride (mmol/L)	D71	Placebo (N=69)	Normal	62 (95.4)	3 (4.6)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	3 (4.4)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Chloride (mmol/L)	D71	Combined GS1-144 (N=207)	Normal	187 (95.4)	5 (2.6)	0	192 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	191 (97.4)	5 (2.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	61 (95.3)	3 (4.7)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	4 (6.0)	0	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Chloride (mmol/L)	D85	GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	184 (93.9)	5 (2.6)	0	189 (96.4)
			Abnormal NCS	7 (3.6)	0	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	191 (97.4)	5 (2.6)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	61 (95.3)	3 (4.7)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Chloride (mmol/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (96.4)	4 (2.0)	0	194 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	192 (97.5)	5 (2.5)	0	197 (100)
Calcium (mmol/L)	D15	Placebo (N=69)	Normal	60 (87.0)	4 (5.8)	0	64 (92.8)
			Abnormal NCS	4 (5.8)	1 (1.4)	0	5 (7.2)
			Abnormal CS	0	0	0	0
			Total	64 (92.8)	5 (7.2)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Calcium (mmol/L)	D15	GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	1 (1.4)	0	67 (95.7)
			Abnormal NCS	3 (4.3)	0	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	69 (98.6)	1 (1.4)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (85.3)	5 (7.4)	0	63 (92.6)
			Abnormal NCS	2 (2.9)	3 (4.4)	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	60 (88.2)	8 (11.8)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	189 (91.7)	7 (3.4)	0	196 (95.1)
			Abnormal NCS	7 (3.4)	3 (1.5)	0	10 (4.9)
			Abnormal CS	0	0	0	0
			Total	196 (95.1)	10 (4.9)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Calcium (mmol/L)	D29	Placebo (N=69)	Normal	58 (86.6)	4 (6.0)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (86.6)	6 (9.0)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	59 (88.1)	8 (11.9)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Calcium (mmol/L)	D29	Combined GS1-144 (N=207)	Normal	189 (93.1)	7 (3.4)	0	196 (96.6)
			Abnormal NCS	4 (2.0)	3 (1.5)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	193 (95.1)	10 (4.9)	0	203 (100)
	D43	Placebo (N=69)	Normal	58 (87.9)	3 (4.5)	0	61 (92.4)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Calcium (mmol/L)	D43	GS1-144 30 mg BID (N=68)	Normal	54 (84.4)	6 (9.4)	0	60 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	56 (87.5)	8 (12.5)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	185 (92.5)	7 (3.5)	0	192 (96.0)
			Abnormal NCS	5 (2.5)	3 (1.5)	0	8 (4.0)
			Abnormal CS	0	0	0	0
			Total	190 (95.0)	10 (5.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Calcium (mmol/L)	D57	GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	52 (82.5)	7 (11.1)	0	59 (93.7)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	184 (93.4)	9 (4.6)	0	193 (98.0)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	187 (94.9)	10 (5.1)	0	197 (100)
	D71	Placebo (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Calcium (mmol/L)	D71	GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	6 (9.5)	0	60 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	181 (92.3)	8 (4.1)	0	189 (96.4)
			Abnormal NCS	5 (2.6)	2 (1.0)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	186 (94.9)	10 (5.1)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Calcium (mmol/L)	D85	Placebo (N=69)	Normal	57 (89.1)	2 (3.1)	0	59 (92.2)
			Abnormal NCS	3 (4.7)	2 (3.1)	0	5 (7.8)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	52 (82.5)	7 (11.1)	0	59 (93.7)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Calcium (mmol/L)	D85	Combined GS1-144 (N=207)	Normal	182 (92.9)	7 (3.6)	0	189 (96.4)
			Abnormal NCS	4 (2.0)	3 (1.5)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	186 (94.9)	10 (5.1)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	4 (6.3)	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Calcium (mmol/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	6 (9.5)	0	60 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	184 (93.4)	7 (3.6)	0	191 (97.0)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	187 (94.9)	10 (5.1)	0	197 (100)
Phosphate (mmol/L)	D15	Placebo (N=69)	Normal	65 (94.2)	0	0	65 (94.2)
			Abnormal NCS	1 (1.4)	3 (4.3)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	2 (2.9)	0	69 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Phosphate (mmol/L)	D15	GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	199 (96.6)	4 (1.9)	0	203 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	201 (97.6)	5 (2.4)	0	206 (100)
	D29	Placebo (N=69)	Normal	62 (92.5)	3 (4.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Phosphate (mmol/L)	D29	GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	2 (2.9)	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	196 (96.6)	4 (2.0)	0	200 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	198 (97.5)	5 (2.5)	0	203 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Phosphate (mmol/L)	D43	Placebo (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	2 (2.9)	0	67 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Phosphate (mmol/L)	D43	Combined GS1-144 (N=207)	Normal	191 (95.5)	4 (2.0)	0	195 (97.5)
			Abnormal NCS	4 (2.0)	1 (0.5)	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	195 (97.5)	5 (2.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	59 (90.8)	2 (3.1)	0	61 (93.8)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	3 (4.4)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	2 (3.0)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Phosphate (mmol/L)	D57	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (95.9)	5 (2.5)	0	194 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	192 (97.5)	5 (2.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	4 (6.2)	0	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	3 (4.4)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Phosphate (mmol/L)	D71	GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	2 (3.1)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.9)	5 (2.6)	0	193 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	191 (97.4)	5 (2.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	61 (95.3)	2 (3.1)	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Phosphate (mmol/L)	D85	GS1-144 30 mg QD (N=70)	Normal	63 (94.0)	3 (4.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	2 (3.0)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (96.4)	5 (2.6)	0	194 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	191 (97.4)	5 (2.6)	0	196 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Phosphate (mmol/L)	Safety Follow-up	Placebo (N=69)	Normal	60 (93.8)	2 (3.1)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Phosphate (mmol/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	188 (95.4)	3 (1.5)	0	191 (97.0)
			Abnormal NCS	4 (2.0)	2 (1.0)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	192 (97.5)	5 (2.5)	0	197 (100)
Magnesium (mmol/L)	D15	Placebo (N=69)	Normal	66 (95.7)	3 (4.3)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	0	0	66 (94.3)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.7)
			Abnormal CS	0	0	0	0
			Total	69 (98.6)	1 (1.4)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	1 (1.5)	0	65 (95.6)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Magnesium (mmol/L)	D15	GS1-144 30 mg BID (N=68)	Normal	57 (83.8)	7 (10.3)	0	64 (94.1)
			Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	60 (88.2)	8 (11.8)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	187 (90.8)	8 (3.9)	0	195 (94.7)
			Abnormal NCS	9 (4.4)	2 (1.0)	0	11 (5.3)
			Abnormal CS	0	0	0	0
			Total	196 (95.1)	10 (4.9)	0	206 (100)
	D29	Placebo (N=69)	Normal	63 (94.0)	3 (4.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	0	0	63 (91.3)
			Abnormal NCS	5 (7.2)	1 (1.4)	0	6 (8.7)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Magnesium (mmol/L)	D29	GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (85.1)	7 (10.4)	0	64 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	59 (88.1)	8 (11.9)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	184 (90.6)	8 (3.9)	0	192 (94.6)
			Abnormal NCS	9 (4.4)	2 (1.0)	0	11 (5.4)
			Abnormal CS	0	0	0	0
			Total	193 (95.1)	10 (4.9)	0	203 (100)
	D43	Placebo (N=69)	Normal	61 (92.4)	3 (4.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Magnesium (mmol/L)	D43	GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	53 (82.8)	8 (12.5)	0	61 (95.3)
			Abnormal NCS	3 (4.7)	0	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	56 (87.5)	8 (12.5)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	185 (92.5)	9 (4.5)	0	194 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	190 (95.0)	10 (5.0)	0	200 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Magnesium (mmol/L)	D57	Placebo (N=69)	Normal	62 (95.4)	3 (4.6)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	0	0	63 (92.6)
			Abnormal NCS	4 (5.9)	1 (1.5)	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	53 (84.1)	7 (11.1)	0	60 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Magnesium (mmol/L)	D57	Combined GS1-144 (N=207)	Normal	180 (91.4)	8 (4.1)	0	188 (95.4)
			Abnormal NCS	7 (3.6)	2 (1.0)	0	9 (4.6)
			Abnormal CS	0	0	0	0
			Total	187 (94.9)	10 (5.1)	0	197 (100)
	D71	Placebo (N=69)	Normal	61 (93.8)	3 (4.6)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Magnesium (mmol/L)	D71	GS1-144 30 mg BID (N=68)	Normal	51 (81.0)	8 (12.7)	0	59 (93.7)
			Abnormal NCS	4 (6.3)	0	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	179 (91.3)	9 (4.6)	0	188 (95.9)
			Abnormal NCS	7 (3.6)	1 (0.5)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	186 (94.9)	10 (5.1)	0	196 (100)
	D85	Placebo (N=69)	Normal	61 (95.3)	3 (4.7)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	5 (7.5)	0	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Magnesium (mmol/L)	D85	GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	7 (11.1)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	177 (90.3)	9 (4.6)	0	186 (94.9)
			Abnormal NCS	9 (4.6)	1 (0.5)	0	10 (5.1)
			Abnormal CS	0	0	0	0
			Total	186 (94.9)	10 (5.1)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	2 (3.1)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Magnesium (mmol/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	1 (1.5)	0	65 (95.6)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	8 (12.7)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	55 (87.3)	8 (12.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (92.9)	10 (5.1)	0	193 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	187 (94.9)	10 (5.1)	0	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Glucose (mmol/L)	D15	Placebo (N=69)	Normal	62 (89.9)	1 (1.4)	0	63 (91.3)
			Abnormal NCS	2 (2.9)	3 (4.3)	0	5 (7.2)
			Abnormal CS	0	0	1 (1.4)	1 (1.4)
			Total	64 (92.8)	4 (5.8)	1 (1.4)	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	0	0	66 (94.3)
			Abnormal NCS	0	3 (4.3)	0	3 (4.3)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	66 (94.3)	4 (5.7)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	2 (2.9)	0	64 (94.1)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (83.8)	4 (5.9)	0	61 (89.7)
			Abnormal NCS	2 (2.9)	3 (4.4)	0	5 (7.4)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	59 (86.8)	7 (10.3)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Glucose (mmol/L)	D15	Combined GS1-144 (N=207)	Normal	185 (89.8)	6 (2.9)	0	191 (92.7)
			Abnormal NCS	5 (2.4)	6 (2.9)	0	11 (5.3)
			Abnormal CS	0	1 (0.5)	3 (1.5)	4 (1.9)
			Total	190 (92.2)	13 (6.3)	3 (1.5)	206 (100)
	D29	Placebo (N=69)	Normal	58 (86.6)	3 (4.5)	0	61 (91.0)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	62 (92.5)	4 (6.0)	1 (1.5)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Glucose (mmol/L)	D29	GS1-144 30 mg BID (N=68)	Normal	54 (80.6)	5 (7.5)	0	59 (88.1)
			Abnormal NCS	5 (7.5)	2 (3.0)	0	7 (10.4)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	59 (88.1)	7 (10.4)	1 (1.5)	67 (100)
		Combined GS1-144 (N=207)	Normal	182 (89.7)	8 (3.9)	0	190 (93.6)
			Abnormal NCS	7 (3.4)	4 (2.0)	0	11 (5.4)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	189 (93.1)	12 (5.9)	2 (1.0)	203 (100)
	D43	Placebo (N=69)	Normal	58 (87.9)	0	0	58 (87.9)
			Abnormal NCS	3 (4.5)	4 (6.1)	0	7 (10.6)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	61 (92.4)	4 (6.1)	1 (1.5)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	2 (2.9)	0	65 (94.2)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Glucose (mmol/L)	D43	GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	52 (81.3)	4 (6.3)	0	56 (87.5)
			Abnormal NCS	4 (6.3)	3 (4.7)	0	7 (10.9)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	56 (87.5)	7 (10.9)	1 (1.6)	64 (100)
		Combined GS1-144 (N=207)	Normal	178 (89.0)	8 (4.0)	0	186 (93.0)
			Abnormal NCS	8 (4.0)	4 (2.0)	0	12 (6.0)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	186 (93.0)	12 (6.0)	2 (1.0)	200 (100)
	D57	Placebo (N=69)	Normal	59 (90.8)	0	0	59 (90.8)
			Abnormal NCS	0	4 (6.2)	0	4 (6.2)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.1)
			Total	60 (92.3)	4 (6.2)	1 (1.5)	65 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Glucose (mmol/L)	D57	GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	2 (2.9)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	52 (82.5)	3 (4.8)	0	55 (87.3)
			Abnormal NCS	1 (1.6)	3 (4.8)	0	4 (6.3)
			Abnormal CS	2 (3.2)	1 (1.6)	1 (1.6)	4 (6.3)
			Total	55 (87.3)	7 (11.1)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	176 (89.3)	6 (3.0)	0	182 (92.4)
			Abnormal NCS	4 (2.0)	5 (2.5)	0	9 (4.6)
			Abnormal CS	3 (1.5)	1 (0.5)	2 (1.0)	6 (3.0)
			Total	183 (92.9)	12 (6.1)	2 (1.0)	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Glucose (mmol/L)	D71	Placebo (N=69)	Normal	58 (89.2)	2 (3.1)	0	60 (92.3)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.1)
			Total	60 (92.3)	4 (6.2)	1 (1.5)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	1 (1.5)	0	62 (91.2)
			Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (90.8)	1 (1.5)	0	60 (92.3)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	51 (81.0)	6 (9.5)	0	57 (90.5)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	2 (3.2)	0	1 (1.6)	3 (4.8)
			Total	55 (87.3)	7 (11.1)	1 (1.6)	63 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Glucose (mmol/L)	D71	Combined GS1-144 (N=207)	Normal	171 (87.2)	8 (4.1)	0	179 (91.3)
			Abnormal NCS	8 (4.1)	3 (1.5)	0	11 (5.6)
			Abnormal CS	3 (1.5)	1 (0.5)	2 (1.0)	6 (3.1)
			Total	182 (92.9)	12 (6.1)	2 (1.0)	196 (100)
	D85	Placebo (N=69)	Normal	59 (92.2)	1 (1.6)	0	60 (93.8)
			Abnormal NCS	0	3 (4.7)	0	3 (4.7)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	59 (92.2)	4 (6.3)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	2 (3.0)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Glucose (mmol/L)	D85	GS1-144 30 mg BID (N=68)	Normal	51 (81.0)	6 (9.5)	0	57 (90.5)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	1 (1.6)	0	1 (1.6)	2 (3.2)
			Total	55 (87.3)	7 (11.1)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	174 (88.8)	9 (4.6)	0	183 (93.4)
			Abnormal NCS	6 (3.1)	3 (1.5)	0	9 (4.6)
			Abnormal CS	2 (1.0)	0	2 (1.0)	4 (2.0)
			Total	182 (92.9)	12 (6.1)	2 (1.0)	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	58 (90.6)	1 (1.6)	0	59 (92.2)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	60 (93.8)	3 (4.7)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.2
Shift of Chemistry by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Glucose (mmol/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	49 (77.8)	7 (11.1)	0	56 (88.9)
			Abnormal NCS	4 (6.3)	0	0	4 (6.3)
			Abnormal CS	1 (1.6)	0	2 (3.2)	3 (4.8)
			Total	54 (85.7)	7 (11.1)	2 (3.2)	63 (100)
		Combined GS1-144 (N=207)	Normal	172 (87.3)	10 (5.1)	0	182 (92.4)
			Abnormal NCS	8 (4.1)	2 (1.0)	0	10 (5.1)
			Abnormal CS	2 (1.0)	0	3 (1.5)	5 (2.5)
			Total	182 (92.4)	12 (6.1)	3 (1.5)	197 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Alanine Aminotransferase (U/L)	Placebo (N=69)	Normal	56 (81.2)	0	0	56 (81.2)
		Abnormal NCS	6 (8.7)	2 (2.9)	0	8 (11.6)
		Abnormal CS	4 (5.8)	0	1 (1.4)	5 (7.2)
		Total	66 (95.7)	2 (2.9)	1 (1.4)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	57 (81.4)	1 (1.4)	1 (1.4)	59 (84.3)
		Abnormal NCS	8 (11.4)	0	0	8 (11.4)
		Abnormal CS	1 (1.4)	2 (2.9)	0	3 (4.3)
		Total	66 (94.3)	3 (4.3)	1 (1.4)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	53 (77.9)	1 (1.5)	0	54 (79.4)
		Abnormal NCS	7 (10.3)	1 (1.5)	0	8 (11.8)
		Abnormal CS	4 (5.9)	1 (1.5)	1 (1.5)	6 (8.8)
		Total	64 (94.1)	3 (4.4)	1 (1.5)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	59 (86.8)	0	0	59 (86.8)
		Abnormal NCS	5 (7.4)	1 (1.5)	0	6 (8.8)
		Abnormal CS	3 (4.4)	0	0	3 (4.4)
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Alanine Aminotransferase (U/L)	Combined GS1-144 (N=207)	Normal	169 (82.0)	2 (1.0)	1 (0.5)	172 (83.5)
		Abnormal NCS	20 (9.7)	2 (1.0)	0	22 (10.7)
		Abnormal CS	8 (3.9)	3 (1.5)	1 (0.5)	12 (5.8)
		Total	197 (95.6)	7 (3.4)	2 (1.0)	206 (100)
Aspartate Aminotransferase (U/L)	Placebo (N=69)	Normal	54 (78.3)	1 (1.4)	0	55 (79.7)
		Abnormal NCS	7 (10.1)	1 (1.4)	0	8 (11.6)
		Abnormal CS	5 (7.2)	0	1 (1.4)	6 (8.7)
		Total	66 (95.7)	2 (2.9)	1 (1.4)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	60 (85.7)	0	0	60 (85.7)
		Abnormal NCS	5 (7.1)	1 (1.4)	0	6 (8.6)
		Abnormal CS	3 (4.3)	1 (1.4)	0	4 (5.7)
		Total	68 (97.1)	2 (2.9)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	54 (79.4)	0	0	54 (79.4)
		Abnormal NCS	7 (10.3)	3 (4.4)	0	10 (14.7)
		Abnormal CS	4 (5.9)	0	0	4 (5.9)
		Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Aspartate Aminotransferase (U/L)	GS1-144 30 mg BID (N=68)	Normal	59 (86.8)	0	0	59 (86.8)
		Abnormal NCS	6 (8.8)	0	0	6 (8.8)
		Abnormal CS	3 (4.4)	0	0	3 (4.4)
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	173 (84.0)	0	0	173 (84.0)
		Abnormal NCS	18 (8.7)	4 (1.9)	0	22 (10.7)
		Abnormal CS	10 (4.9)	1 (0.5)	0	11 (5.3)
		Total	201 (97.6)	5 (2.4)	0	206 (100)
Gamma Glutamyl Transferase (U/L)	Placebo (N=69)	Normal	62 (89.9)	0	0	62 (89.9)
		Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.8)
		Abnormal CS	2 (2.9)	1 (1.4)	0	3 (4.3)
		Total	66 (95.7)	3 (4.3)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	62 (88.6)	1 (1.4)	0	63 (90.0)
		Abnormal NCS	4 (5.7)	2 (2.9)	0	6 (8.6)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Gamma Glutamyl Transferase (U/L)	GS1-144 60 mg QD (N=69)	Normal	56 (82.4)	2 (2.9)	0	58 (85.3)
		Abnormal NCS	3 (4.4)	3 (4.4)	0	6 (8.8)
		Abnormal CS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Total	62 (91.2)	6 (8.8)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	58 (85.3)	0	0	58 (85.3)
		Abnormal NCS	4 (5.9)	3 (4.4)	0	7 (10.3)
		Abnormal CS	1 (1.5)	1 (1.5)	1 (1.5)	3 (4.4)
		Total	63 (92.6)	4 (5.9)	1 (1.5)	68 (100)
	Combined GS1-144 (N=207)	Normal	176 (85.4)	3 (1.5)	0	179 (86.9)
		Abnormal NCS	11 (5.3)	8 (3.9)	0	19 (9.2)
		Abnormal CS	5 (2.4)	2 (1.0)	1 (0.5)	8 (3.9)
		Total	192 (93.2)	13 (6.3)	1 (0.5)	206 (100)
Alkaline Phosphatase (U/L)	Placebo (N=69)	Normal	61 (88.4)	1 (1.4)	0	62 (89.9)
		Abnormal NCS	3 (4.3)	3 (4.3)	0	6 (8.7)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Alkaline Phosphatase (U/L)	GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	0	0	64 (91.4)
		Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.7)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	69 (98.6)	1 (1.4)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	0	0	63 (92.6)
		Abnormal NCS	3 (4.4)	2 (2.9)	0	5 (7.4)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	191 (92.7)	0	0	191 (92.7)
		Abnormal NCS	7 (3.4)	5 (2.4)	0	12 (5.8)
		Abnormal CS	3 (1.5)	0	0	3 (1.5)
		Total	201 (97.6)	5 (2.4)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lactate Dehydrogenase (U/L)	Placebo (N=69)	Normal	60 (87.0)	1 (1.4)	0	61 (88.4)
		Abnormal NCS	5 (7.2)	1 (1.4)	0	6 (8.7)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	61 (87.1)	2 (2.9)	0	63 (90.0)
		Abnormal NCS	6 (8.6)	1 (1.4)	0	7 (10.0)
		Abnormal CS	0	0	0	0
		Total	67 (95.7)	3 (4.3)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	55 (80.9)	2 (2.9)	0	57 (83.8)
		Abnormal NCS	9 (13.2)	1 (1.5)	0	10 (14.7)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	65 (95.6)	3 (4.4)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	57 (83.8)	0	0	57 (83.8)
		Abnormal NCS	8 (11.8)	1 (1.5)	0	9 (13.2)
		Abnormal CS	1 (1.5)	1 (1.5)	0	2 (2.9)
		Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Lactate Dehydrogenase (U/L)	Combined GS1-144 (N=207)	Normal	173 (84.0)	4 (1.9)	0	177 (85.9)
		Abnormal NCS	23 (11.2)	3 (1.5)	0	26 (12.6)
		Abnormal CS	2 (1.0)	1 (0.5)	0	3 (1.5)
		Total	198 (96.1)	8 (3.9)	0	206 (100)
Bilirubin (umol/L)	Placebo (N=69)	Normal	63 (91.3)	0	0	63 (91.3)
		Abnormal NCS	2 (2.9)	4 (5.8)	0	6 (8.7)
		Abnormal CS	0	0	0	0
		Total	65 (94.2)	4 (5.8)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	0	0	69 (98.6)
		Abnormal NCS	1 (1.4)	0	0	1 (1.4)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	0	0	63 (92.6)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Bilirubin (umol/L)	GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
		Abnormal NCS	0	0	0	0
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	198 (96.1)	1 (0.5)	0	199 (96.6)
		Abnormal NCS	4 (1.9)	1 (0.5)	0	5 (2.4)
		Abnormal CS	2 (1.0)	0	0	2 (1.0)
		Total	204 (99.0)	2 (1.0)	0	206 (100)
Direct Bilirubin (umol/L)	Placebo (N=69)	Normal	61 (88.4)	1 (1.4)	0	62 (89.9)
		Abnormal NCS	4 (5.8)	3 (4.3)	0	7 (10.1)
		Abnormal CS	0	0	0	0
		Total	65 (94.2)	4 (5.8)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	68 (97.1)	0	0	68 (97.1)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Direct Bilirubin (umol/L)	GS1-144 60 mg QD (N=69)	Normal	61 (89.7)	1 (1.5)	0	62 (91.2)
		Abnormal NCS	5 (7.4)	1 (1.5)	0	6 (8.8)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
		Abnormal NCS	1 (1.5)	0	0	1 (1.5)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	194 (94.2)	2 (1.0)	0	196 (95.1)
		Abnormal NCS	8 (3.9)	1 (0.5)	0	9 (4.4)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	203 (98.5)	3 (1.5)	0	206 (100)
Protein (g/L)	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	68 (98.6)	1 (1.4)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Protein (g/L)	GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	1 (1.4)	0	66 (94.3)
		Abnormal NCS	4 (5.7)	0	0	4 (5.7)
		Abnormal CS	0	0	0	0
		Total	69 (98.6)	1 (1.4)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	0	0	60 (88.2)
		Abnormal NCS	7 (10.3)	1 (1.5)	0	8 (11.8)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
		Abnormal NCS	4 (5.9)	0	0	4 (5.9)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	187 (90.8)	2 (1.0)	0	189 (91.7)
		Abnormal NCS	15 (7.3)	1 (0.5)	0	16 (7.8)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	203 (98.5)	3 (1.5)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Albumin (g/L)	Placebo (N=69)	Normal	65 (94.2)	0	0	65 (94.2)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	69 (100)	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	0	0	67 (95.7)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	67 (98.5)	0	0	67 (98.5)
		Abnormal NCS	1 (1.5)	0	0	1 (1.5)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	3 (4.4)	0	0	3 (4.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Albumin (g/L)	Combined GS1-144 (N=207)	Normal	198 (96.1)	0	0	198 (96.1)
		Abnormal NCS	7 (3.4)	0	0	7 (3.4)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	206 (100)	0	0	206 (100)
Globulin (g/L)	Placebo (N=69)	Normal	66 (95.7)	0	0	66 (95.7)
		Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
		Abnormal CS	0	0	0	0
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	62 (88.6)	1 (1.4)	0	63 (90.0)
		Abnormal NCS	4 (5.7)	3 (4.3)	0	7 (10.0)
		Abnormal CS	0	0	0	0
		Total	66 (94.3)	4 (5.7)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	0	0	62 (91.2)
		Abnormal NCS	4 (5.9)	2 (2.9)	0	6 (8.8)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Globulin (g/L)	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	0	0	62 (91.2)
		Abnormal NCS	3 (4.4)	2 (2.9)	0	5 (7.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	186 (90.3)	1 (0.5)	0	187 (90.8)
		Abnormal NCS	11 (5.3)	7 (3.4)	0	18 (8.7)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	198 (96.1)	8 (3.9)	0	206 (100)
Creatinine (umol/L)	Placebo (N=69)	Normal	63 (91.3)	0	0	63 (91.3)
		Abnormal NCS	4 (5.8)	2 (2.9)	0	6 (8.7)
		Abnormal CS	0	0	0	0
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	62 (88.6)	0	0	62 (88.6)
		Abnormal NCS	5 (7.1)	3 (4.3)	0	8 (11.4)
		Abnormal CS	0	0	0	0
		Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Creatinine (umol/L)	GS1-144 60 mg QD (N=69)	Normal	56 (82.4)	1 (1.5)	0	57 (83.8)
		Abnormal NCS	7 (10.3)	4 (5.9)	0	11 (16.2)
		Abnormal CS	0	0	0	0
		Total	63 (92.6)	5 (7.4)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	57 (83.8)	0	0	57 (83.8)
		Abnormal NCS	8 (11.8)	3 (4.4)	0	11 (16.2)
		Abnormal CS	0	0	0	0
		Total	65 (95.6)	3 (4.4)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	175 (85.0)	1 (0.5)	0	176 (85.4)
		Abnormal NCS	20 (9.7)	10 (4.9)	0	30 (14.6)
		Abnormal CS	0	0	0	0
		Total	195 (94.7)	11 (5.3)	0	206 (100)
Urea (mmol/L)	Placebo (N=69)	Normal	52 (75.4)	3 (4.3)	0	55 (79.7)
		Abnormal NCS	13 (18.8)	1 (1.4)	0	14 (20.3)
		Abnormal CS	0	0	0	0
		Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urea (mmol/L)	GS1-144 30 mg QD (N=70)	Normal	57 (82.6)	1 (1.4)	0	58 (84.1)
		Abnormal NCS	8 (11.6)	3 (4.3)	0	11 (15.9)
		Abnormal CS	0	0	0	0
		Total	65 (94.2)	4 (5.8)	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	55 (83.3)	2 (3.0)	0	57 (86.4)
		Abnormal NCS	8 (12.1)	1 (1.5)	0	9 (13.6)
		Abnormal CS	0	0	0	0
		Total	63 (95.5)	3 (4.5)	0	66 (100)
	GS1-144 30 mg BID (N=68)	Normal	54 (81.8)	1 (1.5)	0	55 (83.3)
		Abnormal NCS	9 (13.6)	2 (3.0)	0	11 (16.7)
		Abnormal CS	0	0	0	0
		Total	63 (95.5)	3 (4.5)	0	66 (100)
	Combined GS1-144 (N=207)	Normal	166 (82.6)	4 (2.0)	0	170 (84.6)
		Abnormal NCS	25 (12.4)	6 (3.0)	0	31 (15.4)
		Abnormal CS	0	0	0	0
		Total	191 (95.0)	10 (5.0)	0	201 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urea Nitrogen (mmol/L)	Placebo (N=69)	Normal	0	0	0	0
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	0	0	0	0
	GS1-144 30 mg QD (N=70)	Normal	0	0	0	0
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	0	0	0	0
	GS1-144 60 mg QD (N=69)	Normal	2 (100)	0	0	2 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	2 (100)	0	0	2 (100)
	GS1-144 30 mg BID (N=68)	Normal	0	0	0	0
		Abnormal NCS	2 (100)	0	0	2 (100)
		Abnormal CS	0	0	0	0
		Total	2 (100)	0	0	2 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urea Nitrogen (mmol/L)	Combined GS1-144 (N=207)	Normal	2 (50.0)	0	0	2 (50.0)
		Abnormal NCS	2 (50.0)	0	0	2 (50.0)
		Abnormal CS	0	0	0	0
		Total	4 (100)	0	0	4 (100)
Urate (mmol/L)	Placebo (N=69)	Normal	47 (68.1)	2 (2.9)	0	49 (71.0)
		Abnormal NCS	8 (11.6)	1 (1.4)	0	9 (13.0)
		Abnormal CS	3 (4.3)	1 (1.4)	7 (10.1)	11 (15.9)
		Total	58 (84.1)	4 (5.8)	7 (10.1)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	53 (75.7)	2 (2.9)	0	55 (78.6)
		Abnormal NCS	6 (8.6)	4 (5.7)	0	10 (14.3)
		Abnormal CS	3 (4.3)	0	2 (2.9)	5 (7.1)
		Total	62 (88.6)	6 (8.6)	2 (2.9)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	48 (70.6)	0	0	48 (70.6)
		Abnormal NCS	10 (14.7)	2 (2.9)	2 (2.9)	14 (20.6)
		Abnormal CS	5 (7.4)	0	1 (1.5)	6 (8.8)
		Total	63 (92.6)	2 (2.9)	3 (4.4)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urate (mmol/L)	GS1-144 30 mg BID (N=68)	Normal	52 (76.5)	1 (1.5)	0	53 (77.9)
		Abnormal NCS	7 (10.3)	1 (1.5)	1 (1.5)	9 (13.2)
		Abnormal CS	2 (2.9)	0	4 (5.9)	6 (8.8)
		Total	61 (89.7)	2 (2.9)	5 (7.4)	68 (100)
	Combined GS1-144 (N=207)	Normal	153 (74.3)	3 (1.5)	0	156 (75.7)
		Abnormal NCS	23 (11.2)	7 (3.4)	3 (1.5)	33 (16.0)
		Abnormal CS	10 (4.9)	0	7 (3.4)	17 (8.3)
		Total	186 (90.3)	10 (4.9)	10 (4.9)	206 (100)
Cholesterol (mmol/L)	Placebo (N=69)	Normal	18 (26.5)	0	0	18 (26.5)
		Abnormal NCS	5 (7.4)	23 (33.8)	0	28 (41.2)
		Abnormal CS	3 (4.4)	2 (2.9)	17 (25.0)	22 (32.4)
		Total	26 (38.2)	25 (36.8)	17 (25.0)	68 (100)
	GS1-144 30 mg QD (N=70)	Normal	13 (18.6)	2 (2.9)	0	15 (21.4)
		Abnormal NCS	15 (21.4)	17 (24.3)	0	32 (45.7)
		Abnormal CS	9 (12.9)	3 (4.3)	11 (15.7)	23 (32.9)
		Total	37 (52.9)	22 (31.4)	11 (15.7)	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Cholesterol (mmol/L)	GS1-144 60 mg QD (N=69)	Normal	14 (20.9)	2 (3.0)	2 (3.0)	18 (26.9)
		Abnormal NCS	12 (17.9)	14 (20.9)	0	26 (38.8)
		Abnormal CS	5 (7.5)	2 (3.0)	16 (23.9)	23 (34.3)
		Total	31 (46.3)	18 (26.9)	18 (26.9)	67 (100)
	GS1-144 30 mg BID (N=68)	Normal	14 (20.6)	1 (1.5)	0	15 (22.1)
		Abnormal NCS	15 (22.1)	16 (23.5)	0	31 (45.6)
		Abnormal CS	6 (8.8)	3 (4.4)	13 (19.1)	22 (32.4)
		Total	35 (51.5)	20 (29.4)	13 (19.1)	68 (100)
	Combined GS1-144 (N=207)	Normal	41 (20.0)	5 (2.4)	2 (1.0)	48 (23.4)
		Abnormal NCS	42 (20.5)	47 (22.9)	0	89 (43.4)
		Abnormal CS	20 (9.8)	8 (3.9)	40 (19.5)	68 (33.2)
		Total	103 (50.2)	60 (29.3)	42 (20.5)	205 (100)
Triglycerides (mmol/L)	Placebo (N=69)	Normal	42 (61.8)	1 (1.5)	1 (1.5)	44 (64.7)
		Abnormal NCS	8 (11.8)	5 (7.4)	0	13 (19.1)
		Abnormal CS	4 (5.9)	0	7 (10.3)	11 (16.2)
		Total	54 (79.4)	6 (8.8)	8 (11.8)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Triglycerides (mmol/L)	GS1-144 30 mg QD (N=70)	Normal	31 (44.3)	0	1 (1.4)	32 (45.7)
		Abnormal NCS	17 (24.3)	5 (7.1)	0	22 (31.4)
		Abnormal CS	5 (7.1)	2 (2.9)	9 (12.9)	16 (22.9)
		Total	53 (75.7)	7 (10.0)	10 (14.3)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	35 (52.2)	1 (1.5)	1 (1.5)	37 (55.2)
		Abnormal NCS	8 (11.9)	6 (9.0)	0	14 (20.9)
		Abnormal CS	6 (9.0)	0	10 (14.9)	16 (23.9)
		Total	49 (73.1)	7 (10.4)	11 (16.4)	67 (100)
	GS1-144 30 mg BID (N=68)	Normal	41 (60.3)	1 (1.5)	0	42 (61.8)
		Abnormal NCS	14 (20.6)	0	0	14 (20.6)
		Abnormal CS	8 (11.8)	1 (1.5)	3 (4.4)	12 (17.6)
		Total	63 (92.6)	2 (2.9)	3 (4.4)	68 (100)
	Combined GS1-144 (N=207)	Normal	107 (52.2)	2 (1.0)	2 (1.0)	111 (54.1)
		Abnormal NCS	39 (19.0)	11 (5.4)	0	50 (24.4)
		Abnormal CS	19 (9.3)	3 (1.5)	22 (10.7)	44 (21.5)
		Total	165 (80.5)	16 (7.8)	24 (11.7)	205 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
LDL Cholesterol (mmol/L)	Placebo (N=69)	Normal	26 (38.2)	1 (1.5)	0	27 (39.7)
		Abnormal NCS	11 (16.2)	12 (17.6)	0	23 (33.8)
		Abnormal CS	5 (7.4)	1 (1.5)	12 (17.6)	18 (26.5)
		Total	42 (61.8)	14 (20.6)	12 (17.6)	68 (100)
	GS1-144 30 mg QD (N=70)	Normal	20 (28.6)	0	0	20 (28.6)
		Abnormal NCS	14 (20.0)	17 (24.3)	0	31 (44.3)
		Abnormal CS	8 (11.4)	1 (1.4)	10 (14.3)	19 (27.1)
		Total	42 (60.0)	18 (25.7)	10 (14.3)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	17 (25.4)	1 (1.5)	2 (3.0)	20 (29.9)
		Abnormal NCS	12 (17.9)	17 (25.4)	0	29 (43.3)
		Abnormal CS	5 (7.5)	1 (1.5)	12 (17.9)	18 (26.9)
		Total	34 (50.7)	19 (28.4)	14 (20.9)	67 (100)
	GS1-144 30 mg BID (N=68)	Normal	22 (32.4)	0	1 (1.5)	23 (33.8)
		Abnormal NCS	13 (19.1)	15 (22.1)	0	28 (41.2)
		Abnormal CS	5 (7.4)	3 (4.4)	9 (13.2)	17 (25.0)
		Total	40 (58.8)	18 (26.5)	10 (14.7)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
LDL Cholesterol (mmol/L)	Combined GS1-144 (N=207)	Normal	59 (28.8)	1 (0.5)	3 (1.5)	63 (30.7)
		Abnormal NCS	39 (19.0)	49 (23.9)	0	88 (42.9)
		Abnormal CS	18 (8.8)	5 (2.4)	31 (15.1)	54 (26.3)
		Total	116 (56.6)	55 (26.8)	34 (16.6)	205 (100)
HDL Cholesterol (mmol/L)	Placebo (N=69)	Normal	33 (48.5)	0	1 (1.5)	34 (50.0)
		Abnormal NCS	10 (14.7)	16 (23.5)	0	26 (38.2)
		Abnormal CS	2 (2.9)	2 (2.9)	4 (5.9)	8 (11.8)
		Total	45 (66.2)	18 (26.5)	5 (7.4)	68 (100)
	GS1-144 30 mg QD (N=70)	Normal	42 (60.0)	2 (2.9)	0	44 (62.9)
		Abnormal NCS	11 (15.7)	10 (14.3)	0	21 (30.0)
		Abnormal CS	2 (2.9)	1 (1.4)	2 (2.9)	5 (7.1)
		Total	55 (78.6)	13 (18.6)	2 (2.9)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	38 (56.7)	0	0	38 (56.7)
		Abnormal NCS	6 (9.0)	13 (19.4)	0	19 (28.4)
		Abnormal CS	3 (4.5)	1 (1.5)	6 (9.0)	10 (14.9)
		Total	47 (70.1)	14 (20.9)	6 (9.0)	67 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
HDL Cholesterol (mmol/L)	GS1-144 30 mg BID (N=68)	Normal	36 (52.9)	0	0	36 (52.9)
		Abnormal NCS	10 (14.7)	14 (20.6)	0	24 (35.3)
		Abnormal CS	3 (4.4)	1 (1.5)	4 (5.9)	8 (11.8)
		Total	49 (72.1)	15 (22.1)	4 (5.9)	68 (100)
	Combined GS1-144 (N=207)	Normal	116 (56.6)	2 (1.0)	0	118 (57.6)
		Abnormal NCS	27 (13.2)	37 (18.0)	0	64 (31.2)
		Abnormal CS	8 (3.9)	3 (1.5)	12 (5.9)	23 (11.2)
		Total	151 (73.7)	42 (20.5)	12 (5.9)	205 (100)
Potassium (mmol/L)	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
		Abnormal NCS	4 (5.8)	0	0	4 (5.8)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	0	0	66 (94.3)
		Abnormal NCS	4 (5.7)	0	0	4 (5.7)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Potassium (mmol/L)	GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
		Abnormal NCS	3 (4.4)	0	0	3 (4.4)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	0	0	67 (98.5)
		Abnormal NCS	1 (1.5)	0	0	1 (1.5)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	196 (95.1)	2 (1.0)	0	198 (96.1)
		Abnormal NCS	8 (3.9)	0	0	8 (3.9)
		Abnormal CS	0	0	0	0
		Total	204 (99.0)	2 (1.0)	0	206 (100)
Sodium (mmol/L)	Placebo (N=69)	Normal	64 (92.8)	1 (1.4)	0	65 (94.2)
		Abnormal NCS	4 (5.8)	0	0	4 (5.8)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Sodium (mmol/L)	GS1-144 30 mg QD (N=70)	Normal	57 (81.4)	3 (4.3)	0	60 (85.7)
		Abnormal NCS	9 (12.9)	1 (1.4)	0	10 (14.3)
		Abnormal CS	0	0	0	0
		Total	66 (94.3)	4 (5.7)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	0	0	65 (95.6)
		Abnormal NCS	3 (4.4)	0	0	3 (4.4)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	185 (89.8)	4 (1.9)	0	189 (91.7)
		Abnormal NCS	15 (7.3)	2 (1.0)	0	17 (8.3)
		Abnormal CS	0	0	0	0
		Total	200 (97.1)	6 (2.9)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Chloride (mmol/L)	Placebo (N=69)	Normal	62 (89.9)	3 (4.3)	0	65 (94.2)
		Abnormal NCS	4 (5.8)	0	0	4 (5.8)
		Abnormal CS	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	60 (85.7)	2 (2.9)	0	62 (88.6)
		Abnormal NCS	7 (10.0)	1 (1.4)	0	8 (11.4)
		Abnormal CS	0	0	0	0
		Total	67 (95.7)	3 (4.3)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
		Abnormal NCS	4 (5.9)	0	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	0	0	62 (91.2)
		Abnormal NCS	5 (7.4)	1 (1.5)	0	6 (8.8)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Chloride (mmol/L)	Combined GS1-144 (N=207)	Normal	185 (89.8)	3 (1.5)	0	188 (91.3)
		Abnormal NCS	16 (7.8)	2 (1.0)	0	18 (8.7)
		Abnormal CS	0	0	0	0
		Total	201 (97.6)	5 (2.4)	0	206 (100)
Calcium (mmol/L)	Placebo (N=69)	Normal	54 (78.3)	2 (2.9)	0	56 (81.2)
		Abnormal NCS	10 (14.5)	3 (4.3)	0	13 (18.8)
		Abnormal CS	0	0	0	0
		Total	64 (92.8)	5 (7.2)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	62 (88.6)	0	0	62 (88.6)
		Abnormal NCS	7 (10.0)	1 (1.4)	0	8 (11.4)
		Abnormal CS	0	0	0	0
		Total	69 (98.6)	1 (1.4)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	0	0	59 (86.8)
		Abnormal NCS	8 (11.8)	1 (1.5)	0	9 (13.2)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Calcium (mmol/L)	GS1-144 30 mg BID (N=68)	Normal	54 (79.4)	4 (5.9)	0	58 (85.3)
		Abnormal NCS	6 (8.8)	4 (5.9)	0	10 (14.7)
		Abnormal CS	0	0	0	0
		Total	60 (88.2)	8 (11.8)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	175 (85.0)	4 (1.9)	0	179 (86.9)
		Abnormal NCS	21 (10.2)	6 (2.9)	0	27 (13.1)
		Abnormal CS	0	0	0	0
		Total	196 (95.1)	10 (4.9)	0	206 (100)
Phosphate (mmol/L)	Placebo (N=69)	Normal	59 (85.5)	0	0	59 (85.5)
		Abnormal NCS	7 (10.1)	3 (4.3)	0	10 (14.5)
		Abnormal CS	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	63 (90.0)	0	0	63 (90.0)
		Abnormal NCS	4 (5.7)	3 (4.3)	0	7 (10.0)
		Abnormal CS	0	0	0	0
		Total	67 (95.7)	3 (4.3)	0	70 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Phosphate (mmol/L)	GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	1 (1.5)	0	61 (89.7)
		Abnormal NCS	6 (8.8)	1 (1.5)	0	7 (10.3)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	0	0	62 (91.2)
		Abnormal NCS	6 (8.8)	0	0	6 (8.8)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	185 (89.8)	1 (0.5)	0	186 (90.3)
		Abnormal NCS	16 (7.8)	4 (1.9)	0	20 (9.7)
		Abnormal CS	0	0	0	0
		Total	201 (97.6)	5 (2.4)	0	206 (100)
Magnesium (mmol/L)	Placebo (N=69)	Normal	62 (89.9)	2 (2.9)	0	64 (92.8)
		Abnormal NCS	4 (5.8)	1 (1.4)	0	5 (7.2)
		Abnormal CS	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Magnesium (mmol/L)	GS1-144 30 mg QD (N=70)	Normal	58 (82.9)	0	0	58 (82.9)
		Abnormal NCS	11 (15.7)	1 (1.4)	0	12 (17.1)
		Abnormal CS	0	0	0	0
		Total	69 (98.6)	1 (1.4)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	1 (1.5)	0	61 (89.7)
		Abnormal NCS	7 (10.3)	0	0	7 (10.3)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	50 (73.5)	5 (7.4)	0	55 (80.9)
		Abnormal NCS	10 (14.7)	3 (4.4)	0	13 (19.1)
		Abnormal CS	0	0	0	0
		Total	60 (88.2)	8 (11.8)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	168 (81.6)	6 (2.9)	0	174 (84.5)
		Abnormal NCS	28 (13.6)	4 (1.9)	0	32 (15.5)
		Abnormal CS	0	0	0	0
		Total	196 (95.1)	10 (4.9)	0	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Glucose (mmol/L)	Placebo (N=69)	Normal	57 (82.6)	0	0	57 (82.6)
		Abnormal NCS	6 (8.7)	4 (5.8)	0	10 (14.5)
		Abnormal CS	1 (1.4)	0	1 (1.4)	2 (2.9)
		Total	64 (92.8)	4 (5.8)	1 (1.4)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	58 (82.9)	0	0	58 (82.9)
		Abnormal NCS	7 (10.0)	3 (4.3)	0	10 (14.3)
		Abnormal CS	1 (1.4)	1 (1.4)	0	2 (2.9)
		Total	66 (94.3)	4 (5.7)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	1 (1.5)	0	60 (88.2)
		Abnormal NCS	6 (8.8)	1 (1.5)	0	7 (10.3)
		Abnormal CS	0	0	1 (1.5)	1 (1.5)
		Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	43 (63.2)	3 (4.4)	0	46 (67.6)
		Abnormal NCS	13 (19.1)	3 (4.4)	0	16 (23.5)
		Abnormal CS	3 (4.4)	1 (1.5)	2 (2.9)	6 (8.8)
		Total	59 (86.8)	7 (10.3)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.2.3
Shift of Chemistry by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Glucose (mmol/L)	Combined GS1-144 (N=207)	Normal	160 (77.7)	4 (1.9)	0	164 (79.6)
		Abnormal NCS	26 (12.6)	7 (3.4)	0	33 (16.0)
		Abnormal CS	4 (1.9)	2 (1.0)	3 (1.5)	9 (4.4)
		Total	190 (92.2)	13 (6.3)	3 (1.5)	206 (100)

Data Source: Listing 16.2.8.1.3
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Time (s)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	11.359 (0.8352)	11.188 (0.7637)	11.210 (0.9237)	11.178 (0.8542)	11.192 (0.8453)	11.234 (0.8444)
		Median	11.300	11.100	11.000	11.000	11.040	11.100
		Q1 - Q3	10.700 - 11.900	10.610 - 11.700	10.600 - 11.800	10.600 - 11.700	10.600 - 11.700	10.600 - 11.750
		Min - Max	9.90 - 13.60	9.80 - 13.00	9.40 - 13.80	9.70 - 13.50	9.40 - 13.80	9.40 - 13.80
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	11.339 (0.8840)	11.260 (1.2364)	11.314 (0.9180)	11.255 (0.8678)	11.276 (1.0182)	11.292 (0.9851)
		Median	11.100	11.050	11.200	11.100	11.100	11.100
		Q1 - Q3	10.700 - 12.100	10.600 - 11.800	10.600 - 11.900	10.700 - 11.800	10.600 - 11.800	10.600 - 11.900
		Min - Max	9.90 - 13.20	9.70 - 19.10	9.40 - 13.80	9.30 - 13.70	9.30 - 19.10	9.30 - 19.10
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.020 (0.4201)	0.072 (0.8572)	0.091 (0.3647)	0.078 (0.5600)	0.080 (0.6272)	0.055 (0.5831)
		Median	0	0	0.100	0.100	0.090	0
		Q1 - Q3	-0.350 - 0.300	-0.300 - 0.300	-0.150 - 0.300	-0.350 - 0.435	-0.200 - 0.300	-0.300 - 0.300
		Min - Max	-1.40 - 0.80	-1.10 - 6.10	-0.70 - 1.10	-1.10 - 1.80	-1.10 - 6.10	-1.40 - 6.10

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Time (s)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	11.317 (0.8564)	11.242 (0.7911)	11.308 (0.9256)	11.399 (0.8782)	11.316 (0.8642)	11.316 (0.8607)
		Median	11.200	11.100	11.100	11.400	11.100	11.100
		Q1 - Q3	10.700 - 11.900	10.700 - 11.900	10.650 - 12.000	10.800 - 12.000	10.700 - 12.000	10.700 - 11.900
		Min - Max	9.70 - 13.80	9.80 - 13.00	9.60 - 13.70	9.50 - 13.70	9.50 - 13.70	9.50 - 13.80
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.032 (0.4417)	0.064 (0.4653)	0.099 (0.4753)	0.214 (0.5732)	0.125 (0.5081)	0.086 (0.4963)
		Median	0	0.100	0	0.200	0.100	0.085
		Q1 - Q3	-0.300 - 0.300	-0.200 - 0.300	-0.200 - 0.400	-0.200 - 0.600	-0.200 - 0.400	-0.200 - 0.330
		Min - Max	-1.20 - 1.00	-1.10 - 1.60	-0.90 - 1.40	-0.80 - 1.80	-1.10 - 1.80	-1.20 - 1.80
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	11.386 (0.8158)	11.323 (0.8820)	11.374 (0.9260)	11.365 (0.8633)	11.354 (0.8870)	11.362 (0.8685)
		Median	11.300	11.200	11.300	11.300	11.300	11.300
		Q1 - Q3	10.700 - 11.900	10.600 - 11.800	10.700 - 11.900	10.850 - 12.000	10.700 - 11.900	10.700 - 11.900
		Min - Max	10.00 - 13.50	10.00 - 13.80	9.70 - 13.40	9.20 - 13.20	9.20 - 13.80	9.20 - 13.80

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Time (s)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.026 (0.5354)	0.146 (0.6026)	0.165 (0.7091)	0.172 (0.6309)	0.161 (0.6458)	0.127 (0.6220)
		Median	0.010	0.100	0	0.200	0.100	0.100
		Q1 - Q3	-0.200 - 0.300	-0.300 - 0.400	-0.200 - 0.370	-0.300 - 0.600	-0.200 - 0.450	-0.200 - 0.400
		Min - Max	-2.20 - 1.80	-1.00 - 3.10	-1.20 - 3.40	-1.40 - 1.70	-1.40 - 3.40	-2.20 - 3.40
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	11.347 (0.8981)	11.171 (0.8526)	11.294 (0.8831)	11.278 (0.9468)	11.247 (0.8909)	11.272 (0.8920)
		Median	11.200	11.050	11.200	11.200	11.200	11.200
		Q1 - Q3	10.800 - 12.000	10.600 - 11.900	10.700 - 11.900	10.600 - 11.800	10.600 - 11.900	10.600 - 11.900
		Min - Max	9.30 - 13.30	9.50 - 13.00	9.40 - 13.50	9.50 - 14.20	9.40 - 14.20	9.30 - 14.20
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.006 (0.5696)	0.019 (0.4995)	0.086 (0.5773)	0.093 (0.5754)	0.065 (0.5493)	0.050 (0.5539)
		Median	0	0	0	0.100	0	0
		Q1 - Q3	-0.300 - 0.400	-0.400 - 0.200	-0.300 - 0.400	-0.300 - 0.500	-0.300 - 0.400	-0.300 - 0.400
		Min - Max	-1.20 - 2.20	-1.00 - 1.30	-1.00 - 1.90	-1.40 - 1.80	-1.40 - 1.90	-1.40 - 2.20

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Time (s)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	11.476 (1.1769)	11.202 (0.8628)	11.316 (0.9952)	11.190 (0.8704)	11.236 (0.9082)	11.296 (0.9851)
		Median	11.300	11.050	11.200	11.000	11.100	11.200
		Q1 - Q3	10.900 - 12.000	10.500 - 11.900	10.600 - 11.900	10.600 - 11.700	10.570 - 11.800	10.600 - 11.900
		Min - Max	9.90 - 18.00	9.20 - 13.00	9.40 - 13.70	9.30 - 13.60	9.20 - 13.70	9.20 - 18.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.134 (1.0337)	0.050 (0.5709)	0.095 (0.6096)	0.005 (0.5053)	0.051 (0.5626)	0.071 (0.7083)
		Median	0	0	0	0.100	0	0
		Q1 - Q3	-0.400 - 0.300	-0.300 - 0.500	-0.200 - 0.400	-0.200 - 0.300	-0.300 - 0.400	-0.300 - 0.400
		Min - Max	-1.20 - 6.30	-1.30 - 1.40	-1.10 - 2.20	-1.30 - 1.20	-1.30 - 2.20	-1.30 - 6.30
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	11.338 (1.0103)	11.113 (0.7693)	11.232 (0.9151)	11.302 (0.9948)	11.214 (0.8940)	11.244 (0.9236)
		Median	11.100	11.000	11.200	11.300	11.200	11.100
		Q1 - Q3	10.600 - 12.100	10.500 - 11.650	10.600 - 11.800	10.600 - 12.000	10.530 - 11.800	10.600 - 11.800
		Min - Max	9.50 - 13.70	9.60 - 12.80	9.20 - 13.20	9.10 - 13.90	9.10 - 13.90	9.10 - 13.90

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Time (s)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.016 (0.6446)	-0.034 (0.4834)	0.025 (0.5405)	0.114 (0.5633)	0.033 (0.5299)	0.021 (0.5595)
		Median	-0.065	0	0	0.100	0	0
		Q1 - Q3	-0.550 - 0.400	-0.400 - 0.300	-0.300 - 0.400	-0.300 - 0.400	-0.300 - 0.400	-0.400 - 0.400
		Min - Max	-1.30 - 1.70	-1.20 - 1.10	-1.40 - 1.20	-1.10 - 1.50	-1.40 - 1.50	-1.40 - 1.70
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	11.338 (0.8550)	11.159 (0.8750)	11.155 (0.9925)	11.246 (0.9858)	11.185 (0.9474)	11.223 (0.9263)
		Median	11.250	11.000	11.000	11.200	11.000	11.100
		Q1 - Q3	10.750 - 11.900	10.490 - 11.900	10.500 - 11.900	10.600 - 11.700	10.500 - 11.700	10.500 - 11.800
		Min - Max	9.90 - 13.40	9.50 - 12.80	9.60 - 13.70	9.70 - 14.50	9.50 - 14.50	9.50 - 14.50
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.004 (0.4988)	-0.014 (0.4737)	-0.066 (0.5817)	0.066 (0.5299)	-0.006 (0.5297)	-0.004 (0.5214)
		Median	0	0	-0.130	0	0	0
		Q1 - Q3	-0.300 - 0.300	-0.350 - 0.400	-0.400 - 0.200	-0.200 - 0.400	-0.300 - 0.300	-0.300 - 0.300
		Min - Max	-1.20 - 1.20	-1.00 - 1.10	-1.20 - 1.50	-1.40 - 1.50	-1.40 - 1.50	-1.40 - 1.50

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Activated Partial Thromboplastin Time (s)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	29.263 (4.0235)	30.553 (4.4612)	30.062 (4.1879)	30.202 (4.2524)	30.274 (4.2872)	30.021 (4.2383)
		Median	29.200	30.050	29.700	30.400	29.900	29.700
		Q1 - Q3	26.400 - 31.400	26.970 - 33.500	26.580 - 32.600	26.450 - 32.600	26.580 - 33.100	26.540 - 32.600
		Min - Max	20.10 - 43.50	23.80 - 46.80	23.50 - 40.40	23.50 - 40.00	23.50 - 46.80	20.10 - 46.80
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	29.312 (3.9015)	30.433 (4.8320)	30.291 (4.3028)	30.104 (4.0398)	30.277 (4.3888)	30.035 (4.2854)
		Median	28.800	30.300	29.300	30.250	29.800	29.600
		Q1 - Q3	26.800 - 31.400	26.700 - 33.300	26.800 - 33.450	26.750 - 32.800	26.700 - 33.100	26.700 - 32.900
		Min - Max	22.20 - 40.30	22.50 - 54.10	22.60 - 39.20	22.90 - 41.70	22.50 - 54.10	22.20 - 54.10
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.049 (1.3309)	-0.120 (2.0397)	0.179 (1.6831)	-0.099 (1.7235)	-0.014 (1.8209)	0.002 (1.7091)
		Median	0	0.055	0.300	0.190	0.100	0.100
		Q1 - Q3	-0.800 - 0.800	-0.900 - 0.800	-0.400 - 0.900	-1.150 - 1.150	-0.800 - 0.900	-0.800 - 0.900
		Min - Max	-3.20 - 3.60	-8.90 - 7.30	-8.10 - 4.80	-6.90 - 2.80	-8.90 - 7.30	-8.90 - 7.30

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Activated Partial Thromboplastin Time (s)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	29.136 (4.3076)	30.026 (3.9441)	29.961 (4.1321)	30.055 (4.2092)	30.014 (4.0750)	29.796 (4.1433)
		Median	29.100	30.100	29.200	30.000	29.500	29.400
		Q1 - Q3	26.300 - 31.600	27.000 - 32.400	26.750 - 33.700	26.200 - 32.900	26.750 - 33.000	26.500 - 32.500
		Min - Max	20.30 - 42.90	19.00 - 41.30	23.90 - 40.40	22.20 - 40.30	19.00 - 41.30	19.00 - 42.90
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.101 (1.8676)	-0.502 (2.5821)	0.002 (1.5857)	-0.206 (2.0162)	-0.238 (2.1065)	-0.204 (2.0473)
		Median	0	-0.200	0	-0.300	-0.100	-0.100
		Q1 - Q3	-1.200 - 0.900	-1.100 - 0.800	-1.170 - 0.900	-1.100 - 1.100	-1.100 - 0.900	-1.100 - 0.900
		Min - Max	-5.30 - 7.10	-12.10 - 3.20	-4.60 - 3.80	-7.40 - 3.60	-12.10 - 3.80	-12.10 - 7.10
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	29.111 (3.9488)	30.412 (4.4532)	29.851 (4.0016)	29.914 (4.1395)	30.065 (4.1924)	29.828 (4.1466)
		Median	28.800	29.900	29.400	29.250	29.450	29.250
		Q1 - Q3	26.200 - 31.000	26.600 - 33.000	26.400 - 32.900	26.650 - 33.200	26.500 - 33.000	26.500 - 32.700
		Min - Max	22.30 - 43.00	23.57 - 46.70	23.10 - 38.50	22.50 - 40.20	22.50 - 46.70	22.30 - 46.70

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Activated Partial Thromboplastin Time (s)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.244 (1.5818)	-0.116 (1.4656)	-0.108 (1.6099)	-0.455 (1.7934)	-0.222 (1.6241)	-0.227 (1.6108)
		Median	-0.000	-0.400	0.200	-0.450	-0.200	-0.200
		Q1 - Q3	-1.400 - 0.700	-1.000 - 0.900	-0.700 - 0.900	-1.300 - 0.650	-1.000 - 0.800	-1.000 - 0.800
		Min - Max	-5.30 - 3.90	-2.90 - 3.10	-7.60 - 2.70	-6.20 - 3.90	-7.60 - 3.90	-7.60 - 3.90
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	29.233 (4.1143)	30.141 (5.0385)	30.656 (6.4036)	29.729 (4.2100)	30.182 (5.2939)	29.946 (5.0364)
		Median	28.500	30.100	29.600	30.100	29.800	29.400
		Q1 - Q3	26.080 - 31.900	26.470 - 32.900	26.400 - 33.100	26.100 - 32.800	26.400 - 33.000	26.200 - 32.800
		Min - Max	23.00 - 41.70	20.40 - 52.00	23.60 - 70.90	23.40 - 41.80	20.40 - 70.90	20.40 - 70.90
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.088 (1.9622)	-0.373 (2.3507)	0.664 (5.7954)	-0.605 (1.9100)	-0.099 (3.8060)	-0.096 (3.4384)
		Median	0	-0.200	0.250	-0.600	-0.200	-0.100
		Q1 - Q3	-0.900 - 1.000	-1.600 - 1.010	-1.000 - 1.100	-1.300 - 0.700	-1.200 - 1.000	-1.200 - 1.000
		Min - Max	-5.80 - 4.10	-8.40 - 5.20	-5.80 - 44.80	-7.90 - 2.80	-8.40 - 44.80	-8.40 - 44.80

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Activated Partial Thromboplastin Time (s)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	29.316 (3.7984)	30.175 (4.5730)	29.568 (4.1068)	29.465 (4.0342)	29.746 (4.2421)	29.639 (4.1331)
		Median	28.900	29.450	28.800	28.800	29.000	28.900
		Q1 - Q3	26.000 - 31.700	26.800 - 32.750	26.500 - 32.400	26.300 - 32.500	26.450 - 32.500	26.400 - 32.400
		Min - Max	23.60 - 41.40	24.01 - 50.90	23.80 - 40.40	23.10 - 40.30	23.10 - 50.90	23.10 - 50.90
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.005 (1.8900)	-0.339 (1.7204)	-0.465 (2.1420)	-0.869 (2.2492)	-0.551 (2.0450)	-0.415 (2.0179)
		Median	0.200	-0.150	-0.200	-0.400	-0.300	-0.200
		Q1 - Q3	-1.300 - 1.200	-1.120 - 0.700	-1.200 - 0.900	-1.200 - 0.200	-1.195 - 0.500	-1.200 - 0.800
		Min - Max	-5.20 - 4.60	-5.60 - 4.10	-11.20 - 3.00	-8.80 - 2.70	-11.20 - 4.10	-11.20 - 4.60
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	29.436 (4.0363)	30.295 (4.4626)	29.484 (3.8225)	29.530 (3.8510)	29.777 (4.0590)	29.693 (4.0483)
		Median	29.050	29.300	28.600	29.350	29.000	29.000
		Q1 - Q3	26.150 - 31.850	27.300 - 33.200	26.200 - 32.600	25.900 - 32.800	26.300 - 32.800	26.200 - 32.700
		Min - Max	23.10 - 41.90	23.40 - 49.80	24.50 - 38.50	23.60 - 40.40	23.40 - 49.80	23.10 - 49.80

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Activated Partial Thromboplastin Time (s)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.029 (1.6327)	-0.179 (1.6210)	-0.508 (2.1404)	-0.822 (2.0445)	-0.495 (1.9524)	-0.380 (1.8862)
		Median	0.005	-0.200	-0.050	-0.495	-0.200	-0.150
		Q1 - Q3	-0.800 - 0.850	-1.000 - 0.700	-1.390 - 0.700	-1.400 - 0.400	-1.200 - 0.700	-1.200 - 0.700
		Min - Max	-4.20 - 4.70	-5.00 - 3.20	-10.80 - 3.60	-8.40 - 2.10	-10.80 - 3.60	-10.80 - 4.70
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	29.079 (3.5971)	30.036 (4.2636)	29.390 (3.4081)	29.426 (4.0334)	29.625 (3.9118)	29.491 (3.8375)
		Median	28.750	29.350	28.650	28.700	28.900	28.900
		Q1 - Q3	26.275 - 31.700	26.850 - 32.550	26.700 - 31.800	25.900 - 32.500	26.700 - 32.500	26.500 - 32.300
		Min - Max	22.20 - 39.50	23.59 - 45.90	24.40 - 37.10	23.30 - 40.60	23.30 - 45.90	22.20 - 45.90
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.235 (1.6542)	-0.453 (2.0010)	-0.609 (2.2845)	-0.861 (2.2815)	-0.636 (2.1850)	-0.537 (2.0717)
		Median	-0.140	-0.400	-0.200	-0.600	-0.400	-0.300
		Q1 - Q3	-1.300 - 0.800	-1.400 - 1.050	-0.900 - 0.300	-1.600 - 0.800	-1.400 - 0.700	-1.300 - 0.700
		Min - Max	-4.80 - 3.30	-5.70 - 3.20	-12.60 - 3.20	-8.70 - 3.90	-12.60 - 3.90	-12.60 - 3.90

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thrombin Time (s)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	17.215 (1.6484)	16.818 (1.7636)	16.912 (1.7993)	17.139 (1.7961)	16.955 (1.7826)	17.020 (1.7507)
		Median	17.500	17.200	17.400	17.600	17.400	17.400
		Q1 - Q3	16.600 - 18.500	15.650 - 18.000	15.890 - 18.100	16.000 - 18.450	15.800 - 18.200	15.890 - 18.300
		Min - Max	12.90 - 19.50	11.50 - 19.70	11.80 - 19.90	13.20 - 20.00	11.50 - 20.00	11.50 - 20.00
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	17.347 (1.5530)	16.701 (1.8731)	16.976 (1.6960)	16.796 (1.8061)	16.823 (1.7889)	16.955 (1.7449)
		Median	17.600	17.100	17.200	17.350	17.200	17.300
		Q1 - Q3	16.340 - 18.600	15.600 - 17.900	16.145 - 18.350	15.400 - 18.100	15.800 - 18.100	16.000 - 18.200
		Min - Max	11.90 - 20.40	10.50 - 20.70	12.60 - 20.20	13.00 - 20.00	10.50 - 20.70	10.50 - 20.70
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.133 (0.9944)	-0.117 (0.8759)	0.046 (0.8233)	-0.343 (1.0438)	-0.138 (0.9280)	-0.070 (0.9506)
		Median	0	-0.100	0.100	-0.300	-0.100	-0.020
		Q1 - Q3	-0.400 - 0.610	-0.500 - 0.400	-0.450 - 0.550	-0.750 - 0.200	-0.600 - 0.400	-0.500 - 0.500
		Min - Max	-2.40 - 2.90	-3.20 - 1.80	-1.80 - 1.80	-6.00 - 1.80	-6.00 - 1.80	-6.00 - 2.90

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thrombin Time (s)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	17.334 (1.6474)	16.829 (1.6940)	16.838 (1.7426)	17.004 (1.7275)	16.890 (1.7146)	17.000 (1.7060)
		Median	17.900	17.100	17.200	17.400	17.300	17.400
		Q1 - Q3	16.380 - 18.600	16.100 - 17.900	15.900 - 18.000	15.500 - 18.300	15.780 - 18.000	16.000 - 18.300
		Min - Max	13.30 - 20.00	12.70 - 20.30	12.40 - 20.00	12.80 - 20.60	12.40 - 20.60	12.40 - 20.60
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.156 (0.9320)	0.022 (0.9884)	-0.101 (0.8680)	-0.116 (0.8651)	-0.064 (0.9074)	-0.010 (0.9168)
		Median	0.100	0.100	0	0	0	0
		Q1 - Q3	-0.300 - 0.600	-0.700 - 0.600	-0.700 - 0.500	-0.700 - 0.300	-0.700 - 0.500	-0.500 - 0.500
		Min - Max	-2.70 - 2.50	-2.20 - 2.50	-2.10 - 2.00	-2.30 - 1.90	-2.30 - 2.50	-2.70 - 2.50
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	17.152 (1.6910)	16.880 (1.7890)	16.934 (1.8211)	17.088 (1.8198)	16.965 (1.8027)	17.011 (1.7743)
		Median	17.450	17.230	17.200	17.600	17.400	17.400
		Q1 - Q3	16.400 - 18.300	15.700 - 18.100	15.760 - 18.200	15.900 - 18.500	15.750 - 18.200	16.000 - 18.300
		Min - Max	13.30 - 20.80	12.50 - 21.20	11.80 - 20.20	12.30 - 20.10	11.80 - 21.20	11.80 - 21.20

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thrombin Time (s)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.024 (0.9383)	0.073 (0.9860)	-0.005 (0.9680)	-0.067 (1.0219)	0.002 (0.9884)	-0.004 (0.9745)
		Median	-0.200	0	0	-0.300	0	-0.100
		Q1 - Q3	-0.480 - 0.700	-0.600 - 0.700	-0.600 - 0.600	-0.800 - 0.500	-0.650 - 0.600	-0.600 - 0.600
		Min - Max	-2.50 - 2.20	-3.40 - 2.50	-2.70 - 2.10	-2.30 - 2.20	-3.40 - 2.50	-3.40 - 2.50
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	17.350 (1.6890)	16.865 (1.7667)	18.740 (15.6399)	17.206 (1.8407)	17.602 (9.1615)	17.540 (7.9838)
		Median	17.700	17.250	17.300	17.700	17.400	17.400
		Q1 - Q3	16.200 - 18.600	15.585 - 18.100	15.800 - 18.200	15.900 - 18.600	15.800 - 18.300	15.800 - 18.400
		Min - Max	13.30 - 20.70	12.80 - 21.80	11.70 - 143.00	13.40 - 20.60	11.70 - 143.00	11.70 - 143.00
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.148 (0.9602)	0.090 (1.0189)	1.802 (15.4988)	0.058 (1.0012)	0.653 (9.0001)	0.528 (7.8168)
		Median	0.100	0	-0.100	0.100	0	0
		Q1 - Q3	-0.600 - 0.600	-0.550 - 0.500	-0.600 - 0.300	-0.500 - 0.600	-0.600 - 0.500	-0.600 - 0.600
		Min - Max	-1.40 - 2.90	-2.00 - 3.20	-2.30 - 125.60	-2.84 - 2.00	-2.84 - 125.60	-2.84 - 125.60

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thrombin Time (s)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	17.336 (1.7189)	16.767 (1.8106)	16.964 (1.7757)	17.049 (1.8864)	16.923 (1.8185)	17.026 (1.7998)
		Median	17.500	17.050	17.400	17.300	17.200	17.300
		Q1 - Q3	16.100 - 18.500	15.275 - 18.200	15.700 - 18.200	15.500 - 18.500	15.500 - 18.250	15.700 - 18.400
		Min - Max	13.40 - 21.20	13.30 - 19.70	11.20 - 19.70	13.00 - 20.40	11.20 - 20.40	11.20 - 21.20
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.134 (1.0716)	-0.007 (0.8990)	0.054 (0.8569)	-0.100 (1.0563)	-0.017 (0.9367)	0.021 (0.9721)
		Median	0.100	0	0	0.100	0	0
		Q1 - Q3	-0.600 - 0.800	-0.500 - 0.700	-0.600 - 0.800	-0.800 - 0.600	-0.600 - 0.700	-0.600 - 0.700
		Min - Max	-2.50 - 2.70	-2.30 - 2.00	-1.80 - 1.80	-3.70 - 1.90	-3.70 - 2.00	-3.70 - 2.70
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	17.439 (1.7031)	16.831 (2.0100)	16.988 (1.8590)	17.268 (1.7733)	17.023 (1.8851)	17.126 (1.8473)
		Median	17.900	17.100	17.450	17.550	17.400	17.500
		Q1 - Q3	16.350 - 18.800	15.700 - 18.100	16.300 - 18.200	15.700 - 18.600	15.800 - 18.300	15.900 - 18.400
		Min - Max	13.00 - 20.30	10.90 - 20.60	12.10 - 21.70	13.30 - 20.70	10.90 - 21.70	10.90 - 21.70

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thrombin Time (s)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.269 (1.1447)	0.042 (1.0494)	0.050 (0.9342)	0.128 (0.9107)	0.072 (0.9640)	0.121 (1.0129)
		Median	0.100	0.200	0.100	0.100	0.100	0.100
		Q1 - Q3	-0.310 - 1.150	-0.500 - 0.700	-0.600 - 0.700	-0.400 - 0.700	-0.500 - 0.700	-0.500 - 0.800
		Min - Max	-2.70 - 3.20	-3.10 - 2.10	-2.00 - 1.80	-1.76 - 2.00	-3.10 - 2.10	-3.10 - 3.20
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	17.482 (1.6598)	16.972 (1.8080)	17.180 (1.8079)	17.388 (1.8113)	17.175 (1.8077)	17.250 (1.7744)
		Median	17.750	17.250	17.700	17.900	17.600	17.600
		Q1 - Q3	16.280 - 18.650	15.600 - 18.400	15.800 - 18.500	15.800 - 18.600	15.800 - 18.500	16.000 - 18.500
		Min - Max	13.20 - 20.90	12.20 - 20.50	12.70 - 20.50	13.80 - 21.20	12.20 - 21.20	12.20 - 21.20
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.298 (1.0387)	0.150 (1.0290)	0.268 (0.8493)	0.229 (1.0105)	0.215 (0.9626)	0.235 (0.9805)
		Median	0.300	0.150	0.200	0.100	0.200	0.200
		Q1 - Q3	-0.250 - 1.000	-0.200 - 1.000	-0.400 - 0.900	-0.400 - 1.000	-0.300 - 1.000	-0.300 - 1.000
		Min - Max	-1.80 - 3.00	-3.70 - 2.20	-1.80 - 2.00	-2.20 - 2.70	-3.70 - 2.70	-3.70 - 3.00

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Fibrinogen (g/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	3.1523 (0.51605)	3.0086 (0.49703)	3.0870 (0.58136)	2.9822 (0.46400)	3.0260 (0.51606)	3.0576 (0.51802)
		Median	3.0900	3.0350	2.9700	2.9950	3.0000	3.0250
		Q1 - Q3	2.8100 - 3.5700	2.6100 - 3.3600	2.6500 - 3.4900	2.6550 - 3.2900	2.6300 - 3.3600	2.6800 - 3.3850
		Min - Max	2.000 - 4.270	2.120 - 4.320	2.000 - 4.880	2.150 - 4.080	2.000 - 4.880	2.000 - 4.880
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	3.1337 (0.64519)	3.0604 (0.52294)	3.1147 (0.59718)	3.0357 (0.54055)	3.0702 (0.55243)	3.0861 (0.57654)
		Median	3.0300	3.0950	3.0550	2.9900	3.0500	3.0500
		Q1 - Q3	2.6800 - 3.4600	2.6900 - 3.3000	2.7050 - 3.4850	2.6550 - 3.2850	2.6700 - 3.3100	2.6800 - 3.3300
		Min - Max	2.100 - 5.590	2.000 - 4.830	2.050 - 6.030	2.250 - 4.500	2.000 - 6.030	2.000 - 6.030
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.0186 (0.43288)	0.0519 (0.40721)	0.0428 (0.51440)	0.0536 (0.42227)	0.0494 (0.44788)	0.0324 (0.44436)
		Median	-0.0500	-0.0300	0.0350	0.0400	0.0100	0
		Q1 - Q3	-0.2700 - 0.1900	-0.2100 - 0.3900	-0.2500 - 0.2500	-0.1900 - 0.2300	-0.2100 - 0.2500	-0.2100 - 0.2300
		Min - Max	-0.950 - 1.570	-0.710 - 1.450	-1.270 - 2.130	-0.860 - 1.450	-1.270 - 2.130	-1.270 - 2.130

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Fibrinogen (g/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	3.0506 (0.64063)	2.9764 (0.49075)	3.1349 (0.72391)	3.0211 (0.52629)	3.0435 (0.58930)	3.0453 (0.60123)
		Median	3.0200	3.0300	2.9900	2.9300	2.9900	2.9950
		Q1 - Q3	2.5800 - 3.4300	2.5300 - 3.3400	2.6200 - 3.5000	2.6200 - 3.2600	2.5800 - 3.3600	2.5800 - 3.3600
		Min - Max	1.900 - 5.450	2.080 - 4.180	1.900 - 6.060	2.040 - 4.760	1.900 - 6.060	1.900 - 6.060
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.0792 (0.44281)	-0.0168 (0.37051)	0.0796 (0.59655)	0.0446 (0.42645)	0.0353 (0.47277)	0.0069 (0.46734)
		Median	-0.0600	-0.0400	0.0200	0.0300	-0.0100	-0.0150
		Q1 - Q3	-0.3600 - 0.2000	-0.2200 - 0.1700	-0.2200 - 0.3000	-0.2400 - 0.2800	-0.2200 - 0.2800	-0.2400 - 0.2300
		Min - Max	-1.000 - 1.430	-0.870 - 1.100	-1.450 - 2.830	-0.900 - 1.670	-1.450 - 2.830	-1.450 - 2.830
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	3.1685 (0.67273)	3.0335 (0.55720)	3.1654 (0.72003)	3.0391 (0.56208)	3.0795 (0.61790)	3.1015 (0.63182)
		Median	3.1050	3.0400	3.0000	2.9400	2.9950	3.0250
		Q1 - Q3	2.7400 - 3.5600	2.6900 - 3.3100	2.6500 - 3.6600	2.5800 - 3.4600	2.6450 - 3.4500	2.6500 - 3.4700
		Min - Max	1.900 - 5.930	1.910 - 4.870	1.990 - 5.800	2.260 - 4.540	1.910 - 5.800	1.900 - 5.930

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Fibrinogen (g/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.0491 (0.52624)	0.0403 (0.44247)	0.1100 (0.59848)	0.0721 (0.40578)	0.0738 (0.48852)	0.0677 (0.49725)
		Median	0	0.0600	0.0400	0.0900	0.0600	0.0500
		Q1 - Q3	-0.2900 - 0.3000	-0.2200 - 0.2300	-0.2100 - 0.3000	-0.1850 - 0.3200	-0.2100 - 0.2800	-0.2200 - 0.2900
		Min - Max	-0.890 - 2.440	-0.850 - 1.390	-0.860 - 2.870	-1.040 - 1.530	-1.040 - 2.870	-1.040 - 2.870
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	3.0635 (0.65349)	3.0346 (0.52959)	3.1241 (0.76697)	2.9961 (0.51714)	3.0523 (0.61515)	3.0550 (0.62363)
		Median	2.9200	3.0950	3.0600	2.9700	3.0500	3.0100
		Q1 - Q3	2.7000 - 3.3400	2.7050 - 3.4350	2.4900 - 3.6000	2.6400 - 3.3400	2.6400 - 3.4200	2.6400 - 3.3900
		Min - Max	2.000 - 5.180	1.970 - 4.320	1.860 - 6.050	1.950 - 4.410	1.860 - 6.050	1.860 - 6.050
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	-0.0537 (0.45971)	0.0471 (0.40772)	0.0626 (0.61842)	0.0452 (0.39985)	0.0517 (0.48404)	0.0255 (0.47942)
		Median	-0.0600	0	-0.0250	0	0	-0.0100
		Q1 - Q3	-0.3400 - 0.1200	-0.1800 - 0.2600	-0.2600 - 0.3100	-0.1500 - 0.2400	-0.2200 - 0.2700	-0.2400 - 0.2400
		Min - Max	-0.850 - 1.410	-0.890 - 1.350	-1.080 - 3.120	-0.830 - 1.880	-1.080 - 3.120	-1.080 - 3.120

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Fibrinogen (g/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	3.0462 (0.61691)	2.9496 (0.50002)	3.0758 (0.68667)	2.9441 (0.49231)	2.9897 (0.56694)	3.0038 (0.57909)
		Median	3.0200	2.9100	2.9100	2.9800	2.9500	2.9700
		Q1 - Q3	2.5200 - 3.3700	2.6100 - 3.2700	2.5700 - 3.5200	2.5500 - 3.2900	2.5700 - 3.3300	2.5600 - 3.3400
		Min - Max	2.040 - 4.390	1.970 - 4.130	1.870 - 4.890	1.990 - 4.060	1.870 - 4.890	1.870 - 4.890
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.0710 (0.50321)	-0.0379 (0.42139)	0.0054 (0.47993)	-0.0068 (0.38777)	-0.0136 (0.42983)	-0.0279 (0.44891)
		Median	-0.1200	-0.1050	-0.0400	-0.0400	-0.0500	-0.0600
		Q1 - Q3	-0.4400 - 0.2500	-0.3100 - 0.2300	-0.3100 - 0.1900	-0.3100 - 0.1400	-0.3100 - 0.1950	-0.3300 - 0.2300
		Min - Max	-0.860 - 1.430	-1.080 - 1.180	-0.970 - 1.490	-0.510 - 1.910	-1.080 - 1.910	-1.080 - 1.910
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	3.0484 (0.72096)	3.0022 (0.61330)	3.0432 (0.61325)	2.9753 (0.52220)	3.0075 (0.58351)	3.0176 (0.61908)
		Median	2.8750	2.9700	2.9950	2.9400	2.9900	2.9500
		Q1 - Q3	2.5250 - 3.3250	2.5700 - 3.2300	2.6900 - 3.4400	2.5700 - 3.2900	2.6000 - 3.3000	2.5800 - 3.3000
		Min - Max	2.000 - 5.560	1.870 - 5.200	1.800 - 4.800	2.110 - 4.570	1.800 - 5.200	1.800 - 5.560

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Fibrinogen (g/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.0664 (0.52730)	0.0218 (0.45823)	-0.0183 (0.50317)	0.0182 (0.43360)	0.0071 (0.46445)	-0.0111 (0.48073)
		Median	-0.1450	-0.0100	-0.0450	-0.0500	-0.0400	-0.0500
		Q1 - Q3	-0.4300 - 0.1850	-0.2200 - 0.3300	-0.3400 - 0.2100	-0.2100 - 0.2100	-0.2800 - 0.2400	-0.3200 - 0.2200
		Min - Max	-1.030 - 2.280	-1.120 - 1.060	-1.280 - 1.720	-0.760 - 2.420	-1.280 - 2.420	-1.280 - 2.420
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	3.0736 (0.70546)	2.9725 (0.59244)	2.9871 (0.52509)	2.9259 (0.48520)	2.9625 (0.53531)	2.9898 (0.58215)
		Median	2.9300	2.9450	2.9450	2.9000	2.9200	2.9200
		Q1 - Q3	2.6360 - 3.2800	2.5500 - 3.3400	2.6600 - 3.3700	2.5200 - 3.3100	2.5700 - 3.3100	2.6000 - 3.3100
		Min - Max	2.000 - 5.960	1.940 - 4.750	1.960 - 4.350	2.090 - 4.190	1.940 - 4.750	1.940 - 5.960
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.0493 (0.49682)	-0.0138 (0.45142)	-0.0770 (0.36670)	-0.0375 (0.38794)	-0.0426 (0.40318)	-0.0442 (0.42703)
		Median	-0.0100	-0.0200	-0.0700	-0.0700	-0.0700	-0.0400
		Q1 - Q3	-0.3850 - 0.1400	-0.2950 - 0.2450	-0.3200 - 0.1500	-0.3100 - 0.1800	-0.3000 - 0.2000	-0.3100 - 0.1800
		Min - Max	-0.940 - 1.870	-1.140 - 1.800	-1.100 - 0.590	-0.840 - 1.500	-1.140 - 1.800	-1.140 - 1.870

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Intl. Normalized Ratio	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	0.9480 (0.05977)	0.9471 (0.05952)	0.9428 (0.05948)	0.9482 (0.06239)	0.9460 (0.06022)	0.9465 (0.06000)
		Median	0.9400	0.9400	0.9400	0.9450	0.9400	0.9400
		Q1 - Q3	0.9000 - 0.9800	0.9000 - 0.9800	0.9100 - 0.9800	0.9100 - 0.9800	0.9100 - 0.9800	0.9100 - 0.9800
		Min - Max	0.840 - 1.150	0.840 - 1.100	0.820 - 1.080	0.810 - 1.100	0.810 - 1.100	0.810 - 1.150
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	0.9465 (0.05716)	0.9529 (0.08560)	0.9513 (0.06554)	0.9562 (0.06837)	0.9534 (0.07350)	0.9517 (0.06973)
		Median	0.9500	0.9400	0.9500	0.9500	0.9500	0.9500
		Q1 - Q3	0.9000 - 0.9800	0.9000 - 0.9900	0.9000 - 0.9900	0.9100 - 1.0000	0.9000 - 0.9900	0.9000 - 0.9900
		Min - Max	0.860 - 1.140	0.840 - 1.510	0.830 - 1.120	0.800 - 1.150	0.800 - 1.510	0.800 - 1.510
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.0014 (0.03923)	0.0057 (0.07389)	0.0079 (0.03308)	0.0079 (0.05068)	0.0072 (0.05510)	0.0050 (0.05165)
		Median	0	0	0.0100	0.0050	0	0
		Q1 - Q3	-0.0300 - 0.0300	-0.0300 - 0.0300	-0.0150 - 0.0300	-0.0300 - 0.0400	-0.0200 - 0.0300	-0.0300 - 0.0300
		Min - Max	-0.140 - 0.070	-0.100 - 0.510	-0.050 - 0.100	-0.100 - 0.170	-0.100 - 0.510	-0.140 - 0.510

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Intl. Normalized Ratio	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	0.9452 (0.06086)	0.9527 (0.06040)	0.9509 (0.05984)	0.9685 (0.06287)	0.9573 (0.06125)	0.9543 (0.06127)
		Median	0.9400	0.9400	0.9400	0.9700	0.9500	0.9500
		Q1 - Q3	0.9000 - 0.9800	0.9000 - 0.9900	0.9100 - 1.0000	0.9200 - 1.0100	0.9100 - 1.0100	0.9100 - 1.0000
		Min - Max	0.840 - 1.120	0.860 - 1.120	0.820 - 1.070	0.820 - 1.100	0.820 - 1.120	0.820 - 1.120
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-0.0042 (0.04061)	0.0048 (0.04078)	0.0073 (0.04375)	0.0206 (0.05317)	0.0108 (0.04645)	0.0071 (0.04546)
		Median	-0.0100	0.0100	0	0.0200	0.0100	0
		Q1 - Q3	-0.0300 - 0.0300	-0.0200 - 0.0200	-0.0200 - 0.0400	-0.0200 - 0.0500	-0.0200 - 0.0400	-0.0200 - 0.0300
		Min - Max	-0.120 - 0.090	-0.100 - 0.150	-0.090 - 0.120	-0.080 - 0.170	-0.100 - 0.170	-0.120 - 0.170
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	0.9529 (0.05535)	0.9597 (0.06947)	0.9576 (0.08049)	0.9631 (0.07121)	0.9601 (0.07354)	0.9583 (0.06945)
		Median	0.9500	0.9500	0.9500	0.9450	0.9500	0.9500
		Q1 - Q3	0.9100 - 0.9900	0.9100 - 1.0000	0.8900 - 1.0100	0.9150 - 1.0195	0.9100 - 1.0050	0.9100 - 1.0000
		Min - Max	0.850 - 1.120	0.850 - 1.140	0.830 - 1.230	0.790 - 1.120	0.790 - 1.230	0.790 - 1.230

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Intl. Normalized Ratio	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.0032 (0.04372)	0.0117 (0.05512)	0.0140 (0.06585)	0.0155 (0.05827)	0.0137 (0.05961)	0.0111 (0.05620)
		Median	0	0.0100	0	0.0150	0.0100	0.0050
		Q1 - Q3	-0.0200 - 0.0300	-0.0300 - 0.0300	-0.0200 - 0.0400	-0.0250 - 0.0495	-0.0200 - 0.0400	-0.0200 - 0.0400
		Min - Max	-0.140 - 0.170	-0.080 - 0.290	-0.100 - 0.320	-0.130 - 0.160	-0.130 - 0.320	-0.140 - 0.320
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	0.9518 (0.06543)	0.9466 (0.05901)	0.9482 (0.06101)	0.9583 (0.06656)	0.9509 (0.06207)	0.9511 (0.06280)
		Median	0.9500	0.9500	0.9500	0.9500	0.9500	0.9500
		Q1 - Q3	0.9100 - 0.9900	0.9000 - 0.9800	0.9100 - 0.9800	0.9000 - 1.0200	0.9000 - 0.9900	0.9100 - 0.9900
		Min - Max	0.810 - 1.160	0.830 - 1.090	0.800 - 1.080	0.840 - 1.100	0.800 - 1.100	0.800 - 1.160
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.0020 (0.05013)	-0.0012 (0.04290)	0.0053 (0.05154)	0.0103 (0.05430)	0.0047 (0.04965)	0.0040 (0.04968)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.0200 - 0.0400	-0.0300 - 0.0200	-0.0300 - 0.0300	-0.0200 - 0.0400	-0.0300 - 0.0300	-0.0300 - 0.0300
		Min - Max	-0.110 - 0.200	-0.080 - 0.110	-0.100 - 0.170	-0.120 - 0.160	-0.120 - 0.170	-0.120 - 0.200

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Intl. Normalized Ratio	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	0.9538 (0.07154)	0.9491 (0.05566)	0.9529 (0.07301)	0.9508 (0.05832)	0.9509 (0.06243)	0.9516 (0.06469)
		Median	0.9400	0.9500	0.9500	0.9600	0.9500	0.9500
		Q1 - Q3	0.9000 - 1.0100	0.9150 - 0.9850	0.8900 - 0.9900	0.9100 - 0.9900	0.9100 - 0.9900	0.9000 - 0.9900
		Min - Max	0.840 - 1.230	0.830 - 1.070	0.820 - 1.150	0.790 - 1.070	0.790 - 1.150	0.790 - 1.230
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.0040 (0.06110)	0.0013 (0.05166)	0.0095 (0.05444)	0.0029 (0.04168)	0.0045 (0.04954)	0.0044 (0.05254)
		Median	0	0	0	0.0100	0.0050	0
		Q1 - Q3	-0.0400 - 0.0300	-0.0300 - 0.0400	-0.0200 - 0.0300	-0.0200 - 0.0300	-0.0300 - 0.0300	-0.0300 - 0.0300
		Min - Max	-0.090 - 0.320	-0.120 - 0.130	-0.090 - 0.190	-0.090 - 0.080	-0.120 - 0.190	-0.120 - 0.320
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	0.9508 (0.07249)	0.9425 (0.05743)	0.9453 (0.06638)	0.9611 (0.07699)	0.9494 (0.06729)	0.9497 (0.06847)
		Median	0.9500	0.9500	0.9500	0.9550	0.9500	0.9500
		Q1 - Q3	0.8900 - 0.9950	0.9000 - 0.9900	0.8900 - 1.0000	0.9100 - 1.0200	0.9000 - 1.0000	0.8900 - 1.0000
		Min - Max	0.840 - 1.200	0.830 - 1.080	0.800 - 1.100	0.780 - 1.150	0.780 - 1.150	0.780 - 1.200

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.1
Summary of Coagulation
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Prothrombin Intl. Normalized Ratio	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.0003 (0.06024)	-0.0058 (0.04345)	0.0024 (0.04749)	0.0119 (0.04735)	0.0026 (0.04643)	0.0020 (0.05008)
		Median	-0.0050	0	0	0.0100	0	0
		Q1 - Q3	-0.0500 - 0.0350	-0.0400 - 0.0200	-0.0300 - 0.0400	-0.0300 - 0.0400	-0.0300 - 0.0300	-0.0400 - 0.0300
		Min - Max	-0.090 - 0.160	-0.110 - 0.100	-0.090 - 0.100	-0.090 - 0.130	-0.110 - 0.130	-0.110 - 0.160
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	0.9502 (0.05967)	0.9440 (0.05897)	0.9368 (0.06783)	0.9590 (0.07398)	0.9464 (0.06731)	0.9473 (0.06543)
		Median	0.9550	0.9350	0.9250	0.9600	0.9400	0.9400
		Q1 - Q3	0.9000 - 1.0000	0.9000 - 0.9750	0.8900 - 0.9800	0.9100 - 1.0200	0.9000 - 0.9900	0.9000 - 0.9900
		Min - Max	0.820 - 1.070	0.850 - 1.060	0.790 - 1.120	0.830 - 1.180	0.790 - 1.180	0.790 - 1.180
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.0002 (0.05141)	-0.0046 (0.04592)	-0.0073 (0.05448)	0.0095 (0.04963)	-0.0010 (0.05037)	-0.0007 (0.05053)
		Median	0	-0.0050	-0.0200	0	-0.0100	0
		Q1 - Q3	-0.0250 - 0.0300	-0.0350 - 0.0300	-0.0400 - 0.0300	-0.0200 - 0.0300	-0.0300 - 0.0300	-0.0300 - 0.0300
		Min - Max	-0.170 - 0.120	-0.150 - 0.100	-0.110 - 0.140	-0.080 - 0.140	-0.150 - 0.140	-0.170 - 0.140

Data Source: Listing 16.2.8.1.5
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Time (s)	D15	Placebo (N=69)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	1 (1.4)	0	68 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (97.1)	2 (2.9)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Time (s)	D15	Combined GS1-144 (N=207)	Normal	199 (96.6)	2 (1.0)	0	201 (97.6)
			Abnormal NCS	4 (1.9)	1 (0.5)	0	5 (2.4)
			Abnormal CS	0	0	0	0
			Total	203 (98.5)	3 (1.5)	0	206 (100)
	D29	Placebo (N=69)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	2 (2.9)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Time (s)	D29	GS1-144 30 mg BID (N=68)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	198 (97.5)	3 (1.5)	0	201 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	200 (98.5)	3 (1.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	2 (2.9)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Time (s)	D43	GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		Combined GS1-144 (N=207)	Normal	191 (95.5)	3 (1.5)	0	194 (97.0)
			Abnormal NCS	6 (3.0)	0	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	197 (98.5)	3 (1.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	61 (93.8)	1 (1.5)	0	62 (95.4)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Time (s)	D57	GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	0	0	60 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.4)	2 (1.0)	0	190 (96.4)
			Abnormal NCS	6 (3.0)	1 (0.5)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Time (s)	D71	Placebo (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (93.8)	1 (1.5)	0	62 (95.4)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Time (s)	D71	Combined GS1-144 (N=207)	Normal	188 (95.9)	3 (1.5)	0	191 (97.4)
			Abnormal NCS	5 (2.6)	0	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	193 (98.5)	3 (1.5)	0	196 (100)
	D85	Placebo (N=69)	Normal	61 (95.3)	0	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Prothrombin Time (s)	D85	GS1-144 30 mg BID (N=68)	Normal	60 (96.8)	0	0	60 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	62 (100)	0	0	62 (100)
		Combined GS1-144 (N=207)	Normal	188 (96.4)	2 (1.0)	0	190 (97.4)
			Abnormal NCS	4 (2.1)	1 (0.5)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	192 (98.5)	3 (1.5)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Time (s)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	1 (1.5)	0	62 (93.9)
			Abnormal NCS	4 (6.1)	0	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (95.9)	2 (1.0)	0	191 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)
Activated Partial Thromboplastin Time (s)	D15	Placebo (N=69)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Activated Partial Thromboplastin Time (s)	D15	GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	1 (1.4)	0	68 (97.1)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (97.1)	2 (2.9)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	2 (2.9)	0	64 (94.1)
			Abnormal NCS	0	4 (5.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	62 (91.2)	6 (8.8)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	195 (94.7)	3 (1.5)	0	198 (96.1)
			Abnormal NCS	2 (1.0)	6 (2.9)	0	8 (3.9)
			Abnormal CS	0	0	0	0
			Total	197 (95.6)	9 (4.4)	0	206 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Activated Partial Thromboplastin Time (s)	D29	Placebo (N=69)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	2 (2.9)	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	61 (91.0)	6 (9.0)	0	67 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Activated Partial Thromboplastin Time (s)	D29	Combined GS1-144 (N=207)	Normal	191 (94.1)	5 (2.5)	0	196 (96.6)
			Abnormal NCS	3 (1.5)	4 (2.0)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	194 (95.6)	9 (4.4)	0	203 (100)
	D43	Placebo (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Activated Partial Thromboplastin Time (s)	D43	GS1-144 30 mg BID (N=68)	Normal	57 (89.1)	4 (6.3)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	190 (95.0)	5 (2.5)	0	195 (97.5)
			Abnormal NCS	1 (0.5)	4 (2.0)	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	191 (95.5)	9 (4.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Activated Partial Thromboplastin Time (s)	D57	GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	0	0	62 (93.9)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	3 (4.8)	0	59 (93.7)
			Abnormal NCS	1 (1.6)	3 (4.8)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (92.9)	3 (1.5)	0	186 (94.4)
			Abnormal NCS	5 (2.5)	6 (3.0)	0	11 (5.6)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	9 (4.6)	0	197 (100)
	D71	Placebo (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Activated Partial Thromboplastin Time (s)	D71	GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	2 (3.2)	0	59 (93.7)
			Abnormal NCS	0	4 (6.3)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.9)	3 (1.5)	0	189 (96.4)
			Abnormal NCS	1 (0.5)	6 (3.1)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	187 (95.4)	9 (4.6)	0	196 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Activated Partial Thromboplastin Time (s)	D85	Placebo (N=69)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (88.7)	4 (6.5)	0	59 (95.2)
			Abnormal NCS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	56 (90.3)	6 (9.7)	0	62 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Activated Partial Thromboplastin Time (s)	D85	Combined GS1-144 (N=207)	Normal	185 (94.9)	5 (2.6)	0	190 (97.4)
			Abnormal NCS	1 (0.5)	4 (2.1)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	186 (95.4)	9 (4.6)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	0	2 (3.1)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Activated Partial Thromboplastin Time (s)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	5 (7.9)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.4)	6 (3.0)	0	192 (97.5)
			Abnormal NCS	2 (1.0)	3 (1.5)	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	9 (4.6)	0	197 (100)
Thrombin Time (s)	D15	Placebo (N=69)	Normal	68 (98.6)	1 (1.4)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	1 (1.4)	0	70 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (98.6)	1 (1.4)	0	70 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thrombin Time (s)	D15	GS1-144 60 mg QD (N=69)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	204 (99.0)	1 (0.5)	0	205 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	205 (99.5)	1 (0.5)	0	206 (100)
	D29	Placebo (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thrombin Time (s)	D29	GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	1 (1.4)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	201 (99.0)	1 (0.5)	0	202 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	202 (99.5)	1 (0.5)	0	203 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Thrombin Time (s)	D43	Placebo (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Thrombin Time (s)	D43	Combined GS1-144 (N=207)	Normal	197 (98.5)	1 (0.5)	0	198 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	199 (99.5)	1 (0.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thrombin Time (s)	D57	GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (98.0)	1 (0.5)	0	194 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	196 (99.5)	1 (0.5)	0	197 (100)
	D71	Placebo (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Thrombin Time (s)	D71	GS1-144 60 mg QD (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (99.0)	1 (0.5)	0	195 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	195 (99.5)	1 (0.5)	0	196 (100)
	D85	Placebo (N=69)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thrombin Time (s)	D85	GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (100)	0	0	62 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (100)	0	0	62 (100)
		Combined GS1-144 (N=207)	Normal	193 (99.0)	1 (0.5)	0	194 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	194 (99.5)	1 (0.5)	0	195 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Thrombin Time (s)	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thrombin Time (s)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	193 (98.0)	1 (0.5)	0	194 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	196 (99.5)	1 (0.5)	0	197 (100)
Fibrinogen (g/L)	D15	Placebo (N=69)	Normal	59 (85.5)	1 (1.4)	0	60 (87.0)
			Abnormal NCS	4 (5.8)	4 (5.8)	0	8 (11.6)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	63 (91.3)	6 (8.7)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (90.0)	2 (2.9)	0	65 (92.9)
			Abnormal NCS	2 (2.9)	3 (4.3)	0	5 (7.1)
			Abnormal CS	0	0	0	0
			Total	65 (92.9)	5 (7.1)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	2 (2.9)	0	62 (91.2)
			Abnormal NCS	3 (4.4)	2 (2.9)	0	5 (7.4)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Fibrinogen (g/L)	D15	GS1-144 30 mg BID (N=68)	Normal	60 (88.2)	2 (2.9)	0	62 (91.2)
			Abnormal NCS	5 (7.4)	0	0	5 (7.4)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	183 (88.8)	6 (2.9)	0	189 (91.7)
			Abnormal NCS	10 (4.9)	5 (2.4)	0	15 (7.3)
			Abnormal CS	2 (1.0)	0	0	2 (1.0)
			Total	195 (94.7)	11 (5.3)	0	206 (100)
	D29	Placebo (N=69)	Normal	58 (86.6)	4 (6.0)	0	62 (92.5)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	61 (91.0)	6 (9.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	2 (2.9)	0	65 (94.2)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Fibrinogen (g/L)	D29	GS1-144 60 mg QD (N=69)	Normal	58 (86.6)	1 (1.5)	0	59 (88.1)
			Abnormal NCS	5 (7.5)	2 (3.0)	0	7 (10.4)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	182 (89.7)	4 (2.0)	0	186 (91.6)
			Abnormal NCS	11 (5.4)	5 (2.5)	0	16 (7.9)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	194 (95.6)	9 (4.4)	0	203 (100)
	D43	Placebo (N=69)	Normal	55 (83.3)	2 (3.0)	0	57 (86.4)
			Abnormal NCS	5 (7.6)	4 (6.1)	0	9 (13.6)
			Abnormal CS	0	0	0	0
			Total	60 (90.9)	6 (9.1)	0	66 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Fibrinogen (g/L)	D43	GS1-144 30 mg QD (N=70)	Normal	58 (84.1)	2 (2.9)	0	60 (87.0)
			Abnormal NCS	7 (10.1)	2 (2.9)	0	9 (13.0)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	4 (5.8)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (86.6)	1 (1.5)	0	59 (88.1)
			Abnormal NCS	6 (9.0)	2 (3.0)	0	8 (11.9)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	176 (88.0)	4 (2.0)	0	180 (90.0)
			Abnormal NCS	15 (7.5)	5 (2.5)	0	20 (10.0)
			Abnormal CS	0	0	0	0
			Total	191 (95.5)	9 (4.5)	0	200 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Fibrinogen (g/L)	D57	Placebo (N=69)	Normal	55 (84.6)	2 (3.1)	0	57 (87.7)
			Abnormal NCS	4 (6.2)	4 (6.2)	0	8 (12.3)
			Abnormal CS	0	0	0	0
			Total	59 (90.8)	6 (9.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (88.2)	1 (1.5)	0	61 (89.7)
			Abnormal NCS	4 (5.9)	3 (4.4)	0	7 (10.3)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	55 (83.3)	1 (1.5)	0	56 (84.8)
			Abnormal NCS	8 (12.1)	2 (3.0)	0	10 (15.2)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	1 (1.6)	0	57 (90.5)
			Abnormal NCS	5 (7.9)	1 (1.6)	0	6 (9.5)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Fibrinogen (g/L)	D57	Combined GS1-144 (N=207)	Normal	171 (86.8)	3 (1.5)	0	174 (88.3)
			Abnormal NCS	17 (8.6)	6 (3.0)	0	23 (11.7)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	9 (4.6)	0	197 (100)
	D71	Placebo (N=69)	Normal	55 (84.6)	4 (6.2)	0	59 (90.8)
			Abnormal NCS	4 (6.2)	2 (3.1)	0	6 (9.2)
			Abnormal CS	0	0	0	0
			Total	59 (90.8)	6 (9.2)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	4 (5.9)	0	63 (92.6)
			Abnormal NCS	5 (7.4)	0	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	53 (81.5)	0	0	53 (81.5)
			Abnormal NCS	8 (12.3)	3 (4.6)	0	11 (16.9)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	62 (95.4)	3 (4.6)	0	65 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Fibrinogen (g/L)	D71	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	0	60 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	170 (86.7)	6 (3.1)	0	176 (89.8)
			Abnormal NCS	16 (8.2)	3 (1.5)	0	19 (9.7)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	187 (95.4)	9 (4.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	51 (79.7)	2 (3.1)	0	53 (82.8)
			Abnormal NCS	7 (10.9)	4 (6.3)	0	11 (17.2)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (88.1)	2 (3.0)	0	61 (91.0)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (94.0)	4 (6.0)	0	67 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Fibrinogen (g/L)	D85	GS1-144 60 mg QD (N=69)	Normal	56 (84.8)	1 (1.5)	0	57 (86.4)
			Abnormal NCS	7 (10.6)	2 (3.0)	0	9 (13.6)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (90.3)	1 (1.6)	0	57 (91.9)
			Abnormal NCS	4 (6.5)	1 (1.6)	0	5 (8.1)
			Abnormal CS	0	0	0	0
			Total	60 (96.8)	2 (3.2)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	171 (87.7)	4 (2.1)	0	175 (89.7)
			Abnormal NCS	14 (7.2)	5 (2.6)	0	19 (9.7)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	186 (95.4)	9 (4.6)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	55 (85.9)	1 (1.6)	0	56 (87.5)
			Abnormal NCS	3 (4.7)	5 (7.8)	0	8 (12.5)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Fibrinogen (g/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	1 (1.5)	0	60 (88.2)
			Abnormal NCS	5 (7.4)	3 (4.4)	0	8 (11.8)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	0	60 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.4)	5 (2.5)	0	183 (92.9)
			Abnormal NCS	10 (5.1)	4 (2.0)	0	14 (7.1)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	9 (4.6)	0	197 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Intl. Normalized Ratio	D15	Placebo (N=69)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (98.6)	0	0	69 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Intl. Normalized Ratio	D15	Combined GS1-144 (N=207)	Normal	202 (98.1)	1 (0.5)	0	203 (98.5)
			Abnormal NCS	1 (0.5)	2 (1.0)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	203 (98.5)	3 (1.5)	0	206 (100)
	D29	Placebo (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Intl. Normalized Ratio	D29	GS1-144 30 mg BID (N=68)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	200 (98.5)	2 (1.0)	0	202 (99.5)
			Abnormal NCS	0	1 (0.5)	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	200 (98.5)	3 (1.5)	0	203 (100)
	D43	Placebo (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Intl. Normalized Ratio	D43	GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (95.3)	1 (1.6)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	192 (96.0)	2 (1.0)	0	194 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	197 (98.5)	3 (1.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Intl. Normalized Ratio	D57	GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (97.5)	2 (1.0)	0	194 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Prothrombin Intl. Normalized Ratio	D71	Placebo (N=69)	Normal	62 (95.4)	0	0	62 (95.4)
			Abnormal NCS	2 (3.1)	1 (1.5)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	0	0	63 (96.9)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Intl. Normalized Ratio	D71	Combined GS1-144 (N=207)	Normal	190 (96.9)	1 (0.5)	0	191 (97.4)
			Abnormal NCS	3 (1.5)	2 (1.0)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	193 (98.5)	3 (1.5)	0	196 (100)
	D85	Placebo (N=69)	Normal	61 (95.3)	0	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Prothrombin Intl. Normalized Ratio	D85	GS1-144 30 mg BID (N=68)	Normal	58 (93.5)	2 (3.2)	0	60 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (96.8)	2 (3.2)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	188 (96.4)	3 (1.5)	0	191 (97.9)
			Abnormal NCS	4 (2.1)	0	0	4 (2.1)
			Abnormal CS	0	0	0	0
			Total	192 (98.5)	3 (1.5)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.2
Shift of Coagulation by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Prothrombin Intl. Normalized Ratio	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	1 (1.6)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (96.4)	2 (1.0)	0	192 (97.5)
			Abnormal NCS	4 (2.0)	1 (0.5)	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	194 (98.5)	3 (1.5)	0	197 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.3.3
Shift of Coagulation by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Time (s)	Placebo (N=69)	Normal	61 (88.4)	0	0	61 (88.4)
		Abnormal NCS	7 (10.1)	1 (1.4)	0	8 (11.6)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	1 (1.4)	0	65 (92.9)
		Abnormal NCS	4 (5.7)	1 (1.4)	0	5 (7.1)
		Abnormal CS	0	0	0	0
		Total	68 (97.1)	2 (2.9)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	56 (82.4)	1 (1.5)	0	57 (83.8)
		Abnormal NCS	11 (16.2)	0	0	11 (16.2)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	61 (89.7)	0	0	61 (89.7)
		Abnormal NCS	7 (10.3)	0	0	7 (10.3)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.3.3
Shift of Coagulation by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Time (s)	Combined GS1-144 (N=207)	Normal	181 (87.9)	2 (1.0)	0	183 (88.8)
		Abnormal NCS	22 (10.7)	1 (0.5)	0	23 (11.2)
		Abnormal CS	0	0	0	0
		Total	203 (98.5)	3 (1.5)	0	206 (100)
Activated Partial Thromboplastin Time (s)	Placebo (N=69)	Normal	64 (92.8)	0	0	64 (92.8)
		Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.2)
		Abnormal CS	0	0	0	0
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	0	0	64 (91.4)
		Abnormal NCS	4 (5.7)	2 (2.9)	0	6 (8.6)
		Abnormal CS	0	0	0	0
		Total	68 (97.1)	2 (2.9)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.3.3
Shift of Coagulation by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Activated Partial Thromboplastin Time (s)	GS1-144 30 mg BID (N=68)	Normal	58 (85.3)	2 (2.9)	0	60 (88.2)
		Abnormal NCS	3 (4.4)	4 (5.9)	0	7 (10.3)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	62 (91.2)	6 (8.8)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	186 (90.3)	2 (1.0)	0	188 (91.3)
		Abnormal NCS	10 (4.9)	7 (3.4)	0	17 (8.3)
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	197 (95.6)	9 (4.4)	0	206 (100)
Thrombin Time (s)	Placebo (N=69)	Normal	68 (98.6)	1 (1.4)	0	69 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	1 (1.4)	0	67 (95.7)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	0	0	0	0
		Total	69 (98.6)	1 (1.4)	0	70 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.3.3
Shift of Coagulation by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thrombin Time (s)	GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	0	0	65 (95.6)
		Abnormal NCS	3 (4.4)	0	0	3 (4.4)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	0	0	65 (95.6)
		Abnormal NCS	3 (4.4)	0	0	3 (4.4)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	196 (95.1)	1 (0.5)	0	197 (95.6)
		Abnormal NCS	9 (4.4)	0	0	9 (4.4)
		Abnormal CS	0	0	0	0
		Total	205 (99.5)	1 (0.5)	0	206 (100)
Fibrinogen (g/L)	Placebo (N=69)	Normal	45 (65.2)	0	0	45 (65.2)
		Abnormal NCS	18 (26.1)	5 (7.2)	0	23 (33.3)
		Abnormal CS	0	1 (1.4)	0	1 (1.4)
		Total	63 (91.3)	6 (8.7)	0	69 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.3.3
Shift of Coagulation by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Fibrinogen (g/L)	GS1-144 30 mg QD (N=70)	Normal	47 (67.1)	1 (1.4)	0	48 (68.6)
		Abnormal NCS	17 (24.3)	4 (5.7)	0	21 (30.0)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	65 (92.9)	5 (7.1)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	44 (64.7)	0	0	44 (64.7)
		Abnormal NCS	18 (26.5)	4 (5.9)	0	22 (32.4)
		Abnormal CS	2 (2.9)	0	0	2 (2.9)
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	49 (72.1)	1 (1.5)	0	50 (73.5)
		Abnormal NCS	16 (23.5)	1 (1.5)	0	17 (25.0)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	140 (68.0)	2 (1.0)	0	142 (68.9)
		Abnormal NCS	51 (24.8)	9 (4.4)	0	60 (29.1)
		Abnormal CS	4 (1.9)	0	0	4 (1.9)
		Total	195 (94.7)	11 (5.3)	0	206 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.3.3
Shift of Coagulation by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Intl. Normalized Ratio	Placebo (N=69)	Normal	64 (92.8)	0	0	64 (92.8)
		Abnormal NCS	4 (5.8)	1 (1.4)	0	5 (7.2)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	0	0	67 (95.7)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	0	0	59 (86.8)
		Abnormal NCS	8 (11.8)	1 (1.5)	0	9 (13.2)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.3.3
Shift of Coagulation by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Prothrombin Intl. Normalized Ratio	Combined GS1-144 (N=207)	Normal	190 (92.2)	0	0	190 (92.2)
		Abnormal NCS	13 (6.3)	3 (1.5)	0	16 (7.8)
		Abnormal CS	0	0	0	0
		Total	203 (98.5)	3 (1.5)	0	206 (100)

Data Source: Listing 16.2.8.1.5
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triiodothyronine, Free (pmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	4.766 (0.4363)	4.861 (0.5601)	4.917 (0.4857)	4.723 (0.5374)	4.834 (0.5325)	4.817 (0.5102)
		Median	4.800	4.887	4.940	4.700	4.870	4.843
		Q1 - Q3	4.400 - 5.050	4.455 - 5.300	4.610 - 5.230	4.265 - 5.153	4.450 - 5.223	4.427 - 5.175
		Min - Max	3.90 - 5.73	3.50 - 6.13	3.70 - 6.70	3.75 - 6.08	3.50 - 6.70	3.50 - 6.70
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	4.830 (0.5478)	4.838 (0.5528)	4.863 (0.4942)	4.774 (1.0131)	4.825 (0.7208)	4.827 (0.6805)
		Median	4.854	4.860	4.865	4.710	4.793	4.810
		Q1 - Q3	4.500 - 5.070	4.450 - 5.130	4.520 - 5.205	4.270 - 5.049	4.420 - 5.177	4.440 - 5.161
		Min - Max	3.89 - 7.17	3.49 - 6.61	3.40 - 5.88	3.50 - 11.49	3.40 - 11.49	3.40 - 11.49
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.064 (0.4245)	-0.023 (0.4207)	-0.048 (0.4846)	0.051 (0.9149)	-0.007 (0.6416)	0.011 (0.5947)
		Median	0.050	-0.005	-0.046	-0.033	-0.030	0
		Q1 - Q3	-0.170 - 0.250	-0.319 - 0.292	-0.273 - 0.215	-0.375 - 0.305	-0.310 - 0.270	-0.280 - 0.260
		Min - Max	-0.77 - 1.74	-1.20 - 0.74	-2.10 - 1.08	-1.38 - 6.49	-2.10 - 6.49	-2.10 - 6.49

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triiodothyronine, Free (pmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	4.793 (0.5216)	4.858 (0.5374)	4.776 (0.4418)	4.698 (0.6316)	4.778 (0.5437)	4.782 (0.5374)
		Median	4.860	4.800	4.808	4.700	4.790	4.800
		Q1 - Q3	4.350 - 5.140	4.500 - 5.250	4.469 - 5.110	4.190 - 5.120	4.400 - 5.146	4.390 - 5.140
		Min - Max	3.70 - 6.10	3.80 - 6.31	3.70 - 5.88	3.30 - 6.57	3.30 - 6.57	3.30 - 6.57
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.016 (0.4692)	-0.005 (0.4408)	-0.134 (0.5392)	-0.028 (0.4353)	-0.055 (0.4748)	-0.038 (0.4736)
		Median	0.100	-0.020	-0.038	-0.046	-0.030	-0.015
		Q1 - Q3	-0.399 - 0.320	-0.290 - 0.220	-0.340 - 0.160	-0.310 - 0.190	-0.310 - 0.200	-0.320 - 0.266
		Min - Max	-0.91 - 1.28	-1.00 - 0.89	-2.60 - 0.92	-1.01 - 1.16	-2.60 - 1.16	-2.60 - 1.28
	D43	Observed Value						
		n	66	69	67	63	199	265
		Mean (SD)	5.075 (2.0037)	4.826 (0.6917)	4.811 (0.4806)	4.631 (0.5856)	4.759 (0.5970)	4.838 (1.1290)
		Median	4.805	4.800	4.840	4.578	4.800	4.800
		Q1 - Q3	4.440 - 5.120	4.350 - 5.350	4.510 - 5.084	4.140 - 5.090	4.310 - 5.120	4.380 - 5.120
		Min - Max	3.84 - 20.56	3.39 - 7.13	3.60 - 6.46	3.57 - 6.02	3.39 - 7.13	3.39 - 20.56

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triiodothyronine, Free (pmol/L)	D43	Change from Baseline						
		n	66	69	67	63	199	265
		Mean (SD)	0.300 (2.0540)	-0.037 (0.5718)	-0.100 (0.5156)	-0.084 (0.5076)	-0.073 (0.5313)	0.020 (1.1299)
		Median	0.061	-0.031	-0.080	-0.120	-0.090	-0.020
		Q1 - Q3	-0.160 - 0.310	-0.338 - 0.260	-0.470 - 0.209	-0.370 - 0.238	-0.390 - 0.238	-0.330 - 0.260
		Min - Max	-1.06 - 16.36	-1.21 - 2.14	-1.90 - 0.99	-1.14 - 0.91	-1.90 - 2.14	-1.90 - 16.36
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	4.842 (0.5946)	4.792 (0.5300)	4.786 (0.6080)	4.619 (0.5955)	4.735 (0.5806)	4.761 (0.5848)
		Median	4.878	4.900	4.690	4.460	4.727	4.729
		Q1 - Q3	4.409 - 5.220	4.442 - 5.166	4.430 - 5.030	4.160 - 5.110	4.340 - 5.110	4.340 - 5.150
		Min - Max	3.58 - 6.14	3.27 - 5.74	3.86 - 7.53	3.57 - 6.17	3.27 - 7.53	3.27 - 7.53
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.065 (0.5191)	-0.071 (0.4548)	-0.117 (0.6014)	-0.105 (0.4326)	-0.097 (0.5002)	-0.057 (0.5088)
		Median	0.061	-0.111	-0.100	-0.130	-0.110	-0.100
		Q1 - Q3	-0.280 - 0.324	-0.400 - 0.215	-0.315 - 0.120	-0.390 - 0.240	-0.390 - 0.200	-0.330 - 0.240
		Min - Max	-1.34 - 1.40	-1.27 - 1.30	-2.30 - 2.30	-1.41 - 0.71	-2.30 - 2.30	-2.30 - 2.30

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triiodothyronine, Free (pmol/L)	D71	Observed Value						
		n	65	68	65	62	195	260
		Mean (SD)	4.789 (0.5052)	4.827 (0.5742)	4.831 (0.4737)	4.741 (0.6722)	4.801 (0.5759)	4.798 (0.5581)
		Median	4.870	4.770	4.820	4.680	4.780	4.795
		Q1 - Q3	4.340 - 5.180	4.369 - 5.155	4.550 - 5.120	4.200 - 5.170	4.350 - 5.150	4.349 - 5.155
		Min - Max	3.60 - 5.78	3.59 - 6.21	3.60 - 6.07	3.60 - 6.24	3.59 - 6.24	3.59 - 6.24
	D71	Change from Baseline						
		n	65	68	65	62	195	260
		Mean (SD)	0.011 (0.3663)	-0.036 (0.4779)	-0.075 (0.5504)	0.019 (0.4892)	-0.031 (0.5055)	-0.021 (0.4742)
		Median	-0.030	-0.073	-0.046	-0.013	-0.040	-0.035
		Q1 - Q3	-0.270 - 0.260	-0.344 - 0.261	-0.288 - 0.240	-0.300 - 0.242	-0.323 - 0.242	-0.309 - 0.250
		Min - Max	-0.60 - 0.95	-0.90 - 1.83	-3.10 - 1.10	-1.15 - 1.25	-3.10 - 1.83	-3.10 - 1.83
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	4.807 (0.5427)	4.785 (0.5788)	4.722 (0.4269)	4.645 (0.5771)	4.719 (0.5320)	4.741 (0.5350)
		Median	4.918	4.762	4.726	4.662	4.716	4.760
		Q1 - Q3	4.455 - 5.171	4.370 - 5.084	4.460 - 5.000	4.200 - 5.084	4.370 - 5.050	4.400 - 5.081
		Min - Max	3.31 - 5.91	3.60 - 6.97	3.90 - 5.75	3.61 - 6.27	3.60 - 6.97	3.31 - 6.97

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Triiodothyronine, Free (pmol/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.020 (0.4846)	-0.068 (0.4695)	-0.180 (0.4916)	-0.074 (0.4547)	-0.108 (0.4730)	-0.076 (0.4781)
		Median	-0.015	-0.110	-0.200	-0.195	-0.169	-0.100
		Q1 - Q3	-0.295 - 0.311	-0.369 - 0.160	-0.440 - 0.110	-0.415 - 0.240	-0.400 - 0.190	-0.380 - 0.220
		Min - Max	-1.15 - 1.48	-1.50 - 1.64	-2.60 - 0.95	-1.09 - 0.91	-2.60 - 1.64	-2.60 - 1.64
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	4.779 (0.5563)	4.732 (0.5988)	4.696 (0.4253)	4.636 (0.7917)	4.689 (0.6184)	4.711 (0.6039)
		Median	4.925	4.736	4.718	4.420	4.700	4.740
		Q1 - Q3	4.320 - 5.130	4.300 - 5.176	4.460 - 5.000	4.132 - 5.065	4.260 - 5.054	4.280 - 5.070
		Min - Max	3.55 - 5.90	3.10 - 6.14	3.69 - 5.61	3.70 - 9.23	3.10 - 9.23	3.10 - 9.23
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.007 (0.4140)	-0.121 (0.4846)	-0.217 (0.5043)	-0.079 (0.6516)	-0.140 (0.5498)	-0.107 (0.5222)
		Median	-0.005	-0.100	-0.174	-0.110	-0.120	-0.100
		Q1 - Q3	-0.290 - 0.262	-0.341 - 0.159	-0.461 - 0.073	-0.410 - 0.160	-0.400 - 0.123	-0.384 - 0.170
		Min - Max	-1.23 - 1.00	-1.60 - 0.70	-2.60 - 0.74	-1.22 - 3.59	-2.60 - 3.59	-2.60 - 3.59

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyroxine, Free (pmol/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	14.387 (2.3234)	14.412 (2.3037)	15.185 (2.8364)	14.371 (2.4200)	14.656 (2.5454)	14.589 (2.4903)
		Median	14.070	14.000	14.560	14.430	14.430	14.400
		Q1 - Q3	12.615 - 15.833	12.872 - 16.260	13.020 - 16.700	12.585 - 15.950	12.872 - 16.300	12.810 - 16.280
		Min - Max	9.02 - 21.00	9.89 - 19.82	10.69 - 25.76	9.26 - 21.95	9.26 - 25.76	9.02 - 25.76
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	14.538 (2.1837)	14.384 (2.1415)	14.774 (2.4352)	14.440 (2.2306)	14.531 (2.2666)	14.533 (2.2422)
		Median	14.803	14.065	14.811	14.538	14.538	14.650
		Q1 - Q3	13.001 - 15.870	12.911 - 15.833	13.000 - 16.388	12.635 - 16.055	12.900 - 16.080	12.900 - 16.020
		Min - Max	9.59 - 18.72	9.33 - 19.18	9.54 - 21.83	9.87 - 19.18	9.33 - 21.83	9.33 - 21.83
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.150 (1.3746)	-0.028 (1.2712)	-0.320 (1.5356)	0.069 (1.8359)	-0.092 (1.5631)	-0.032 (1.5193)
		Median	0.300	-0.145	-0.179	-0.124	-0.129	-0.040
		Q1 - Q3	-0.900 - 1.030	-0.800 - 0.850	-1.025 - 0.500	-0.895 - 0.865	-0.950 - 0.760	-0.930 - 0.800
		Min - Max	-3.34 - 4.37	-2.35 - 3.35	-4.89 - 4.35	-4.50 - 6.75	-4.89 - 6.75	-4.89 - 6.75

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyroxine, Free (pmol/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	14.390 (2.2022)	14.161 (2.0959)	14.762 (2.3333)	14.373 (2.1664)	14.429 (2.2031)	14.419 (2.1988)
		Median	14.100	14.110	14.610	14.740	14.440	14.418
		Q1 - Q3	13.240 - 16.219	12.620 - 15.446	13.310 - 15.970	12.750 - 15.680	12.830 - 15.800	13.000 - 15.860
		Min - Max	8.14 - 18.83	10.05 - 19.23	9.93 - 21.74	9.87 - 20.03	9.87 - 21.74	8.14 - 21.74
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.048 (1.3491)	-0.261 (1.3881)	-0.240 (1.6892)	0.006 (1.6101)	-0.166 (1.5629)	-0.113 (1.5131)
		Median	0.200	-0.300	-0.100	0.100	-0.129	0
		Q1 - Q3	-0.770 - 1.010	-0.950 - 0.600	-1.280 - 0.901	-1.030 - 0.810	-1.190 - 0.810	-1.000 - 0.901
		Min - Max	-3.31 - 2.63	-4.51 - 2.34	-4.02 - 4.25	-4.65 - 3.73	-4.65 - 4.25	-4.65 - 4.25
	D43	Observed Value						
		n	66	69	67	63	199	265
		Mean (SD)	14.660 (2.2696)	14.651 (2.4090)	14.902 (2.5167)	14.226 (2.3789)	14.601 (2.4398)	14.616 (2.3945)
		Median	14.408	14.760	14.740	14.250	14.740	14.540
		Q1 - Q3	12.808 - 16.760	13.150 - 16.219	13.450 - 16.470	12.690 - 15.280	13.080 - 16.130	13.001 - 16.219
		Min - Max	10.23 - 19.10	9.57 - 20.85	7.98 - 23.65	9.63 - 21.60	7.98 - 23.65	7.98 - 23.65

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyroxine, Free (pmol/L)	D43	Change from Baseline						
		n	66	69	67	63	199	265
		Mean (SD)	0.315 (1.6515)	0.229 (1.4134)	-0.100 (1.4050)	-0.053 (1.6847)	0.029 (1.5015)	0.100 (1.5420)
		Median	0.380	0	-0.200	-0.230	-0.070	0.020
		Q1 - Q3	-0.510 - 1.210	-0.515 - 1.100	-0.900 - 1.030	-1.000 - 0.850	-0.810 - 1.030	-0.780 - 1.090
		Min - Max	-3.91 - 5.54	-3.09 - 3.60	-3.40 - 2.70	-5.42 - 4.38	-5.42 - 4.38	-5.42 - 5.54
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	14.534 (2.3721)	14.606 (2.3038)	14.903 (2.4404)	14.610 (2.1992)	14.707 (2.3106)	14.664 (2.3226)
		Median	14.250	14.568	14.916	14.700	14.700	14.625
		Q1 - Q3	12.970 - 15.600	12.870 - 15.981	13.240 - 16.450	12.800 - 16.270	13.110 - 16.200	13.070 - 16.090
		Min - Max	9.64 - 20.40	9.26 - 21.88	9.67 - 23.89	10.14 - 19.01	9.26 - 23.89	9.26 - 23.89
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.152 (1.6362)	0.175 (1.4347)	-0.132 (1.5749)	0.336 (1.5203)	0.123 (1.5149)	0.131 (1.5427)
		Median	0.300	0.220	-0.065	0.232	0.020	0.145
		Q1 - Q3	-0.772 - 0.901	-0.605 - 1.130	-0.901 - 0.900	-0.550 - 1.416	-0.710 - 1.100	-0.772 - 1.070
		Min - Max	-3.82 - 4.38	-3.60 - 3.09	-5.66 - 3.48	-3.07 - 4.58	-5.66 - 4.58	-5.66 - 4.58

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyroxine, Free (pmol/L)	D71	Observed Value						
		n	65	68	65	62	195	260
		Mean (SD)	14.321 (2.3754)	14.330 (2.2298)	14.937 (2.4324)	14.562 (2.2889)	14.606 (2.3195)	14.535 (2.3323)
		Median	14.100	14.159	14.810	14.275	14.500	14.355
		Q1 - Q3	12.615 - 15.720	12.642 - 15.941	13.400 - 16.347	13.090 - 16.050	13.020 - 16.170	12.935 - 16.095
		Min - Max	8.45 - 18.40	10.04 - 19.82	8.87 - 21.94	10.18 - 20.60	8.87 - 21.94	8.45 - 21.94
	D71	Change from Baseline						
		n	65	68	65	62	195	260
		Mean (SD)	-0.061 (1.8002)	-0.101 (1.4838)	-0.116 (1.6620)	0.255 (1.6985)	0.007 (1.6148)	-0.010 (1.6598)
		Median	0.060	0.010	-0.240	0.515	0.070	0.067
		Q1 - Q3	-1.070 - 1.200	-0.920 - 0.565	-1.200 - 1.110	-0.644 - 1.000	-0.990 - 1.000	-0.995 - 1.043
		Min - Max	-4.95 - 3.48	-4.87 - 3.10	-3.82 - 4.21	-3.75 - 5.41	-4.87 - 5.41	-4.95 - 5.41
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	14.369 (2.3745)	14.253 (2.1307)	14.788 (2.3076)	14.358 (2.1148)	14.467 (2.1885)	14.443 (2.2316)
		Median	13.886	14.288	15.000	14.358	14.500	14.430
		Q1 - Q3	12.750 - 16.305	12.400 - 16.090	13.140 - 16.100	12.670 - 15.910	12.743 - 16.090	12.743 - 16.090
		Min - Max	9.86 - 20.00	10.27 - 18.92	9.75 - 21.73	9.42 - 18.66	9.42 - 21.73	9.42 - 21.73

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyroxine, Free (pmol/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	-0.013 (1.7282)	-0.124 (1.4930)	-0.247 (1.6923)	0.086 (1.6419)	-0.099 (1.6075)	-0.077 (1.6352)
		Median	0.119	0.250	-0.310	0.050	0	0
		Q1 - Q3	-1.175 - 0.930	-1.030 - 0.900	-1.250 - 1.110	-1.000 - 1.000	-1.110 - 1.000	-1.120 - 1.000
		Min - Max	-4.72 - 3.48	-5.41 - 3.22	-5.02 - 3.22	-3.55 - 4.27	-5.41 - 4.27	-5.41 - 4.27
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	14.395 (2.5942)	14.177 (2.1546)	14.638 (2.3936)	14.317 (2.2114)	14.376 (2.2521)	14.381 (2.3354)
		Median	13.965	14.645	14.700	14.159	14.545	14.288
		Q1 - Q3	12.625 - 16.395	12.050 - 16.026	13.310 - 15.961	13.100 - 15.500	12.743 - 15.833	12.743 - 15.961
		Min - Max	9.30 - 22.00	10.25 - 18.38	9.42 - 22.13	8.50 - 19.89	8.50 - 22.13	8.50 - 22.13
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.012 (1.6496)	-0.190 (1.6824)	-0.382 (1.7078)	0.039 (1.7156)	-0.181 (1.7015)	-0.140 (1.6873)
		Median	-0.090	-0.055	-0.370	0.400	0	0
		Q1 - Q3	-1.175 - 1.185	-1.264 - 0.900	-1.430 - 0.800	-1.070 - 0.950	-1.270 - 0.900	-1.200 - 1.000
		Min - Max	-5.07 - 3.90	-4.35 - 4.25	-5.02 - 3.27	-5.01 - 4.30	-5.02 - 4.30	-5.07 - 4.30

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyrotropin (mIU/L)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	2.154 (1.1961)	2.361 (1.5485)	2.108 (1.1516)	2.278 (1.2711)	2.249 (1.3333)	2.225 (1.2989)
		Median	1.940	1.910	1.780	2.090	1.960	1.955
		Q1 - Q3	1.339 - 2.685	1.170 - 3.250	1.260 - 2.790	1.346 - 2.675	1.240 - 2.960	1.270 - 2.920
		Min - Max	0.28 - 5.94	0.16 - 8.67	0.29 - 5.18	0.47 - 6.51	0.16 - 8.67	0.16 - 8.67
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	2.158 (1.1671)	2.226 (1.3195)	1.988 (1.0705)	2.017 (1.0150)	2.078 (1.1440)	2.098 (1.1482)
		Median	1.890	1.972	1.588	1.853	1.742	1.807
		Q1 - Q3	1.340 - 2.637	1.250 - 2.781	1.289 - 2.420	1.243 - 2.495	1.260 - 2.590	1.271 - 2.630
		Min - Max	0.58 - 6.78	0.58 - 6.59	0.40 - 4.49	0.21 - 5.18	0.21 - 6.59	0.21 - 6.78
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.004 (1.0014)	-0.135 (0.7898)	-0.147 (0.7578)	-0.261 (0.6869)	-0.181 (0.7450)	-0.134 (0.8189)
		Median	-0.087	-0.055	-0.084	-0.154	-0.090	-0.087
		Q1 - Q3	-0.362 - 0.390	-0.391 - 0.260	-0.360 - 0.179	-0.770 - 0.147	-0.562 - 0.181	-0.510 - 0.210
		Min - Max	-2.08 - 4.78	-2.92 - 1.92	-2.97 - 1.56	-2.37 - 1.29	-2.97 - 1.92	-2.97 - 4.78

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyrotropin (mIU/L)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	2.158 (1.2517)	2.272 (1.3699)	1.905 (0.9487)	1.908 (0.9288)	2.031 (1.1126)	2.062 (1.1476)
		Median	1.834	1.870	1.570	1.780	1.780	1.780
		Q1 - Q3	1.399 - 2.654	1.310 - 2.764	1.260 - 2.510	1.213 - 2.513	1.258 - 2.550	1.270 - 2.592
		Min - Max	0.41 - 7.03	0.66 - 7.39	0.13 - 4.29	0.34 - 4.34	0.13 - 7.39	0.13 - 7.39
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.008 (0.8302)	-0.101 (0.9050)	-0.235 (0.7937)	-0.307 (0.7091)	-0.213 (0.8082)	-0.158 (0.8178)
		Median	-0.019	-0.120	-0.150	-0.320	-0.215	-0.131
		Q1 - Q3	-0.322 - 0.334	-0.511 - 0.360	-0.592 - 0.240	-0.714 - 0.127	-0.595 - 0.271	-0.550 - 0.280
		Min - Max	-2.26 - 2.87	-3.12 - 2.71	-2.73 - 1.72	-2.30 - 1.48	-3.12 - 2.71	-3.12 - 2.87
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	1.967 (1.2287)	2.322 (1.5864)	1.954 (1.0958)	2.086 (1.0205)	2.123 (1.2696)	2.085 (1.2591)
		Median	1.709	1.880	1.700	1.961	1.805	1.786
		Q1 - Q3	1.185 - 2.351	1.200 - 2.979	1.250 - 2.328	1.330 - 2.525	1.227 - 2.664	1.214 - 2.540
		Min - Max	0.09 - 6.93	0.43 - 7.81	0.15 - 5.77	0.40 - 4.56	0.15 - 7.81	0.09 - 7.81

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyrotropin (mIU/L)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.166 (0.9515)	-0.051 (1.0146)	-0.186 (0.6527)	-0.160 (0.7708)	-0.131 (0.8275)	-0.140 (0.8582)
		Median	0	-0.050	-0.164	-0.260	-0.120	-0.103
		Q1 - Q3	-0.646 - 0.230	-0.430 - 0.440	-0.560 - 0.160	-0.631 - 0.352	-0.535 - 0.327	-0.570 - 0.310
		Min - Max	-3.19 - 3.14	-3.84 - 2.67	-1.69 - 1.65	-2.27 - 1.56	-3.84 - 2.67	-3.84 - 3.14
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	2.141 (1.4634)	2.264 (1.3047)	2.114 (1.3190)	2.086 (1.0112)	2.157 (1.2200)	2.153 (1.2818)
		Median	1.841	1.940	1.855	1.801	1.870	1.847
		Q1 - Q3	1.137 - 2.620	1.300 - 2.730	1.240 - 2.418	1.393 - 2.610	1.300 - 2.610	1.280 - 2.620
		Min - Max	0.12 - 7.71	0.75 - 7.12	0.30 - 7.82	0.62 - 5.35	0.30 - 7.82	0.12 - 7.82
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.006 (1.0677)	-0.118 (0.8773)	-0.007 (1.0021)	-0.183 (0.8378)	-0.102 (0.9075)	-0.075 (0.9487)
		Median	0.023	-0.056	0.005	-0.169	-0.055	-0.048
		Q1 - Q3	-0.340 - 0.460	-0.687 - 0.311	-0.378 - 0.320	-0.730 - 0.303	-0.640 - 0.304	-0.618 - 0.320
		Min - Max	-2.89 - 2.80	-3.04 - 2.49	-2.75 - 5.24	-2.66 - 2.36	-3.04 - 5.24	-3.04 - 5.24

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyrotropin (mIU/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	2.053 (1.2848)	2.281 (1.3424)	2.079 (1.2104)	2.346 (1.6671)	2.235 (1.4130)	2.190 (1.3820)
		Median	1.781	2.095	1.730	2.060	1.930	1.887
		Q1 - Q3	1.311 - 2.540	1.310 - 2.789	1.272 - 2.650	1.450 - 2.860	1.335 - 2.722	1.320 - 2.660
		Min - Max	0.43 - 7.73	0.55 - 6.64	0.42 - 6.04	0.56 - 13.00	0.42 - 13.00	0.42 - 13.00
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.081 (0.9572)	-0.101 (0.9433)	-0.053 (0.7372)	0.077 (1.6957)	-0.028 (1.1849)	-0.041 (1.1309)
		Median	-0.053	-0.048	-0.043	-0.074	-0.048	-0.050
		Q1 - Q3	-0.440 - 0.420	-0.506 - 0.357	-0.410 - 0.281	-0.491 - 0.440	-0.480 - 0.338	-0.477 - 0.370
		Min - Max	-2.59 - 3.13	-2.88 - 3.06	-1.92 - 2.45	-3.14 - 11.67	-3.14 - 11.67	-3.14 - 11.67
	D85	Observed Value						
		n	64	67	66	62	195	259
		Mean (SD)	2.103 (1.2141)	2.467 (1.5173)	1.963 (1.0372)	2.099 (1.0912)	2.180 (1.2509)	2.161 (1.2400)
		Median	1.902	2.049	1.767	1.745	1.874	1.874
		Q1 - Q3	1.336 - 2.445	1.450 - 3.001	1.150 - 2.434	1.460 - 2.430	1.340 - 2.734	1.340 - 2.640
		Min - Max	0.49 - 5.73	0.09 - 6.83	0.38 - 5.03	0.52 - 5.59	0.09 - 6.83	0.09 - 6.83

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Thyrotropin (mIU/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	0.009 (1.0724)	0.098 (0.9293)	-0.158 (0.7624)	-0.172 (0.8256)	-0.074 (0.8477)	-0.054 (0.9069)
		Median	-0.013	0.110	-0.073	0.025	0.018	-0.005
		Q1 - Q3	-0.605 - 0.441	-0.470 - 0.573	-0.410 - 0.263	-0.630 - 0.328	-0.496 - 0.360	-0.538 - 0.367
		Min - Max	-2.74 - 4.59	-2.97 - 2.15	-3.05 - 2.19	-2.46 - 1.42	-3.05 - 2.19	-3.05 - 4.59
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	2.021 (1.1149)	2.295 (1.4764)	2.113 (1.2696)	2.224 (1.2606)	2.211 (1.3372)	2.165 (1.2868)
		Median	1.821	1.940	1.832	2.010	1.930	1.893
		Q1 - Q3	1.270 - 2.525	1.330 - 2.697	1.214 - 2.526	1.360 - 2.820	1.310 - 2.690	1.275 - 2.614
		Min - Max	0.10 - 5.94	0.09 - 7.46	0.50 - 7.26	0.36 - 6.96	0.09 - 7.46	0.09 - 7.46
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-0.139 (0.8242)	-0.065 (0.8694)	-0.038 (1.0864)	-0.115 (0.8356)	-0.072 (0.9336)	-0.088 (0.9069)
		Median	0.001	-0.091	-0.025	-0.080	-0.070	-0.050
		Q1 - Q3	-0.574 - 0.312	-0.383 - 0.365	-0.533 - 0.355	-0.564 - 0.280	-0.496 - 0.340	-0.500 - 0.340
		Min - Max	-2.74 - 1.86	-3.46 - 2.23	-2.70 - 6.25	-2.61 - 3.29	-3.46 - 6.25	-3.46 - 6.25

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Parathyroid Hormone, Whole (ng/L)	Baseline	Observed Value						
		n	69	70	69	67	206	275
		Mean (SD)	46.719 (17.9252)	44.461 (17.1299)	49.401 (16.6075)	46.868 (16.1034)	46.899 (16.6697)	46.854 (16.9602)
		Median	43.189	43.810	48.942	44.260	45.050	44.321
		Q1 - Q3	32.400 - 55.826	32.100 - 51.800	36.000 - 61.500	35.400 - 53.990	34.514 - 55.200	34.180 - 55.826
		Min - Max	20.00 - 94.00	15.84 - 118.82	22.63 - 90.80	20.10 - 94.92	15.84 - 118.82	15.84 - 118.82
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	46.482 (17.4494)	46.724 (18.4794)	51.264 (19.2425)	47.655 (15.4528)	48.530 (17.8283)	48.016 (17.7246)
		Median	43.280	42.550	50.592	45.675	45.975	45.000
		Q1 - Q3	33.000 - 57.700	33.600 - 57.700	36.230 - 59.050	35.090 - 57.322	34.797 - 58.200	34.360 - 58.200
		Min - Max	17.50 - 98.10	13.40 - 116.00	8.30 - 100.80	21.69 - 81.50	8.30 - 116.00	8.30 - 116.00
	D15	Change from Baseline						
		n	69	70	68	67	205	274
		Mean (SD)	-0.237 (10.6774)	2.263 (10.7589)	1.634 (11.6979)	0.953 (11.8956)	1.626 (11.4089)	1.157 (11.2392)
		Median	0	2.500	-0.100	1.300	1.470	1.240
		Q1 - Q3	-8.298 - 7.600	-2.500 - 7.600	-5.085 - 7.619	-6.900 - 9.200	-3.961 - 7.720	-4.840 - 7.720
		Min - Max	-22.30 - 22.90	-41.50 - 32.40	-24.10 - 28.90	-36.00 - 23.30	-41.50 - 32.40	-41.50 - 32.40

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Parathyroid Hormone, Whole (ng/L)	D29	Observed Value						
		n	67	69	67	66	202	269
		Mean (SD)	47.996 (20.0535)	47.742 (23.6747)	50.299 (15.7006)	50.233 (16.5468)	49.404 (18.9880)	49.053 (19.2306)
		Median	45.030	45.600	51.299	48.750	47.450	46.700
		Q1 - Q3	31.770 - 61.030	32.911 - 54.600	38.700 - 59.409	37.900 - 58.466	36.500 - 58.466	35.720 - 58.900
		Min - Max	16.50 - 110.40	15.47 - 158.30	23.01 - 92.90	25.73 - 101.50	15.47 - 158.30	15.47 - 158.30
	D29	Change from Baseline						
		n	67	69	67	65	201	268
		Mean (SD)	1.569 (14.1240)	3.335 (16.4718)	0.357 (11.9454)	3.386 (11.7450)	2.359 (13.6196)	2.161 (13.7250)
		Median	0.300	2.080	0.189	3.866	1.800	1.454
		Q1 - Q3	-5.300 - 8.720	-3.900 - 9.300	-8.570 - 6.978	-2.600 - 8.570	-3.961 - 8.500	-4.808 - 8.535
		Min - Max	-34.95 - 59.30	-53.66 - 77.00	-29.80 - 31.40	-25.60 - 34.65	-53.66 - 77.00	-53.66 - 77.00
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	47.942 (23.5304)	47.487 (19.4195)	49.443 (17.4480)	49.264 (14.6113)	48.711 (17.2690)	48.520 (18.9701)
		Median	41.435	45.300	47.056	46.665	46.415	45.300
		Q1 - Q3	33.600 - 56.980	34.800 - 56.800	34.300 - 61.100	38.225 - 57.290	36.238 - 58.550	34.600 - 58.100
		Min - Max	13.30 - 149.10	17.60 - 142.30	20.60 - 97.40	16.97 - 92.00	16.97 - 142.30	13.30 - 149.10

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Parathyroid Hormone, Whole (ng/L)	D43	Change from Baseline						
		n	66	69	67	63	199	265
		Mean (SD)	1.114 (16.1971)	3.080 (12.3246)	-0.500 (10.2130)	1.990 (10.7117)	1.530 (11.1876)	1.426 (12.5895)
		Median	1.391	3.510	-1.886	2.100	1.700	1.700
		Q1 - Q3	-5.430 - 7.700	-3.700 - 8.900	-7.000 - 5.752	-3.772 - 8.110	-5.000 - 8.000	-5.000 - 7.800
		Min - Max	-43.10 - 59.30	-43.85 - 47.10	-22.91 - 32.70	-27.52 - 30.30	-43.85 - 47.10	-43.85 - 59.30
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	52.981 (25.0316)	46.647 (17.0810)	50.979 (18.2325)	50.359 (18.5022)	49.285 (17.9448)	50.202 (19.9505)
		Median	46.490	45.500	48.046	44.000	46.100	46.251
		Q1 - Q3	37.900 - 60.700	34.405 - 57.400	38.600 - 60.000	37.531 - 64.970	37.110 - 60.100	37.110 - 60.700
		Min - Max	15.94 - 151.00	17.56 - 103.10	21.69 - 111.20	19.43 - 92.37	17.56 - 111.20	15.94 - 151.00
	D57	Change from Baseline						
		n	65	68	66	62	196	261
		Mean (SD)	6.099 (18.5887)	2.987 (13.6547)	1.044 (12.4768)	3.255 (13.0389)	2.417 (13.0427)	3.334 (14.6692)
		Median	5.300	2.894	0.100	0.770	1.745	2.500
		Q1 - Q3	-3.018 - 12.259	-4.125 - 11.987	-7.150 - 7.600	-4.400 - 9.520	-4.600 - 10.145	-4.400 - 10.730
		Min - Max	-31.08 - 76.70	-45.26 - 48.53	-26.80 - 34.90	-33.96 - 41.89	-45.26 - 48.53	-45.26 - 76.70

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Parathyroid Hormone, Whole (ng/L)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	52.045 (27.7908)	49.506 (19.5361)	52.693 (24.6172)	51.461 (18.4450)	51.191 (20.9754)	51.404 (22.8084)
		Median	48.960	46.400	45.950	47.000	46.750	47.000
		Q1 - Q3	34.100 - 57.190	36.050 - 58.350	35.645 - 65.500	37.700 - 67.280	36.150 - 61.600	35.900 - 59.700
		Min - Max	17.30 - 196.50	20.40 - 121.40	17.92 - 127.50	16.97 - 99.40	16.97 - 127.50	16.97 - 196.50
	D71	Change from Baseline						
		n	65	68	65	62	195	260
		Mean (SD)	5.164 (22.1469)	5.845 (13.6515)	2.585 (17.0015)	4.345 (12.3722)	4.282 (14.4801)	4.502 (16.6853)
		Median	0.700	4.875	0.500	3.966	3.430	3.300
		Q1 - Q3	-5.100 - 11.500	-0.700 - 12.544	-9.619 - 10.100	-3.500 - 11.680	-4.400 - 12.110	-4.850 - 11.895
		Min - Max	-31.20 - 105.50	-39.23 - 40.10	-31.00 - 62.90	-29.64 - 43.82	-39.23 - 62.90	-39.23 - 105.50
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	51.020 (22.9122)	49.454 (17.6803)	49.863 (20.3063)	51.339 (17.0021)	50.198 (18.3251)	50.400 (19.5103)
		Median	43.395	44.700	46.135	46.760	45.815	45.400
		Q1 - Q3	34.089 - 61.900	37.900 - 60.600	36.200 - 59.200	38.900 - 61.800	37.300 - 60.326	36.836 - 60.395
		Min - Max	17.73 - 142.20	18.64 - 101.20	16.03 - 125.40	21.31 - 115.60	16.03 - 125.40	16.03 - 142.20

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.1
Summary of Thyroid and Parathyroid Function
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Parathyroid Hormone, Whole (ng/L)	D85	Change from Baseline						
		n	64	67	66	62	195	259
		Mean (SD)	4.098 (16.3013)	5.889 (12.1301)	-0.073 (14.4111)	4.217 (12.3146)	3.340 (13.1824)	3.527 (13.9880)
		Median	2.673	4.338	-0.533	4.200	3.300	3.100
		Q1 - Q3	-5.929 - 14.473	-0.400 - 10.100	-9.147 - 7.700	-4.100 - 11.110	-3.860 - 9.870	-4.200 - 10.400
		Min - Max	-32.00 - 51.92	-38.38 - 46.20	-29.70 - 49.40	-28.82 - 39.90	-38.38 - 49.40	-38.38 - 51.92
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	47.889 (19.9728)	48.672 (16.5626)	52.019 (21.4093)	49.283 (17.4122)	49.989 (18.5428)	49.474 (18.8859)
		Median	45.650	46.206	48.305	44.415	46.600	46.300
		Q1 - Q3	32.662 - 59.980	37.860 - 59.850	35.500 - 64.300	36.600 - 62.100	36.900 - 61.900	36.200 - 61.200
		Min - Max	15.65 - 128.70	20.28 - 121.20	17.73 - 133.30	16.79 - 103.50	16.79 - 133.30	15.65 - 133.30
	Safety Follow-up	Change from Baseline						
		n	64	68	66	62	196	260
		Mean (SD)	1.123 (13.6317)	4.348 (13.0808)	1.906 (14.4117)	2.413 (12.5378)	2.914 (13.3543)	2.473 (13.4189)
		Median	0.977	3.273	0.785	0.630	2.055	1.285
		Q1 - Q3	-6.018 - 8.300	-1.602 - 10.800	-6.100 - 10.750	-3.400 - 8.570	-3.945 - 10.387	-4.610 - 9.945
		Min - Max	-30.50 - 37.70	-52.34 - 36.97	-25.93 - 57.30	-27.16 - 37.41	-52.34 - 57.30	-52.34 - 57.30

Data Source: Listing 16.2.8.1.7
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Triiodothyronine, Free (pmol/L)	D15	Placebo (N=69)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	70 (100)	0	0	70 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Triiodothyronine, Free (pmol/L)	D15	Combined GS1-144 (N=207)	Normal	204 (99.0)	0	0	204 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	206 (100)	0	0	206 (100)
	D29	Placebo (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triiodothyronine, Free (pmol/L)	D29	GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	203 (100)	0	0	203 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	203 (100)	0	0	203 (100)
	D43	Placebo (N=69)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triiodothyronine, Free (pmol/L)	D43	GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	196 (98.5)	0	0	196 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	199 (100)	0	0	199 (100)
	D57	Placebo (N=69)	Normal	64 (98.5)	0	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triiodothyronine, Free (pmol/L)	D57	GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (98.5)	0	0	194 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	197 (100)	0	0	197 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Triiodothyronine, Free (pmol/L)	D71	Placebo (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (98.4)	0	0	61 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (100)	0	0	62 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triiodothyronine, Free (pmol/L)	D71	Combined GS1-144 (N=207)	Normal	193 (99.0)	0	0	193 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	195 (100)	0	0	195 (100)
	D85	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Triiodothyronine, Free (pmol/L)	D85	GS1-144 30 mg BID (N=68)	Normal	61 (98.4)	0	0	61 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (100)	0	0	62 (100)
		Combined GS1-144 (N=207)	Normal	193 (99.0)	0	0	193 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	195 (100)	0	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Triiodothyronine, Free (pmol/L)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (98.5)	0	0	194 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	197 (100)	0	0	197 (100)
Thyroxine, Free (pmol/L)	D15	Placebo (N=69)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyroxine, Free (pmol/L)	D15	GS1-144 30 mg QD (N=70)	Normal	70 (100)	0	0	70 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	70 (100)	0	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	2 (2.9)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	203 (98.5)	2 (1.0)	0	205 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	204 (99.0)	2 (1.0)	0	206 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyroxine, Free (pmol/L)	D29	Placebo (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyroxine, Free (pmol/L)	D29	Combined GS1-144 (N=207)	Normal	200 (98.5)	2 (1.0)	0	202 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	201 (99.0)	2 (1.0)	0	203 (100)
	D43	Placebo (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyroxine, Free (pmol/L)	D43	GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	197 (99.0)	1 (0.5)	0	198 (99.5)
			Abnormal NCS	0	1 (0.5)	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	197 (99.0)	2 (1.0)	0	199 (100)
	D57	Placebo (N=69)	Normal	64 (98.5)	0	0	64 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyroxine, Free (pmol/L)	D57	GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	195 (99.0)	1 (0.5)	0	196 (99.5)
			Abnormal NCS	0	1 (0.5)	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	195 (99.0)	2 (1.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyroxine, Free (pmol/L)	D71	GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	2 (3.1)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (100)	0	0	62 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (100)	0	0	62 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.9)	2 (1.0)	0	193 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	193 (99.0)	2 (1.0)	0	195 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyroxine, Free (pmol/L)	D85	Placebo (N=69)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	2 (3.0)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (100)	0	0	62 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (100)	0	0	62 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyroxine, Free (pmol/L)	D85	Combined GS1-144 (N=207)	Normal	190 (97.4)	2 (1.0)	0	192 (98.5)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	193 (99.0)	2 (1.0)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (92.6)	0	0	63 (92.6)
			Abnormal NCS	5 (7.4)	0	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	2 (3.0)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyroxine, Free (pmol/L)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.4)	2 (1.0)	0	190 (96.4)
			Abnormal NCS	7 (3.6)	0	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	195 (99.0)	2 (1.0)	0	197 (100)
Thyrotropin (mIU/L)	D15	Placebo (N=69)	Normal	62 (89.9)	4 (5.8)	0	66 (95.7)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	64 (92.8)	5 (7.2)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (87.1)	3 (4.3)	0	64 (91.4)
			Abnormal NCS	3 (4.3)	2 (2.9)	1 (1.4)	6 (8.6)
			Abnormal CS	0	0	0	0
			Total	64 (91.4)	5 (7.1)	1 (1.4)	70 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyrotropin (mIU/L)	D15	GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	4 (5.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	190 (92.2)	7 (3.4)	0	197 (95.6)
			Abnormal NCS	4 (1.9)	4 (1.9)	1 (0.5)	9 (4.4)
			Abnormal CS	0	0	0	0
			Total	194 (94.2)	11 (5.3)	1 (0.5)	206 (100)
	D29	Placebo (N=69)	Normal	59 (88.1)	2 (3.0)	0	61 (91.0)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Total	62 (92.5)	5 (7.5)	0	67 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyrotropin (mIU/L)	D29	GS1-144 30 mg QD (N=70)	Normal	61 (88.4)	3 (4.3)	1 (1.4)	65 (94.2)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	63 (91.3)	5 (7.2)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (94.0)	3 (4.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	188 (92.6)	8 (3.9)	1 (0.5)	197 (97.0)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Abnormal CS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Total	192 (94.6)	10 (4.9)	1 (0.5)	203 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyrotropin (mIU/L)	D43	Placebo (N=69)	Normal	56 (84.8)	3 (4.5)	0	59 (89.4)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.1)
			Abnormal CS	3 (4.5)	0	0	3 (4.5)
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (85.5)	3 (4.3)	0	62 (89.9)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	2 (2.9)	1 (1.4)	1 (1.4)	4 (5.8)
			Total	63 (91.3)	5 (7.2)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (92.5)	2 (3.0)	0	64 (95.5)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (95.3)	3 (4.7)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyrotropin (mIU/L)	D43	Combined GS1-144 (N=207)	Normal	182 (91.0)	8 (4.0)	0	190 (95.0)
			Abnormal NCS	4 (2.0)	1 (0.5)	0	5 (2.5)
			Abnormal CS	3 (1.5)	1 (0.5)	1 (0.5)	5 (2.5)
			Total	189 (94.5)	10 (5.0)	1 (0.5)	200 (100)
	D57	Placebo (N=69)	Normal	56 (86.2)	4 (6.2)	0	60 (92.3)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	3 (4.4)	0	65 (95.6)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	1 (1.5)	1 (1.5)	2 (2.9)
			Total	62 (91.2)	5 (7.4)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (90.9)	1 (1.5)	0	61 (92.4)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	64 (97.0)	2 (3.0)	0	66 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyrotropin (mIU/L)	D57	GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	181 (91.9)	6 (3.0)	0	187 (94.9)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.0)
			Abnormal CS	2 (1.0)	1 (0.5)	1 (0.5)	4 (2.0)
			Total	186 (94.4)	10 (5.1)	1 (0.5)	197 (100)
	D71	Placebo (N=69)	Normal	57 (87.7)	4 (6.2)	0	61 (93.8)
			Abnormal NCS	3 (4.6)	0	0	3 (4.6)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	4 (5.9)	0	63 (92.6)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	2 (2.9)	0	1 (1.5)	3 (4.4)
			Total	62 (91.2)	5 (7.4)	1 (1.5)	68 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyrotropin (mIU/L)	D71	GS1-144 60 mg QD (N=69)	Normal	60 (92.3)	2 (3.1)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	2 (3.1)	0	0	2 (3.1)
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	3 (4.8)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	177 (90.3)	9 (4.6)	0	186 (94.9)
			Abnormal NCS	4 (2.0)	1 (0.5)	0	5 (2.6)
			Abnormal CS	4 (2.0)	0	1 (0.5)	5 (2.6)
			Total	185 (94.4)	10 (5.1)	1 (0.5)	196 (100)
	D85	Placebo (N=69)	Normal	55 (85.9)	3 (4.7)	0	58 (90.6)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	3 (4.7)	0	0	3 (4.7)
			Total	59 (92.2)	5 (7.8)	0	64 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyrotropin (mIU/L)	D85	GS1-144 30 mg QD (N=70)	Normal	56 (83.6)	3 (4.5)	1 (1.5)	60 (89.6)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Total	61 (91.0)	5 (7.5)	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (95.2)	3 (4.8)	0	62 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	59 (95.2)	3 (4.8)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	176 (90.3)	8 (4.1)	1 (0.5)	185 (94.9)
			Abnormal NCS	5 (2.6)	1 (0.5)	0	6 (3.1)
			Abnormal CS	3 (1.5)	1 (0.5)	0	4 (2.1)
			Total	184 (94.4)	10 (5.1)	1 (0.5)	195 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyrotropin (mIU/L)	Safety Follow-up	Placebo (N=69)	Normal	57 (89.1)	2 (3.1)	0	59 (92.2)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	1 (1.6)	0	1 (1.6)
			Total	59 (92.2)	5 (7.8)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (88.2)	3 (4.4)	0	63 (92.6)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	1 (1.5)	1 (1.5)	1 (1.5)	3 (4.4)
			Total	62 (91.2)	5 (7.4)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	1 (1.5)	0	60 (90.9)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	3 (4.5)	0	0	3 (4.5)
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	0	60 (95.2)
			Abnormal NCS	0	2 (3.2)	0	2 (3.2)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Thyrotropin (mIU/L)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	177 (89.8)	6 (3.0)	0	183 (92.9)
			Abnormal NCS	3 (1.5)	4 (2.0)	0	7 (3.6)
			Abnormal CS	5 (2.5)	1 (0.5)	1 (0.5)	7 (3.6)
			Total	185 (93.9)	11 (5.6)	1 (0.5)	197 (100)
Parathyroid Hormone, Whole (ng/L)	D15	Placebo (N=69)	Normal	56 (81.2)	2 (2.9)	0	58 (84.1)
			Abnormal NCS	1 (1.4)	8 (11.6)	0	9 (13.0)
			Abnormal CS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Total	58 (84.1)	11 (15.9)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	0	0	64 (91.4)
			Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Abnormal CS	2 (2.9)	2 (2.9)	0	4 (5.7)
			Total	67 (95.7)	3 (4.3)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (83.8)	1 (1.5)	0	58 (85.3)
			Abnormal NCS	4 (5.9)	4 (5.9)	0	8 (11.8)
			Abnormal CS	2 (2.9)	0	0	2 (2.9)
			Total	63 (92.6)	5 (7.4)	0	68 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Parathyroid Hormone, Whole (ng/L)	D15	GS1-144 30 mg BID (N=68)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	61 (91.0)	6 (9.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	181 (88.3)	4 (2.0)	0	185 (90.2)
			Abnormal NCS	6 (2.9)	7 (3.4)	0	13 (6.3)
			Abnormal CS	4 (2.0)	3 (1.5)	0	7 (3.4)
			Total	191 (93.2)	14 (6.8)	0	205 (100)
	D29	Placebo (N=69)	Normal	52 (77.6)	5 (7.5)	0	57 (85.1)
			Abnormal NCS	2 (3.0)	5 (7.5)	0	7 (10.4)
			Abnormal CS	3 (4.5)	0	0	3 (4.5)
			Total	57 (85.1)	10 (14.9)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (88.4)	0	0	61 (88.4)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	4 (5.8)	1 (1.4)	0	5 (7.2)
			Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Parathyroid Hormone, Whole (ng/L)	D29	GS1-144 60 mg QD (N=69)	Normal	58 (86.6)	2 (3.0)	0	60 (89.6)
			Abnormal NCS	3 (4.5)	3 (4.5)	0	6 (9.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (87.7)	2 (3.1)	0	59 (90.8)
			Abnormal NCS	2 (3.1)	1 (1.5)	0	3 (4.6)
			Abnormal CS	0	3 (4.6)	0	3 (4.6)
			Total	59 (90.8)	6 (9.2)	0	65 (100)
		Combined GS1-144 (N=207)	Normal	176 (87.6)	4 (2.0)	0	180 (89.6)
			Abnormal NCS	6 (3.0)	6 (3.0)	0	12 (6.0)
			Abnormal CS	5 (2.5)	4 (2.0)	0	9 (4.5)
			Total	187 (93.0)	14 (7.0)	0	201 (100)
	D43	Placebo (N=69)	Normal	54 (81.8)	5 (7.6)	0	59 (89.4)
			Abnormal NCS	0	4 (6.1)	0	4 (6.1)
			Abnormal CS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Total	56 (84.8)	10 (15.2)	0	66 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Parathyroid Hormone, Whole (ng/L)	D43	GS1-144 30 mg QD (N=70)	Normal	62 (89.9)	0	0	62 (89.9)
			Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
			Abnormal CS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.0)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (87.3)	3 (4.8)	0	58 (92.1)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	3 (4.8)	0	3 (4.8)
			Total	57 (90.5)	6 (9.5)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (89.4)	4 (2.0)	0	182 (91.5)
			Abnormal NCS	6 (3.0)	4 (2.0)	0	10 (5.0)
			Abnormal CS	1 (0.5)	6 (3.0)	0	7 (3.5)
			Total	185 (93.0)	14 (7.0)	0	199 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Parathyroid Hormone, Whole (ng/L)	D57	Placebo (N=69)	Normal	49 (75.4)	3 (4.6)	0	52 (80.0)
			Abnormal NCS	3 (4.6)	5 (7.7)	0	8 (12.3)
			Abnormal CS	3 (4.6)	2 (3.1)	0	5 (7.7)
			Total	55 (84.6)	10 (15.4)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	59 (86.8)	0	0	59 (86.8)
			Abnormal NCS	3 (4.4)	2 (2.9)	0	5 (7.4)
			Abnormal CS	4 (5.9)	0	0	4 (5.9)
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (84.8)	2 (3.0)	0	58 (87.9)
			Abnormal NCS	4 (6.1)	2 (3.0)	0	6 (9.1)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	50 (80.6)	2 (3.2)	0	52 (83.9)
			Abnormal NCS	4 (6.5)	3 (4.8)	0	7 (11.3)
			Abnormal CS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Total	56 (90.3)	6 (9.7)	0	62 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Parathyroid Hormone, Whole (ng/L)	D57	Combined GS1-144 (N=207)	Normal	165 (84.2)	4 (2.0)	0	169 (86.2)
			Abnormal NCS	11 (5.6)	7 (3.6)	0	18 (9.2)
			Abnormal CS	7 (3.6)	2 (1.0)	0	9 (4.6)
			Total	183 (93.4)	13 (6.6)	0	196 (100)
	D71	Placebo (N=69)	Normal	50 (76.9)	5 (7.7)	0	55 (84.6)
			Abnormal NCS	1 (1.5)	3 (4.6)	0	4 (6.2)
			Abnormal CS	4 (6.2)	2 (3.1)	0	6 (9.2)
			Total	55 (84.6)	10 (15.4)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (88.2)	0	0	60 (88.2)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	4 (5.9)	1 (1.5)	0	5 (7.4)
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	53 (81.5)	2 (3.1)	0	55 (84.6)
			Abnormal NCS	4 (6.2)	2 (3.1)	0	6 (9.2)
			Abnormal CS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Total	60 (92.3)	5 (7.7)	0	65 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Parathyroid Hormone, Whole (ng/L)	D71	GS1-144 30 mg BID (N=68)	Normal	52 (83.9)	3 (4.8)	0	55 (88.7)
			Abnormal NCS	3 (4.8)	2 (3.2)	0	5 (8.1)
			Abnormal CS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Total	56 (90.3)	6 (9.7)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	165 (84.6)	5 (2.6)	0	170 (87.2)
			Abnormal NCS	9 (4.6)	5 (2.6)	0	14 (7.2)
			Abnormal CS	8 (4.1)	3 (1.5)	0	11 (5.6)
			Total	182 (93.3)	13 (6.7)	0	195 (100)
	D85	Placebo (N=69)	Normal	50 (78.1)	4 (6.3)	0	54 (84.4)
			Abnormal NCS	0	3 (4.7)	0	3 (4.7)
			Abnormal CS	4 (6.3)	3 (4.7)	0	7 (10.9)
			Total	54 (84.4)	10 (15.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	0	0	60 (89.6)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Parathyroid Hormone, Whole (ng/L)	D85	GS1-144 60 mg QD (N=69)	Normal	57 (86.4)	1 (1.5)	0	58 (87.9)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.6)
			Abnormal CS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	52 (83.9)	2 (3.2)	0	54 (87.1)
			Abnormal NCS	3 (4.8)	2 (3.2)	0	5 (8.1)
			Abnormal CS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Total	56 (90.3)	6 (9.7)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	169 (86.7)	3 (1.5)	0	172 (88.2)
			Abnormal NCS	7 (3.6)	6 (3.1)	0	13 (6.7)
			Abnormal CS	6 (3.1)	4 (2.1)	0	10 (5.1)
			Total	182 (93.3)	13 (6.7)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	52 (81.3)	6 (9.4)	0	58 (90.6)
			Abnormal NCS	0	3 (4.7)	0	3 (4.7)
			Abnormal CS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Total	54 (84.4)	10 (15.6)	0	64 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.2
Shift of Thyroid and Parathyroid Function by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Parathyroid Hormone, Whole (ng/L)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
			Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	56 (84.8)	2 (3.0)	0	58 (87.9)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	2 (3.0)	2 (3.0)	0	4 (6.1)
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	52 (83.9)	2 (3.2)	0	54 (87.1)
			Abnormal NCS	3 (4.8)	2 (3.2)	0	5 (8.1)
			Abnormal CS	1 (1.6)	2 (3.2)	0	3 (4.8)
			Total	56 (90.3)	6 (9.7)	0	62 (100)
		Combined GS1-144 (N=207)	Normal	170 (86.7)	5 (2.6)	0	175 (89.3)
			Abnormal NCS	9 (4.6)	4 (2.0)	0	13 (6.6)
			Abnormal CS	3 (1.5)	5 (2.6)	0	8 (4.1)
			Total	182 (92.9)	14 (7.1)	0	196 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.4.3
Shift of Thyroid and Parathyroid Function by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Triiodothyronine, Free (pmol/L)	Placebo (N=69)	Normal	64 (92.8)	0	0	64 (92.8)
		Abnormal NCS	4 (5.8)	0	0	4 (5.8)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	69 (100)	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	0	0	65 (92.9)
		Abnormal NCS	5 (7.1)	0	0	5 (7.1)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	4 (5.9)	0	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.4.3
Shift of Thyroid and Parathyroid Function by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Triiodothyronine, Free (pmol/L)	Combined GS1-144 (N=207)	Normal	195 (94.7)	0	0	195 (94.7)
		Abnormal NCS	11 (5.3)	0	0	11 (5.3)
		Abnormal CS	0	0	0	0
		Total	206 (100)	0	0	206 (100)
Thyroxine, Free (pmol/L)	Placebo (N=69)	Normal	65 (94.2)	0	0	65 (94.2)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	69 (100)	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	63 (90.0)	0	0	63 (90.0)
		Abnormal NCS	7 (10.0)	0	0	7 (10.0)
		Abnormal CS	0	0	0	0
		Total	70 (100)	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
		Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.4.3
Shift of Thyroid and Parathyroid Function by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyroxine, Free (pmol/L)	GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	0	0	65 (95.6)
		Abnormal NCS	3 (4.4)	0	0	3 (4.4)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	193 (93.7)	1 (0.5)	0	194 (94.2)
		Abnormal NCS	11 (5.3)	1 (0.5)	0	12 (5.8)
		Abnormal CS	0	0	0	0
		Total	204 (99.0)	2 (1.0)	0	206 (100)
Thyrotropin (mIU/L)	Placebo (N=69)	Normal	56 (81.2)	1 (1.4)	0	57 (82.6)
		Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
		Abnormal CS	7 (10.1)	2 (2.9)	0	9 (13.0)
		Total	64 (92.8)	5 (7.2)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	53 (75.7)	3 (4.3)	0	56 (80.0)
		Abnormal NCS	7 (10.0)	1 (1.4)	0	8 (11.4)
		Abnormal CS	4 (5.7)	1 (1.4)	1 (1.4)	6 (8.6)
		Total	64 (91.4)	5 (7.1)	1 (1.4)	70 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.4.3
Shift of Thyroid and Parathyroid Function by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Thyrotropin (mIU/L)	GS1-144 60 mg QD (N=69)	Normal	56 (82.4)	0	0	56 (82.4)
		Abnormal NCS	5 (7.4)	2 (2.9)	0	7 (10.3)
		Abnormal CS	5 (7.4)	0	0	5 (7.4)
		Total	66 (97.1)	2 (2.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	58 (85.3)	2 (2.9)	0	60 (88.2)
		Abnormal NCS	5 (7.4)	2 (2.9)	0	7 (10.3)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	167 (81.1)	5 (2.4)	0	172 (83.5)
		Abnormal NCS	17 (8.3)	5 (2.4)	0	22 (10.7)
		Abnormal CS	10 (4.9)	1 (0.5)	1 (0.5)	12 (5.8)
		Total	194 (94.2)	11 (5.3)	1 (0.5)	206 (100)
Parathyroid Hormone, Whole (ng/L)	Placebo (N=69)	Normal	48 (69.6)	2 (2.9)	0	50 (72.5)
		Abnormal NCS	4 (5.8)	5 (7.2)	0	9 (13.0)
		Abnormal CS	6 (8.7)	4 (5.8)	0	10 (14.5)
		Total	58 (84.1)	11 (15.9)	0	69 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.4.3
Shift of Thyroid and Parathyroid Function by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Parathyroid Hormone, Whole (ng/L)	GS1-144 30 mg QD (N=70)	Normal	54 (77.1)	0	0	54 (77.1)
		Abnormal NCS	5 (7.1)	1 (1.4)	0	6 (8.6)
		Abnormal CS	8 (11.4)	2 (2.9)	0	10 (14.3)
		Total	67 (95.7)	3 (4.3)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	49 (72.1)	0	0	49 (72.1)
		Abnormal NCS	9 (13.2)	3 (4.4)	0	12 (17.6)
		Abnormal CS	5 (7.4)	2 (2.9)	0	7 (10.3)
		Total	63 (92.6)	5 (7.4)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	51 (76.1)	0	0	51 (76.1)
		Abnormal NCS	8 (11.9)	3 (4.5)	0	11 (16.4)
		Abnormal CS	2 (3.0)	3 (4.5)	0	5 (7.5)
		Total	61 (91.0)	6 (9.0)	0	67 (100)
	Combined GS1-144 (N=207)	Normal	154 (75.1)	0	0	154 (75.1)
		Abnormal NCS	22 (10.7)	7 (3.4)	0	29 (14.1)
		Abnormal CS	15 (7.3)	7 (3.4)	0	22 (10.7)
		Total	191 (93.2)	14 (6.8)	0	205 (100)

Data Source: Listing 16.2.8.1.7
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D15	Placebo (N=69)	Normal	66 (95.7)	1 (1.4)	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (92.6)	2 (2.9)	0	65 (95.6)
			Abnormal NCS	1 (1.5)	2 (2.9)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	3 (4.4)	0	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D15	Combined GS1-144 (N=207)	Normal	192 (93.7)	6 (2.9)	0	198 (96.6)
			Abnormal NCS	4 (2.0)	3 (1.5)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	196 (95.6)	9 (4.4)	0	205 (100)
	D29	Placebo (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D29	GS1-144 30 mg BID (N=68)	Normal	63 (94.0)	4 (6.0)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	189 (93.6)	5 (2.5)	0	194 (96.0)
			Abnormal NCS	4 (2.0)	4 (2.0)	0	8 (4.0)
			Abnormal CS	0	0	0	0
			Total	193 (95.5)	9 (4.5)	0	202 (100)
	D43	Placebo (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D43	GS1-144 60 mg QD (N=69)	Normal	62 (92.5)	2 (3.0)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	3 (4.7)	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	188 (94.5)	5 (2.5)	0	193 (97.0)
			Abnormal NCS	2 (1.0)	4 (2.0)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	190 (95.5)	9 (4.5)	0	199 (100)
	D57	Placebo (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D57	GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	3 (4.8)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	185 (94.4)	6 (3.1)	0	191 (97.4)
			Abnormal NCS	2 (1.0)	3 (1.5)	0	5 (2.6)
			Abnormal CS	0	0	0	0
			Total	187 (95.4)	9 (4.6)	0	196 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D71	Placebo (N=69)	Normal	64 (98.5)	0	0	64 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (92.3)	1 (1.5)	0	61 (93.8)
			Abnormal NCS	1 (1.5)	3 (4.6)	0	4 (6.2)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	3 (4.8)	0	60 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D71	Combined GS1-144 (N=207)	Normal	182 (93.3)	5 (2.6)	0	187 (95.9)
			Abnormal NCS	4 (2.1)	4 (2.1)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	186 (95.4)	9 (4.6)	0	195 (100)
	D85	Placebo (N=69)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	1 (1.5)	0	62 (93.9)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	D85	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	3 (4.8)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (93.8)	5 (2.6)	0	188 (96.4)
			Abnormal NCS	3 (1.5)	4 (2.1)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	186 (95.4)	9 (4.6)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	1 (1.5)	0	62 (93.9)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	4 (6.3)	0	60 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (93.4)	6 (3.1)	0	189 (96.4)
			Abnormal NCS	4 (2.0)	3 (1.5)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	187 (95.4)	9 (4.6)	0	196 (100)
Urine Glucose	D15	Placebo (N=69)	Normal	68 (98.6)	1 (1.4)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Glucose	D15	GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (1.4)	1 (1.4)
			Total	68 (98.6)	0	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	203 (99.0)	1 (0.5)	0	204 (99.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	203 (99.0)	1 (0.5)	1 (0.5)	205 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Glucose	D29	Placebo (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	67 (98.5)	0	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Glucose	D29	Combined GS1-144 (N=207)	Normal	200 (99.0)	1 (0.5)	0	201 (99.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	200 (99.0)	1 (0.5)	1 (0.5)	202 (100)
	D43	Placebo (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	67 (98.5)	0	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urine Glucose	D43	GS1-144 30 mg BID (N=68)	Normal	63 (98.4)	0	0	63 (98.4)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	64 (100)	0	0	64 (100)
		Combined GS1-144 (N=207)	Normal	196 (98.5)	1 (0.5)	0	197 (99.0)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	197 (99.0)	1 (0.5)	1 (0.5)	199 (100)
	D57	Placebo (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	66 (98.5)	0	1 (1.5)	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Glucose	D57	GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (99.0)	1 (0.5)	0	195 (99.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	194 (99.0)	1 (0.5)	1 (0.5)	196 (100)
	D71	Placebo (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urine Glucose	D71	GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	66 (98.5)	0	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	190 (97.4)	1 (0.5)	0	191 (97.9)
			Abnormal NCS	3 (1.5)	0	0	3 (1.5)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	193 (99.0)	1 (0.5)	1 (0.5)	195 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Glucose	D85	Placebo (N=69)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (98.5)	0	0	65 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	65 (98.5)	0	1 (1.5)	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Glucose	D85	Combined GS1-144 (N=207)	Normal	192 (98.5)	1 (0.5)	0	193 (99.0)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	193 (99.0)	1 (0.5)	1 (0.5)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	63 (98.4)	1 (1.6)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	66 (98.5)	0	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	0	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urine Glucose	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (98.0)	0	0	192 (98.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	194 (99.0)	1 (0.5)	1 (0.5)	196 (100)
Specific Gravity	D15	Placebo (N=69)	Normal	59 (85.5)	2 (2.9)	0	61 (88.4)
			Abnormal NCS	3 (4.3)	5 (7.2)	0	8 (11.6)
			Abnormal CS	0	0	0	0
			Total	62 (89.9)	7 (10.1)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	2 (2.9)	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Specific Gravity	D15	GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	3 (4.4)	0	65 (95.6)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (89.7)	4 (5.9)	0	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	63 (92.6)	5 (7.4)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	189 (92.2)	9 (4.4)	0	198 (96.6)
			Abnormal NCS	5 (2.4)	2 (1.0)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	194 (94.6)	11 (5.4)	0	205 (100)
	D29	Placebo (N=69)	Normal	57 (85.1)	6 (9.0)	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	60 (89.6)	7 (10.4)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Specific Gravity	D29	GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	2 (2.9)	0	63 (92.6)
			Abnormal NCS	4 (5.9)	1 (1.5)	0	5 (7.4)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	0	62 (92.5)
			Abnormal NCS	3 (4.5)	2 (3.0)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (88.1)	4 (6.0)	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	181 (89.6)	7 (3.5)	0	188 (93.1)
			Abnormal NCS	10 (5.0)	4 (2.0)	0	14 (6.9)
			Abnormal CS	0	0	0	0
			Total	191 (94.6)	11 (5.4)	0	202 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Specific Gravity	D43	Placebo (N=69)	Normal	55 (83.3)	4 (6.1)	0	59 (89.4)
			Abnormal NCS	4 (6.1)	3 (4.5)	0	7 (10.6)
			Abnormal CS	0	0	0	0
			Total	59 (89.4)	7 (10.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (88.2)	2 (2.9)	0	62 (91.2)
			Abnormal NCS	5 (7.4)	1 (1.5)	0	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (92.2)	4 (6.3)	0	63 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Specific Gravity	D43	Combined GS1-144 (N=207)	Normal	182 (91.5)	8 (4.0)	0	190 (95.5)
			Abnormal NCS	6 (3.0)	3 (1.5)	0	9 (4.5)
			Abnormal CS	0	0	0	0
			Total	188 (94.5)	11 (5.5)	0	199 (100)
	D57	Placebo (N=69)	Normal	56 (84.8)	6 (9.1)	0	62 (93.9)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	59 (89.4)	7 (10.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (92.5)	1 (1.5)	0	63 (94.0)
			Abnormal NCS	2 (3.0)	2 (3.0)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Specific Gravity	D57	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	3 (4.8)	0	61 (96.8)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	182 (92.9)	5 (2.6)	0	187 (95.4)
			Abnormal NCS	4 (2.0)	5 (2.6)	0	9 (4.6)
			Abnormal CS	0	0	0	0
			Total	186 (94.9)	10 (5.1)	0	196 (100)
	D71	Placebo (N=69)	Normal	57 (87.7)	5 (7.7)	0	62 (95.4)
			Abnormal NCS	1 (1.5)	2 (3.1)	0	3 (4.6)
			Abnormal CS	0	0	0	0
			Total	58 (89.2)	7 (10.8)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	2 (3.0)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Specific Gravity	D71	GS1-144 60 mg QD (N=69)	Normal	62 (95.4)	1 (1.5)	0	63 (96.9)
			Abnormal NCS	0	2 (3.1)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	3 (4.6)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	1 (1.6)	0	59 (93.7)
			Abnormal NCS	1 (1.6)	3 (4.8)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	180 (92.3)	4 (2.1)	0	184 (94.4)
			Abnormal NCS	5 (2.6)	6 (3.1)	0	11 (5.6)
			Abnormal CS	0	0	0	0
			Total	185 (94.9)	10 (5.1)	0	195 (100)
	D85	Placebo (N=69)	Normal	56 (87.5)	5 (7.8)	0	61 (95.3)
			Abnormal NCS	1 (1.6)	2 (3.1)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	57 (89.1)	7 (10.9)	0	64 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Specific Gravity	D85	GS1-144 30 mg QD (N=70)	Normal	62 (93.9)	2 (3.0)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	3 (4.8)	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (93.8)	6 (3.1)	0	189 (96.9)
			Abnormal NCS	2 (1.0)	4 (2.1)	0	6 (3.1)
			Abnormal CS	0	0	0	0
			Total	185 (94.9)	10 (5.1)	0	195 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Specific Gravity	Safety Follow-up	Placebo (N=69)	Normal	57 (89.1)	5 (7.8)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	58 (90.6)	6 (9.4)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	2 (3.0)	0	62 (92.5)
			Abnormal NCS	4 (6.0)	1 (1.5)	0	5 (7.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	0	0	62 (93.9)
			Abnormal NCS	1 (1.5)	3 (4.5)	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	2 (3.2)	0	58 (92.1)
			Abnormal NCS	3 (4.8)	2 (3.2)	0	5 (7.9)
			Abnormal CS	0	0	0	0
			Total	59 (93.7)	4 (6.3)	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Specific Gravity	Safety Follow-up	Combined GS1-144 (N=207)	Normal	178 (90.8)	4 (2.0)	0	182 (92.9)
			Abnormal NCS	8 (4.1)	6 (3.1)	0	14 (7.1)
			Abnormal CS	0	0	0	0
			Total	186 (94.9)	10 (5.1)	0	196 (100)
Occult Blood	D15	Placebo (N=69)	Normal	36 (52.2)	7 (10.1)	2 (2.9)	45 (65.2)
			Abnormal NCS	9 (13.0)	9 (13.0)	2 (2.9)	20 (29.0)
			Abnormal CS	0	0	4 (5.8)	4 (5.8)
			Total	45 (65.2)	16 (23.2)	8 (11.6)	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	34 (49.3)	8 (11.6)	1 (1.4)	43 (62.3)
			Abnormal NCS	8 (11.6)	15 (21.7)	0	23 (33.3)
			Abnormal CS	0	1 (1.4)	2 (2.9)	3 (4.3)
			Total	42 (60.9)	24 (34.8)	3 (4.3)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	34 (50.0)	5 (7.4)	0	39 (57.4)
			Abnormal NCS	8 (11.8)	15 (22.1)	0	23 (33.8)
			Abnormal CS	0	1 (1.5)	5 (7.4)	6 (8.8)
			Total	42 (61.8)	21 (30.9)	5 (7.4)	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Occult Blood	D15	GS1-144 30 mg BID (N=68)	Normal	36 (52.9)	10 (14.7)	0	46 (67.6)
			Abnormal NCS	6 (8.8)	15 (22.1)	0	21 (30.9)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	43 (63.2)	25 (36.8)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	104 (50.7)	23 (11.2)	1 (0.5)	128 (62.4)
			Abnormal NCS	22 (10.7)	45 (22.0)	0	67 (32.7)
			Abnormal CS	1 (0.5)	2 (1.0)	7 (3.4)	10 (4.9)
			Total	127 (62.0)	70 (34.1)	8 (3.9)	205 (100)
	D29	Placebo (N=69)	Normal	39 (58.2)	3 (4.5)	0	42 (62.7)
			Abnormal NCS	5 (7.5)	12 (17.9)	2 (3.0)	19 (28.4)
			Abnormal CS	0	0	6 (9.0)	6 (9.0)
			Total	44 (65.7)	15 (22.4)	8 (11.9)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	31 (45.6)	5 (7.4)	0	36 (52.9)
			Abnormal NCS	10 (14.7)	19 (27.9)	1 (1.5)	30 (44.1)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	41 (60.3)	24 (35.3)	3 (4.4)	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Occult Blood	D29	GS1-144 60 mg QD (N=69)	Normal	33 (49.3)	5 (7.5)	0	38 (56.7)
			Abnormal NCS	9 (13.4)	14 (20.9)	1 (1.5)	24 (35.8)
			Abnormal CS	0	1 (1.5)	4 (6.0)	5 (7.5)
			Total	42 (62.7)	20 (29.9)	5 (7.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	35 (52.2)	9 (13.4)	0	44 (65.7)
			Abnormal NCS	7 (10.4)	16 (23.9)	0	23 (34.3)
			Abnormal CS	0	0	0	0
			Total	42 (62.7)	25 (37.3)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	99 (49.0)	19 (9.4)	0	118 (58.4)
			Abnormal NCS	26 (12.9)	49 (24.3)	2 (1.0)	77 (38.1)
			Abnormal CS	0	1 (0.5)	6 (3.0)	7 (3.5)
			Total	125 (61.9)	69 (34.2)	8 (4.0)	202 (100)
	D43	Placebo (N=69)	Normal	37 (56.1)	2 (3.0)	0	39 (59.1)
			Abnormal NCS	6 (9.1)	12 (18.2)	3 (4.5)	21 (31.8)
			Abnormal CS	1 (1.5)	0	5 (7.6)	6 (9.1)
			Total	44 (66.7)	14 (21.2)	8 (12.1)	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Occult Blood	D43	GS1-144 30 mg QD (N=70)	Normal	34 (50.0)	9 (13.2)	1 (1.5)	44 (64.7)
			Abnormal NCS	7 (10.3)	15 (22.1)	0	22 (32.4)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	41 (60.3)	24 (35.3)	3 (4.4)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	33 (49.3)	6 (9.0)	1 (1.5)	40 (59.7)
			Abnormal NCS	9 (13.4)	12 (17.9)	1 (1.5)	22 (32.8)
			Abnormal CS	0	2 (3.0)	3 (4.5)	5 (7.5)
			Total	42 (62.7)	20 (29.9)	5 (7.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	34 (53.1)	7 (10.9)	0	41 (64.1)
			Abnormal NCS	5 (7.8)	18 (28.1)	0	23 (35.9)
			Abnormal CS	0	0	0	0
			Total	39 (60.9)	25 (39.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	101 (50.8)	22 (11.1)	2 (1.0)	125 (62.8)
			Abnormal NCS	21 (10.6)	45 (22.6)	1 (0.5)	67 (33.7)
			Abnormal CS	0	2 (1.0)	5 (2.5)	7 (3.5)
			Total	122 (61.3)	69 (34.7)	8 (4.0)	199 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Occult Blood	D57	Placebo (N=69)	Normal	35 (53.0)	6 (9.1)	0	41 (62.1)
			Abnormal NCS	8 (12.1)	8 (12.1)	3 (4.5)	19 (28.8)
			Abnormal CS	1 (1.5)	0	5 (7.6)	6 (9.1)
			Total	44 (66.7)	14 (21.2)	8 (12.1)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	31 (46.3)	5 (7.5)	1 (1.5)	37 (55.2)
			Abnormal NCS	9 (13.4)	18 (26.9)	1 (1.5)	28 (41.8)
			Abnormal CS	0	1 (1.5)	1 (1.5)	2 (3.0)
			Total	40 (59.7)	24 (35.8)	3 (4.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	30 (45.5)	7 (10.6)	1 (1.5)	38 (57.6)
			Abnormal NCS	12 (18.2)	11 (16.7)	1 (1.5)	24 (36.4)
			Abnormal CS	0	2 (3.0)	2 (3.0)	4 (6.1)
			Total	42 (63.6)	20 (30.3)	4 (6.1)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	30 (47.6)	9 (14.3)	0	39 (61.9)
			Abnormal NCS	8 (12.7)	16 (25.4)	0	24 (38.1)
			Abnormal CS	0	0	0	0
			Total	38 (60.3)	25 (39.7)	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Occult Blood	D57	Combined GS1-144 (N=207)	Normal	91 (46.4)	21 (10.7)	2 (1.0)	114 (58.2)
			Abnormal NCS	29 (14.8)	45 (23.0)	2 (1.0)	76 (38.8)
			Abnormal CS	0	3 (1.5)	3 (1.5)	6 (3.1)
			Total	120 (61.2)	69 (35.2)	7 (3.6)	196 (100)
	D71	Placebo (N=69)	Normal	38 (58.5)	2 (3.1)	3 (4.6)	43 (66.2)
			Abnormal NCS	6 (9.2)	11 (16.9)	0	17 (26.2)
			Abnormal CS	0	0	5 (7.7)	5 (7.7)
			Total	44 (67.7)	13 (20.0)	8 (12.3)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	30 (44.8)	7 (10.4)	2 (3.0)	39 (58.2)
			Abnormal NCS	9 (13.4)	17 (25.4)	0	26 (38.8)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.0)
			Total	40 (59.7)	24 (35.8)	3 (4.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	32 (49.2)	6 (9.2)	1 (1.5)	39 (60.0)
			Abnormal NCS	8 (12.3)	11 (16.9)	2 (3.1)	21 (32.3)
			Abnormal CS	1 (1.5)	3 (4.6)	1 (1.5)	5 (7.7)
			Total	41 (63.1)	20 (30.8)	4 (6.2)	65 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Occult Blood	D71	GS1-144 30 mg BID (N=68)	Normal	32 (50.8)	6 (9.5)	0	38 (60.3)
			Abnormal NCS	5 (7.9)	19 (30.2)	0	24 (38.1)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	38 (60.3)	25 (39.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	94 (48.2)	19 (9.7)	3 (1.5)	116 (59.5)
			Abnormal NCS	22 (11.3)	47 (24.1)	2 (1.0)	71 (36.4)
			Abnormal CS	3 (1.5)	3 (1.5)	2 (1.0)	8 (4.1)
			Total	119 (61.0)	69 (35.4)	7 (3.6)	195 (100)
	D85	Placebo (N=69)	Normal	35 (54.7)	3 (4.7)	2 (3.1)	40 (62.5)
			Abnormal NCS	8 (12.5)	10 (15.6)	1 (1.6)	19 (29.7)
			Abnormal CS	0	0	5 (7.8)	5 (7.8)
			Total	43 (67.2)	13 (20.3)	8 (12.5)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	31 (47.0)	6 (9.1)	2 (3.0)	39 (59.1)
			Abnormal NCS	8 (12.1)	18 (27.3)	0	26 (39.4)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	39 (59.1)	24 (36.4)	3 (4.5)	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Occult Blood	D85	GS1-144 60 mg QD (N=69)	Normal	28 (42.4)	7 (10.6)	2 (3.0)	37 (56.1)
			Abnormal NCS	14 (21.2)	11 (16.7)	1 (1.5)	26 (39.4)
			Abnormal CS	0	2 (3.0)	1 (1.5)	3 (4.5)
			Total	42 (63.6)	20 (30.3)	4 (6.1)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	33 (52.4)	7 (11.1)	0	40 (63.5)
			Abnormal NCS	4 (6.3)	17 (27.0)	0	21 (33.3)
			Abnormal CS	1 (1.6)	1 (1.6)	0	2 (3.2)
			Total	38 (60.3)	25 (39.7)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	92 (47.2)	20 (10.3)	4 (2.1)	116 (59.5)
			Abnormal NCS	26 (13.3)	46 (23.6)	1 (0.5)	73 (37.4)
			Abnormal CS	1 (0.5)	3 (1.5)	2 (1.0)	6 (3.1)
			Total	119 (61.0)	69 (35.4)	7 (3.6)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	38 (59.4)	5 (7.8)	4 (6.3)	47 (73.4)
			Abnormal NCS	5 (7.8)	7 (10.9)	1 (1.6)	13 (20.3)
			Abnormal CS	1 (1.6)	0	3 (4.7)	4 (6.3)
			Total	44 (68.8)	12 (18.8)	8 (12.5)	64 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Occult Blood	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	28 (41.8)	7 (10.4)	1 (1.5)	36 (53.7)
			Abnormal NCS	12 (17.9)	17 (25.4)	0	29 (43.3)
			Abnormal CS	0	0	2 (3.0)	2 (3.0)
			Total	40 (59.7)	24 (35.8)	3 (4.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	31 (47.0)	5 (7.6)	2 (3.0)	38 (57.6)
			Abnormal NCS	9 (13.6)	12 (18.2)	0	21 (31.8)
			Abnormal CS	1 (1.5)	3 (4.5)	3 (4.5)	7 (10.6)
			Total	41 (62.1)	20 (30.3)	5 (7.6)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	32 (50.8)	7 (11.1)	0	39 (61.9)
			Abnormal NCS	5 (7.9)	17 (27.0)	0	22 (34.9)
			Abnormal CS	2 (3.2)	0	0	2 (3.2)
			Total	39 (61.9)	24 (38.1)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	91 (46.4)	19 (9.7)	3 (1.5)	113 (57.7)
			Abnormal NCS	26 (13.3)	46 (23.5)	0	72 (36.7)
			Abnormal CS	3 (1.5)	3 (1.5)	5 (2.6)	11 (5.6)
			Total	120 (61.2)	68 (34.7)	8 (4.1)	196 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	D15	Placebo (N=69)	Normal	65 (94.2)	0	1 (1.4)	66 (95.7)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	1 (1.4)	1 (1.4)	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (92.8)	2 (2.9)	0	66 (95.7)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	66 (95.7)	3 (4.3)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	2 (2.9)	0	61 (89.7)
			Abnormal NCS	4 (5.9)	2 (2.9)	0	6 (8.8)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	D15	Combined GS1-144 (N=207)	Normal	188 (91.7)	6 (2.9)	0	194 (94.6)
			Abnormal NCS	7 (3.4)	3 (1.5)	0	10 (4.9)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	196 (95.6)	9 (4.4)	0	205 (100)
	D29	Placebo (N=69)	Normal	61 (91.0)	1 (1.5)	1 (1.5)	63 (94.0)
			Abnormal NCS	4 (6.0)	0	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	1 (1.5)	1 (1.5)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (86.6)	2 (3.0)	0	60 (89.6)
			Abnormal NCS	4 (6.0)	2 (3.0)	0	6 (9.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (94.0)	4 (6.0)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urine Protein	D29	GS1-144 30 mg BID (N=68)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	186 (92.1)	5 (2.5)	0	191 (94.6)
			Abnormal NCS	6 (3.0)	4 (2.0)	0	10 (5.0)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	193 (95.5)	9 (4.5)	0	202 (100)
	D43	Placebo (N=69)	Normal	62 (93.9)	1 (1.5)	1 (1.5)	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	1 (1.5)	1 (1.5)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	2 (2.9)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	D43	GS1-144 60 mg QD (N=69)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (95.3)	1 (1.6)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	185 (93.0)	6 (3.0)	0	191 (96.0)
			Abnormal NCS	4 (2.0)	2 (1.0)	0	6 (3.0)
			Abnormal CS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Total	190 (95.5)	9 (4.5)	0	199 (100)
	D57	Placebo (N=69)	Normal	63 (95.5)	1 (1.5)	1 (1.5)	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	1 (1.5)	1 (1.5)	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	D57	GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	2 (3.0)	0	61 (92.4)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	182 (92.9)	6 (3.1)	0	188 (95.9)
			Abnormal NCS	5 (2.6)	2 (1.0)	0	7 (3.6)
			Abnormal CS	0	1 (0.5)	0	1 (0.5)
			Total	187 (95.4)	9 (4.6)	0	196 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	D71	Placebo (N=69)	Normal	61 (93.8)	1 (1.5)	1 (1.5)	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	1 (1.5)	1 (1.5)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	58 (89.2)	3 (4.6)	0	61 (93.8)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.1)
			Abnormal CS	2 (3.1)	0	0	2 (3.1)
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	1 (1.6)	0	59 (93.7)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	D71	Combined GS1-144 (N=207)	Normal	180 (92.3)	6 (3.1)	0	186 (95.4)
			Abnormal NCS	4 (2.1)	3 (1.5)	0	7 (3.6)
			Abnormal CS	2 (1.0)	0	0	2 (1.0)
			Total	186 (95.4)	9 (4.6)	0	195 (100)
	D85	Placebo (N=69)	Normal	59 (92.2)	1 (1.6)	1 (1.6)	61 (95.3)
			Abnormal NCS	3 (4.7)	0	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	1 (1.6)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (95.5)	2 (3.0)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (90.9)	3 (4.5)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	D85	GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	1 (1.6)	0	55 (87.3)
			Abnormal NCS	7 (11.1)	1 (1.6)	0	8 (12.7)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	177 (90.8)	6 (3.1)	0	183 (93.8)
			Abnormal NCS	9 (4.6)	3 (1.5)	0	12 (6.2)
			Abnormal CS	0	0	0	0
			Total	186 (95.4)	9 (4.6)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	61 (95.3)	1 (1.6)	1 (1.6)	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	1 (1.6)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	2 (3.0)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	58 (87.9)	3 (4.5)	0	61 (92.4)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.1)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	2 (3.2)	0	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	61 (96.8)	2 (3.2)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	180 (91.8)	6 (3.1)	0	186 (94.9)
			Abnormal NCS	6 (3.1)	3 (1.5)	0	9 (4.6)
			Abnormal CS	1 (0.5)	0	0	1 (0.5)
			Total	187 (95.4)	9 (4.6)	0	196 (100)
Urine Bilirubin	D15	Placebo (N=69)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D15	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	205 (100)	0	0	205 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	205 (100)	0	0	205 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D29	Placebo (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D29	Combined GS1-144 (N=207)	Normal	201 (99.5)	0	0	201 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	202 (100)	0	0	202 (100)
	D43	Placebo (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D43	GS1-144 30 mg BID (N=68)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		Combined GS1-144 (N=207)	Normal	198 (100)	0	0	198 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	198 (100)	0	0	198 (100)
	D57	Placebo (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D57	GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	196 (100)	0	0	196 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	196 (100)	0	0	196 (100)
	D71	Placebo (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D71	GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (99.5)	0	0	194 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	195 (100)	0	0	195 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D85	Placebo (N=69)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (100)	0	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	D85	Combined GS1-144 (N=207)	Normal	194 (100)	0	0	194 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	194 (100)	0	0	194 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	196 (100)	0	0	196 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	196 (100)	0	0	196 (100)
Urobilinogen	D15	Placebo (N=69)	Normal	69 (100)	0	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urobilinogen	D15	GS1-144 60 mg QD (N=69)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	1 (1.5)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	202 (98.5)	2 (1.0)	0	204 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	203 (99.0)	2 (1.0)	0	205 (100)
	D29	Placebo (N=69)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	D29	GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	200 (99.0)	2 (1.0)	0	202 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	200 (99.0)	2 (1.0)	0	202 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	D43	Placebo (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	D43	Combined GS1-144 (N=207)	Normal	196 (98.5)	1 (0.5)	0	197 (99.0)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	197 (99.0)	2 (1.0)	0	199 (100)
	D57	Placebo (N=69)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	D57	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (98.5)	2 (1.0)	0	194 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	193 (99.0)	2 (1.0)	0	195 (100)
	D71	Placebo (N=69)	Normal	64 (98.5)	0	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (100)	0	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urobilinogen	D71	GS1-144 60 mg QD (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (99.0)	1 (0.5)	0	193 (99.5)
			Abnormal NCS	0	1 (0.5)	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	192 (99.0)	2 (1.0)	0	194 (100)
	D85	Placebo (N=69)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	D85	GS1-144 30 mg QD (N=70)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.9)	2 (1.0)	0	193 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	193 (99.0)	2 (1.0)	0	195 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	Safety Follow-up	Placebo (N=69)	Normal	64 (100)	0	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (100)	0	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	1 (1.6)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	Safety Follow-up	Combined GS1-144 (N=207)	Normal	193 (98.5)	2 (1.0)	0	195 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	194 (99.0)	2 (1.0)	0	196 (100)
Ketones	D15	Placebo (N=69)	Normal	68 (98.6)	1 (1.4)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (98.6)	1 (1.4)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	69 (100)	0	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	D15	GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		Combined GS1-144 (N=207)	Normal	198 (97.1)	1 (0.5)	0	199 (97.5)
			Abnormal NCS	5 (2.5)	0	0	5 (2.5)
			Abnormal CS	0	0	0	0
			Total	203 (99.5)	1 (0.5)	0	204 (100)
	D29	Placebo (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (100)	0	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	D29	GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	67 (100)	0	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		Combined GS1-144 (N=207)	Normal	199 (98.5)	0	0	199 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	201 (99.5)	1 (0.5)	0	202 (100)
	D43	Placebo (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	D43	GS1-144 30 mg QD (N=70)	Normal	67 (98.5)	0	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	68 (100)	0	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (98.5)	1 (1.5)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	196 (99.0)	1 (0.5)	0	197 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	197 (99.5)	1 (0.5)	0	198 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	D57	Placebo (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	D57	Combined GS1-144 (N=207)	Normal	194 (99.0)	1 (0.5)	0	195 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	195 (99.5)	1 (0.5)	0	196 (100)
	D71	Placebo (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (98.5)	0	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (98.5)	1 (1.5)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	D71	GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	193 (99.0)	1 (0.5)	0	194 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	194 (99.5)	1 (0.5)	0	195 (100)
	D85	Placebo (N=69)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (100)	0	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	D85	GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (100)	0	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	194 (99.5)	1 (0.5)	0	195 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	194 (99.5)	1 (0.5)	0	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	61 (95.3)	1 (1.6)	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	64 (95.5)	0	0	64 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	67 (100)	0	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (98.5)	1 (1.5)	0	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (100)	0	0	63 (100)
		Combined GS1-144 (N=207)	Normal	191 (97.4)	1 (0.5)	0	192 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	195 (99.5)	1 (0.5)	0	196 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Leukocytes	D15	Placebo (N=69)	Normal	39 (56.5)	5 (7.2)	0	44 (63.8)
			Abnormal NCS	10 (14.5)	7 (10.1)	3 (4.3)	20 (29.0)
			Abnormal CS	1 (1.4)	1 (1.4)	3 (4.3)	5 (7.2)
			Total	50 (72.5)	13 (18.8)	6 (8.7)	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	36 (52.2)	11 (15.9)	1 (1.4)	48 (69.6)
			Abnormal NCS	10 (14.5)	5 (7.2)	1 (1.4)	16 (23.2)
			Abnormal CS	1 (1.4)	3 (4.3)	1 (1.4)	5 (7.2)
			Total	47 (68.1)	19 (27.5)	3 (4.3)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	43 (63.2)	5 (7.4)	1 (1.5)	49 (72.1)
			Abnormal NCS	8 (11.8)	5 (7.4)	0	13 (19.1)
			Abnormal CS	1 (1.5)	0	5 (7.4)	6 (8.8)
			Total	52 (76.5)	10 (14.7)	6 (8.8)	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	41 (60.3)	11 (16.2)	0	52 (76.5)
			Abnormal NCS	9 (13.2)	6 (8.8)	0	15 (22.1)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	50 (73.5)	18 (26.5)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urine Leukocytes	D15	Combined GS1-144 (N=207)	Normal	120 (58.5)	27 (13.2)	2 (1.0)	149 (72.7)
			Abnormal NCS	27 (13.2)	16 (7.8)	1 (0.5)	44 (21.5)
			Abnormal CS	2 (1.0)	4 (2.0)	6 (2.9)	12 (5.9)
			Total	149 (72.7)	47 (22.9)	9 (4.4)	205 (100)
	D29	Placebo (N=69)	Normal	40 (59.7)	5 (7.5)	3 (4.5)	48 (71.6)
			Abnormal NCS	8 (11.9)	7 (10.4)	2 (3.0)	17 (25.4)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.0)
			Total	49 (73.1)	12 (17.9)	6 (9.0)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	36 (52.9)	12 (17.6)	1 (1.5)	49 (72.1)
			Abnormal NCS	10 (14.7)	6 (8.8)	1 (1.5)	17 (25.0)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (2.9)
			Total	47 (69.1)	18 (26.5)	3 (4.4)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	38 (56.7)	6 (9.0)	5 (7.5)	49 (73.1)
			Abnormal NCS	11 (16.4)	4 (6.0)	0	15 (22.4)
			Abnormal CS	2 (3.0)	0	1 (1.5)	3 (4.5)
			Total	51 (76.1)	10 (14.9)	6 (9.0)	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Leukocytes	D29	GS1-144 30 mg BID (N=68)	Normal	43 (64.2)	9 (13.4)	0	52 (77.6)
			Abnormal NCS	7 (10.4)	8 (11.9)	0	15 (22.4)
			Abnormal CS	0	0	0	0
			Total	50 (74.6)	17 (25.4)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	117 (57.9)	27 (13.4)	6 (3.0)	150 (74.3)
			Abnormal NCS	28 (13.9)	18 (8.9)	1 (0.5)	47 (23.3)
			Abnormal CS	3 (1.5)	0	2 (1.0)	5 (2.5)
			Total	148 (73.3)	45 (22.3)	9 (4.5)	202 (100)
	D43	Placebo (N=69)	Normal	39 (59.1)	4 (6.1)	5 (7.6)	48 (72.7)
			Abnormal NCS	7 (10.6)	8 (12.1)	1 (1.5)	16 (24.2)
			Abnormal CS	2 (3.0)	0	0	2 (3.0)
			Total	48 (72.7)	12 (18.2)	6 (9.1)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	38 (55.9)	12 (17.6)	2 (2.9)	52 (76.5)
			Abnormal NCS	8 (11.8)	6 (8.8)	0	14 (20.6)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (2.9)
			Total	47 (69.1)	18 (26.5)	3 (4.4)	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Leukocytes	D43	GS1-144 60 mg QD (N=69)	Normal	41 (61.2)	3 (4.5)	3 (4.5)	47 (70.1)
			Abnormal NCS	9 (13.4)	7 (10.4)	1 (1.5)	17 (25.4)
			Abnormal CS	1 (1.5)	0	2 (3.0)	3 (4.5)
			Total	51 (76.1)	10 (14.9)	6 (9.0)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	40 (62.5)	10 (15.6)	0	50 (78.1)
			Abnormal NCS	7 (10.9)	6 (9.4)	0	13 (20.3)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	48 (75.0)	16 (25.0)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	119 (59.8)	25 (12.6)	5 (2.5)	149 (74.9)
			Abnormal NCS	24 (12.1)	19 (9.5)	1 (0.5)	44 (22.1)
			Abnormal CS	3 (1.5)	0	3 (1.5)	6 (3.0)
			Total	146 (73.4)	44 (22.1)	9 (4.5)	199 (100)
	D57	Placebo (N=69)	Normal	42 (63.6)	6 (9.1)	2 (3.0)	50 (75.8)
			Abnormal NCS	5 (7.6)	6 (9.1)	4 (6.1)	15 (22.7)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	48 (72.7)	12 (18.2)	6 (9.1)	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urine Leukocytes	D57	GS1-144 30 mg QD (N=70)	Normal	37 (55.2)	13 (19.4)	2 (3.0)	52 (77.6)
			Abnormal NCS	9 (13.4)	5 (7.5)	0	14 (20.9)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	46 (68.7)	18 (26.9)	3 (4.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	44 (66.7)	4 (6.1)	1 (1.5)	49 (74.2)
			Abnormal NCS	5 (7.6)	6 (9.1)	3 (4.5)	14 (21.2)
			Abnormal CS	1 (1.5)	0	2 (3.0)	3 (4.5)
			Total	50 (75.8)	10 (15.2)	6 (9.1)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	41 (65.1)	13 (20.6)	0	54 (85.7)
			Abnormal NCS	5 (7.9)	3 (4.8)	0	8 (12.7)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	47 (74.6)	16 (25.4)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	122 (62.2)	30 (15.3)	3 (1.5)	155 (79.1)
			Abnormal NCS	19 (9.7)	14 (7.1)	3 (1.5)	36 (18.4)
			Abnormal CS	2 (1.0)	0	3 (1.5)	5 (2.6)
			Total	143 (73.0)	44 (22.4)	9 (4.6)	196 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Leukocytes	D71	Placebo (N=69)	Normal	39 (60.0)	5 (7.7)	2 (3.1)	46 (70.8)
			Abnormal NCS	7 (10.8)	7 (10.8)	3 (4.6)	17 (26.2)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.1)
			Total	47 (72.3)	12 (18.5)	6 (9.2)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	40 (59.7)	11 (16.4)	0	51 (76.1)
			Abnormal NCS	4 (6.0)	7 (10.4)	1 (1.5)	12 (17.9)
			Abnormal CS	2 (3.0)	0	2 (3.0)	4 (6.0)
			Total	46 (68.7)	18 (26.9)	3 (4.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	39 (60.0)	4 (6.2)	3 (4.6)	46 (70.8)
			Abnormal NCS	10 (15.4)	5 (7.7)	1 (1.5)	16 (24.6)
			Abnormal CS	0	1 (1.5)	2 (3.1)	3 (4.6)
			Total	49 (75.4)	10 (15.4)	6 (9.2)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	40 (63.5)	10 (15.9)	0	50 (79.4)
			Abnormal NCS	4 (6.3)	6 (9.5)	0	10 (15.9)
			Abnormal CS	3 (4.8)	0	0	3 (4.8)
			Total	47 (74.6)	16 (25.4)	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Urine Leukocytes	D71	Combined GS1-144 (N=207)	Normal	119 (61.0)	25 (12.8)	3 (1.5)	147 (75.4)
			Abnormal NCS	18 (9.2)	18 (9.2)	2 (1.0)	38 (19.5)
			Abnormal CS	5 (2.6)	1 (0.5)	4 (2.1)	10 (5.1)
			Total	142 (72.8)	44 (22.6)	9 (4.6)	195 (100)
	D85	Placebo (N=69)	Normal	37 (57.8)	7 (10.9)	2 (3.1)	46 (71.9)
			Abnormal NCS	8 (12.5)	5 (7.8)	2 (3.1)	15 (23.4)
			Abnormal CS	1 (1.6)	0	2 (3.1)	3 (4.7)
			Total	46 (71.9)	12 (18.8)	6 (9.4)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	40 (60.6)	11 (16.7)	0	51 (77.3)
			Abnormal NCS	5 (7.6)	7 (10.6)	1 (1.5)	13 (19.7)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.0)
			Total	46 (69.7)	18 (27.3)	2 (3.0)	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	38 (57.6)	5 (7.6)	4 (6.1)	47 (71.2)
			Abnormal NCS	11 (16.7)	5 (7.6)	2 (3.0)	18 (27.3)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	50 (75.8)	10 (15.2)	6 (9.1)	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urine Leukocytes	D85	GS1-144 30 mg BID (N=68)	Normal	38 (60.3)	11 (17.5)	0	49 (77.8)
			Abnormal NCS	7 (11.1)	5 (7.9)	0	12 (19.0)
			Abnormal CS	2 (3.2)	0	0	2 (3.2)
			Total	47 (74.6)	16 (25.4)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	116 (59.5)	27 (13.8)	4 (2.1)	147 (75.4)
			Abnormal NCS	23 (11.8)	17 (8.7)	3 (1.5)	43 (22.1)
			Abnormal CS	4 (2.1)	0	1 (0.5)	5 (2.6)
			Total	143 (73.3)	44 (22.6)	8 (4.1)	195 (100)
	Safety Follow-up	Placebo (N=69)	Normal	40 (62.5)	6 (9.4)	4 (6.3)	50 (78.1)
			Abnormal NCS	4 (6.3)	6 (9.4)	1 (1.6)	11 (17.2)
			Abnormal CS	2 (3.1)	0	1 (1.6)	3 (4.7)
			Total	46 (71.9)	12 (18.8)	6 (9.4)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	34 (50.7)	13 (19.4)	0	47 (70.1)
			Abnormal NCS	13 (19.4)	5 (7.5)	1 (1.5)	19 (28.4)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	47 (70.1)	18 (26.9)	2 (3.0)	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Leukocytes	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	40 (60.6)	4 (6.1)	3 (4.5)	47 (71.2)
			Abnormal NCS	8 (12.1)	6 (9.1)	2 (3.0)	16 (24.2)
			Abnormal CS	2 (3.0)	0	1 (1.5)	3 (4.5)
			Total	50 (75.8)	10 (15.2)	6 (9.1)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	38 (60.3)	12 (19.0)	0	50 (79.4)
			Abnormal NCS	6 (9.5)	4 (6.3)	0	10 (15.9)
			Abnormal CS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Total	46 (73.0)	17 (27.0)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	112 (57.1)	29 (14.8)	3 (1.5)	144 (73.5)
			Abnormal NCS	27 (13.8)	15 (7.7)	3 (1.5)	45 (23.0)
			Abnormal CS	4 (2.0)	1 (0.5)	2 (1.0)	7 (3.6)
			Total	143 (73.0)	45 (23.0)	8 (4.1)	196 (100)
Urine Erythrocytes	D15	Placebo (N=69)	Normal	51 (73.9)	6 (8.7)	4 (5.8)	61 (88.4)
			Abnormal NCS	4 (5.8)	2 (2.9)	0	6 (8.7)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	55 (79.7)	8 (11.6)	6 (8.7)	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Erythrocytes	D15	GS1-144 30 mg QD (N=70)	Normal	50 (72.5)	7 (10.1)	1 (1.4)	58 (84.1)
			Abnormal NCS	7 (10.1)	2 (2.9)	0	9 (13.0)
			Abnormal CS	1 (1.4)	1 (1.4)	0	2 (2.9)
			Total	58 (84.1)	10 (14.5)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	48 (71.6)	4 (6.0)	0	52 (77.6)
			Abnormal NCS	6 (9.0)	5 (7.5)	0	11 (16.4)
			Abnormal CS	0	1 (1.5)	3 (4.5)	4 (6.0)
			Total	54 (80.6)	10 (14.9)	3 (4.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	55 (82.1)	4 (6.0)	0	59 (88.1)
			Abnormal NCS	1 (1.5)	6 (9.0)	0	7 (10.4)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	57 (85.1)	10 (14.9)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	153 (75.4)	15 (7.4)	1 (0.5)	169 (83.3)
			Abnormal NCS	14 (6.9)	13 (6.4)	0	27 (13.3)
			Abnormal CS	2 (1.0)	2 (1.0)	3 (1.5)	7 (3.4)
			Total	169 (83.3)	30 (14.8)	4 (2.0)	203 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Erythrocytes	D29	Placebo (N=69)	Normal	52 (77.6)	4 (6.0)	4 (6.0)	60 (89.6)
			Abnormal NCS	2 (3.0)	3 (4.5)	0	5 (7.5)
			Abnormal CS	0	0	2 (3.0)	2 (3.0)
			Total	54 (80.6)	7 (10.4)	6 (9.0)	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	54 (79.4)	8 (11.8)	0	62 (91.2)
			Abnormal NCS	3 (4.4)	2 (2.9)	1 (1.5)	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	57 (83.8)	10 (14.7)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	51 (77.3)	5 (7.6)	1 (1.5)	57 (86.4)
			Abnormal NCS	2 (3.0)	4 (6.1)	0	6 (9.1)
			Abnormal CS	0	1 (1.5)	2 (3.0)	3 (4.5)
			Total	53 (80.3)	10 (15.2)	3 (4.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	51 (77.3)	7 (10.6)	0	58 (87.9)
			Abnormal NCS	5 (7.6)	3 (4.5)	0	8 (12.1)
			Abnormal CS	0	0	0	0
			Total	56 (84.8)	10 (15.2)	0	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urine Erythrocytes	D29	Combined GS1-144 (N=207)	Normal	156 (78.0)	20 (10.0)	1 (0.5)	177 (88.5)
			Abnormal NCS	10 (5.0)	9 (4.5)	1 (0.5)	20 (10.0)
			Abnormal CS	0	1 (0.5)	2 (1.0)	3 (1.5)
			Total	166 (83.0)	30 (15.0)	4 (2.0)	200 (100)
	D43	Placebo (N=69)	Normal	50 (75.8)	4 (6.1)	3 (4.5)	57 (86.4)
			Abnormal NCS	4 (6.1)	1 (1.5)	3 (4.5)	8 (12.1)
			Abnormal CS	0	1 (1.5)	0	1 (1.5)
			Total	54 (81.8)	6 (9.1)	6 (9.1)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	54 (79.4)	3 (4.4)	1 (1.5)	58 (85.3)
			Abnormal NCS	3 (4.4)	7 (10.3)	0	10 (14.7)
			Abnormal CS	0	0	0	0
			Total	57 (83.8)	10 (14.7)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	48 (72.7)	6 (9.1)	0	54 (81.8)
			Abnormal NCS	5 (7.6)	2 (3.0)	1 (1.5)	8 (12.1)
			Abnormal CS	0	2 (3.0)	2 (3.0)	4 (6.1)
			Total	53 (80.3)	10 (15.2)	3 (4.5)	66 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Erythrocytes	D43	GS1-144 30 mg BID (N=68)	Normal	50 (78.1)	5 (7.8)	0	55 (85.9)
			Abnormal NCS	4 (6.3)	5 (7.8)	0	9 (14.1)
			Abnormal CS	0	0	0	0
			Total	54 (84.4)	10 (15.6)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	152 (76.8)	14 (7.1)	1 (0.5)	167 (84.3)
			Abnormal NCS	12 (6.1)	14 (7.1)	1 (0.5)	27 (13.6)
			Abnormal CS	0	2 (1.0)	2 (1.0)	4 (2.0)
			Total	164 (82.8)	30 (15.2)	4 (2.0)	198 (100)
	D57	Placebo (N=69)	Normal	49 (75.4)	5 (7.7)	5 (7.7)	59 (90.8)
			Abnormal NCS	3 (4.6)	1 (1.5)	0	4 (6.2)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.1)
			Total	53 (81.5)	6 (9.2)	6 (9.2)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	54 (80.6)	7 (10.4)	0	61 (91.0)
			Abnormal NCS	2 (3.0)	3 (4.5)	1 (1.5)	6 (9.0)
			Abnormal CS	0	0	0	0
			Total	56 (83.6)	10 (14.9)	1 (1.5)	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urine Erythrocytes	D57	GS1-144 60 mg QD (N=69)	Normal	46 (70.8)	5 (7.7)	1 (1.5)	52 (80.0)
			Abnormal NCS	7 (10.8)	2 (3.1)	0	9 (13.8)
			Abnormal CS	0	3 (4.6)	1 (1.5)	4 (6.2)
			Total	53 (81.5)	10 (15.4)	2 (3.1)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	48 (76.2)	6 (9.5)	0	54 (85.7)
			Abnormal NCS	5 (7.9)	4 (6.3)	0	9 (14.3)
			Abnormal CS	0	0	0	0
			Total	53 (84.1)	10 (15.9)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	148 (75.9)	18 (9.2)	1 (0.5)	167 (85.6)
			Abnormal NCS	14 (7.2)	9 (4.6)	1 (0.5)	24 (12.3)
			Abnormal CS	0	3 (1.5)	1 (0.5)	4 (2.1)
			Total	162 (83.1)	30 (15.4)	3 (1.5)	195 (100)
	D71	Placebo (N=69)	Normal	49 (76.6)	3 (4.7)	2 (3.1)	54 (84.4)
			Abnormal NCS	3 (4.7)	3 (4.7)	2 (3.1)	8 (12.5)
			Abnormal CS	0	0	2 (3.1)	2 (3.1)
			Total	52 (81.3)	6 (9.4)	6 (9.4)	64 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Erythrocytes	D71	GS1-144 30 mg QD (N=70)	Normal	52 (77.6)	5 (7.5)	1 (1.5)	58 (86.6)
			Abnormal NCS	3 (4.5)	5 (7.5)	0	8 (11.9)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	56 (83.6)	10 (14.9)	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	48 (75.0)	5 (7.8)	2 (3.1)	55 (85.9)
			Abnormal NCS	3 (4.7)	2 (3.1)	0	5 (7.8)
			Abnormal CS	1 (1.6)	3 (4.7)	0	4 (6.3)
			Total	52 (81.3)	10 (15.6)	2 (3.1)	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	45 (71.4)	3 (4.8)	0	48 (76.2)
			Abnormal NCS	7 (11.1)	7 (11.1)	0	14 (22.2)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	53 (84.1)	10 (15.9)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	145 (74.7)	13 (6.7)	3 (1.5)	161 (83.0)
			Abnormal NCS	13 (6.7)	14 (7.2)	0	27 (13.9)
			Abnormal CS	3 (1.5)	3 (1.5)	0	6 (3.1)
			Total	161 (83.0)	30 (15.5)	3 (1.5)	194 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Erythrocytes	D85	Placebo (N=69)	Normal	48 (75.0)	2 (3.1)	4 (6.3)	54 (84.4)
			Abnormal NCS	3 (4.7)	4 (6.3)	0	7 (10.9)
			Abnormal CS	1 (1.6)	0	2 (3.1)	3 (4.7)
			Total	52 (81.3)	6 (9.4)	6 (9.4)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	52 (78.8)	6 (9.1)	1 (1.5)	59 (89.4)
			Abnormal NCS	3 (4.5)	4 (6.1)	0	7 (10.6)
			Abnormal CS	0	0	0	0
			Total	55 (83.3)	10 (15.2)	1 (1.5)	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	48 (75.0)	4 (6.3)	0	52 (81.3)
			Abnormal NCS	4 (6.3)	4 (6.3)	2 (3.1)	10 (15.6)
			Abnormal CS	0	2 (3.1)	0	2 (3.1)
			Total	52 (81.3)	10 (15.6)	2 (3.1)	64 (100)
		GS1-144 30 mg BID (N=68)	Normal	48 (76.2)	4 (6.3)	0	52 (82.5)
			Abnormal NCS	3 (4.8)	6 (9.5)	0	9 (14.3)
			Abnormal CS	2 (3.2)	0	0	2 (3.2)
			Total	53 (84.1)	10 (15.9)	0	63 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Urine Erythrocytes	D85	Combined GS1-144 (N=207)	Normal	148 (76.7)	14 (7.3)	1 (0.5)	163 (84.5)
			Abnormal NCS	10 (5.2)	14 (7.3)	2 (1.0)	26 (13.5)
			Abnormal CS	2 (1.0)	2 (1.0)	0	4 (2.1)
			Total	160 (82.9)	30 (15.5)	3 (1.6)	193 (100)
	Safety Follow-up	Placebo (N=69)	Normal	50 (78.1)	4 (6.3)	3 (4.7)	57 (89.1)
			Abnormal NCS	2 (3.1)	2 (3.1)	2 (3.1)	6 (9.4)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	52 (81.3)	6 (9.4)	6 (9.4)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	52 (77.6)	7 (10.4)	1 (1.5)	60 (89.6)
			Abnormal NCS	4 (6.0)	3 (4.5)	0	7 (10.4)
			Abnormal CS	0	0	0	0
			Total	56 (83.6)	10 (14.9)	1 (1.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	48 (73.8)	6 (9.2)	0	54 (83.1)
			Abnormal NCS	4 (6.2)	2 (3.1)	0	6 (9.2)
			Abnormal CS	0	2 (3.1)	3 (4.6)	5 (7.7)
			Total	52 (80.0)	10 (15.4)	3 (4.6)	65 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.1
Shift of Urinalysis by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Erythrocytes	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	46 (73.0)	5 (7.9)	0	51 (81.0)
			Abnormal NCS	5 (7.9)	5 (7.9)	0	10 (15.9)
			Abnormal CS	2 (3.2)	0	0	2 (3.2)
			Total	53 (84.1)	10 (15.9)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	146 (74.9)	18 (9.2)	1 (0.5)	165 (84.6)
			Abnormal NCS	13 (6.7)	10 (5.1)	0	23 (11.8)
			Abnormal CS	2 (1.0)	2 (1.0)	3 (1.5)	7 (3.6)
			Total	161 (82.6)	30 (15.4)	4 (2.1)	195 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	Placebo (N=69)	Normal	65 (94.2)	0	0	65 (94.2)
		Abnormal NCS	3 (4.3)	1 (1.4)	0	4 (5.8)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	0	0	66 (95.7)
		Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
		Abnormal NCS	2 (2.9)	3 (4.4)	0	5 (7.4)
		Abnormal CS	0	0	0	0
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	56 (82.4)	2 (2.9)	0	58 (85.3)
		Abnormal NCS	8 (11.8)	2 (2.9)	0	10 (14.7)
		Abnormal CS	0	0	0	0
		Total	64 (94.1)	4 (5.9)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
pH	Combined GS1-144 (N=207)	Normal	184 (89.8)	3 (1.5)	0	187 (91.2)
		Abnormal NCS	12 (5.9)	6 (2.9)	0	18 (8.8)
		Abnormal CS	0	0	0	0
		Total	196 (95.6)	9 (4.4)	0	205 (100)
Urine Glucose	Placebo (N=69)	Normal	68 (98.6)	1 (1.4)	0	69 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	1 (1.4)	1 (1.4)
		Total	68 (98.6)	0	1 (1.4)	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	0	0	66 (97.1)
		Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Glucose	GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	0	0	66 (97.1)
		Abnormal NCS	1 (1.5)	0	0	1 (1.5)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	200 (97.6)	0	0	200 (97.6)
		Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
		Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
		Total	203 (99.0)	1 (0.5)	1 (0.5)	205 (100)
Specific Gravity	Placebo (N=69)	Normal	51 (73.9)	1 (1.4)	0	52 (75.4)
		Abnormal NCS	11 (15.9)	6 (8.7)	0	17 (24.6)
		Abnormal CS	0	0	0	0
		Total	62 (89.9)	7 (10.1)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	55 (79.7)	1 (1.4)	0	56 (81.2)
		Abnormal NCS	11 (15.9)	2 (2.9)	0	13 (18.8)
		Abnormal CS	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Specific Gravity	GS1-144 60 mg QD (N=69)	Normal	58 (85.3)	0	0	58 (85.3)
		Abnormal NCS	7 (10.3)	3 (4.4)	0	10 (14.7)
		Abnormal CS	0	0	0	0
		Total	65 (95.6)	3 (4.4)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	58 (85.3)	1 (1.5)	0	59 (86.8)
		Abnormal NCS	5 (7.4)	4 (5.9)	0	9 (13.2)
		Abnormal CS	0	0	0	0
		Total	63 (92.6)	5 (7.4)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	171 (83.4)	2 (1.0)	0	173 (84.4)
		Abnormal NCS	23 (11.2)	9 (4.4)	0	32 (15.6)
		Abnormal CS	0	0	0	0
		Total	194 (94.6)	11 (5.4)	0	205 (100)
Occult Blood	Placebo (N=69)	Normal	25 (36.2)	1 (1.4)	0	26 (37.7)
		Abnormal NCS	17 (24.6)	15 (21.7)	2 (2.9)	34 (49.3)
		Abnormal CS	3 (4.3)	0	6 (8.7)	9 (13.0)
		Total	45 (65.2)	16 (23.2)	8 (11.6)	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Occult Blood	GS1-144 30 mg QD (N=70)	Normal	16 (23.2)	0	0	16 (23.2)
		Abnormal NCS	25 (36.2)	22 (31.9)	1 (1.4)	48 (69.6)
		Abnormal CS	1 (1.4)	2 (2.9)	2 (2.9)	5 (7.2)
		Total	42 (60.9)	24 (34.8)	3 (4.3)	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	22 (32.4)	2 (2.9)	0	24 (35.3)
		Abnormal NCS	18 (26.5)	16 (23.5)	0	34 (50.0)
		Abnormal CS	2 (2.9)	3 (4.4)	5 (7.4)	10 (14.7)
		Total	42 (61.8)	21 (30.9)	5 (7.4)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	26 (38.2)	2 (2.9)	0	28 (41.2)
		Abnormal NCS	14 (20.6)	22 (32.4)	0	36 (52.9)
		Abnormal CS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Total	43 (63.2)	25 (36.8)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	64 (31.2)	4 (2.0)	0	68 (33.2)
		Abnormal NCS	57 (27.8)	60 (29.3)	1 (0.5)	118 (57.6)
		Abnormal CS	6 (2.9)	6 (2.9)	7 (3.4)	19 (9.3)
		Total	127 (62.0)	70 (34.1)	8 (3.9)	205 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	Placebo (N=69)	Normal	57 (82.6)	0	1 (1.4)	58 (84.1)
		Abnormal NCS	10 (14.5)	1 (1.4)	0	11 (15.9)
		Abnormal CS	0	0	0	0
		Total	67 (97.1)	1 (1.4)	1 (1.4)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	61 (88.4)	1 (1.4)	0	62 (89.9)
		Abnormal NCS	5 (7.2)	2 (2.9)	0	7 (10.1)
		Abnormal CS	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	47 (69.1)	1 (1.5)	0	48 (70.6)
		Abnormal NCS	13 (19.1)	2 (2.9)	0	15 (22.1)
		Abnormal CS	4 (5.9)	1 (1.5)	0	5 (7.4)
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	53 (77.9)	0	0	53 (77.9)
		Abnormal NCS	13 (19.1)	2 (2.9)	0	15 (22.1)
		Abnormal CS	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Protein	Combined GS1-144 (N=207)	Normal	161 (78.5)	2 (1.0)	0	163 (79.5)
		Abnormal NCS	31 (15.1)	6 (2.9)	0	37 (18.0)
		Abnormal CS	4 (2.0)	1 (0.5)	0	5 (2.4)
		Total	196 (95.6)	9 (4.4)	0	205 (100)
Urine Bilirubin	Placebo (N=69)	Normal	67 (97.1)	0	0	67 (97.1)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
		Abnormal NCS	1 (1.4)	0	0	1 (1.4)
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Bilirubin	GS1-144 30 mg BID (N=68)	Normal	67 (98.5)	0	0	67 (98.5)
		Abnormal NCS	1 (1.5)	0	0	1 (1.5)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	203 (99.0)	0	0	203 (99.0)
		Abnormal NCS	2 (1.0)	0	0	2 (1.0)
		Abnormal CS	0	0	0	0
		Total	205 (100)	0	0	205 (100)
Urobilinogen	Placebo (N=69)	Normal	68 (98.6)	0	0	68 (98.6)
		Abnormal NCS	1 (1.4)	0	0	1 (1.4)
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	68 (98.6)	0	0	68 (98.6)
		Abnormal NCS	1 (1.4)	0	0	1 (1.4)
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urobilinogen	GS1-144 60 mg QD (N=69)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	0	0	65 (95.6)
		Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	198 (96.6)	1 (0.5)	0	199 (97.1)
		Abnormal NCS	5 (2.4)	1 (0.5)	0	6 (2.9)
		Abnormal CS	0	0	0	0
		Total	203 (99.0)	2 (1.0)	0	205 (100)
Ketones	Placebo (N=69)	Normal	65 (94.2)	1 (1.4)	0	66 (95.7)
		Abnormal NCS	3 (4.3)	0	0	3 (4.3)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ketones	GS1-144 30 mg QD (N=70)	Normal	62 (89.9)	0	0	62 (89.9)
		Abnormal NCS	7 (10.1)	0	0	7 (10.1)
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	64 (94.1)	0	0	64 (94.1)
		Abnormal NCS	3 (4.4)	1 (1.5)	0	4 (5.9)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	0	0	66 (97.1)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	Combined GS1-144 (N=207)	Normal	192 (93.7)	0	0	192 (93.7)
		Abnormal NCS	12 (5.9)	1 (0.5)	0	13 (6.3)
		Abnormal CS	0	0	0	0
		Total	204 (99.5)	1 (0.5)	0	205 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Leukocytes	Placebo (N=69)	Normal	25 (36.2)	1 (1.4)	0	26 (37.7)
		Abnormal NCS	21 (30.4)	11 (15.9)	2 (2.9)	34 (49.3)
		Abnormal CS	4 (5.8)	1 (1.4)	4 (5.8)	9 (13.0)
		Total	50 (72.5)	13 (18.8)	6 (8.7)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	21 (30.4)	5 (7.2)	0	26 (37.7)
		Abnormal NCS	24 (34.8)	11 (15.9)	0	35 (50.7)
		Abnormal CS	2 (2.9)	3 (4.3)	3 (4.3)	8 (11.6)
		Total	47 (68.1)	19 (27.5)	3 (4.3)	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	23 (33.8)	0	0	23 (33.8)
		Abnormal NCS	25 (36.8)	9 (13.2)	0	34 (50.0)
		Abnormal CS	4 (5.9)	1 (1.5)	6 (8.8)	11 (16.2)
		Total	52 (76.5)	10 (14.7)	6 (8.8)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	26 (38.2)	2 (2.9)	0	28 (41.2)
		Abnormal NCS	19 (27.9)	15 (22.1)	0	34 (50.0)
		Abnormal CS	5 (7.4)	1 (1.5)	0	6 (8.8)
		Total	50 (73.5)	18 (26.5)	0	68 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Leukocytes	Combined GS1-144 (N=207)	Normal	70 (34.1)	7 (3.4)	0	77 (37.6)
		Abnormal NCS	68 (33.2)	35 (17.1)	0	103 (50.2)
		Abnormal CS	11 (5.4)	5 (2.4)	9 (4.4)	25 (12.2)
		Total	149 (72.7)	47 (22.9)	9 (4.4)	205 (100)
Urine Erythrocytes	Placebo (N=69)	Normal	41 (59.4)	1 (1.4)	1 (1.4)	43 (62.3)
		Abnormal NCS	13 (18.8)	6 (8.7)	1 (1.4)	20 (29.0)
		Abnormal CS	1 (1.4)	1 (1.4)	4 (5.8)	6 (8.7)
		Total	55 (79.7)	8 (11.6)	6 (8.7)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	41 (59.4)	1 (1.4)	0	42 (60.9)
		Abnormal NCS	15 (21.7)	8 (11.6)	1 (1.4)	24 (34.8)
		Abnormal CS	2 (2.9)	1 (1.4)	0	3 (4.3)
		Total	58 (84.1)	10 (14.5)	1 (1.4)	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	38 (56.7)	2 (3.0)	0	40 (59.7)
		Abnormal NCS	15 (22.4)	4 (6.0)	0	19 (28.4)
		Abnormal CS	1 (1.5)	4 (6.0)	3 (4.5)	8 (11.9)
		Total	54 (80.6)	10 (14.9)	3 (4.5)	67 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.5.2
Shift of Urinalysis by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Urine Erythrocytes	GS1-144 30 mg BID (N=68)	Normal	42 (62.7)	2 (3.0)	0	44 (65.7)
		Abnormal NCS	11 (16.4)	8 (11.9)	0	19 (28.4)
		Abnormal CS	4 (6.0)	0	0	4 (6.0)
		Total	57 (85.1)	10 (14.9)	0	67 (100)
	Combined GS1-144 (N=207)	Normal	121 (59.6)	5 (2.5)	0	126 (62.1)
		Abnormal NCS	41 (20.2)	20 (9.9)	1 (0.5)	62 (30.5)
		Abnormal CS	7 (3.4)	5 (2.5)	3 (1.5)	15 (7.4)
		Total	169 (83.3)	30 (14.8)	4 (2.0)	203 (100)

Data Source: Listing 16.2.8.1.9
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.4.6.1
Summary of Elevated Liver Function Tests
SS

Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Baseline Values						
ALT or AST > 1.0 – 1.5 x ULN	4 (5.8)	5 (7.1)	6 (8.7)	1 (1.5)	12 (5.8)	16 (5.8)
ALT or AST > 1.5 x ULN	0	0	0	0	0	0
TBIL > 1.0 – 1.5 x ULN	4 (5.8)	0	1 (1.4)	1 (1.5)	2 (1.0)	6 (2.2)
TBIL > 1.5 x ULN	0	0	0	0	0	0
Worst Post-Baseline Values						
ALT > 1.5 x ULN	4 (5.8)	3 (4.3)	7 (10.1)	3 (4.4)	13 (6.3)	17 (6.2)
ALT > 2 x ULN	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.5)	4 (1.9)	5 (1.8)
ALT > 3 x ULN	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
ALT > 5 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
ALT > 8 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
AST > 1.5 x ULN	1 (1.4)	2 (2.9)	2 (2.9)	3 (4.4)	7 (3.4)	8 (2.9)
AST > 2 x ULN	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.9)	4 (1.9)	5 (1.8)
AST > 3 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
AST > 5 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
AST > 8 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
ALT or AST > 3 x ULN	1 (1.4)	0	1 (1.4)	1 (1.5)	2 (1.0)	3 (1.1)
ALT or AST > 5 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
ALT or AST > 8 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
ALT or AST > 10 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)

Data Source: Listing 16.2.8.1.11
ALP = Alkaline Phosphatase; ALT = Alanine Aminotransferase; AST = Aspartate Aminotransferase; INR = Prothrombin International Normalized Ratio; TBIL = Total Bilirubin; ULN = Upper Limit of Normal.
Subjects may be counted in multiple categories.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst post-baseline values including all post-baseline data after first study drug administration.

Table 14.3.4.6.1
Summary of Elevated Liver Function Tests
SS

Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
ALT or AST > 20 x ULN	1 (1.4)	0	0	1 (1.5)	1 (0.5)	2 (0.7)
TBIL > 2 x ULN	0	0	0	0	0	0
ALP > 2 x ULN	0	0	0	0	0	0
(ALT or AST > 3 x ULN) and (TBIL > 1.5 x ULN)	0	0	0	1 (1.5)	1 (0.5)	1 (0.4)
(ALT or AST > 3 x ULN) and (TBIL > 2 x ULN or INR>1.5)	0	0	0	0	0	0

Data Source: Listing 16.2.8.1.11

ALP = Alkaline Phosphatase; ALT = Alanine Aminotransferase; AST = Aspartate Aminotransferase; INR = Prothrombin International Normalized Ratio; TBIL = Total Bilirubin; ULN = Upper Limit of Normal.

Subjects may be counted in multiple categories.

Baseline values were defined as the last available measurement value prior to the first study drug administration.

Summarizing the worst post-baseline values including all post-baseline data after first study drug administration.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Alanine Aminotransferase Increased	Placebo (N=69)	Grade 0	58 (84.1)	1 (1.4)	0	0	0	59 (85.5)
		Grade 1	8 (11.6)	1 (1.4)	0	0	0	9 (13.0)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	1 (1.4)	0	0	0	0	1 (1.4)
		Total	67 (97.1)	2 (2.9)	0	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Grade 0	57 (81.4)	4 (5.7)	0	0	0	61 (87.1)
		Grade 1	9 (12.9)	0	0	0	0	9 (12.9)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	66 (94.3)	4 (5.7)	0	0	0	70 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Alanine Aminotransferase Increased	GS1-144 60 mg QD (N=69)	Grade 0	54 (79.4)	1 (1.5)	0	0	0	55 (80.9)
		Grade 1	10 (14.7)	2 (2.9)	0	0	0	12 (17.6)
		Grade 2	1 (1.5)	0	0	0	0	1 (1.5)
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	65 (95.6)	3 (4.4)	0	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Grade 0	59 (86.8)	1 (1.5)	0	0	0	60 (88.2)
		Grade 1	7 (10.3)	0	0	0	0	7 (10.3)
		Grade 2	0	0	0	0	0	0
		Grade 3	1 (1.5)	0	0	0	0	1 (1.5)
		Grade 4	0	0	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	0	0	68 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Alanine Aminotransferase Increased	Combined GS1-144 (N=207)	Grade 0	170 (82.5)	6 (2.9)	0	0	0	176 (85.4)
		Grade 1	26 (12.6)	2 (1.0)	0	0	0	28 (13.6)
		Grade 2	1 (0.5)	0	0	0	0	1 (0.5)
		Grade 3	1 (0.5)	0	0	0	0	1 (0.5)
		Grade 4	0	0	0	0	0	0
		Total	198 (96.1)	8 (3.9)	0	0	0	206 (100)
Aspartate Aminotransferase Increased	Placebo (N=69)	Grade 0	57 (82.6)	3 (4.3)	0	0	0	60 (87.0)
		Grade 1	8 (11.6)	0	0	0	0	8 (11.6)
		Grade 2	0	0	0	0	0	0
		Grade 3	1 (1.4)	0	0	0	0	1 (1.4)
		Grade 4	0	0	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	0	0	69 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Aspartate Aminotransferase Increased	GS1-144 30 mg QD (N=70)	Grade 0	61 (87.1)	1 (1.4)	0	0	0	62 (88.6)
		Grade 1	7 (10.0)	1 (1.4)	0	0	0	8 (11.4)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	68 (97.1)	2 (2.9)	0	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Grade 0	57 (83.8)	2 (2.9)	0	0	0	59 (86.8)
		Grade 1	9 (13.2)	0	0	0	0	9 (13.2)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	66 (97.1)	2 (2.9)	0	0	0	68 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Aspartate Aminotransferase Increased	GS1-144 30 mg BID (N=68)	Grade 0	61 (89.7)	0	0	0	0	61 (89.7)
		Grade 1	6 (8.8)	0	0	0	0	6 (8.8)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	1 (1.5)	0	0	0	0	1 (1.5)
		Total	68 (100)	0	0	0	0	68 (100)
	Combined GS1-144 (N=207)	Grade 0	179 (86.9)	3 (1.5)	0	0	0	182 (88.3)
		Grade 1	22 (10.7)	1 (0.5)	0	0	0	23 (11.2)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	1 (0.5)	0	0	0	0	1 (0.5)
		Total	202 (98.1)	4 (1.9)	0	0	0	206 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Blood Bilirubin Increased	Placebo (N=69)	Grade 0	63 (91.3)	0	0	0	0	63 (91.3)
		Grade 1	2 (2.9)	4 (5.8)	0	0	0	6 (8.7)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	65 (94.2)	4 (5.8)	0	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Grade 0	69 (98.6)	0	0	0	0	69 (98.6)
		Grade 1	1 (1.4)	0	0	0	0	1 (1.4)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	70 (100)	0	0	0	0	70 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Blood Bilirubin Increased	GS1-144 60 mg QD (N=69)	Grade 0	63 (92.6)	0	0	0	0	63 (92.6)
		Grade 1	4 (5.9)	1 (1.5)	0	0	0	5 (7.4)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Grade 0	66 (97.1)	1 (1.5)	0	0	0	67 (98.5)
		Grade 1	0	0	0	0	0	0
		Grade 2	1 (1.5)	0	0	0	0	1 (1.5)
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	0	0	68 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Blood Bilirubin Increased	Combined GS1-144 (N=207)	Grade 0	198 (96.1)	1 (0.5)	0	0	0	199 (96.6)
		Grade 1	5 (2.4)	1 (0.5)	0	0	0	6 (2.9)
		Grade 2	1 (0.5)	0	0	0	0	1 (0.5)
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	204 (99.0)	2 (1.0)	0	0	0	206 (100)
GGT Increased	Placebo (N=69)	Grade 0	63 (91.3)	3 (4.3)	0	0	0	66 (95.7)
		Grade 1	2 (2.9)	0	0	0	0	2 (2.9)
		Grade 2	1 (1.4)	0	0	0	0	1 (1.4)
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	0	0	69 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
GGT Increased	GS1-144 30 mg QD (N=70)	Grade 0	64 (91.4)	2 (2.9)	0	0	0	66 (94.3)
		Grade 1	3 (4.3)	0	0	0	0	3 (4.3)
		Grade 2	0	0	0	0	0	0
		Grade 3	1 (1.4)	0	0	0	0	1 (1.4)
		Grade 4	0	0	0	0	0	0
		Total	68 (97.1)	2 (2.9)	0	0	0	70 (100)
	GS1-144 60 mg QD (N=69)	Grade 0	56 (82.4)	6 (8.8)	0	0	0	62 (91.2)
		Grade 1	4 (5.9)	0	0	0	0	4 (5.9)
		Grade 2	2 (2.9)	0	0	0	0	2 (2.9)
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	62 (91.2)	6 (8.8)	0	0	0	68 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
GGT Increased	GS1-144 30 mg BID (N=68)	Grade 0	59 (86.8)	3 (4.4)	1 (1.5)	0	0	63 (92.6)
		Grade 1	4 (5.9)	0	0	0	0	4 (5.9)
		Grade 2	0	1 (1.5)	0	0	0	1 (1.5)
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	63 (92.6)	4 (5.9)	1 (1.5)	0	0	68 (100)
	Combined GS1-144 (N=207)	Grade 0	179 (86.9)	11 (5.3)	1 (0.5)	0	0	191 (92.7)
		Grade 1	11 (5.3)	0	0	0	0	11 (5.3)
		Grade 2	2 (1.0)	1 (0.5)	0	0	0	3 (1.5)
		Grade 3	1 (0.5)	0	0	0	0	1 (0.5)
		Grade 4	0	0	0	0	0	0
		Total	193 (93.7)	12 (5.8)	1 (0.5)	0	0	206 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Alkaline Phosphatase Increased	Placebo (N=69)	Grade 0	63 (91.3)	3 (4.3)	0	0	0	66 (95.7)
		Grade 1	3 (4.3)	0	0	0	0	3 (4.3)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	66 (95.7)	3 (4.3)	0	0	0	69 (100)
	GS1-144 30 mg QD (N=70)	Grade 0	67 (95.7)	1 (1.4)	0	0	0	68 (97.1)
		Grade 1	2 (2.9)	0	0	0	0	2 (2.9)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	69 (98.6)	1 (1.4)	0	0	0	70 (100)

Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Alkaline Phosphatase Increased	GS1-144 60 mg QD (N=69)	Grade 0	67 (98.5)	0	0	0	0	67 (98.5)
		Grade 1	1 (1.5)	0	0	0	0	1 (1.5)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	68 (100)	0	0	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Grade 0	67 (98.5)	0	0	0	0	67 (98.5)
		Grade 1	1 (1.5)	0	0	0	0	1 (1.5)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	68 (100)	0	0	0	0	68 (100)

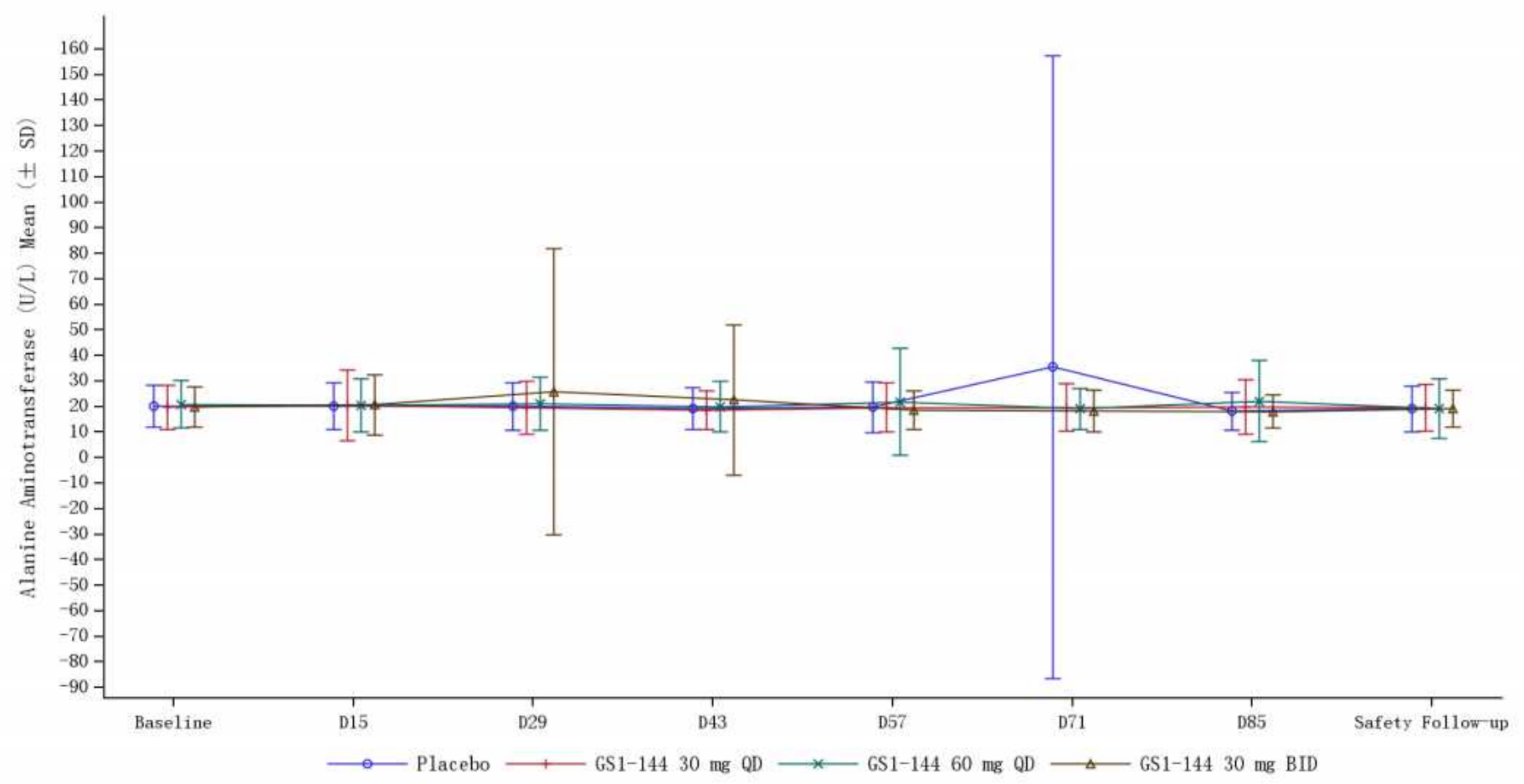
Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Table 14.3.4.6.2
Shift of CTCAE Grade for Liver Function Parameters
SS

Term	Treatment Group	Worst Grade Post-Baseline	Baseline Grade 0 n (%)	Baseline Grade 1 n (%)	Baseline Grade 2 n (%)	Baseline Grade 3 n (%)	Baseline Grade 4 n (%)	Baseline Total n (%)
Alkaline Phosphatase Increased	Combined GS1-144 (N=207)	Grade 0	201 (97.6)	1 (0.5)	0	0	0	202 (98.1)
		Grade 1	4 (1.9)	0	0	0	0	4 (1.9)
		Grade 2	0	0	0	0	0	0
		Grade 3	0	0	0	0	0	0
		Grade 4	0	0	0	0	0	0
		Total	205 (99.5)	1 (0.5)	0	0	0	206 (100)

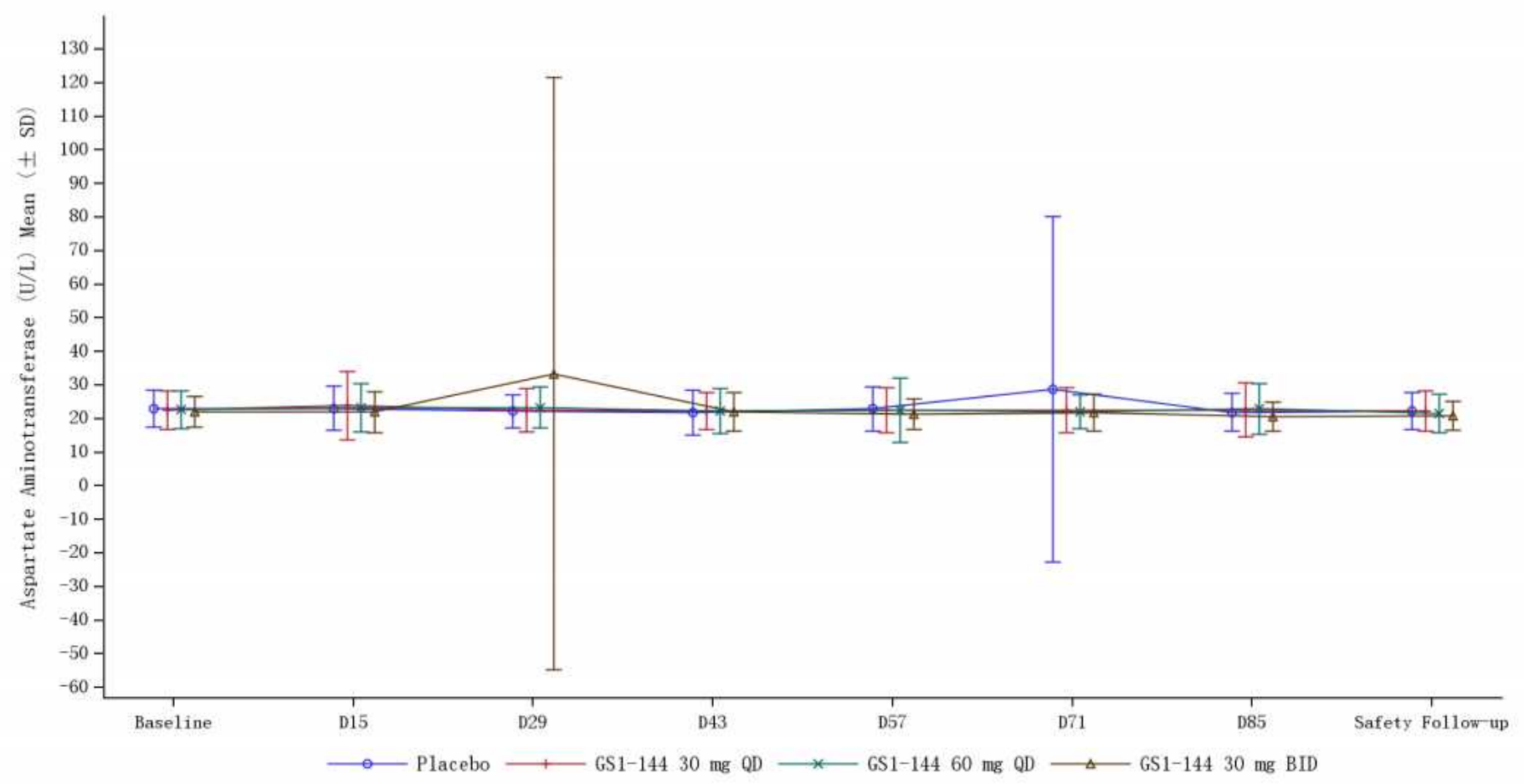
Data Source: Listing 16.2.8.1.12
CTCAE = Common Terminology Criteria for Adverse Events.
National Cancer Institute (NCI) CTCAE version 5.0 applied.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst grade including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per term.

Figure 14.3.4.6.3
Line Plot of Observed Value Over Time in Liver Function Parameters
SS



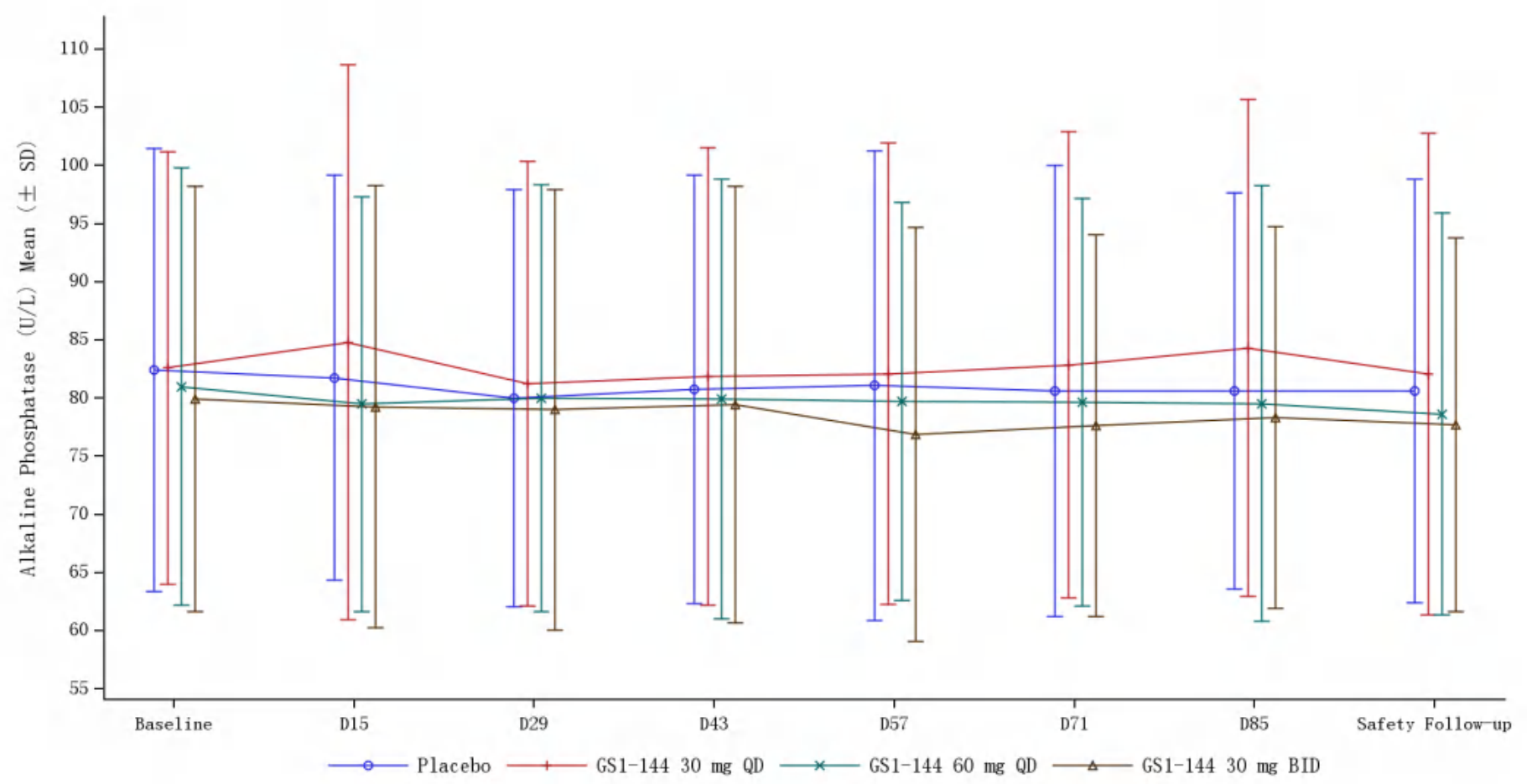
Data Source: Table 14.3.4.2.1

Figure 14.3.4.6.3
Line Plot of Observed Value Over Time in Liver Function Parameters
SS



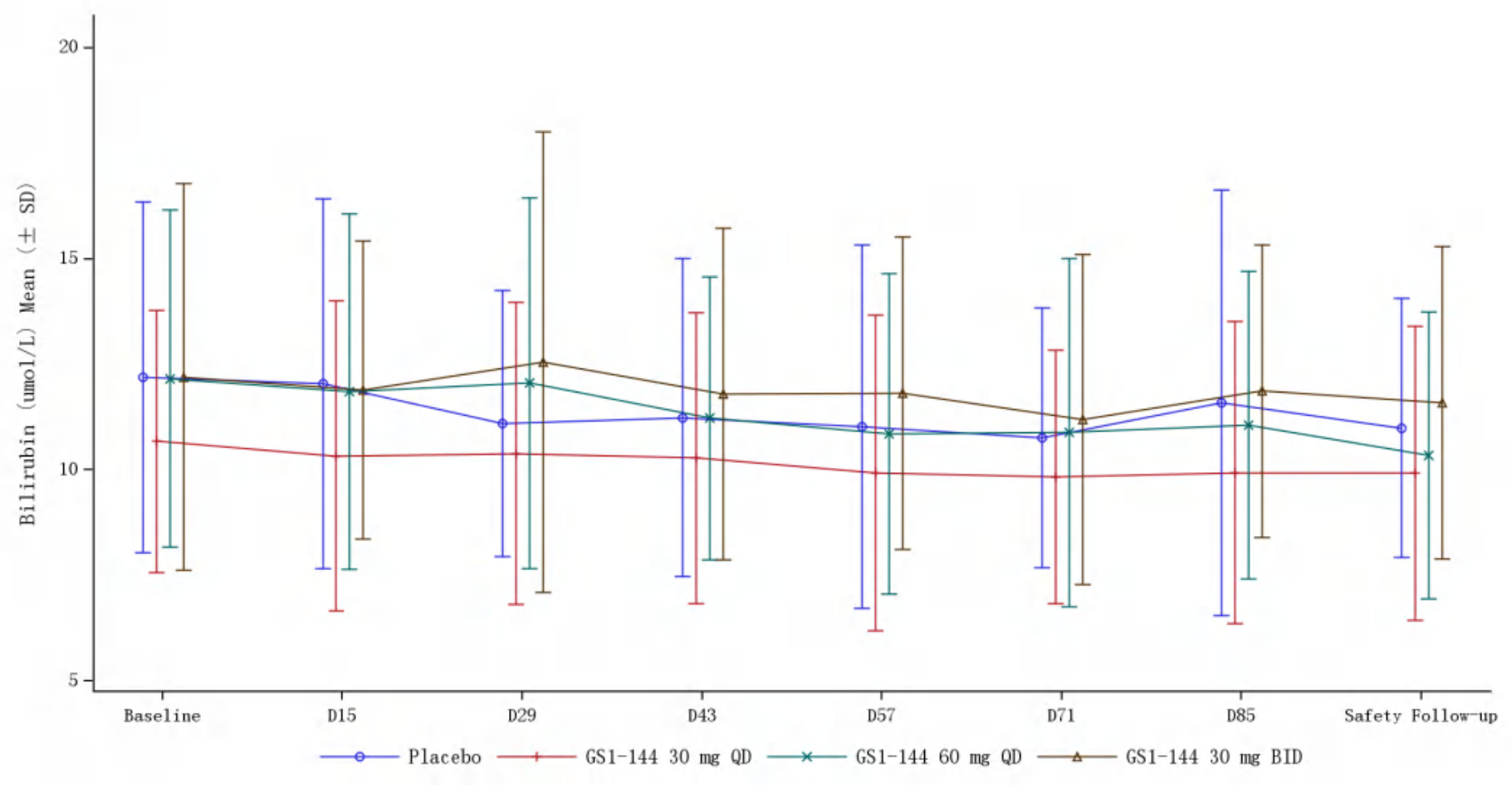
Data Source: Table 14.3.4.2.1

Figure 14.3.4.6.3
Line Plot of Observed Value Over Time in Liver Function Parameters
SS



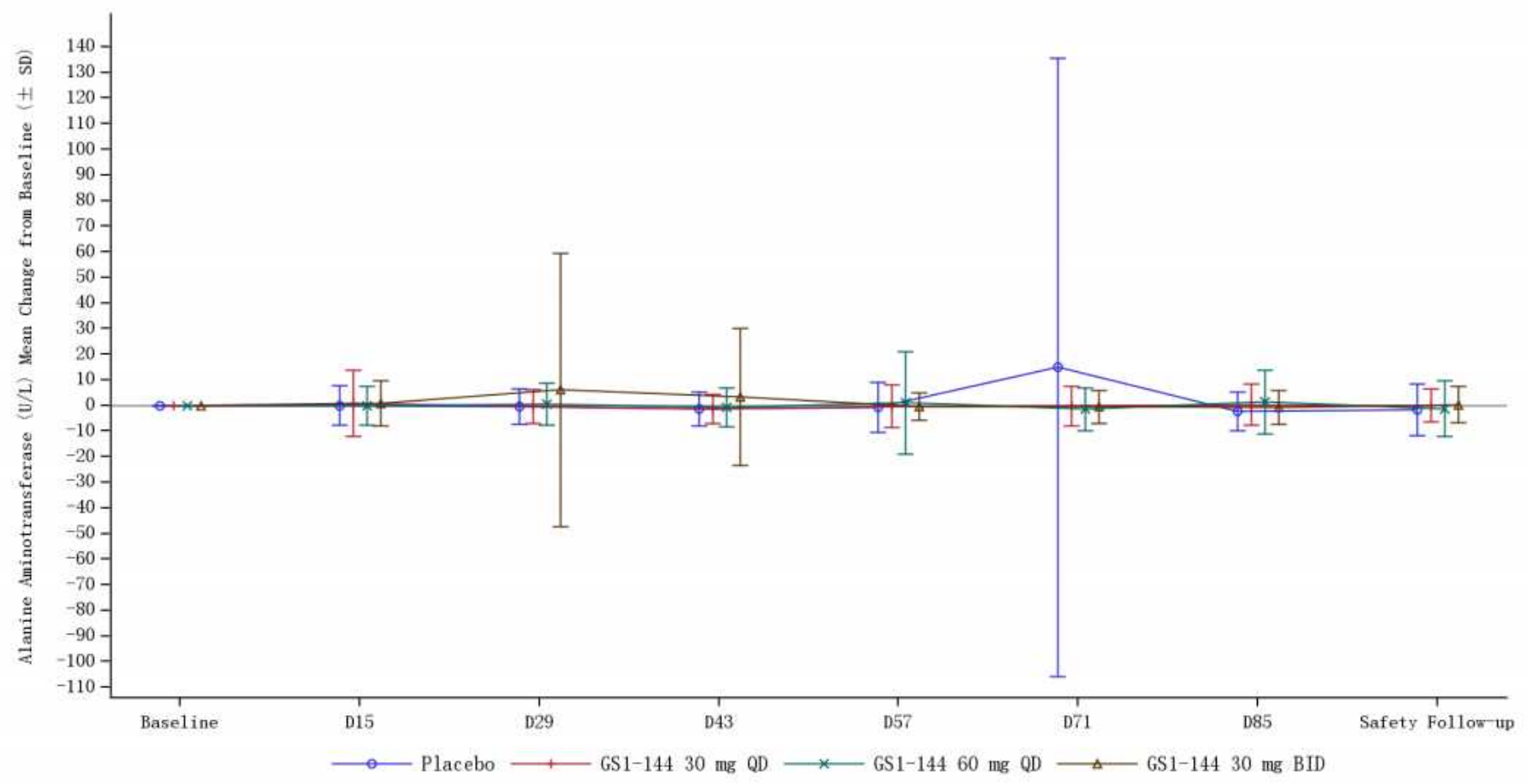
Data Source: Table 14.3.4.2.1

Figure 14.3.4.6.3
Line Plot of Observed Value Over Time in Liver Function Parameters
SS



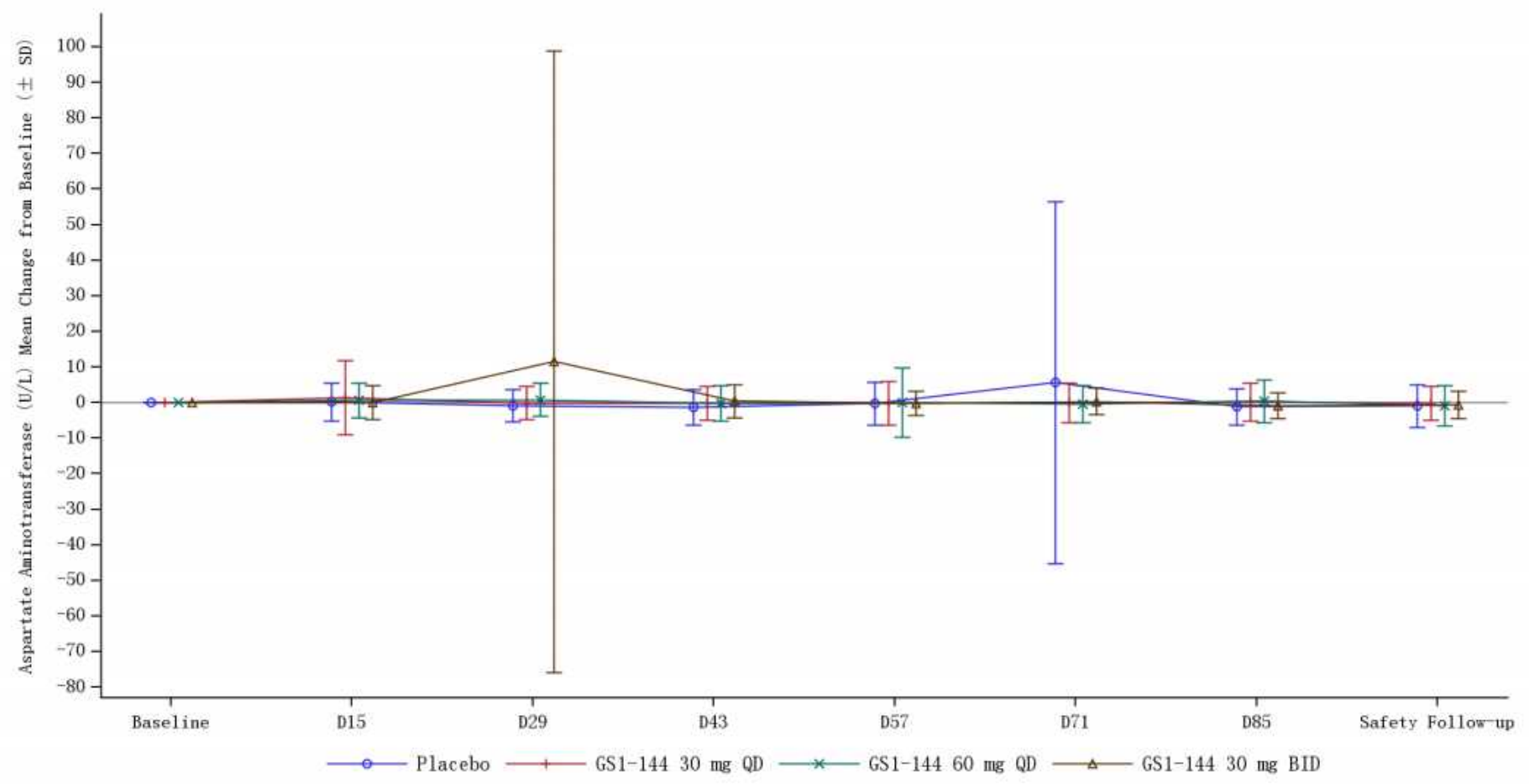
Data Source: Table 14.3.4.2.1

Figure 14.3.4.6.4
Line Plot of Change from Baseline Over Time in Liver Function Parameters
SS



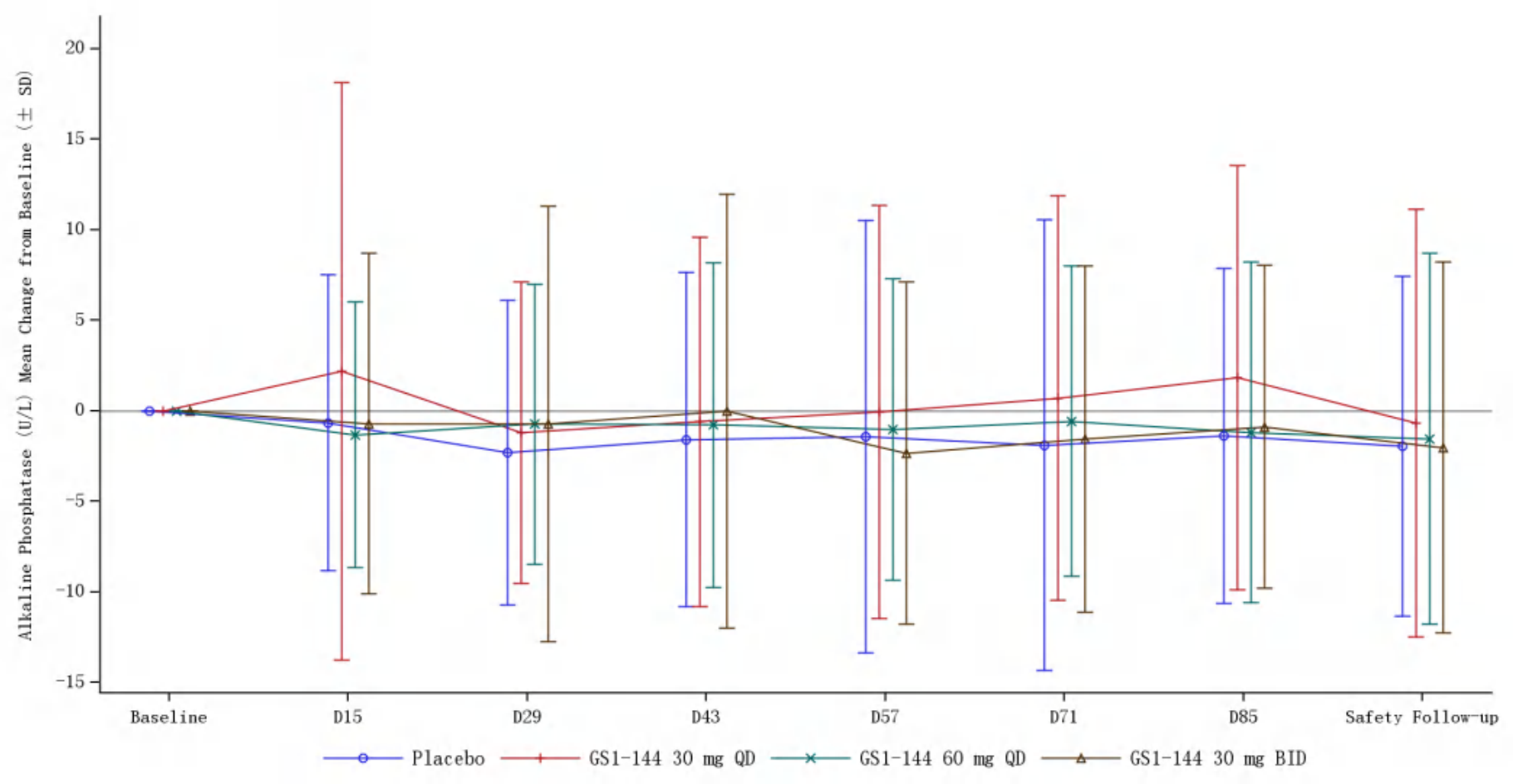
Data Source: Table 14.3.4.2.1

Figure 14.3.4.6.4
Line Plot of Change from Baseline Over Time in Liver Function Parameters
SS



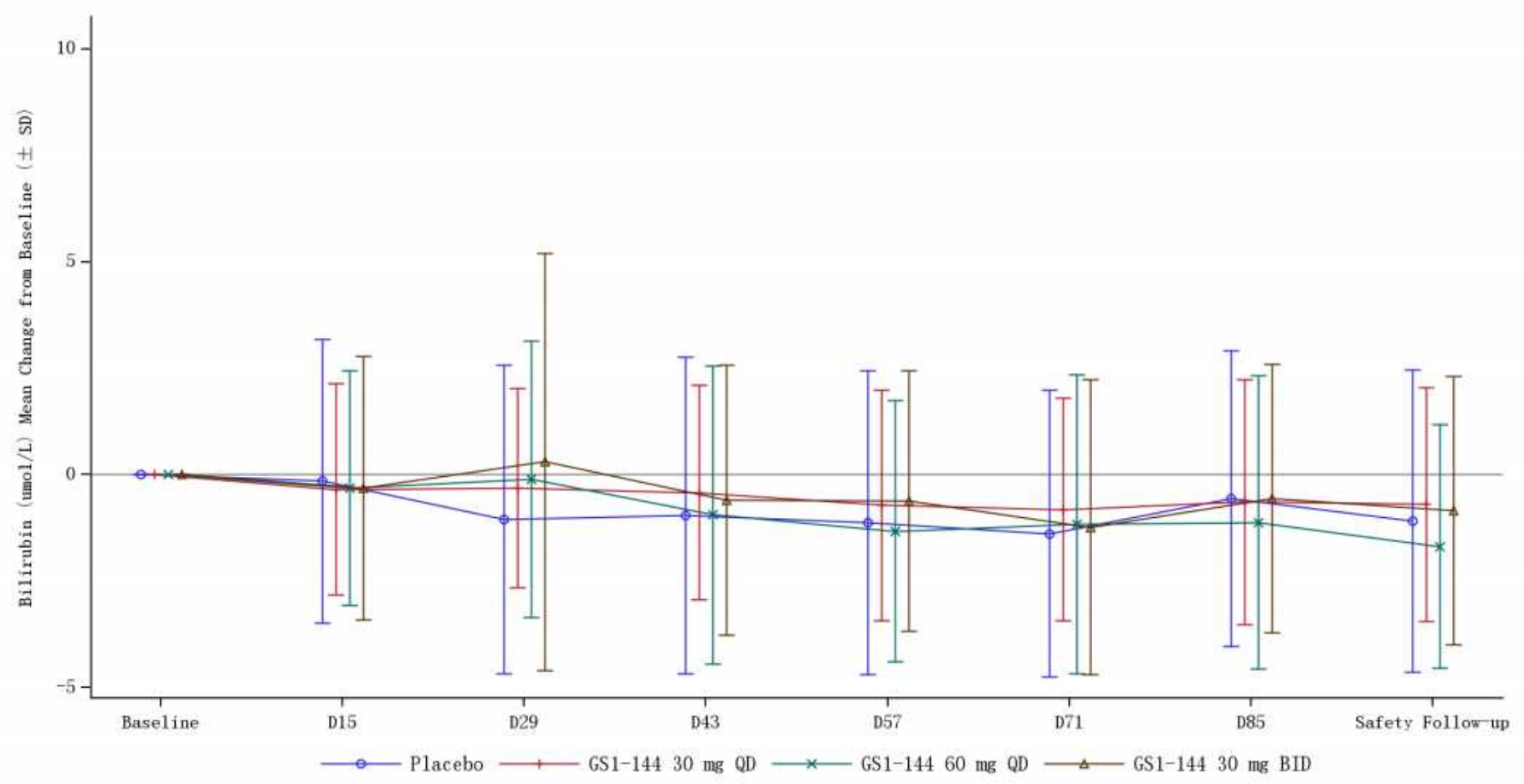
Data Source: Table 14.3.4.2.1

Figure 14.3.4.6.4
Line Plot of Change from Baseline Over Time in Liver Function Parameters
SS



Data Source: Table 14.3.4.2.1

Figure 14.3.4.6.4
Line Plot of Change from Baseline Over Time in Liver Function Parameters
SS



Data Source: Table 14.3.4.2.1

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
ECG Mean Heart Rate (beats/min)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	69.43 (9.441)	67.98 (7.418)	69.55 (8.070)	68.25 (8.875)	68.59 (8.126)	68.80 (8.463)
		Median	69.00	67.25	68.00	67.25	67.50	68.00
		Q1 - Q3	61.50 - 76.50	63.50 - 72.50	64.50 - 73.00	61.00 - 74.50	63.50 - 73.00	62.50 - 73.75
		Min - Max	53.5 - 95.0	48.0 - 89.0	50.5 - 93.5	51.0 - 91.0	48.0 - 93.5	48.0 - 95.0
	D1 (4 Hours Post-dose)	Observed Value						
		n	64	68	67	67	202	266
		Mean (SD)	72.75 (11.279)	70.69 (8.582)	71.90 (9.846)	70.75 (8.970)	71.11 (9.117)	71.50 (9.684)
		Median	69.50	70.00	70.00	69.00	70.00	70.00
		Q1 - Q3	65.00 - 80.50	65.50 - 75.00	66.00 - 77.00	65.00 - 77.00	65.00 - 76.00	65.00 - 77.00
		Min - Max	53.0 - 105.0	48.0 - 94.0	51.0 - 106.0	51.0 - 97.0	48.0 - 106.0	48.0 - 106.0
	D1 (4 Hours Post-dose)	Change from Baseline						
		n	64	68	67	67	202	266
		Mean (SD)	2.70 (7.700)	2.75 (5.454)	2.16 (6.508)	2.63 (6.271)	2.51 (6.066)	2.56 (6.482)
		Median	1.25	3.50	1.50	2.50	2.75	2.50
		Q1 - Q3	-2.00 - 6.75	-0.75 - 6.00	-2.50 - 8.00	-2.00 - 6.50	-2.00 - 6.50	-2.00 - 6.50
		Min - Max	-12.0 - 26.5	-13.5 - 14.0	-10.0 - 13.5	-8.5 - 20.5	-13.5 - 20.5	-13.5 - 26.5

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
ECG Mean Heart Rate (beats/min)	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	69.28 (9.345)	67.60 (8.284)	68.04 (7.716)	68.66 (10.802)	68.10 (8.993)	68.39 (9.080)
		Median	69.00	67.00	67.50	66.50	67.00	67.00
		Q1 - Q3	63.00 - 76.00	62.00 - 72.00	63.00 - 73.00	62.50 - 73.00	62.00 - 73.00	62.00 - 74.00
		Min - Max	53.0 - 101.0	50.0 - 88.0	54.0 - 93.0	50.0 - 107.0	50.0 - 107.0	50.0 - 107.0
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.15 (6.296)	-0.38 (5.035)	-1.26 (6.209)	0.41 (8.508)	-0.41 (6.727)	-0.34 (6.611)
		Median	-0.50	-1.00	-0.50	-1.00	-1.00	-1.00
		Q1 - Q3	-3.50 - 2.00	-3.50 - 3.00	-6.25 - 3.00	-5.25 - 3.50	-4.50 - 3.00	-4.50 - 3.00
		Min - Max	-14.0 - 26.5	-19.5 - 15.0	-25.0 - 13.0	-18.0 - 31.5	-25.0 - 31.5	-25.0 - 31.5
	D29	Observed Value						
		n	68	69	67	67	203	271
		Mean (SD)	69.04 (8.933)	67.86 (9.655)	68.70 (7.847)	67.96 (10.091)	68.17 (9.215)	68.39 (9.136)
		Median	69.50	66.00	69.00	66.00	67.00	68.00
		Q1 - Q3	61.50 - 76.00	62.00 - 73.00	63.00 - 74.00	61.00 - 75.00	62.00 - 74.00	62.00 - 74.00
		Min - Max	47.0 - 93.0	45.0 - 107.0	53.0 - 94.0	51.0 - 95.0	45.0 - 107.0	45.0 - 107.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
ECG Mean Heart Rate (beats/min)	D29	Change from Baseline						
		n	68	69	67	67	203	271
		Mean (SD)	-0.51 (6.470)	-0.01 (6.148)	-0.50 (6.949)	-0.13 (7.968)	-0.21 (7.020)	-0.29 (6.876)
		Median	-1.00	-1.00	-0.50	-1.00	-0.50	-0.50
		Q1 - Q3	-4.00 - 4.00	-4.50 - 3.50	-4.00 - 4.00	-4.50 - 3.00	-4.50 - 3.50	-4.00 - 3.50
		Min - Max	-19.0 - 14.5	-10.5 - 24.5	-25.5 - 14.0	-16.5 - 31.5	-25.5 - 31.5	-25.5 - 31.5
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	70.62 (9.128)	67.09 (7.851)	67.51 (7.795)	67.63 (9.823)	67.40 (8.475)	68.20 (8.736)
		Median	70.00	67.00	68.00	66.00	67.00	67.00
		Q1 - Q3	63.00 - 78.00	62.00 - 72.00	61.00 - 73.00	62.00 - 73.00	62.00 - 72.00	62.00 - 74.00
		Min - Max	55.0 - 90.0	49.0 - 100.0	54.0 - 86.0	49.0 - 98.0	49.0 - 100.0	49.0 - 100.0
	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.80 (8.645)	-0.78 (5.510)	-1.69 (7.620)	-0.75 (6.517)	-1.08 (6.578)	-0.61 (7.175)
		Median	0	-1.00	-1.00	-0.50	-0.50	-0.50
		Q1 - Q3	-4.00 - 4.00	-4.50 - 2.00	-7.00 - 3.50	-4.25 - 2.50	-5.00 - 2.50	-5.00 - 3.00
		Min - Max	-16.0 - 35.0	-11.0 - 19.5	-23.5 - 16.0	-20.0 - 17.0	-23.5 - 19.5	-23.5 - 35.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
ECG Mean Heart Rate (beats/min)	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	70.23 (10.554)	67.19 (8.820)	68.41 (8.394)	67.29 (9.161)	67.63 (8.764)	68.28 (9.294)
		Median	68.50	66.00	67.50	66.00	67.00	67.00
		Q1 - Q3	62.00 - 76.00	61.50 - 73.00	61.00 - 73.00	61.00 - 75.00	61.00 - 74.00	61.00 - 74.00
		Min - Max	54.0 - 100.0	48.0 - 96.0	53.0 - 91.0	48.0 - 90.0	48.0 - 96.0	48.0 - 100.0
	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	0.40 (8.108)	-0.75 (7.306)	-0.86 (7.773)	-0.73 (7.155)	-0.78 (7.381)	-0.48 (7.572)
		Median	-0.75	-1.25	-1.25	-1.50	-1.50	-1.00
		Q1 - Q3	-5.00 - 5.50	-4.75 - 2.00	-5.00 - 3.00	-5.00 - 4.00	-5.00 - 2.50	-5.00 - 3.50
		Min - Max	-16.5 - 24.0	-19.5 - 28.0	-25.5 - 24.0	-19.5 - 17.5	-25.5 - 28.0	-25.5 - 28.0
	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	69.12 (9.604)	67.82 (7.519)	68.69 (8.658)	67.95 (10.279)	68.15 (8.819)	68.39 (9.012)
		Median	67.00	68.00	67.00	66.00	67.00	67.00
		Q1 - Q3	62.00 - 73.00	62.50 - 72.00	62.00 - 73.00	61.00 - 74.00	62.00 - 73.00	62.00 - 73.00
		Min - Max	49.0 - 91.0	52.0 - 87.0	54.0 - 93.0	49.0 - 99.0	49.0 - 99.0	49.0 - 99.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
ECG Mean Heart Rate (beats/min)	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-0.92 (7.554)	-0.12 (5.407)	-0.68 (6.377)	-0.06 (6.401)	-0.29 (6.042)	-0.44 (6.442)
		Median	-0.50	-0.50	-1.00	-0.50	-0.50	-0.50
		Q1 - Q3	-6.50 - 4.00	-3.50 - 4.00	-4.50 - 2.50	-3.50 - 4.50	-4.00 - 4.00	-4.00 - 4.00
		Min - Max	-18.0 - 20.0	-11.5 - 12.0	-14.0 - 14.5	-16.5 - 20.0	-16.5 - 20.0	-18.0 - 20.0
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	69.77 (9.950)	68.03 (8.183)	69.03 (9.272)	67.35 (9.333)	68.15 (8.916)	68.55 (9.188)
		Median	69.00	67.00	67.50	66.00	67.00	67.00
		Q1 - Q3	62.50 - 75.50	63.00 - 71.00	63.00 - 74.00	61.00 - 73.00	63.00 - 72.50	63.00 - 73.00
		Min - Max	50.0 - 91.0	50.0 - 92.0	50.0 - 103.0	50.0 - 96.0	50.0 - 103.0	50.0 - 103.0
	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-0.40 (7.366)	0.21 (5.817)	-0.23 (7.916)	-0.67 (6.506)	-0.22 (6.777)	-0.27 (6.912)
		Median	0	0	-0.75	-0.50	-0.50	-0.50
		Q1 - Q3	-4.75 - 3.50	-4.00 - 3.00	-5.50 - 4.00	-4.50 - 2.00	-4.50 - 3.00	-4.50 - 3.00
		Min - Max	-20.0 - 19.5	-12.5 - 17.5	-20.5 - 28.0	-16.0 - 15.5	-20.5 - 28.0	-20.5 - 28.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
ECG Mean Heart Rate (beats/min)	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	69.03 (8.385)	68.53 (7.695)	68.08 (7.410)	66.67 (8.386)	67.78 (7.830)	68.09 (7.972)
		Median	67.00	68.00	67.00	67.00	67.00	67.00
		Q1 - Q3	64.00 - 73.50	64.00 - 73.00	62.00 - 74.00	61.00 - 73.00	62.00 - 73.00	62.00 - 73.00
		Min - Max	57.0 - 97.0	53.0 - 91.0	53.0 - 84.0	51.0 - 89.0	51.0 - 91.0	51.0 - 97.0
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.09 (7.906)	0.78 (4.742)	-1.23 (6.040)	-1.58 (6.088)	-0.65 (5.711)	-0.76 (6.306)
		Median	-2.25	0.50	-0.50	-1.50	-0.50	-1.00
		Q1 - Q3	-5.00 - 4.00	-2.50 - 4.00	-4.00 - 2.50	-6.00 - 2.00	-4.00 - 3.00	-4.00 - 3.50
		Min - Max	-23.0 - 31.0	-10.5 - 10.5	-18.5 - 11.5	-17.5 - 15.5	-18.5 - 15.5	-23.0 - 31.0
RR Interval, Aggregate (ms)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	881.38 (116.648)	894.81 (98.931)	880.54 (100.542)	895.71 (114.036)	890.35 (104.370)	888.11 (107.423)
		Median	870.50	893.00	885.50	892.50	889.50	886.25
		Q1 - Q3	779.50 - 976.00	828.50 - 945.50	822.00 - 937.50	811.00 - 984.25	822.00 - 954.50	816.50 - 963.25
		Min - Max	632.0 - 1122.5	684.5 - 1250.5	655.5 - 1188.0	659.5 - 1178.0	655.5 - 1250.5	632.0 - 1250.5

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
RR Interval, Aggregate (ms)	D1 (4 Hours Post-dose)	Observed Value						
		n	64	68	67	67	202	266
		Mean (SD)	841.44 (124.003)	861.03 (106.439)	846.91 (113.739)	861.34 (107.811)	856.45 (109.024)	852.84 (112.750)
		Median	863.50	857.00	857.00	870.00	857.00	857.00
		Q1 - Q3	732.00 - 923.00	800.00 - 916.00	778.00 - 909.00	779.00 - 923.00	789.00 - 923.00	779.00 - 923.00
		Min - Max	571.0 - 1132.0	638.0 - 1250.0	566.0 - 1176.0	619.0 - 1176.0	566.0 - 1250.0	566.0 - 1250.0
	D1 (4 Hours Post-dose)	Change from Baseline						
		n	64	68	67	67	202	266
		Mean (SD)	-31.84 (83.824)	-34.60 (69.092)	-31.66 (83.510)	-36.10 (79.046)	-34.12 (77.047)	-33.57 (78.575)
		Median	-18.50	-45.75	-27.50	-37.00	-37.25	-34.75
		Q1 - Q3	-89.75 - 21.25	-76.50 - 6.25	-94.00 - 32.50	-82.00 - 21.00	-85.50 - 19.00	-85.50 - 20.00
		Min - Max	-286.0 - 110.0	-184.0 - 204.0	-251.0 - 141.5	-212.5 - 105.0	-251.0 - 204.0	-286.0 - 204.0
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	880.74 (115.473)	900.16 (109.315)	892.54 (99.317)	893.41 (128.985)	895.42 (112.673)	891.73 (113.349)
		Median	870.00	896.00	889.00	902.50	896.00	896.00
		Q1 - Q3	789.00 - 952.00	833.00 - 968.00	822.00 - 952.00	822.00 - 960.00	822.00 - 968.00	811.00 - 968.00
		Min - Max	594.0 - 1132.0	682.0 - 1200.0	641.0 - 1111.0	561.0 - 1200.0	561.0 - 1200.0	561.0 - 1200.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
RR Interval, Aggregate (ms)	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.64 (75.796)	5.35 (65.988)	9.31 (82.520)	-2.29 (98.219)	4.13 (82.869)	2.93 (81.043)
		Median	5.50	8.75	-0.25	9.25	8.50	7.50
		Q1 - Q3	-33.50 - 50.50	-50.50 - 41.50	-50.25 - 64.50	-47.25 - 58.75	-50.00 - 52.50	-45.50 - 52.00
		Min - Max	-313.5 - 142.5	-151.0 - 269.0	-165.0 - 271.0	-364.5 - 179.5	-364.5 - 271.0	-364.5 - 271.0
	D29	Observed Value						
		n	68	69	67	67	203	271
		Mean (SD)	884.46 (122.569)	901.13 (125.884)	885.24 (105.090)	900.96 (124.867)	895.83 (118.713)	892.97 (119.565)
		Median	863.50	909.00	869.00	909.00	895.00	882.00
		Q1 - Q3	789.00 - 976.00	822.00 - 968.00	811.00 - 952.00	800.00 - 984.00	811.00 - 968.00	811.00 - 968.00
		Min - Max	645.0 - 1277.0	561.0 - 1333.0	634.0 - 1176.0	632.0 - 1176.0	561.0 - 1333.0	561.0 - 1333.0
	D29	Change from Baseline						
		n	68	69	67	67	203	271
		Mean (SD)	4.61 (82.501)	4.91 (76.331)	0.60 (88.510)	3.28 (97.173)	2.95 (87.232)	3.37 (85.922)
		Median	8.50	11.50	0	8.00	7.50	8.00
		Q1 - Q3	-59.50 - 51.25	-41.50 - 60.00	-54.00 - 54.50	-40.50 - 69.50	-45.50 - 56.00	-49.50 - 55.00
		Min - Max	-198.0 - 199.0	-258.0 - 175.0	-231.0 - 222.5	-364.5 - 209.5	-364.5 - 222.5	-364.5 - 222.5

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
RR Interval, Aggregate (ms)	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	863.35 (112.478)	905.65 (101.857)	903.34 (109.060)	904.80 (124.625)	904.61 (111.391)	894.37 (112.869)
		Median	857.50	896.00	882.00	909.00	896.00	896.00
		Q1 - Q3	769.00 - 952.00	833.00 - 968.00	822.00 - 1000.00	822.00 - 968.00	833.00 - 976.00	811.00 - 968.00
		Min - Max	661.0 - 1091.0	600.0 - 1224.0	692.0 - 1154.0	612.0 - 1224.0	600.0 - 1224.0	600.0 - 1224.0
	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-13.00 (102.419)	9.43 (69.998)	18.70 (101.883)	11.21 (79.396)	13.11 (84.433)	6.63 (89.744)
		Median	-2.25	4.50	9.00	5.50	7.00	6.25
		Q1 - Q3	-48.50 - 57.00	-29.00 - 54.50	-52.50 - 87.50	-31.75 - 63.25	-34.75 - 61.50	-37.50 - 59.50
		Min - Max	-424.0 - 159.5	-228.0 - 138.5	-221.0 - 320.0	-144.5 - 205.5	-228.0 - 320.0	-424.0 - 320.0
	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	872.70 (128.671)	907.54 (117.111)	889.52 (106.870)	908.46 (126.686)	901.80 (116.745)	894.49 (120.263)
		Median	876.00	909.00	884.00	909.00	896.00	896.00
		Q1 - Q3	789.00 - 968.00	822.00 - 976.00	822.00 - 984.00	800.00 - 984.00	811.00 - 984.00	811.00 - 984.00
		Min - Max	600.0 - 1111.0	625.0 - 1250.0	659.0 - 1132.0	667.0 - 1250.0	625.0 - 1250.0	600.0 - 1250.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
RR Interval, Aggregate (ms)	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	-3.65 (97.998)	12.21 (89.904)	5.46 (93.479)	11.16 (92.902)	9.61 (91.652)	6.29 (93.272)
		Median	7.50	14.25	9.50	18.00	11.00	10.50
		Q1 - Q3	-68.00 - 62.50	-31.25 - 67.75	-42.50 - 62.50	-50.00 - 72.50	-41.50 - 64.50	-50.00 - 64.50
		Min - Max	-314.5 - 204.5	-258.0 - 207.0	-272.0 - 278.5	-242.5 - 263.5	-272.0 - 278.5	-314.5 - 278.5
	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	883.78 (118.990)	895.04 (99.435)	886.45 (107.868)	902.41 (133.850)	894.56 (113.817)	891.88 (114.990)
		Median	896.00	882.00	896.00	909.00	896.00	896.00
		Q1 - Q3	822.00 - 968.00	833.00 - 960.00	822.00 - 968.00	811.00 - 984.00	822.00 - 968.00	822.00 - 968.00
		Min - Max	659.0 - 1224.0	690.0 - 1154.0	645.0 - 1111.0	606.0 - 1224.0	606.0 - 1224.0	606.0 - 1224.0
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	10.43 (89.343)	-0.29 (70.301)	3.72 (79.074)	5.11 (80.850)	2.78 (76.380)	4.68 (79.695)
		Median	5.50	2.75	7.50	6.00	5.50	5.50
		Q1 - Q3	-50.50 - 81.50	-56.25 - 41.25	-61.50 - 62.00	-58.50 - 53.50	-60.00 - 53.50	-58.50 - 60.00
		Min - Max	-236.0 - 214.5	-137.0 - 155.5	-188.0 - 176.5	-163.5 - 209.5	-188.0 - 209.5	-236.0 - 214.5

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
RR Interval, Aggregate (ms)	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	876.67 (123.142)	894.28 (105.144)	883.59 (111.755)	907.29 (124.291)	894.86 (113.620)	890.38 (116.059)
		Median	870.00	896.00	889.00	909.00	896.00	895.50
		Q1 - Q3	794.50 - 960.00	845.00 - 943.00	811.00 - 952.00	822.00 - 984.00	833.00 - 952.00	822.00 - 952.00
		Min - Max	657.0 - 1200.0	652.0 - 1200.0	583.0 - 1200.0	625.0 - 1200.0	583.0 - 1200.0	583.0 - 1200.0
	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	4.80 (83.314)	-2.63 (76.027)	-0.46 (92.786)	9.98 (84.309)	2.16 (84.357)	2.81 (83.948)
		Median	0	0.50	7.25	4.50	6.00	5.00
		Q1 - Q3	-51.00 - 66.00	-50.00 - 43.00	-56.00 - 63.50	-32.50 - 67.00	-44.75 - 57.50	-48.50 - 60.75
		Min - Max	-193.0 - 188.5	-201.5 - 216.0	-228.5 - 346.5	-213.0 - 202.0	-228.5 - 346.5	-228.5 - 346.5
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	880.75 (99.481)	885.90 (96.579)	891.79 (99.128)	913.97 (114.658)	896.85 (103.683)	892.90 (102.714)
		Median	896.00	882.00	895.50	896.00	896.00	896.00
		Q1 - Q3	816.50 - 938.00	822.00 - 938.00	811.00 - 968.00	822.00 - 984.00	822.00 - 968.00	822.00 - 968.00
		Min - Max	619.0 - 1053.0	659.0 - 1132.0	714.0 - 1132.0	674.0 - 1176.0	659.0 - 1176.0	619.0 - 1176.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
RR Interval, Aggregate (ms)	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	8.17 (90.356)	-11.89 (66.226)	8.44 (73.664)	19.31 (78.943)	4.90 (73.749)	5.70 (77.977)
		Median	26.75	-8.25	8.00	20.50	6.50	8.00
		Q1 - Q3	-53.50 - 54.75	-55.25 - 30.00	-34.00 - 50.50	-31.50 - 71.50	-44.50 - 43.00	-46.00 - 48.00
		Min - Max	-290.5 - 269.5	-155.5 - 155.0	-177.0 - 257.5	-192.0 - 226.5	-192.0 - 257.5	-290.5 - 269.5
PR Interval, Aggregate (ms)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	150.77 (16.096)	152.89 (18.613)	150.28 (16.798)	151.05 (20.773)	151.41 (18.728)	151.25 (18.080)
		Median	150.00	152.50	148.00	148.50	148.50	149.50
		Q1 - Q3	138.00 - 160.00	138.00 - 168.00	137.00 - 161.50	133.25 - 165.50	137.00 - 165.00	137.00 - 163.75
		Min - Max	122.0 - 194.0	122.0 - 194.0	119.0 - 198.5	109.5 - 200.0	109.5 - 200.0	109.5 - 200.0
	D1 (4 Hours Post-dose)	Observed Value						
		n	64	68	67	67	202	266
		Mean (SD)	152.25 (17.775)	155.07 (21.218)	151.36 (17.937)	151.63 (20.351)	152.70 (19.864)	152.59 (19.350)
		Median	153.00	156.00	150.00	151.00	152.00	152.00
		Q1 - Q3	138.00 - 163.00	138.00 - 172.00	138.00 - 164.00	136.00 - 166.00	138.00 - 167.00	138.00 - 166.00
		Min - Max	118.0 - 194.0	117.0 - 196.0	114.0 - 192.0	111.0 - 200.0	111.0 - 200.0	111.0 - 200.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
PR Interval, Aggregate (ms)	D1 (4 Hours Post-dose)	Change from Baseline						
		n	64	68	67	67	202	266
		Mean (SD)	1.41 (9.234)	2.26 (9.352)	1.12 (9.629)	0.69 (9.147)	1.36 (9.355)	1.37 (9.309)
		Median	1.50	2.00	0	1.00	1.00	1.00
		Q1 - Q3	-5.00 - 8.00	-4.00 - 7.25	-4.50 - 6.50	-4.00 - 6.00	-4.00 - 6.50	-4.00 - 7.00
		Min - Max	-16.0 - 33.0	-24.0 - 31.0	-18.0 - 33.0	-23.5 - 27.0	-24.0 - 33.0	-24.0 - 33.0
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	150.90 (16.625)	152.00 (19.640)	151.44 (18.187)	151.49 (21.485)	151.65 (19.720)	151.46 (18.964)
		Median	151.00	150.50	148.00	151.50	150.00	150.00
		Q1 - Q3	139.00 - 162.00	137.00 - 165.00	138.00 - 166.50	134.00 - 164.50	136.00 - 165.00	137.00 - 164.00
		Min - Max	122.0 - 188.0	104.0 - 194.0	108.0 - 196.0	108.0 - 196.0	104.0 - 196.0	104.0 - 196.0
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.13 (9.208)	-0.89 (8.394)	1.13 (6.963)	0.43 (10.224)	0.22 (8.627)	0.19 (8.760)
		Median	0	-0.50	0.50	0.75	0	0
		Q1 - Q3	-5.00 - 6.00	-5.00 - 3.50	-2.25 - 6.00	-4.50 - 5.00	-4.00 - 5.00	-4.50 - 5.00
		Min - Max	-19.5 - 20.0	-20.5 - 25.0	-19.0 - 15.0	-20.0 - 32.0	-20.5 - 32.0	-20.5 - 32.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
PR Interval, Aggregate (ms)	D29	Observed Value						
		n	68	69	67	67	203	271
		Mean (SD)	150.66 (17.197)	155.22 (19.559)	152.90 (18.414)	151.90 (22.225)	153.35 (20.073)	152.68 (19.396)
		Median	151.50	151.00	154.00	150.00	152.00	152.00
		Q1 - Q3	138.50 - 161.00	138.00 - 168.00	136.00 - 165.00	138.00 - 169.00	138.00 - 168.00	138.00 - 166.00
		Min - Max	116.0 - 194.0	124.0 - 204.0	120.0 - 210.0	68.0 - 202.0	68.0 - 210.0	68.0 - 210.0
	D29	Change from Baseline						
		n	68	69	67	67	203	271
		Mean (SD)	0.21 (8.981)	2.55 (11.300)	2.12 (9.162)	0.58 (15.562)	1.76 (12.258)	1.37 (11.528)
		Median	0	1.00	1.50	1.00	1.00	1.00
		Q1 - Q3	-4.50 - 6.00	-5.00 - 7.00	-5.00 - 9.00	-6.00 - 9.00	-5.00 - 8.00	-5.00 - 8.00
		Min - Max	-30.0 - 18.0	-19.0 - 52.0	-16.5 - 24.0	-89.0 - 37.0	-89.0 - 52.0	-89.0 - 52.0
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	149.95 (16.677)	153.77 (19.627)	152.69 (18.060)	151.44 (20.251)	152.66 (19.249)	151.99 (18.651)
		Median	150.50	152.00	154.00	152.50	153.50	152.00
		Q1 - Q3	136.00 - 163.00	138.00 - 172.00	140.00 - 164.00	132.00 - 167.50	136.00 - 168.00	136.00 - 164.00
		Min - Max	120.0 - 188.0	118.0 - 191.0	120.0 - 194.0	103.0 - 196.0	103.0 - 196.0	103.0 - 196.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
PR Interval, Aggregate (ms)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.64 (10.442)	1.10 (11.240)	1.91 (10.321)	-0.93 (9.458)	0.72 (10.403)	0.39 (10.410)
		Median	0	0.50	0	-2.00	0	0
		Q1 - Q3	-9.00 - 6.50	-4.50 - 6.00	-5.00 - 8.50	-5.50 - 5.00	-5.00 - 6.00	-6.00 - 6.00
		Min - Max	-22.0 - 20.5	-19.0 - 32.0	-21.5 - 41.0	-26.0 - 22.0	-26.0 - 41.0	-26.0 - 41.0
	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	151.12 (16.664)	153.57 (19.665)	153.17 (18.213)	154.49 (20.708)	153.73 (19.446)	153.08 (18.790)
		Median	150.00	150.50	152.00	152.00	152.00	152.00
		Q1 - Q3	137.00 - 162.00	139.00 - 164.00	142.00 - 165.00	136.00 - 168.00	140.00 - 165.00	138.00 - 165.00
		Min - Max	120.0 - 200.0	122.0 - 198.0	118.0 - 198.0	127.0 - 216.0	118.0 - 216.0	118.0 - 216.0
	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	0.53 (9.616)	0.69 (9.026)	2.27 (8.936)	2.52 (12.839)	1.80 (10.351)	1.48 (10.169)
		Median	1.00	1.00	0.50	1.50	1.00	1.00
		Q1 - Q3	-3.50 - 8.00	-2.25 - 4.75	-4.00 - 8.00	-6.00 - 8.00	-4.00 - 7.00	-4.00 - 7.00
		Min - Max	-22.0 - 20.5	-24.0 - 34.0	-13.5 - 33.0	-22.0 - 49.0	-24.0 - 49.0	-24.0 - 49.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
PR Interval, Aggregate (ms)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	151.88 (17.269)	152.82 (20.790)	152.74 (18.661)	152.27 (21.340)	152.62 (20.190)	152.43 (19.474)
		Median	152.00	152.00	150.00	151.00	152.00	152.00
		Q1 - Q3	140.00 - 163.00	136.00 - 165.50	136.00 - 168.00	136.00 - 169.00	136.00 - 168.00	137.00 - 165.00
		Min - Max	114.0 - 196.0	118.0 - 200.0	120.0 - 200.0	103.0 - 192.0	103.0 - 200.0	103.0 - 200.0
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.22 (11.527)	-0.06 (11.805)	1.98 (8.099)	0.29 (10.482)	0.73 (10.254)	0.85 (10.565)
		Median	1.50	-2.00	1.50	0	0	0
		Q1 - Q3	-6.00 - 8.00	-4.25 - 4.75	-3.00 - 6.00	-5.00 - 7.00	-4.00 - 5.25	-5.00 - 6.00
		Min - Max	-26.0 - 26.0	-34.0 - 40.0	-16.5 - 26.5	-26.0 - 31.0	-34.0 - 40.0	-34.0 - 40.0
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	151.36 (18.695)	152.13 (19.592)	151.35 (18.417)	153.68 (21.499)	152.37 (19.770)	152.12 (19.480)
		Median	152.00	152.00	152.00	151.00	152.00	152.00
		Q1 - Q3	137.00 - 162.50	138.00 - 164.00	140.00 - 164.00	135.00 - 168.00	136.00 - 164.00	136.00 - 164.00
		Min - Max	114.0 - 196.0	120.0 - 200.0	116.0 - 198.0	120.0 - 204.0	116.0 - 204.0	114.0 - 204.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
PR Interval, Aggregate (ms)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	0.75 (10.504)	-0.43 (9.227)	0.45 (8.555)	1.71 (12.196)	0.55 (10.063)	0.60 (10.153)
		Median	0	-1.00	-0.75	0	-0.25	0
		Q1 - Q3	-6.00 - 6.25	-6.00 - 4.00	-6.00 - 6.00	-4.50 - 6.00	-5.00 - 6.00	-5.00 - 6.00
		Min - Max	-23.0 - 28.5	-22.0 - 24.0	-17.5 - 22.5	-26.5 - 48.0	-26.5 - 48.0	-26.5 - 48.0
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	151.03 (19.405)	152.16 (19.373)	153.06 (17.122)	153.38 (20.964)	152.85 (19.100)	152.41 (19.154)
		Median	151.50	152.00	150.50	152.00	152.00	152.00
		Q1 - Q3	137.00 - 160.00	137.00 - 163.50	140.00 - 166.00	136.00 - 170.00	138.00 - 166.00	138.00 - 164.00
		Min - Max	120.0 - 200.0	114.0 - 196.0	122.0 - 188.0	108.0 - 200.0	108.0 - 200.0	108.0 - 200.0
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.11 (12.530)	-0.19 (11.616)	2.42 (10.183)	1.32 (13.403)	1.17 (11.769)	0.91 (11.944)
		Median	0	0	4.00	0.50	0.50	0.50
		Q1 - Q3	-8.00 - 6.00	-4.50 - 5.00	-4.00 - 8.00	-6.00 - 8.00	-5.00 - 7.50	-6.00 - 7.00
		Min - Max	-27.0 - 48.5	-48.0 - 36.0	-28.0 - 27.5	-26.0 - 52.0	-48.0 - 52.0	-48.0 - 52.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QRS Duration, Aggregate (ms)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	86.26 (7.766)	87.54 (9.338)	86.07 (7.777)	85.99 (10.482)	86.54 (9.243)	86.47 (8.884)
		Median	86.50	86.25	86.00	85.00	86.00	86.00
		Q1 - Q3	81.50 - 90.00	82.00 - 93.50	80.50 - 90.50	79.25 - 92.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	63.0 - 106.0	70.0 - 125.5	69.5 - 108.0	68.5 - 133.0	68.5 - 133.0	63.0 - 133.0
	D1 (4 Hours Post-dose)	Observed Value						
		n	64	68	67	67	202	266
		Mean (SD)	86.78 (8.588)	86.88 (8.812)	85.60 (7.363)	86.49 (11.831)	86.33 (9.484)	86.44 (9.263)
		Median	87.50	87.00	85.00	85.00	86.00	86.00
		Q1 - Q3	82.00 - 92.00	82.00 - 92.00	80.00 - 90.00	78.00 - 92.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	62.0 - 108.0	69.0 - 114.0	70.0 - 100.0	61.0 - 134.0	61.0 - 134.0	61.0 - 134.0
	D1 (4 Hours Post-dose)	Change from Baseline						
		n	64	68	67	67	202	266
		Mean (SD)	0.86 (3.479)	-0.97 (5.128)	-0.14 (4.963)	0.54 (5.654)	-0.19 (5.267)	0.06 (4.911)
		Median	1.00	0	0	1.00	0	0.50
		Q1 - Q3	-1.50 - 3.00	-2.75 - 2.00	-2.00 - 3.50	-2.00 - 3.50	-2.00 - 2.50	-2.00 - 3.00
		Min - Max	-10.0 - 9.0	-20.5 - 10.0	-12.0 - 12.0	-29.0 - 14.5	-29.0 - 14.5	-29.0 - 14.5

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QRS Duration, Aggregate (ms)	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	86.32 (7.522)	87.91 (11.241)	86.35 (7.026)	87.59 (11.334)	87.29 (10.055)	87.05 (9.480)
		Median	88.00	88.00	86.00	86.00	87.00	87.00
		Q1 - Q3	81.00 - 92.00	81.00 - 94.00	82.00 - 90.00	78.00 - 94.50	81.00 - 92.00	81.00 - 92.00
		Min - Max	66.0 - 99.0	66.0 - 127.0	70.0 - 104.0	70.0 - 138.0	66.0 - 138.0	66.0 - 138.0
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.06 (4.063)	0.37 (6.411)	0.33 (4.263)	1.60 (6.042)	0.76 (5.661)	0.59 (5.308)
		Median	0	-0.50	0	0.25	0	0
		Q1 - Q3	-2.00 - 3.00	-4.00 - 3.00	-2.00 - 2.00	-2.00 - 3.25	-2.00 - 2.50	-2.00 - 3.00
		Min - Max	-10.0 - 10.0	-10.0 - 28.0	-10.0 - 12.0	-7.5 - 28.0	-10.0 - 28.0	-10.0 - 28.0
	D29	Observed Value						
		n	68	69	67	67	203	271
		Mean (SD)	85.63 (7.709)	87.55 (10.304)	86.25 (7.456)	86.93 (11.564)	86.92 (9.893)	86.59 (9.396)
		Median	85.00	86.00	86.00	87.00	86.00	86.00
		Q1 - Q3	80.00 - 92.00	80.00 - 93.00	80.00 - 92.00	80.00 - 92.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	64.0 - 98.0	66.0 - 120.0	74.0 - 103.0	66.0 - 142.0	66.0 - 142.0	64.0 - 142.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QRS Duration, Aggregate (ms)	D29	Change from Baseline						
		n	68	69	67	67	203	271
		Mean (SD)	-0.84 (4.821)	-0.25 (7.064)	0.19 (4.800)	1.00 (6.620)	0.31 (6.238)	0.02 (5.927)
		Median	-1.00	-0.50	0.50	0	0	0
		Q1 - Q3	-4.00 - 1.00	-4.00 - 2.00	-2.00 - 3.00	-3.00 - 3.50	-3.00 - 2.50	-3.50 - 2.00
		Min - Max	-10.0 - 15.0	-19.5 - 28.0	-12.0 - 14.0	-14.0 - 24.0	-19.5 - 28.0	-19.5 - 28.0
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	85.91 (7.678)	88.09 (10.324)	86.28 (7.535)	87.08 (10.061)	87.16 (9.373)	86.85 (8.985)
		Median	86.00	88.00	86.00	86.00	86.00	86.00
		Q1 - Q3	82.00 - 92.00	80.00 - 94.00	80.00 - 90.00	80.00 - 92.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	66.0 - 102.0	68.0 - 124.0	70.0 - 104.0	70.0 - 134.0	68.0 - 134.0	66.0 - 134.0
	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.58 (5.469)	0.29 (6.468)	0.22 (5.784)	1.05 (5.138)	0.51 (5.821)	0.24 (5.745)
		Median	-1.00	0	0	0.75	0	0
		Q1 - Q3	-4.00 - 2.00	-3.00 - 2.50	-4.00 - 3.50	-2.00 - 3.50	-2.50 - 3.00	-3.00 - 3.00
		Min - Max	-19.5 - 18.0	-11.0 - 30.0	-12.0 - 26.0	-12.0 - 16.5	-12.0 - 30.0	-19.5 - 30.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QRS Duration, Aggregate (ms)	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	85.39 (7.329)	87.56 (10.463)	86.45 (7.330)	86.03 (11.202)	86.70 (9.765)	86.37 (9.219)
		Median	86.00	86.50	84.50	84.00	86.00	86.00
		Q1 - Q3	80.00 - 91.00	82.00 - 91.50	82.00 - 92.00	78.00 - 92.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	64.0 - 97.0	70.0 - 138.0	72.0 - 101.0	70.0 - 138.0	70.0 - 138.0	64.0 - 138.0
	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	-1.09 (4.787)	-0.15 (6.581)	0.73 (5.718)	-0.05 (6.247)	0.18 (6.176)	-0.14 (5.876)
		Median	-0.50	0	0.50	0	0	0
		Q1 - Q3	-3.50 - 2.00	-3.00 - 1.50	-2.00 - 3.50	-3.50 - 3.00	-3.00 - 2.50	-3.00 - 2.00
		Min - Max	-19.0 - 9.5	-18.5 - 29.0	-14.0 - 15.0	-14.0 - 22.5	-18.5 - 29.0	-19.0 - 29.0
	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	86.86 (10.175)	88.15 (11.657)	86.98 (8.488)	86.62 (10.399)	87.27 (10.254)	87.17 (10.217)
		Median	86.00	88.00	86.00	86.00	86.00	86.00
		Q1 - Q3	80.00 - 92.00	80.00 - 93.50	82.00 - 92.00	80.00 - 92.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	66.0 - 140.0	70.0 - 131.0	70.0 - 116.0	64.0 - 130.0	64.0 - 131.0	64.0 - 140.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QRS Duration, Aggregate (ms)	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.40 (7.838)	0.44 (6.134)	1.26 (5.682)	0.54 (4.348)	0.74 (5.447)	0.66 (6.115)
		Median	0	0	1.50	0	0	0
		Q1 - Q3	-3.50 - 2.00	-3.25 - 2.00	-2.00 - 4.00	-2.00 - 2.50	-2.50 - 3.00	-2.50 - 3.00
		Min - Max	-12.0 - 51.0	-10.0 - 30.0	-12.5 - 20.0	-9.0 - 15.5	-12.5 - 30.0	-12.5 - 51.0
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	86.75 (10.604)	87.66 (9.570)	86.92 (7.689)	87.00 (11.312)	87.20 (9.566)	87.09 (9.812)
		Median	87.50	88.00	86.50	84.00	87.00	87.00
		Q1 - Q3	80.00 - 91.50	82.00 - 90.00	82.00 - 92.00	80.00 - 94.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	60.0 - 140.0	68.0 - 122.0	72.0 - 105.0	68.0 - 138.0	68.0 - 138.0	60.0 - 140.0
	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	0.59 (8.148)	-0.12 (4.616)	1.20 (5.222)	0.92 (7.151)	0.66 (5.735)	0.64 (6.396)
		Median	0	-1.00	1.00	0	0	0
		Q1 - Q3	-3.00 - 2.00	-2.50 - 3.00	-2.00 - 4.00	-3.00 - 2.00	-2.50 - 2.75	-2.50 - 2.50
		Min - Max	-20.0 - 51.0	-10.0 - 13.0	-10.0 - 18.0	-12.0 - 36.0	-12.0 - 36.0	-20.0 - 51.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QRS Duration, Aggregate (ms)	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	87.34 (10.387)	87.24 (9.651)	87.21 (8.644)	86.43 (11.477)	86.97 (9.921)	87.06 (10.018)
		Median	88.00	87.50	86.50	84.00	86.00	86.00
		Q1 - Q3	82.00 - 92.50	80.50 - 92.00	82.00 - 91.00	79.00 - 92.00	80.00 - 92.00	80.00 - 92.00
		Min - Max	66.0 - 140.0	68.0 - 120.0	70.0 - 108.0	72.0 - 142.0	68.0 - 142.0	66.0 - 142.0
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.78 (8.721)	-0.63 (7.320)	1.15 (5.553)	0.18 (6.250)	0.23 (6.438)	0.36 (7.052)
		Median	-1.00	0	0.25	0	0	0
		Q1 - Q3	-2.50 - 3.25	-3.25 - 4.00	-2.00 - 4.50	-4.00 - 2.50	-3.00 - 4.00	-3.00 - 4.00
		Min - Max	-18.0 - 51.0	-43.5 - 11.0	-10.0 - 16.5	-14.0 - 24.0	-43.5 - 24.0	-43.5 - 51.0
QT Interval, Aggregate (ms)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	390.09 (24.667)	391.90 (22.622)	390.17 (23.604)	390.84 (22.745)	390.98 (22.893)	390.76 (23.307)
		Median	390.50	392.00	390.00	393.50	392.00	392.00
		Q1 - Q3	373.00 - 408.00	380.00 - 404.00	374.50 - 403.50	373.50 - 407.75	377.00 - 404.50	375.00 - 405.75
		Min - Max	338.0 - 450.0	305.5 - 442.0	338.0 - 458.5	333.0 - 444.0	305.5 - 458.5	305.5 - 458.5

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QT Interval, Aggregate (ms)	D1 (4 Hours Post-dose)	Observed Value						
		n	64	68	67	67	202	266
		Mean (SD)	381.33 (31.623)	385.84 (24.562)	382.07 (22.891)	383.00 (22.902)	383.65 (23.409)	383.09 (25.580)
		Median	389.00	384.00	382.00	384.00	384.00	384.00
		Q1 - Q3	364.00 - 406.00	368.00 - 402.50	369.00 - 398.00	366.00 - 398.00	368.00 - 400.00	366.00 - 401.00
		Min - Max	290.0 - 432.0	339.0 - 444.0	318.0 - 433.0	322.0 - 440.0	318.0 - 444.0	290.0 - 444.0
	D1 (4 Hours Post-dose)	Change from Baseline						
		n	64	68	67	67	202	266
		Mean (SD)	-7.41 (20.270)	-6.35 (20.155)	-8.12 (16.663)	-8.19 (19.181)	-7.55 (18.658)	-7.52 (19.019)
		Median	-4.00	-4.75	-8.00	-9.00	-8.00	-7.25
		Q1 - Q3	-17.00 - 5.00	-21.00 - 3.50	-16.50 - 0.50	-22.00 - 7.00	-20.50 - 4.00	-20.00 - 4.50
		Min - Max	-91.0 - 33.0	-47.0 - 80.5	-53.0 - 32.0	-56.0 - 32.0	-56.0 - 80.5	-91.0 - 80.5
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	390.87 (22.956)	396.09 (22.911)	392.68 (22.220)	390.28 (28.975)	393.04 (24.863)	392.50 (24.376)
		Median	394.00	400.00	393.00	392.00	395.50	394.00
		Q1 - Q3	376.00 - 404.00	380.00 - 408.00	375.00 - 408.00	371.00 - 404.00	374.00 - 407.00	376.00 - 406.00
		Min - Max	324.0 - 444.0	344.0 - 454.0	336.0 - 439.0	306.0 - 458.0	306.0 - 458.0	306.0 - 458.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QT Interval, Aggregate (ms)	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.78 (18.931)	4.19 (20.622)	1.74 (18.184)	-0.56 (19.202)	1.81 (19.378)	1.55 (19.237)
		Median	1.50	4.75	0.75	-0.50	2.00	2.00
		Q1 - Q3	-4.50 - 10.50	-9.00 - 14.00	-7.25 - 12.75	-13.50 - 11.00	-11.00 - 12.00	-9.00 - 12.00
		Min - Max	-86.0 - 64.0	-37.0 - 104.5	-54.5 - 71.0	-38.0 - 49.0	-54.5 - 104.5	-86.0 - 104.5
	D29	Observed Value						
		n	68	69	67	67	203	271
		Mean (SD)	390.00 (23.381)	393.68 (26.817)	390.28 (27.057)	391.82 (26.088)	391.95 (26.563)	391.46 (25.773)
		Median	392.00	395.00	388.00	394.00	394.00	394.00
		Q1 - Q3	371.50 - 408.00	378.00 - 408.00	370.00 - 408.00	374.00 - 408.00	374.00 - 408.00	372.00 - 408.00
		Min - Max	332.0 - 438.0	310.0 - 456.0	326.0 - 453.0	324.0 - 456.0	310.0 - 456.0	310.0 - 456.0
	D29	Change from Baseline						
		n	68	69	67	67	203	271
		Mean (SD)	-0.21 (20.740)	1.51 (20.105)	-0.72 (23.003)	0.79 (19.139)	0.53 (20.725)	0.35 (20.693)
		Median	-1.00	4.00	1.00	2.00	2.00	1.00
		Q1 - Q3	-13.50 - 15.00	-10.00 - 14.50	-11.50 - 12.00	-10.00 - 14.00	-11.00 - 13.00	-11.00 - 14.00
		Min - Max	-50.0 - 56.0	-85.0 - 44.0	-104.0 - 63.0	-63.0 - 47.0	-104.0 - 63.0	-104.0 - 63.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QT Interval, Aggregate (ms)	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	387.62 (24.542)	395.20 (24.537)	392.06 (23.858)	390.91 (29.823)	392.78 (26.066)	391.50 (25.747)
		Median	388.00	394.00	388.00	390.00	392.00	390.00
		Q1 - Q3	372.00 - 403.00	381.00 - 408.00	376.00 - 410.00	374.00 - 411.00	376.50 - 410.00	374.00 - 408.00
		Min - Max	334.0 - 438.0	332.0 - 448.0	344.0 - 450.0	320.0 - 460.0	320.0 - 460.0	320.0 - 460.0
	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-1.87 (23.563)	3.03 (18.048)	1.05 (20.754)	0.41 (19.424)	1.53 (19.361)	0.68 (20.490)
		Median	0.75	2.00	3.00	2.50	2.00	2.00
		Q1 - Q3	-15.00 - 12.50	-5.00 - 14.00	-11.00 - 16.50	-13.75 - 12.00	-8.00 - 14.00	-10.00 - 14.00
		Min - Max	-76.5 - 52.0	-63.0 - 46.5	-52.5 - 47.0	-48.0 - 40.0	-63.0 - 47.0	-76.5 - 52.0
	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	388.03 (27.565)	400.18 (27.859)	391.59 (27.222)	392.37 (30.874)	394.80 (28.775)	393.10 (28.576)
		Median	389.50	400.00	390.50	390.00	394.00	392.00
		Q1 - Q3	371.00 - 408.00	376.00 - 416.50	372.00 - 410.00	364.00 - 412.00	372.00 - 415.00	372.00 - 413.00
		Min - Max	308.0 - 448.0	348.0 - 472.0	328.0 - 452.0	334.0 - 464.0	328.0 - 472.0	308.0 - 472.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QT Interval, Aggregate (ms)	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	-1.46 (25.697)	8.43 (27.106)	0.37 (22.430)	1.11 (23.838)	3.39 (24.725)	2.17 (25.012)
		Median	0	8.50	4.00	4.00	4.50	4.00
		Q1 - Q3	-16.00 - 14.50	-4.50 - 20.75	-9.00 - 14.00	-11.00 - 17.00	-9.00 - 16.00	-10.00 - 16.00
		Min - Max	-80.0 - 60.0	-53.5 - 146.5	-74.0 - 47.0	-60.0 - 68.0	-74.0 - 146.5	-80.0 - 146.5
	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	392.31 (25.447)	394.13 (26.599)	394.14 (28.023)	391.35 (30.344)	393.24 (28.201)	393.01 (27.496)
		Median	392.00	394.50	395.00	398.00	396.00	394.00
		Q1 - Q3	378.00 - 407.00	380.00 - 408.00	373.00 - 413.00	368.00 - 410.00	374.50 - 410.50	376.00 - 410.00
		Min - Max	338.0 - 468.0	294.0 - 460.0	342.0 - 476.0	314.0 - 468.0	294.0 - 476.0	294.0 - 476.0
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	3.42 (20.132)	2.39 (18.103)	3.08 (19.927)	0.10 (19.896)	1.88 (19.246)	2.27 (19.442)
		Median	3.00	5.00	4.00	4.00	4.00	4.00
		Q1 - Q3	-5.50 - 18.00	-9.75 - 13.75	-12.00 - 16.00	-11.00 - 12.00	-11.00 - 13.75	-9.50 - 15.00
		Min - Max	-58.0 - 52.0	-35.0 - 44.0	-40.5 - 62.0	-40.0 - 60.0	-40.5 - 62.0	-58.0 - 62.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QT Interval, Aggregate (ms)	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	392.98 (26.726)	393.99 (26.753)	393.14 (26.402)	394.68 (25.596)	393.92 (26.140)	393.69 (26.237)
		Median	392.00	396.00	393.50	396.00	396.00	394.00
		Q1 - Q3	377.00 - 406.50	378.00 - 413.00	375.00 - 412.00	382.00 - 408.00	376.00 - 410.50	376.00 - 408.00
		Min - Max	332.0 - 488.0	267.0 - 440.0	329.0 - 452.0	338.0 - 454.0	267.0 - 454.0	267.0 - 488.0
	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	4.30 (23.943)	1.57 (19.222)	1.92 (22.821)	3.43 (19.737)	2.29 (20.571)	2.78 (21.419)
		Median	4.00	3.00	2.25	2.50	2.50	3.25
		Q1 - Q3	-9.00 - 19.75	-10.50 - 13.00	-9.50 - 15.00	-12.00 - 17.00	-10.00 - 15.00	-10.00 - 15.50
		Min - Max	-54.0 - 60.0	-47.0 - 52.0	-72.5 - 62.0	-44.0 - 53.5	-72.5 - 62.0	-72.5 - 62.0
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	393.55 (25.154)	395.29 (21.657)	391.41 (22.116)	394.68 (25.811)	393.80 (23.157)	393.74 (23.613)
		Median	393.00	394.50	390.00	396.00	393.00	393.00
		Q1 - Q3	378.50 - 410.50	378.00 - 413.00	378.00 - 406.00	374.00 - 412.00	376.00 - 410.00	378.00 - 410.00
		Min - Max	336.0 - 440.0	356.0 - 443.0	350.0 - 452.0	337.0 - 449.0	337.0 - 452.0	336.0 - 452.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QT Interval, Aggregate (ms)	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	4.15 (21.309)	2.46 (22.288)	0.57 (20.744)	3.94 (20.255)	2.30 (21.075)	2.75 (21.107)
		Median	6.75	3.00	2.00	5.00	4.00	4.00
		Q1 - Q3	-8.50 - 16.00	-11.50 - 13.00	-12.00 - 12.00	-10.00 - 14.00	-11.00 - 13.00	-11.00 - 14.00
		Min - Max	-54.0 - 63.0	-40.0 - 102.5	-54.5 - 66.0	-72.5 - 48.0	-72.5 - 102.5	-72.5 - 102.5
QTcF Interval, Aggregate (ms)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	407.51 (16.984)	407.19 (19.652)	407.46 (16.800)	406.13 (15.479)	406.93 (17.343)	407.08 (17.225)
		Median	407.00	406.75	407.50	408.00	407.50	407.00
		Q1 - Q3	398.00 - 415.50	398.50 - 421.50	398.50 - 417.50	396.00 - 415.25	398.00 - 418.00	398.00 - 418.00
		Min - Max	363.0 - 451.0	307.0 - 446.5	366.0 - 441.0	366.0 - 436.0	307.0 - 446.5	307.0 - 451.0
	D1 (4 Hours Post-dose)	Observed Value						
		n	64	68	67	67	202	266
		Mean (SD)	404.39 (22.879)	405.93 (17.722)	404.42 (16.281)	402.96 (16.174)	404.44 (16.706)	404.43 (18.334)
		Median	405.50	406.00	404.00	406.00	405.50	405.50
		Q1 - Q3	394.00 - 417.00	392.00 - 416.50	394.00 - 415.00	394.00 - 413.00	394.00 - 415.00	394.00 - 416.00
		Min - Max	321.0 - 450.0	368.0 - 440.0	366.0 - 442.0	363.0 - 441.0	363.0 - 442.0	321.0 - 450.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QTcF Interval, Aggregate (ms)	D1 (4 Hours Post-dose)	Change from Baseline						
		n	64	68	67	67	202	266
		Mean (SD)	-2.92 (16.699)	-1.46 (18.173)	-3.37 (11.049)	-3.28 (15.235)	-2.70 (15.072)	-2.75 (15.447)
		Median	-1.00	-2.00	-3.00	-1.00	-2.50	-2.00
		Q1 - Q3	-8.25 - 6.75	-9.00 - 5.00	-10.00 - 3.50	-12.00 - 6.00	-10.50 - 5.00	-10.00 - 6.00
		Min - Max	-100.0 - 17.5	-35.5 - 108.0	-40.0 - 22.5	-51.0 - 28.0	-51.0 - 108.0	-100.0 - 108.0
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	408.41 (16.112)	410.76 (17.311)	408.25 (16.895)	405.87 (19.537)	408.32 (17.970)	408.34 (17.494)
		Median	410.00	412.00	407.50	406.50	408.50	409.00
		Q1 - Q3	399.00 - 416.00	400.00 - 421.00	399.00 - 419.00	393.00 - 418.50	398.00 - 421.00	399.00 - 419.00
		Min - Max	372.0 - 446.0	368.0 - 449.0	357.0 - 440.0	350.0 - 447.0	350.0 - 449.0	350.0 - 449.0
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	0.90 (13.326)	3.56 (18.737)	0.40 (13.872)	-0.26 (14.706)	1.26 (15.955)	1.17 (15.315)
		Median	-0.50	2.50	0.25	-0.75	1.25	0.50
		Q1 - Q3	-6.50 - 8.50	-7.00 - 13.00	-9.00 - 10.25	-9.00 - 8.75	-8.50 - 11.00	-8.00 - 10.00
		Min - Max	-38.5 - 64.0	-40.5 - 105.0	-41.5 - 31.0	-32.0 - 34.0	-41.5 - 105.0	-41.5 - 105.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QTcF Interval, Aggregate (ms)	D29	Observed Value						
		n	68	69	67	67	203	271
		Mean (SD)	406.94 (15.917)	408.26 (19.593)	406.76 (20.273)	406.25 (17.166)	407.10 (18.988)	407.06 (18.237)
		Median	407.00	413.00	405.00	407.00	408.00	408.00
		Q1 - Q3	396.00 - 416.00	397.00 - 422.00	394.00 - 422.00	400.00 - 415.00	397.00 - 420.00	397.00 - 419.00
		Min - Max	369.0 - 446.0	335.0 - 448.0	347.0 - 458.0	341.0 - 440.0	335.0 - 458.0	335.0 - 458.0
	D29	Change from Baseline						
		n	68	69	67	67	203	271
		Mean (SD)	-0.91 (14.768)	0.99 (17.194)	-0.94 (15.331)	0.25 (14.276)	0.11 (15.606)	-0.15 (15.379)
		Median	-2.00	0.50	2.50	0	0.50	0
		Q1 - Q3	-8.75 - 7.75	-5.50 - 9.00	-6.00 - 8.00	-11.00 - 7.00	-7.00 - 8.00	-7.00 - 8.00
		Min - Max	-36.0 - 48.0	-71.5 - 40.0	-80.5 - 29.0	-33.0 - 46.0	-80.5 - 46.0	-80.5 - 48.0
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	407.53 (16.617)	408.83 (19.113)	406.12 (19.906)	404.66 (20.237)	406.59 (19.721)	406.82 (18.972)
		Median	406.50	410.00	406.00	406.50	407.00	407.00
		Q1 - Q3	398.00 - 416.00	394.00 - 423.00	396.00 - 419.00	389.50 - 417.00	393.00 - 419.00	394.00 - 419.00
		Min - Max	353.0 - 444.0	348.0 - 448.0	334.0 - 448.0	358.0 - 454.0	334.0 - 454.0	334.0 - 454.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QTcF Interval, Aggregate (ms)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.11 (15.794)	1.56 (14.803)	-1.58 (15.428)	-1.38 (14.787)	-0.44 (15.005)	-0.35 (15.175)
		Median	0	3.50	1.00	-0.25	1.50	1.25
		Q1 - Q3	-12.00 - 10.50	-7.50 - 11.00	-9.50 - 8.00	-10.25 - 8.00	-9.50 - 8.50	-9.50 - 9.00
		Min - Max	-46.0 - 39.0	-53.5 - 41.0	-53.0 - 24.0	-48.0 - 41.5	-53.5 - 41.5	-53.5 - 41.5
	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	406.73 (18.389)	413.68 (17.819)	407.56 (21.469)	405.59 (21.171)	409.04 (20.377)	408.46 (19.887)
		Median	407.50	414.00	409.00	406.00	411.00	409.00
		Q1 - Q3	396.00 - 418.00	399.50 - 426.00	394.00 - 423.00	390.00 - 422.00	394.00 - 423.00	396.00 - 422.00
		Min - Max	365.0 - 452.0	377.0 - 450.0	356.0 - 447.0	350.0 - 447.0	350.0 - 450.0	350.0 - 452.0
	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	-0.91 (18.180)	6.71 (21.614)	-0.45 (16.868)	-0.65 (16.631)	1.96 (18.803)	1.24 (18.656)
		Median	-1.25	4.25	2.50	-1.50	2.50	2.00
		Q1 - Q3	-14.00 - 9.50	-4.25 - 17.50	-7.00 - 9.50	-10.50 - 7.50	-7.50 - 11.50	-8.00 - 11.00
		Min - Max	-58.5 - 58.0	-39.0 - 132.0	-53.0 - 36.5	-44.0 - 37.0	-53.0 - 132.0	-58.5 - 132.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QTcF Interval, Aggregate (ms)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	409.38 (18.231)	409.38 (24.125)	410.62 (20.506)	405.75 (22.140)	408.62 (22.317)	408.81 (21.341)
		Median	408.00	411.50	411.00	406.00	410.00	410.00
		Q1 - Q3	400.00 - 420.00	399.00 - 426.00	399.00 - 424.00	393.00 - 421.00	397.00 - 423.50	399.00 - 422.00
		Min - Max	362.0 - 463.0	297.0 - 450.0	363.0 - 460.0	338.0 - 452.0	297.0 - 460.0	297.0 - 463.0
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	1.93 (12.363)	2.42 (16.807)	2.57 (14.073)	-0.49 (14.725)	1.53 (15.263)	1.63 (14.573)
		Median	2.00	2.75	2.50	1.00	2.00	2.00
		Q1 - Q3	-5.00 - 9.00	-9.25 - 14.75	-5.00 - 10.50	-8.50 - 11.00	-7.50 - 11.50	-6.50 - 11.00
		Min - Max	-29.5 - 30.5	-45.5 - 49.0	-35.5 - 55.5	-39.0 - 30.0	-45.5 - 55.5	-45.5 - 55.5
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	411.31 (20.431)	409.36 (22.891)	410.20 (19.635)	408.40 (19.013)	409.33 (20.527)	409.82 (20.482)
		Median	412.00	411.00	410.00	408.00	409.50	410.00
		Q1 - Q3	398.50 - 423.50	401.00 - 423.00	397.00 - 421.00	398.00 - 418.00	398.00 - 422.00	398.00 - 422.00
		Min - Max	354.0 - 468.0	282.0 - 457.0	359.0 - 455.0	348.0 - 452.0	282.0 - 457.0	282.0 - 468.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.1
Summary of 12-Lead Electrocardiogram
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
QTcF Interval, Aggregate (ms)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	3.84 (19.072)	1.92 (17.036)	2.18 (16.549)	2.16 (17.232)	2.08 (16.850)	2.52 (17.402)
		Median	5.25	3.00	3.50	0.50	2.25	2.75
		Q1 - Q3	-6.25 - 14.25	-5.00 - 13.50	-7.00 - 12.00	-7.50 - 12.50	-6.75 - 12.25	-6.50 - 12.75
		Min - Max	-46.5 - 70.5	-55.0 - 44.0	-70.5 - 43.0	-47.0 - 43.5	-70.5 - 44.0	-70.5 - 70.5
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	410.81 (17.671)	411.99 (16.598)	407.05 (17.935)	407.24 (19.256)	408.81 (17.986)	409.30 (17.896)
		Median	410.00	413.00	406.00	409.00	409.00	409.00
		Q1 - Q3	401.00 - 420.00	399.50 - 424.50	394.00 - 419.00	395.00 - 419.00	397.00 - 422.00	398.00 - 421.00
		Min - Max	357.0 - 454.0	377.0 - 454.0	372.0 - 444.0	341.0 - 451.0	341.0 - 454.0	341.0 - 454.0
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	2.70 (15.116)	4.24 (20.390)	-0.68 (16.361)	1.10 (17.881)	1.59 (18.338)	1.86 (17.581)
		Median	3.50	4.00	0	-0.50	1.00	1.50
		Q1 - Q3	-6.25 - 11.75	-5.75 - 12.25	-8.50 - 6.00	-7.50 - 10.50	-7.00 - 10.00	-7.00 - 10.00
		Min - Max	-35.5 - 43.5	-45.5 - 116.0	-66.0 - 50.0	-85.0 - 56.5	-85.0 - 116.0	-85.0 - 116.0

Data Source: Listing 16.2.8.2.1
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D1 (4 Hours Post-dose)	Placebo (N=69)	Normal	30 (46.9)	10 (15.6)	0	40 (62.5)
			Abnormal NCS	2 (3.1)	21 (32.8)	0	23 (35.9)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	32 (50.0)	31 (48.4)	1 (1.6)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	30 (44.1)	12 (17.6)	1 (1.5)	43 (63.2)
			Abnormal NCS	5 (7.4)	19 (27.9)	0	24 (35.3)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	36 (52.9)	31 (45.6)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	26 (38.8)	12 (17.9)	0	38 (56.7)
			Abnormal NCS	5 (7.5)	22 (32.8)	1 (1.5)	28 (41.8)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	31 (46.3)	34 (50.7)	2 (3.0)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	24 (35.8)	14 (20.9)	1 (1.5)	39 (58.2)
			Abnormal NCS	5 (7.5)	22 (32.8)	1 (1.5)	28 (41.8)
			Abnormal CS	0	0	0	0
			Total	29 (43.3)	36 (53.7)	2 (3.0)	67 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D1 (4 Hours Post-dose)	Combined GS1-144 (N=207)	Normal	80 (39.6)	38 (18.8)	2 (1.0)	120 (59.4)
			Abnormal NCS	15 (7.4)	63 (31.2)	2 (1.0)	80 (39.6)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	96 (47.5)	101 (50.0)	5 (2.5)	202 (100)
	D15	Placebo (N=69)	Normal	31 (44.9)	16 (23.2)	0	47 (68.1)
			Abnormal NCS	2 (2.9)	17 (24.6)	0	19 (27.5)
			Abnormal CS	1 (1.4)	0	2 (2.9)	3 (4.3)
			Total	34 (49.3)	33 (47.8)	2 (2.9)	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	27 (38.6)	12 (17.1)	0	39 (55.7)
			Abnormal NCS	10 (14.3)	19 (27.1)	1 (1.4)	30 (42.9)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	37 (52.9)	32 (45.7)	1 (1.4)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	21 (30.9)	19 (27.9)	1 (1.5)	41 (60.3)
			Abnormal NCS	9 (13.2)	17 (25.0)	0	26 (38.2)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	30 (44.1)	36 (52.9)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D15	GS1-144 30 mg BID (N=68)	Normal	25 (36.8)	12 (17.6)	0	37 (54.4)
			Abnormal NCS	5 (7.4)	23 (33.8)	0	28 (41.2)
			Abnormal CS	0	1 (1.5)	2 (2.9)	3 (4.4)
			Total	30 (44.1)	36 (52.9)	2 (2.9)	68 (100)
		Combined GS1-144 (N=207)	Normal	73 (35.4)	43 (20.9)	1 (0.5)	117 (56.8)
			Abnormal NCS	24 (11.7)	59 (28.6)	1 (0.5)	84 (40.8)
			Abnormal CS	0	2 (1.0)	3 (1.5)	5 (2.4)
			Total	97 (47.1)	104 (50.5)	5 (2.4)	206 (100)
	D29	Placebo (N=69)	Normal	30 (44.1)	13 (19.1)	1 (1.5)	44 (64.7)
			Abnormal NCS	4 (5.9)	19 (27.9)	0	23 (33.8)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	34 (50.0)	32 (47.1)	2 (2.9)	68 (100)
		GS1-144 30 mg QD (N=70)	Normal	30 (43.5)	12 (17.4)	1 (1.4)	43 (62.3)
			Abnormal NCS	6 (8.7)	20 (29.0)	0	26 (37.7)
			Abnormal CS	0	0	0	0
			Total	36 (52.2)	32 (46.4)	1 (1.4)	69 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D29	GS1-144 60 mg QD (N=69)	Normal	25 (37.3)	12 (17.9)	0	37 (55.2)
			Abnormal NCS	5 (7.5)	23 (34.3)	1 (1.5)	29 (43.3)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	30 (44.8)	35 (52.2)	2 (3.0)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	25 (37.3)	6 (9.0)	0	31 (46.3)
			Abnormal NCS	4 (6.0)	27 (40.3)	1 (1.5)	32 (47.8)
			Abnormal CS	0	3 (4.5)	1 (1.5)	4 (6.0)
			Total	29 (43.3)	36 (53.7)	2 (3.0)	67 (100)
		Combined GS1-144 (N=207)	Normal	80 (39.4)	30 (14.8)	1 (0.5)	111 (54.7)
			Abnormal NCS	15 (7.4)	70 (34.5)	2 (1.0)	87 (42.9)
			Abnormal CS	0	3 (1.5)	2 (1.0)	5 (2.5)
			Total	95 (46.8)	103 (50.7)	5 (2.5)	203 (100)
	D43	Placebo (N=69)	Normal	28 (42.4)	15 (22.7)	1 (1.5)	44 (66.7)
			Abnormal NCS	6 (9.1)	15 (22.7)	0	21 (31.8)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	34 (51.5)	30 (45.5)	2 (3.0)	66 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D43	GS1-144 30 mg QD (N=70)	Normal	26 (37.7)	10 (14.5)	1 (1.4)	37 (53.6)
			Abnormal NCS	10 (14.5)	21 (30.4)	0	31 (44.9)
			Abnormal CS	0	1 (1.4)	0	1 (1.4)
			Total	36 (52.2)	32 (46.4)	1 (1.4)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	24 (35.8)	15 (22.4)	0	39 (58.2)
			Abnormal NCS	6 (9.0)	20 (29.9)	1 (1.5)	27 (40.3)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	30 (44.8)	35 (52.2)	2 (3.0)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	25 (39.1)	12 (18.8)	0	37 (57.8)
			Abnormal NCS	4 (6.3)	19 (29.7)	0	23 (35.9)
			Abnormal CS	0	2 (3.1)	2 (3.1)	4 (6.3)
			Total	29 (45.3)	33 (51.6)	2 (3.1)	64 (100)
		Combined GS1-144 (N=207)	Normal	75 (37.5)	37 (18.5)	1 (0.5)	113 (56.5)
			Abnormal NCS	20 (10.0)	60 (30.0)	1 (0.5)	81 (40.5)
			Abnormal CS	0	3 (1.5)	3 (1.5)	6 (3.0)
			Total	95 (47.5)	100 (50.0)	5 (2.5)	200 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Interpretation	D57	Placebo (N=69)	Normal	32 (48.5)	13 (19.7)	0	45 (68.2)
			Abnormal NCS	2 (3.0)	16 (24.2)	0	18 (27.3)
			Abnormal CS	0	1 (1.5)	2 (3.0)	3 (4.5)
			Total	34 (51.5)	30 (45.5)	2 (3.0)	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	29 (42.6)	11 (16.2)	1 (1.5)	41 (60.3)
			Abnormal NCS	7 (10.3)	20 (29.4)	0	27 (39.7)
			Abnormal CS	0	0	0	0
			Total	36 (52.9)	31 (45.6)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	26 (39.4)	13 (19.7)	0	39 (59.1)
			Abnormal NCS	4 (6.1)	20 (30.3)	0	24 (36.4)
			Abnormal CS	0	1 (1.5)	2 (3.0)	3 (4.5)
			Total	30 (45.5)	34 (51.5)	2 (3.0)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	22 (34.9)	9 (14.3)	1 (1.6)	32 (50.8)
			Abnormal NCS	6 (9.5)	22 (34.9)	0	28 (44.4)
			Abnormal CS	0	2 (3.2)	1 (1.6)	3 (4.8)
			Total	28 (44.4)	33 (52.4)	2 (3.2)	63 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D57	Combined GS1-144 (N=207)	Normal	77 (39.1)	33 (16.8)	2 (1.0)	112 (56.9)
			Abnormal NCS	17 (8.6)	62 (31.5)	0	79 (40.1)
			Abnormal CS	0	3 (1.5)	3 (1.5)	6 (3.0)
			Total	94 (47.7)	98 (49.7)	5 (2.5)	197 (100)
	D71	Placebo (N=69)	Normal	30 (46.2)	13 (20.0)	1 (1.5)	44 (67.7)
			Abnormal NCS	4 (6.2)	16 (24.6)	0	20 (30.8)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	34 (52.3)	29 (44.6)	2 (3.1)	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	31 (45.6)	14 (20.6)	1 (1.5)	46 (67.6)
			Abnormal NCS	4 (5.9)	16 (23.5)	0	20 (29.4)
			Abnormal CS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Total	36 (52.9)	31 (45.6)	1 (1.5)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	26 (40.0)	13 (20.0)	0	39 (60.0)
			Abnormal NCS	4 (6.2)	19 (29.2)	0	23 (35.4)
			Abnormal CS	0	1 (1.5)	2 (3.1)	3 (4.6)
			Total	30 (46.2)	33 (50.8)	2 (3.1)	65 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D71	GS1-144 30 mg BID (N=68)	Normal	22 (34.9)	8 (12.7)	0	30 (47.6)
			Abnormal NCS	6 (9.5)	24 (38.1)	1 (1.6)	31 (49.2)
			Abnormal CS	0	1 (1.6)	1 (1.6)	2 (3.2)
			Total	28 (44.4)	33 (52.4)	2 (3.2)	63 (100)
		Combined GS1-144 (N=207)	Normal	79 (40.3)	35 (17.9)	1 (0.5)	115 (58.7)
			Abnormal NCS	14 (7.1)	59 (30.1)	1 (0.5)	74 (37.8)
			Abnormal CS	1 (0.5)	3 (1.5)	3 (1.5)	7 (3.6)
			Total	94 (48.0)	97 (49.5)	5 (2.6)	196 (100)
	D85	Placebo (N=69)	Normal	27 (42.2)	10 (15.6)	0	37 (57.8)
			Abnormal NCS	6 (9.4)	18 (28.1)	0	24 (37.5)
			Abnormal CS	1 (1.6)	0	2 (3.1)	3 (4.7)
			Total	34 (53.1)	28 (43.8)	2 (3.1)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	32 (47.8)	14 (20.9)	0	46 (68.7)
			Abnormal NCS	4 (6.0)	17 (25.4)	0	21 (31.3)
			Abnormal CS	0	0	0	0
			Total	36 (53.7)	31 (46.3)	0	67 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	D85	GS1-144 60 mg QD (N=69)	Normal	23 (34.8)	18 (27.3)	1 (1.5)	42 (63.6)
			Abnormal NCS	7 (10.6)	16 (24.2)	0	23 (34.8)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	30 (45.5)	34 (51.5)	2 (3.0)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	23 (36.5)	10 (15.9)	1 (1.6)	34 (54.0)
			Abnormal NCS	4 (6.3)	21 (33.3)	0	25 (39.7)
			Abnormal CS	1 (1.6)	2 (3.2)	1 (1.6)	4 (6.3)
			Total	28 (44.4)	33 (52.4)	2 (3.2)	63 (100)
		Combined GS1-144 (N=207)	Normal	78 (39.8)	42 (21.4)	2 (1.0)	122 (62.2)
			Abnormal NCS	15 (7.7)	54 (27.6)	0	69 (35.2)
			Abnormal CS	1 (0.5)	2 (1.0)	2 (1.0)	5 (2.6)
			Total	94 (48.0)	98 (50.0)	4 (2.0)	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	25 (39.1)	18 (28.1)	0	43 (67.2)
			Abnormal NCS	8 (12.5)	11 (17.2)	1 (1.6)	20 (31.3)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	33 (51.6)	29 (45.3)	2 (3.1)	64 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.1
Shift of 12-Lead Electrocardiogram by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Interpretation	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	28 (41.2)	14 (20.6)	0	42 (61.8)
			Abnormal NCS	8 (11.8)	18 (26.5)	0	26 (38.2)
			Abnormal CS	0	0	0	0
			Total	36 (52.9)	32 (47.1)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	26 (39.4)	14 (21.2)	0	40 (60.6)
			Abnormal NCS	4 (6.1)	19 (28.8)	1 (1.5)	24 (36.4)
			Abnormal CS	0	1 (1.5)	1 (1.5)	2 (3.0)
			Total	30 (45.5)	34 (51.5)	2 (3.0)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	22 (34.9)	11 (17.5)	1 (1.6)	34 (54.0)
			Abnormal NCS	6 (9.5)	22 (34.9)	0	28 (44.4)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	28 (44.4)	33 (52.4)	2 (3.2)	63 (100)
		Combined GS1-144 (N=207)	Normal	76 (38.6)	39 (19.8)	1 (0.5)	116 (58.9)
			Abnormal NCS	18 (9.1)	59 (29.9)	1 (0.5)	78 (39.6)
			Abnormal CS	0	1 (0.5)	2 (1.0)	3 (1.5)
			Total	94 (47.7)	99 (50.3)	4 (2.0)	197 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.2.2
Shift of 12-Lead Electrocardiogram by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Interpretation	Placebo (N=69)	Normal	15 (21.7)	2 (2.9)	0	17 (24.6)
		Abnormal NCS	18 (26.1)	30 (43.5)	0	48 (69.6)
		Abnormal CS	1 (1.4)	1 (1.4)	2 (2.9)	4 (5.8)
		Total	34 (49.3)	33 (47.8)	2 (2.9)	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	12 (17.1)	2 (2.9)	0	14 (20.0)
		Abnormal NCS	23 (32.9)	29 (41.4)	0	52 (74.3)
		Abnormal CS	2 (2.9)	1 (1.4)	1 (1.4)	4 (5.7)
		Total	37 (52.9)	32 (45.7)	1 (1.4)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	11 (15.9)	1 (1.4)	0	12 (17.4)
		Abnormal NCS	20 (29.0)	32 (46.4)	0	52 (75.4)
		Abnormal CS	0	3 (4.3)	2 (2.9)	5 (7.2)
		Total	31 (44.9)	36 (52.2)	2 (2.9)	69 (100)
	GS1-144 30 mg BID (N=68)	Normal	13 (19.1)	1 (1.5)	0	14 (20.6)
		Abnormal NCS	16 (23.5)	32 (47.1)	0	48 (70.6)
		Abnormal CS	1 (1.5)	3 (4.4)	2 (2.9)	6 (8.8)
		Total	30 (44.1)	36 (52.9)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline.

Table 14.3.5.2.2
Shift of 12-Lead Electrocardiogram by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Interpretation	Combined GS1-144 (N=207)	Normal	36 (17.4)	4 (1.9)	0	40 (19.3)
		Abnormal NCS	59 (28.5)	93 (44.9)	0	152 (73.4)
		Abnormal CS	3 (1.4)	7 (3.4)	5 (2.4)	15 (7.2)
		Total	98 (47.3)	104 (50.2)	5 (2.4)	207 (100)

Data Source: Listing 16.2.8.2.1
NCS = not clinically significant; CS = clinically significant.
Baseline interpretations were defined as the worst one of those two measurements collected prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline.

Table 14.3.5.3.1
Category of QTcF by Visit
SS

Visit	Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Baseline	QTcF	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)
	<= 450 msec	68 (98.6)	70 (100)	69 (100)	68 (100)	207 (100)	275 (99.6)
	> 450 to <= 480 msec	1 (1.4)	0	0	0	0	1 (0.4)
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0
D1 (4 Hours Post-dose)	QTcF	64 (100)	68 (100)	67 (100)	67 (100)	202 (100)	266 (100)
	<= 450 msec	64 (100)	68 (100)	67 (100)	67 (100)	202 (100)	266 (100)
	> 450 to <= 480 msec	0	0	0	0	0	0
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0
	QTcF Change from Baseline	64 (100)	68 (100)	67 (100)	67 (100)	202 (100)	266 (100)
	<= 0 msec	33 (51.6)	40 (58.8)	40 (59.7)	38 (56.7)	118 (58.4)	151 (56.8)
	> 0 to <= 30 msec	31 (48.4)	27 (39.7)	27 (40.3)	29 (43.3)	83 (41.1)	114 (42.9)
	> 30 to <= 60 msec	0	0	0	0	0	0
	> 60 msec	0	1 (1.5)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.8.2.1
QTcF = Corrected QT Interval for heart rate by Fridericia's cube root formula.
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.
Percentages for observed value were based on number of subjects at specific visit.
Percentages for change from baseline were based on number of subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.3.1
Category of QTcF by Visit
SS

Visit	Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
D15	QTcF	69 (100)	70 (100)	68 (100)	68 (100)	206 (100)	275 (100)
	<= 450 msec	69 (100)	70 (100)	68 (100)	68 (100)	206 (100)	275 (100)
	> 450 to <= 480 msec	0	0	0	0	0	0
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0
	QTcF Change from Baseline	69 (100)	70 (100)	68 (100)	68 (100)	206 (100)	275 (100)
	<= 0 msec	37 (53.6)	30 (42.9)	34 (50.0)	35 (51.5)	99 (48.1)	136 (49.5)
	> 0 to <= 30 msec	31 (44.9)	37 (52.9)	33 (48.5)	32 (47.1)	102 (49.5)	133 (48.4)
	> 30 to <= 60 msec	0	2 (2.9)	1 (1.5)	1 (1.5)	4 (1.9)	4 (1.5)
	> 60 msec	1 (1.4)	1 (1.4)	0	0	1 (0.5)	2 (0.7)
D29	QTcF	68 (100)	69 (100)	67 (100)	67 (100)	203 (100)	271 (100)
	<= 450 msec	68 (100)	69 (100)	66 (98.5)	67 (100)	202 (99.5)	270 (99.6)
	> 450 to <= 480 msec	0	0	1 (1.5)	0	1 (0.5)	1 (0.4)
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0

Data Source: Listing 16.2.8.2.1
QTcF = Corrected QT Interval for heart rate by Fridericia's cube root formula.
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.
Percentages for observed value were based on number of subjects at specific visit.
Percentages for change from baseline were based on number of subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.3.1
Category of QTcF by Visit
SS

Visit	Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
D29	QTcF Change from Baseline	68 (100)	69 (100)	67 (100)	67 (100)	203 (100)	271 (100)
	<= 0 msec	39 (57.4)	33 (47.8)	31 (46.3)	34 (50.7)	98 (48.3)	137 (50.6)
	> 0 to <= 30 msec	28 (41.2)	34 (49.3)	36 (53.7)	31 (46.3)	101 (49.8)	129 (47.6)
	> 30 to <= 60 msec	1 (1.5)	2 (2.9)	0	2 (3.0)	4 (2.0)	5 (1.8)
	> 60 msec	0	0	0	0	0	0
D43	QTcF	66 (100)	69 (100)	67 (100)	64 (100)	200 (100)	266 (100)
	<= 450 msec	66 (100)	69 (100)	67 (100)	63 (98.4)	199 (99.5)	265 (99.6)
	> 450 to <= 480 msec	0	0	0	1 (1.6)	1 (0.5)	1 (0.4)
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0
	QTcF Change from Baseline	66 (100)	69 (100)	67 (100)	64 (100)	200 (100)	266 (100)
	<= 0 msec	35 (53.0)	30 (43.5)	28 (41.8)	33 (51.6)	91 (45.5)	126 (47.4)
	> 0 to <= 30 msec	29 (43.9)	37 (53.6)	39 (58.2)	30 (46.9)	106 (53.0)	135 (50.8)
	> 30 to <= 60 msec	2 (3.0)	2 (2.9)	0	1 (1.6)	3 (1.5)	5 (1.9)
	> 60 msec	0	0	0	0	0	0

Data Source: Listing 16.2.8.2.1
QTcF = Corrected QT Interval for heart rate by Fridericia's cube root formula.
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.
Percentages for observed value were based on number of subjects at specific visit.
Percentages for change from baseline were based on number of subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.3.1
Category of QTcF by Visit
SS

Visit	Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
D57	QTcF	66 (100)	68 (100)	66 (100)	63 (100)	197 (100)	263 (100)
	<= 450 msec	65 (98.5)	68 (100)	66 (100)	63 (100)	197 (100)	262 (99.6)
	> 450 to <= 480 msec	1 (1.5)	0	0	0	0	1 (0.4)
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0
	QTcF Change from Baseline	66 (100)	68 (100)	66 (100)	63 (100)	197 (100)	263 (100)
	<= 0 msec	35 (53.0)	24 (35.3)	30 (45.5)	33 (52.4)	87 (44.2)	122 (46.4)
	> 0 to <= 30 msec	28 (42.4)	41 (60.3)	35 (53.0)	28 (44.4)	104 (52.8)	132 (50.2)
	> 30 to <= 60 msec	3 (4.5)	2 (2.9)	1 (1.5)	2 (3.2)	5 (2.5)	8 (3.0)
	> 60 msec	0	1 (1.5)	0	0	1 (0.5)	1 (0.4)
D71	QTcF	65 (100)	68 (100)	65 (100)	63 (100)	196 (100)	261 (100)
	<= 450 msec	64 (98.5)	68 (100)	64 (98.5)	62 (98.4)	194 (99.0)	258 (98.9)
	> 450 to <= 480 msec	1 (1.5)	0	1 (1.5)	1 (1.6)	2 (1.0)	3 (1.1)
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0

Data Source: Listing 16.2.8.2.1
QTcF = Corrected QT Interval for heart rate by Fridericia's cube root formula.
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.
Percentages for observed value were based on number of subjects at specific visit.
Percentages for change from baseline were based on number of subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.3.1
Category of QTcF by Visit
SS

Visit	Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
D71	QTcF Change from Baseline	65 (100)	68 (100)	65 (100)	63 (100)	196 (100)	261 (100)
	<= 0 msec	29 (44.6)	30 (44.1)	29 (44.6)	31 (49.2)	90 (45.9)	119 (45.6)
	> 0 to <= 30 msec	35 (53.8)	36 (52.9)	35 (53.8)	32 (50.8)	103 (52.6)	138 (52.9)
	> 30 to <= 60 msec	1 (1.5)	2 (2.9)	1 (1.5)	0	3 (1.5)	4 (1.5)
	> 60 msec	0	0	0	0	0	0
D85	QTcF	64 (100)	67 (100)	66 (100)	63 (100)	196 (100)	260 (100)
	<= 450 msec	61 (95.3)	66 (98.5)	65 (98.5)	62 (98.4)	193 (98.5)	254 (97.7)
	> 450 to <= 480 msec	3 (4.7)	1 (1.5)	1 (1.5)	1 (1.6)	3 (1.5)	6 (2.3)
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0
	QTcF Change from Baseline	64 (100)	67 (100)	66 (100)	63 (100)	196 (100)	260 (100)
	<= 0 msec	27 (42.2)	27 (40.3)	29 (43.9)	31 (49.2)	87 (44.4)	114 (43.8)
	> 0 to <= 30 msec	34 (53.1)	39 (58.2)	35 (53.0)	29 (46.0)	103 (52.6)	137 (52.7)
	> 30 to <= 60 msec	2 (3.1)	1 (1.5)	2 (3.0)	3 (4.8)	6 (3.1)	8 (3.1)
	> 60 msec	1 (1.6)	0	0	0	0	1 (0.4)

Data Source: Listing 16.2.8.2.1
QTcF = Corrected QT Interval for heart rate by Fridericia's cube root formula.
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.
Percentages for observed value were based on number of subjects at specific visit.
Percentages for change from baseline were based on number of subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.3.1
Category of QTcF by Visit
SS

Visit	Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
Safety Follow-up	QTcF	64 (100)	68 (100)	66 (100)	63 (100)	197 (100)	261 (100)
	<= 450 msec	63 (98.4)	67 (98.5)	66 (100)	62 (98.4)	195 (99.0)	258 (98.9)
	> 450 to <= 480 msec	1 (1.6)	1 (1.5)	0	1 (1.6)	2 (1.0)	3 (1.1)
	> 480 to <= 500 msec	0	0	0	0	0	0
	> 500 msec	0	0	0	0	0	0
	QTcF Change from Baseline	64 (100)	68 (100)	66 (100)	63 (100)	197 (100)	261 (100)
	<= 0 msec	27 (42.2)	28 (41.2)	33 (50.0)	33 (52.4)	94 (47.7)	121 (46.4)
	> 0 to <= 30 msec	35 (54.7)	38 (55.9)	31 (47.0)	29 (46.0)	98 (49.7)	133 (51.0)
	> 30 to <= 60 msec	2 (3.1)	1 (1.5)	2 (3.0)	1 (1.6)	4 (2.0)	6 (2.3)
	> 60 msec	0	1 (1.5)	0	0	1 (0.5)	1 (0.4)

Data Source: Listing 16.2.8.2.1
QTcF = Corrected QT Interval for heart rate by Fridericia's cube root formula.
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.
Percentages for observed value were based on number of subjects at specific visit.
Percentages for change from baseline were based on number of subjects with non-missing values at both baseline and specific visit.

Table 14.3.5.3.2
Category of QTcF by Worst Result
SS

Category	Placebo N = 69 n (%)	GS1-144 30 mg QD N = 70 n (%)	GS1-144 60 mg QD N = 69 n (%)	GS1-144 30 mg BID N = 68 n (%)	Combined GS1-144 N = 207 n (%)	Overall N = 276 n (%)
QTcF						
<= 450 msec	66 (95.7)	68 (97.1)	66 (95.7)	64 (94.1)	198 (95.7)	264 (95.7)
> 450 to <= 480 msec	3 (4.3)	2 (2.9)	3 (4.3)	4 (5.9)	9 (4.3)	12 (4.3)
> 480 to <= 500 msec	0	0	0	0	0	0
> 500 msec	0	0	0	0	0	0
QTcF Change from Baseline						
<= 0 msec	7 (10.1)	5 (7.1)	6 (8.7)	6 (8.8)	17 (8.2)	24 (8.7)
> 0 to <= 30 msec	56 (81.2)	57 (81.4)	57 (82.6)	56 (82.4)	170 (82.1)	226 (81.9)
> 30 to <= 60 msec	4 (5.8)	7 (10.0)	6 (8.7)	6 (8.8)	19 (9.2)	23 (8.3)
> 60 msec	2 (2.9)	1 (1.4)	0	0	1 (0.5)	3 (1.1)

Data Source: Listing 16.2.8.2.1
QTcF = Corrected QT Interval for heart rate by Fridericia's cube root formula.
Baseline values were defined as the average of last two measurements collected prior to the first study drug administration.
Worst Results were defined as the maximum post-baseline QTcF value.
Percentages for observed value were based on number of subjects with non-missing post-baseline QTcF value.
Percentages for change from baseline were based on number of subjects with non-missing values at both baseline and post-baseline QTcF value.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ear Temperature (C)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	36.32 (0.296)	36.38 (0.314)	36.33 (0.322)	36.29 (0.322)	36.34 (0.320)	36.33 (0.314)
		Median	36.40	36.40	36.40	36.30	36.40	36.40
		Q1 - Q3	36.10 - 36.50	36.20 - 36.50	36.20 - 36.50	36.10 - 36.50	36.20 - 36.50	36.20 - 36.50
		Min - Max	35.2 - 36.9	35.1 - 37.2	35.5 - 36.8	35.4 - 37.0	35.1 - 37.2	35.1 - 37.2
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	36.32 (0.296)	36.33 (0.277)	36.29 (0.351)	36.27 (0.391)	36.30 (0.341)	36.30 (0.330)
		Median	36.40	36.30	36.40	36.40	36.35	36.40
		Q1 - Q3	36.20 - 36.50	36.20 - 36.50	36.20 - 36.50	36.00 - 36.50	36.10 - 36.50	36.20 - 36.50
		Min - Max	35.5 - 37.1	35.5 - 37.0	35.0 - 36.8	34.7 - 36.9	34.7 - 37.0	34.7 - 37.1
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.00 (0.289)	-0.06 (0.320)	-0.04 (0.388)	-0.02 (0.385)	-0.04 (0.364)	-0.03 (0.347)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.10 - 0.10	-0.20 - 0.10	-0.20 - 0.15	-0.20 - 0.20	-0.20 - 0.20	-0.20 - 0.20
		Min - Max	-0.9 - 0.8	-1.0 - 1.0	-1.8 - 0.8	-1.3 - 0.8	-1.8 - 1.0	-1.8 - 1.0

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ear Temperature (C)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	36.39 (0.292)	36.35 (0.270)	36.28 (0.300)	36.31 (0.270)	36.31 (0.280)	36.33 (0.284)
		Median	36.40	36.40	36.40	36.30	36.40	36.40
		Q1 - Q3	36.20 - 36.60	36.20 - 36.50	36.10 - 36.50	36.10 - 36.50	36.10 - 36.50	36.10 - 36.50
		Min - Max	35.6 - 37.3	35.8 - 36.9	35.2 - 36.8	35.5 - 36.9	35.2 - 36.9	35.2 - 37.3
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	0.07 (0.342)	-0.03 (0.348)	-0.04 (0.349)	0.02 (0.391)	-0.02 (0.363)	0.00 (0.359)
		Median	0	-0.10	-0.10	0	0	0
		Q1 - Q3	-0.20 - 0.30	-0.20 - 0.10	-0.20 - 0.10	-0.10 - 0.20	-0.20 - 0.20	-0.20 - 0.20
		Min - Max	-0.8 - 0.9	-1.0 - 1.4	-1.1 - 1.0	-1.2 - 0.9	-1.2 - 1.4	-1.2 - 1.4
	D43	Observed Value						
		n	65	69	67	64	200	265
		Mean (SD)	36.36 (0.257)	36.32 (0.260)	36.31 (0.274)	36.32 (0.283)	36.32 (0.271)	36.33 (0.268)
		Median	36.40	36.30	36.30	36.30	36.30	36.30
		Q1 - Q3	36.20 - 36.50	36.20 - 36.50	36.20 - 36.50	36.10 - 36.50	36.10 - 36.50	36.10 - 36.50
		Min - Max	35.3 - 36.9	35.6 - 37.0	35.1 - 36.8	35.3 - 36.9	35.1 - 37.0	35.1 - 37.0

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ear Temperature (C)	D43	Change from Baseline						
		n	65	69	67	64	200	265
		Mean (SD)	0.05 (0.346)	-0.06 (0.320)	-0.02 (0.416)	0.04 (0.308)	-0.01 (0.352)	0.00 (0.351)
		Median	0.10	-0.10	0	0	0	0
		Q1 - Q3	-0.20 - 0.30	-0.20 - 0.10	-0.20 - 0.30	-0.10 - 0.20	-0.20 - 0.10	-0.20 - 0.20
		Min - Max	-1.2 - 1.0	-0.8 - 1.1	-1.5 - 0.8	-1.1 - 0.7	-1.5 - 1.1	-1.5 - 1.1
	D57	Observed Value						
		n	65	68	66	63	197	262
		Mean (SD)	36.34 (0.256)	36.32 (0.300)	36.33 (0.278)	36.32 (0.299)	36.32 (0.291)	36.33 (0.282)
		Median	36.40	36.35	36.40	36.40	36.40	36.40
		Q1 - Q3	36.10 - 36.50	36.10 - 36.50	36.20 - 36.50	36.10 - 36.50	36.10 - 36.50	36.10 - 36.50
		Min - Max	35.5 - 36.8	35.0 - 36.9	35.1 - 36.8	35.1 - 36.9	35.0 - 36.9	35.0 - 36.9
	D57	Change from Baseline						
		n	65	68	66	63	197	262
		Mean (SD)	0.02 (0.333)	-0.06 (0.371)	0.01 (0.333)	0.03 (0.335)	-0.01 (0.348)	0.00 (0.344)
		Median	0	-0.10	0	0.10	0	0
		Q1 - Q3	-0.20 - 0.20	-0.30 - 0.10	-0.20 - 0.20	-0.10 - 0.30	-0.20 - 0.20	-0.20 - 0.20
		Min - Max	-0.8 - 0.8	-1.2 - 1.4	-0.6 - 0.9	-0.8 - 0.6	-1.2 - 1.4	-1.2 - 1.4

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ear Temperature (C)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	36.35 (0.229)	36.38 (0.251)	36.27 (0.232)	36.35 (0.277)	36.33 (0.257)	36.34 (0.250)
		Median	36.40	36.40	36.30	36.40	36.40	36.40
		Q1 - Q3	36.20 - 36.50	36.20 - 36.60	36.10 - 36.50	36.20 - 36.50	36.10 - 36.50	36.20 - 36.50
		Min - Max	35.7 - 36.8	35.8 - 36.9	35.7 - 36.7	35.8 - 37.3	35.7 - 37.3	35.7 - 37.3
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	0.03 (0.308)	0.00 (0.335)	-0.05 (0.316)	0.07 (0.371)	0.01 (0.342)	0.01 (0.334)
		Median	0	0	0	0.10	0	0
		Q1 - Q3	-0.10 - 0.10	-0.20 - 0.20	-0.30 - 0.20	-0.10 - 0.30	-0.20 - 0.20	-0.20 - 0.20
		Min - Max	-0.9 - 1.0	-0.7 - 1.3	-0.8 - 0.6	-1.0 - 0.8	-1.0 - 1.3	-1.0 - 1.3
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	36.35 (0.237)	36.41 (0.280)	36.35 (0.231)	36.30 (0.289)	36.36 (0.270)	36.35 (0.261)
		Median	36.40	36.40	36.40	36.30	36.40	36.40
		Q1 - Q3	36.20 - 36.50	36.20 - 36.60	36.20 - 36.50	36.20 - 36.50	36.20 - 36.50	36.20 - 36.50
		Min - Max	35.9 - 37.0	35.9 - 37.1	35.6 - 36.8	35.1 - 36.7	35.1 - 37.1	35.1 - 37.1

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Ear Temperature (C)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	0.04 (0.301)	0.03 (0.359)	0.03 (0.334)	0.02 (0.360)	0.03 (0.350)	0.03 (0.338)
		Median	0	0	0	0	0	0
		Q1 - Q3	-0.10 - 0.20	-0.20 - 0.20	-0.20 - 0.20	-0.10 - 0.30	-0.20 - 0.20	-0.20 - 0.20
		Min - Max	-0.5 - 1.0	-0.9 - 1.4	-0.8 - 0.9	-1.5 - 0.7	-1.5 - 1.4	-1.5 - 1.4
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	36.36 (0.225)	36.40 (0.228)	36.28 (0.266)	36.33 (0.285)	36.34 (0.263)	36.34 (0.254)
		Median	36.40	36.40	36.30	36.40	36.40	36.40
		Q1 - Q3	36.20 - 36.50	36.30 - 36.60	36.10 - 36.50	36.10 - 36.50	36.10 - 36.50	36.10 - 36.50
		Min - Max	35.9 - 36.9	36.0 - 37.0	35.1 - 36.8	35.7 - 37.1	35.1 - 37.1	35.1 - 37.1
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	0.04 (0.329)	0.02 (0.359)	-0.04 (0.334)	0.04 (0.359)	0.01 (0.350)	0.02 (0.345)
		Median	0	0	0	0.10	0	0
		Q1 - Q3	-0.20 - 0.20	-0.20 - 0.20	-0.20 - 0.10	-0.10 - 0.30	-0.20 - 0.20	-0.20 - 0.20
		Min - Max	-0.8 - 1.1	-0.7 - 1.5	-0.8 - 0.6	-0.8 - 0.9	-0.8 - 1.5	-0.8 - 1.5

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Pulse Rate (beats/min)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	75.0 (10.61)	75.7 (9.14)	75.0 (8.09)	74.3 (8.35)	75.0 (8.52)	75.0 (9.07)
		Median	76.0	74.5	75.0	74.5	75.0	75.0
		Q1 - Q3	67.0 - 82.0	69.0 - 82.0	69.0 - 80.0	69.0 - 79.0	69.0 - 81.0	69.0 - 81.0
		Min - Max	55 - 98	55 - 99	58 - 98	58 - 94	55 - 99	55 - 99
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	75.0 (9.68)	74.1 (9.32)	73.8 (8.15)	73.9 (9.57)	73.9 (8.99)	74.2 (9.16)
		Median	75.0	73.0	73.0	72.5	73.0	73.0
		Q1 - Q3	68.0 - 80.0	67.0 - 80.0	68.0 - 79.0	66.5 - 80.0	68.0 - 79.0	68.0 - 80.0
		Min - Max	55 - 101	54 - 97	58 - 95	57 - 102	54 - 102	54 - 102
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-0.0 (8.94)	-1.6 (7.54)	-1.0 (7.85)	-0.4 (8.04)	-1.0 (7.79)	-0.8 (8.09)
		Median	1.0	-1.0	-0.5	-0.5	-1.0	-1.0
		Q1 - Q3	-5.0 - 6.0	-5.0 - 4.0	-5.0 - 4.0	-5.0 - 4.0	-5.0 - 4.0	-5.0 - 4.0
		Min - Max	-23 - 24	-18 - 14	-24 - 14	-21 - 21	-24 - 21	-24 - 24

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Pulse Rate (beats/min)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	73.4 (8.82)	73.0 (8.17)	74.4 (7.44)	73.3 (9.08)	73.6 (8.24)	73.5 (8.37)
		Median	73.0	72.0	75.0	71.0	74.0	73.0
		Q1 - Q3	67.0 - 80.0	68.0 - 77.0	69.0 - 80.0	67.0 - 80.0	68.0 - 79.0	68.0 - 80.0
		Min - Max	55 - 90	49 - 98	56 - 88	61 - 101	49 - 101	49 - 101
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.9 (8.16)	-2.6 (8.33)	-0.2 (8.60)	-1.0 (8.55)	-1.3 (8.51)	-1.4 (8.41)
		Median	-2.0	-3.0	0	-1.0	-1.0	-1.0
		Q1 - Q3	-7.0 - 4.0	-7.0 - 2.0	-4.0 - 6.0	-7.0 - 6.0	-6.0 - 5.0	-6.0 - 4.0
		Min - Max	-24 - 19	-22 - 18	-33 - 14	-16 - 20	-33 - 20	-33 - 20
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	75.8 (9.63)	73.6 (8.26)	73.1 (6.99)	73.6 (8.46)	73.4 (7.89)	74.0 (8.40)
		Median	76.0	74.0	73.0	72.0	73.0	73.5
		Q1 - Q3	69.0 - 83.0	68.0 - 78.0	69.0 - 78.0	68.0 - 79.0	68.0 - 78.0	68.0 - 80.0
		Min - Max	56 - 106	51 - 95	56 - 90	54 - 100	51 - 100	51 - 106

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Pulse Rate (beats/min)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	0.3 (10.40)	-2.1 (7.96)	-1.6 (8.13)	-0.7 (7.79)	-1.5 (7.95)	-1.0 (8.63)
		Median	-0.5	-2.0	0	-1.5	-1.0	-1.0
		Q1 - Q3	-7.0 - 5.0	-8.0 - 4.0	-8.0 - 5.0	-7.0 - 3.0	-8.0 - 4.0	-8.0 - 4.0
		Min - Max	-23 - 29	-19 - 17	-21 - 16	-15 - 17	-21 - 17	-23 - 29
	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	75.3 (10.29)	72.8 (8.26)	72.9 (8.21)	73.3 (9.19)	73.0 (8.51)	73.6 (9.02)
		Median	74.5	73.0	72.5	73.0	73.0	73.0
		Q1 - Q3	69.0 - 82.0	67.5 - 78.0	67.0 - 77.0	66.0 - 79.0	67.0 - 78.0	67.0 - 80.0
		Min - Max	54 - 99	55 - 96	55 - 92	57 - 98	55 - 98	54 - 99
	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	-0.2 (10.12)	-2.9 (9.28)	-1.7 (9.09)	-0.7 (8.09)	-1.8 (8.85)	-1.4 (9.19)
		Median	-2.0	-3.0	0	-2.0	-1.0	-1.0
		Q1 - Q3	-7.0 - 6.0	-10.0 - 4.0	-8.0 - 4.0	-6.0 - 5.0	-8.0 - 4.0	-7.0 - 4.0
		Min - Max	-22 - 35	-25 - 24	-26 - 21	-17 - 18	-26 - 24	-26 - 35

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Pulse Rate (beats/min)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	73.9 (9.13)	74.3 (8.72)	73.5 (7.31)	72.9 (8.40)	73.6 (8.15)	73.7 (8.39)
		Median	73.0	72.5	73.0	73.0	73.0	73.0
		Q1 - Q3	67.0 - 81.0	68.0 - 80.5	68.0 - 78.0	66.0 - 80.0	68.0 - 80.0	67.0 - 80.0
		Min - Max	53 - 93	53 - 96	59 - 88	56 - 93	53 - 96	53 - 96
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.6 (9.70)	-1.4 (9.12)	-1.0 (7.99)	-1.1 (7.43)	-1.2 (8.19)	-1.3 (8.57)
		Median	-2.0	-1.0	-1.0	-1.0	-1.0	-1.0
		Q1 - Q3	-8.0 - 4.0	-7.0 - 4.0	-6.0 - 4.0	-7.0 - 4.0	-7.0 - 4.0	-7.0 - 4.0
		Min - Max	-18 - 30	-25 - 25	-20 - 16	-18 - 14	-25 - 25	-25 - 30
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	73.4 (8.50)	74.5 (9.09)	73.5 (8.89)	71.5 (8.65)	73.2 (8.92)	73.3 (8.81)
		Median	72.0	75.0	72.0	70.0	72.0	72.0
		Q1 - Q3	67.0 - 82.0	68.0 - 80.0	66.0 - 80.0	65.0 - 78.0	67.0 - 78.5	67.0 - 79.0
		Min - Max	54 - 89	50 - 98	59 - 92	54 - 93	50 - 98	50 - 98

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Pulse Rate (beats/min)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-2.2 (9.12)	-1.0 (9.57)	-1.1 (9.13)	-2.5 (7.80)	-1.5 (8.86)	-1.7 (8.92)
		Median	-2.0	-1.0	-1.0	-3.0	-2.0	-2.0
		Q1 - Q3	-9.0 - 5.0	-6.0 - 5.0	-7.0 - 5.0	-8.0 - 3.0	-7.0 - 4.0	-8.0 - 4.0
		Min - Max	-26 - 21	-21 - 21	-20 - 22	-21 - 14	-21 - 22	-26 - 22
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	73.5 (8.03)	75.1 (8.12)	72.8 (7.50)	72.0 (7.53)	73.3 (7.81)	73.4 (7.85)
		Median	73.0	74.0	72.0	72.0	73.0	73.0
		Q1 - Q3	69.0 - 78.5	70.5 - 79.5	66.0 - 78.0	67.0 - 76.0	68.0 - 78.0	68.0 - 78.0
		Min - Max	58 - 97	52 - 94	57 - 91	58 - 95	52 - 95	52 - 97
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-1.9 (9.66)	-0.3 (9.02)	-1.8 (8.51)	-2.0 (7.64)	-1.4 (8.42)	-1.5 (8.72)
		Median	-2.0	1.0	-3.0	-2.0	-2.0	-2.0
		Q1 - Q3	-8.0 - 4.0	-8.0 - 5.0	-8.0 - 4.0	-7.0 - 3.0	-7.0 - 4.0	-8.0 - 4.0
		Min - Max	-23 - 19	-25 - 16	-22 - 22	-22 - 15	-25 - 22	-25 - 22

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Systolic Blood Pressure (mmHg)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	118.0 (12.83)	119.1 (13.19)	119.2 (13.30)	118.1 (11.49)	118.8 (12.64)	118.6 (12.67)
		Median	117.0	116.0	121.0	118.5	118.0	118.0
		Q1 - Q3	108.0 - 126.0	110.0 - 127.0	110.0 - 128.0	108.0 - 127.5	109.0 - 128.0	109.0 - 128.0
		Min - Max	93 - 157	94 - 159	87 - 145	96 - 147	87 - 159	87 - 159
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	115.3 (12.88)	117.3 (12.34)	116.6 (13.88)	118.0 (12.30)	117.3 (12.81)	116.8 (12.83)
		Median	116.0	115.5	116.0	117.0	116.0	116.0
		Q1 - Q3	105.0 - 124.0	109.0 - 124.0	108.0 - 126.0	109.0 - 126.0	109.0 - 126.0	108.0 - 125.0
		Min - Max	91 - 143	90 - 151	86 - 150	91 - 153	86 - 153	86 - 153
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-2.7 (10.79)	-1.8 (8.85)	-2.5 (11.30)	-0.1 (10.12)	-1.5 (10.13)	-1.8 (10.29)
		Median	-2.0	-2.0	-3.0	0	-2.0	-2.0
		Q1 - Q3	-9.0 - 4.0	-9.0 - 4.0	-12.0 - 3.0	-6.0 - 6.5	-9.0 - 5.0	-9.0 - 5.0
		Min - Max	-33 - 27	-26 - 22	-21 - 38	-23 - 21	-26 - 38	-33 - 38

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Systolic Blood Pressure (mmHg)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	116.9 (12.93)	115.7 (13.03)	115.4 (12.80)	117.1 (11.86)	116.1 (12.54)	116.3 (12.62)
		Median	116.0	115.0	115.0	118.0	116.0	116.0
		Q1 - Q3	107.0 - 124.0	105.0 - 124.0	104.0 - 125.0	110.0 - 123.0	106.0 - 124.0	107.0 - 124.0
		Min - Max	96 - 170	92 - 148	90 - 139	90 - 140	90 - 148	90 - 170
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-1.4 (11.75)	-3.5 (10.56)	-3.7 (9.99)	-1.1 (11.73)	-2.8 (10.79)	-2.4 (11.03)
		Median	-2.0	-3.0	-4.0	-2.0	-3.0	-3.0
		Q1 - Q3	-8.0 - 4.0	-10.0 - 4.0	-10.0 - 2.0	-9.0 - 5.0	-10.0 - 4.0	-9.0 - 4.0
		Min - Max	-35 - 31	-36 - 23	-31 - 25	-32 - 32	-36 - 32	-36 - 32
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	117.7 (11.09)	115.3 (12.94)	116.3 (11.89)	116.8 (11.71)	116.1 (12.16)	116.5 (11.90)
		Median	117.0	116.0	115.0	116.0	116.0	116.0
		Q1 - Q3	110.0 - 125.0	106.0 - 125.0	108.0 - 127.0	109.0 - 124.0	108.0 - 125.0	109.0 - 125.0
		Min - Max	90 - 145	89 - 142	91 - 139	93 - 148	89 - 148	89 - 148

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Systolic Blood Pressure (mmHg)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.3 (12.60)	-3.8 (10.34)	-2.8 (9.64)	-1.8 (10.54)	-2.8 (10.16)	-2.2 (10.85)
		Median	0.5	-4.0	-4.0	-2.0	-3.0	-3.0
		Q1 - Q3	-8.0 - 8.0	-11.0 - 4.0	-9.0 - 3.0	-8.0 - 3.5	-9.5 - 4.0	-9.0 - 5.0
		Min - Max	-35 - 25	-39 - 25	-23 - 29	-29 - 30	-39 - 30	-39 - 30
	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	115.9 (12.20)	115.4 (12.69)	116.4 (13.14)	116.4 (11.98)	116.1 (12.57)	116.0 (12.45)
		Median	117.0	115.5	115.0	119.0	116.0	116.0
		Q1 - Q3	107.0 - 123.0	107.0 - 124.0	107.0 - 129.0	106.0 - 125.0	107.0 - 126.0	107.0 - 125.0
		Min - Max	89 - 149	88 - 145	87 - 139	86 - 139	86 - 145	86 - 149
	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	-2.0 (11.49)	-3.6 (10.08)	-2.7 (10.16)	-2.1 (11.75)	-2.8 (10.63)	-2.6 (10.84)
		Median	-2.0	-4.0	-4.0	-1.0	-3.0	-3.0
		Q1 - Q3	-10.0 - 6.0	-10.5 - 3.0	-10.0 - 3.0	-11.0 - 5.0	-10.0 - 4.0	-10.0 - 4.0
		Min - Max	-29 - 23	-34 - 22	-22 - 20	-28 - 23	-34 - 23	-34 - 23

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Systolic Blood Pressure (mmHg)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	115.6 (10.65)	114.9 (12.34)	115.4 (13.29)	116.8 (11.56)	115.7 (12.39)	115.7 (11.96)
		Median	116.0	115.0	116.0	117.0	116.0	116.0
		Q1 - Q3	109.0 - 122.0	107.0 - 123.5	107.0 - 125.0	108.0 - 123.0	107.0 - 124.0	107.0 - 123.0
		Min - Max	86 - 148	89 - 154	87 - 138	92 - 147	87 - 154	86 - 154
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-2.6 (12.03)	-4.2 (8.70)	-3.7 (10.54)	-1.8 (9.97)	-3.2 (9.75)	-3.1 (10.35)
		Median	-2.0	-4.5	-3.0	-2.0	-3.5	-3.0
		Q1 - Q3	-9.0 - 3.0	-10.5 - 3.5	-12.0 - 4.0	-7.0 - 2.0	-10.0 - 3.0	-10.0 - 3.0
		Min - Max	-34 - 29	-23 - 12	-27 - 27	-27 - 25	-27 - 27	-34 - 29
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	115.3 (11.86)	115.6 (12.88)	116.1 (11.80)	117.6 (12.29)	116.4 (12.30)	116.1 (12.18)
		Median	115.0	113.0	113.5	116.0	114.5	115.0
		Q1 - Q3	108.0 - 120.5	105.0 - 126.0	109.0 - 126.0	108.0 - 124.0	107.5 - 126.0	108.0 - 125.5
		Min - Max	87 - 145	92 - 142	93 - 139	95 - 146	92 - 146	87 - 146

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Systolic Blood Pressure (mmHg)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-2.8 (11.44)	-3.3 (10.59)	-3.1 (9.41)	-0.9 (9.95)	-2.4 (10.01)	-2.5 (10.35)
		Median	-1.5	-1.0	-3.0	0	-2.0	-2.0
		Q1 - Q3	-10.0 - 5.0	-11.0 - 4.0	-10.0 - 3.0	-8.0 - 5.0	-10.0 - 4.0	-10.0 - 5.0
		Min - Max	-27 - 31	-34 - 16	-26 - 20	-33 - 22	-34 - 22	-34 - 31
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	115.7 (11.41)	114.7 (12.47)	117.2 (12.47)	117.4 (11.86)	116.4 (12.28)	116.2 (12.05)
		Median	115.0	112.5	118.0	117.0	116.0	116.0
		Q1 - Q3	108.5 - 123.5	105.0 - 124.0	105.0 - 129.0	107.0 - 124.0	106.0 - 125.0	107.0 - 124.0
		Min - Max	86 - 139	85 - 140	97 - 138	95 - 150	85 - 150	85 - 150
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-2.2 (13.28)	-4.3 (11.31)	-1.8 (11.03)	-0.9 (9.30)	-2.4 (10.65)	-2.3 (11.33)
		Median	0	-4.0	-0.5	-1.0	-2.0	-1.0
		Q1 - Q3	-11.0 - 5.0	-12.0 - 3.0	-10.0 - 5.0	-8.0 - 5.0	-10.0 - 5.0	-10.0 - 5.0
		Min - Max	-55 - 27	-35 - 23	-23 - 27	-24 - 22	-35 - 27	-55 - 27

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Diastolic Blood Pressure (mmHg)	Baseline	Observed Value						
		n	69	70	69	68	207	276
		Mean (SD)	77.1 (8.94)	75.8 (8.45)	77.1 (9.12)	78.2 (7.63)	77.0 (8.44)	77.0 (8.55)
		Median	77.0	75.5	77.0	77.5	77.0	77.0
		Q1 - Q3	71.0 - 84.0	70.0 - 81.0	72.0 - 84.0	71.5 - 83.0	71.0 - 83.0	71.0 - 83.0
		Min - Max	58 - 101	55 - 100	60 - 97	67 - 100	55 - 100	55 - 101
	D15	Observed Value						
		n	69	70	68	68	206	275
		Mean (SD)	75.6 (9.09)	75.2 (8.31)	74.3 (9.94)	77.4 (9.26)	75.6 (9.23)	75.6 (9.18)
		Median	76.0	75.0	74.0	78.0	75.0	75.0
		Q1 - Q3	67.0 - 81.0	70.0 - 80.0	68.0 - 82.0	71.5 - 83.5	69.0 - 83.0	69.0 - 82.0
		Min - Max	60 - 96	56 - 96	50 - 96	57 - 103	50 - 103	50 - 103
	D15	Change from Baseline						
		n	69	70	68	68	206	275
		Mean (SD)	-1.5 (8.20)	-0.6 (6.42)	-2.7 (7.20)	-0.9 (7.26)	-1.4 (6.99)	-1.4 (7.30)
		Median	-1.0	-1.0	-3.0	-1.0	-1.5	-1.0
		Q1 - Q3	-6.0 - 4.0	-4.0 - 2.0	-8.0 - 2.5	-6.0 - 3.0	-6.0 - 3.0	-6.0 - 3.0
		Min - Max	-33 - 16	-16 - 17	-18 - 14	-15 - 18	-18 - 18	-33 - 18

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Diastolic Blood Pressure (mmHg)	D29	Observed Value						
		n	67	69	67	67	203	270
		Mean (SD)	75.4 (7.63)	74.9 (8.16)	74.5 (8.94)	76.3 (8.45)	75.2 (8.51)	75.3 (8.29)
		Median	76.0	75.0	74.0	75.0	75.0	75.0
		Q1 - Q3	70.0 - 80.0	69.0 - 81.0	68.0 - 80.0	70.0 - 82.0	69.0 - 80.0	69.0 - 80.0
		Min - Max	60 - 100	60 - 94	50 - 100	60 - 102	50 - 102	50 - 102
	D29	Change from Baseline						
		n	67	69	67	67	203	270
		Mean (SD)	-2.1 (7.50)	-0.9 (6.53)	-2.7 (7.49)	-1.9 (7.03)	-1.8 (7.03)	-1.9 (7.13)
		Median	0	-2.0	-2.0	-1.0	-2.0	-2.0
		Q1 - Q3	-9.0 - 3.0	-5.0 - 2.0	-9.0 - 3.0	-7.0 - 3.0	-7.0 - 3.0	-7.0 - 3.0
		Min - Max	-18 - 14	-17 - 17	-23 - 14	-18 - 12	-23 - 17	-23 - 17
	D43	Observed Value						
		n	66	69	67	64	200	266
		Mean (SD)	76.8 (6.74)	73.4 (8.01)	73.6 (9.13)	76.1 (8.71)	74.4 (8.67)	75.0 (8.28)
		Median	76.0	72.0	74.0	76.0	75.0	75.0
		Q1 - Q3	72.0 - 82.0	67.0 - 80.0	66.0 - 81.0	70.0 - 81.5	67.0 - 81.0	68.0 - 81.0
		Min - Max	61 - 97	55 - 88	57 - 94	56 - 98	55 - 98	55 - 98

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Diastolic Blood Pressure (mmHg)	D43	Change from Baseline						
		n	66	69	67	64	200	266
		Mean (SD)	-0.5 (8.61)	-2.4 (6.49)	-3.6 (7.93)	-2.1 (7.67)	-2.7 (7.37)	-2.2 (7.74)
		Median	0	-2.0	-3.0	-3.0	-3.0	-2.0
		Q1 - Q3	-5.0 - 5.0	-6.0 - 1.0	-10.0 - 2.0	-8.0 - 3.0	-7.0 - 2.0	-7.0 - 3.0
		Min - Max	-23 - 21	-23 - 11	-22 - 15	-19 - 18	-23 - 18	-23 - 21
	D57	Observed Value						
		n	66	68	66	63	197	263
		Mean (SD)	75.4 (7.31)	74.1 (7.91)	74.2 (9.21)	75.7 (8.05)	74.6 (8.40)	74.8 (8.13)
		Median	75.0	74.0	74.5	76.0	74.0	75.0
		Q1 - Q3	70.0 - 81.0	68.0 - 79.5	67.0 - 80.0	70.0 - 82.0	68.0 - 81.0	69.0 - 81.0
		Min - Max	61 - 94	61 - 89	50 - 93	55 - 91	50 - 93	50 - 94
	D57	Change from Baseline						
		n	66	68	66	63	197	263
		Mean (SD)	-1.9 (8.32)	-1.5 (7.64)	-3.2 (6.91)	-2.5 (8.05)	-2.4 (7.53)	-2.3 (7.72)
		Median	-1.5	-1.0	-3.0	-3.0	-2.0	-2.0
		Q1 - Q3	-7.0 - 3.0	-6.0 - 3.0	-7.0 - 1.0	-8.0 - 3.0	-7.0 - 2.0	-7.0 - 2.0
		Min - Max	-25 - 17	-25 - 16	-34 - 21	-23 - 16	-34 - 21	-34 - 21

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Diastolic Blood Pressure (mmHg)	D71	Observed Value						
		n	65	68	65	63	196	261
		Mean (SD)	75.5 (8.12)	74.2 (8.30)	74.2 (9.61)	75.6 (8.34)	74.7 (8.75)	74.9 (8.59)
		Median	75.0	73.0	75.0	76.0	75.0	75.0
		Q1 - Q3	69.0 - 82.0	68.5 - 79.0	68.0 - 82.0	68.0 - 82.0	68.0 - 81.0	69.0 - 81.0
		Min - Max	59 - 91	60 - 93	54 - 97	57 - 92	54 - 97	54 - 97
	D71	Change from Baseline						
		n	65	68	65	63	196	261
		Mean (SD)	-1.9 (8.62)	-1.4 (6.62)	-3.2 (7.46)	-2.6 (8.42)	-2.4 (7.51)	-2.3 (7.79)
		Median	-1.0	-2.0	-3.0	-4.0	-3.0	-2.0
		Q1 - Q3	-7.0 - 3.0	-5.0 - 2.0	-8.0 - 0	-9.0 - 2.0	-8.0 - 1.0	-7.0 - 2.0
		Min - Max	-22 - 21	-16 - 18	-26 - 19	-25 - 20	-26 - 20	-26 - 21
	D85	Observed Value						
		n	64	67	66	63	196	260
		Mean (SD)	74.5 (7.94)	73.8 (8.53)	73.8 (7.43)	75.4 (8.65)	74.3 (8.21)	74.4 (8.13)
		Median	74.0	75.0	74.5	74.0	74.5	74.5
		Q1 - Q3	69.0 - 80.0	69.0 - 79.0	69.0 - 79.0	68.0 - 81.0	69.0 - 79.0	69.0 - 80.0
		Min - Max	60 - 95	55 - 98	58 - 88	60 - 97	55 - 98	55 - 98

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.1
Summary of Vital Signs
SS

Test	Visit	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Diastolic Blood Pressure (mmHg)	D85	Change from Baseline						
		n	64	67	66	63	196	260
		Mean (SD)	-2.8 (8.26)	-1.7 (6.25)	-3.5 (6.98)	-2.8 (7.45)	-2.7 (6.91)	-2.7 (7.25)
		Median	-2.0	-2.0	-3.5	-3.0	-3.0	-2.5
		Q1 - Q3	-7.5 - 1.5	-5.0 - 2.0	-8.0 - 1.0	-8.0 - 2.0	-7.5 - 2.0	-7.5 - 2.0
		Min - Max	-22 - 16	-20 - 14	-23 - 18	-20 - 19	-23 - 19	-23 - 19
	Safety Follow-up	Observed Value						
		n	64	68	66	63	197	261
		Mean (SD)	74.2 (7.29)	74.8 (8.11)	75.0 (8.01)	75.2 (8.83)	75.0 (8.27)	74.8 (8.04)
		Median	74.5	74.0	75.5	75.0	75.0	75.0
		Q1 - Q3	68.5 - 80.5	69.0 - 80.5	69.0 - 80.0	68.0 - 80.0	69.0 - 80.0	69.0 - 80.0
		Min - Max	60 - 87	56 - 94	54 - 90	56 - 99	54 - 99	54 - 99
	Safety Follow-up	Change from Baseline						
		n	64	68	66	63	197	261
		Mean (SD)	-3.2 (9.44)	-0.9 (7.05)	-2.2 (9.22)	-2.9 (7.76)	-2.0 (8.06)	-2.3 (8.42)
		Median	-3.5	-1.0	-3.0	-3.0	-2.0	-2.0
		Q1 - Q3	-9.0 - 2.5	-5.0 - 3.0	-8.0 - 3.0	-8.0 - 3.0	-7.0 - 3.0	-7.0 - 3.0
		Min - Max	-29 - 20	-19 - 16	-24 - 19	-25 - 14	-25 - 19	-29 - 20

Data Source: Listing 16.2.8.3.1
Baseline values were defined as the last available measurement value prior to the first study drug administration.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	D15	Placebo (N=69)	Normal	67 (97.1)	0	0	67 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	68 (97.1)	2 (2.9)	0	70 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	68 (97.1)	2 (2.9)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (91.2)	2 (2.9)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	4 (5.9)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	1 (1.5)	0	64 (94.1)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.9)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	D15	Combined GS1-144 (N=207)	Normal	193 (93.7)	5 (2.4)	0	198 (96.1)
			Abnormal NCS	4 (1.9)	4 (1.9)	0	8 (3.9)
			Abnormal CS	0	0	0	0
			Total	197 (95.6)	9 (4.4)	0	206 (100)
	D29	Placebo (N=69)	Normal	64 (95.5)	2 (3.0)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	2 (2.9)	0	69 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (89.6)	3 (4.5)	0	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	D29	GS1-144 30 mg BID (N=68)	Normal	62 (92.5)	3 (4.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	3 (4.5)	0	67 (100)
		Combined GS1-144 (N=207)	Normal	189 (93.1)	8 (3.9)	0	197 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	194 (95.6)	9 (4.4)	0	203 (100)
	D43	Placebo (N=69)	Normal	62 (95.4)	2 (3.1)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	2 (2.9)	0	68 (98.6)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	D43	GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	4 (6.0)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (93.8)	3 (4.7)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	61 (95.3)	3 (4.7)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	187 (93.5)	9 (4.5)	0	196 (98.0)
			Abnormal NCS	4 (2.0)	0	0	4 (2.0)
			Abnormal CS	0	0	0	0
			Total	191 (95.5)	9 (4.5)	0	200 (100)
	D57	Placebo (N=69)	Normal	63 (96.9)	2 (3.1)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Ear Temperature (C)	D57	GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	2 (2.9)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	3 (4.5)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	3 (4.8)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	186 (94.4)	8 (4.1)	0	194 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	9 (4.6)	0	197 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	D71	Placebo (N=69)	Normal	63 (96.9)	2 (3.1)	0	65 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	2 (2.9)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (92.3)	4 (6.2)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	3 (4.8)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	D71	Combined GS1-144 (N=207)	Normal	186 (94.9)	9 (4.6)	0	195 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	187 (95.4)	9 (4.6)	0	196 (100)
	D85	Placebo (N=69)	Normal	62 (96.9)	2 (3.1)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	2 (3.0)	0	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	4 (6.1)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	D85	GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	3 (4.8)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	185 (94.4)	9 (4.6)	0	194 (99.0)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	0	0	0	0
			Total	187 (95.4)	9 (4.6)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	2 (3.1)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	2 (2.9)	0	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	Safety Follow-up	GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	4 (6.1)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	3 (4.8)	0	63 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	3 (4.8)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	187 (94.9)	9 (4.6)	0	196 (99.5)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	0	0	0	0
			Total	188 (95.4)	9 (4.6)	0	197 (100)
Pulse Rate (beats/min)	D15	Placebo (N=69)	Normal	62 (89.9)	2 (2.9)	0	64 (92.8)
			Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.8)
			Abnormal CS	1 (1.4)	0	0	1 (1.4)
			Total	65 (94.2)	4 (5.8)	0	69 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Pulse Rate (beats/min)	D15	GS1-144 30 mg QD (N=70)	Normal	67 (95.7)	0	0	67 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	68 (97.1)	2 (2.9)	0	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (95.6)	0	0	65 (95.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	0	0	0	0
			Total	67 (98.5)	1 (1.5)	0	68 (100)
		Combined GS1-144 (N=207)	Normal	198 (96.1)	1 (0.5)	0	199 (96.6)
			Abnormal NCS	4 (1.9)	3 (1.5)	0	7 (3.4)
			Abnormal CS	0	0	0	0
			Total	202 (98.1)	4 (1.9)	0	206 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Pulse Rate (beats/min)	D29	Placebo (N=69)	Normal	63 (94.0)	3 (4.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	4 (6.0)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (95.7)	0	0	66 (95.7)
			Abnormal NCS	1 (1.4)	2 (2.9)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (95.5)	1 (1.5)	0	65 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Pulse Rate (beats/min)	D29	Combined GS1-144 (N=207)	Normal	195 (96.1)	2 (1.0)	0	197 (97.0)
			Abnormal NCS	4 (2.0)	2 (1.0)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	199 (98.0)	4 (2.0)	0	203 (100)
	D43	Placebo (N=69)	Normal	60 (90.9)	3 (4.5)	0	63 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	1 (1.4)	0	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (98.5)	1 (1.5)	0	67 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Pulse Rate (beats/min)	D43	GS1-144 30 mg BID (N=68)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		Combined GS1-144 (N=207)	Normal	194 (97.0)	3 (1.5)	0	197 (98.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	196 (98.0)	4 (2.0)	0	200 (100)
	D57	Placebo (N=69)	Normal	61 (92.4)	2 (3.0)	0	63 (95.5)
			Abnormal NCS	0	2 (3.0)	0	2 (3.0)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	62 (93.9)	4 (6.1)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (95.6)	1 (1.5)	0	66 (97.1)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Pulse Rate (beats/min)	D57	GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	1 (1.5)	0	63 (95.5)
			Abnormal NCS	3 (4.5)	0	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	1 (1.6)	0	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	188 (95.4)	3 (1.5)	0	191 (97.0)
			Abnormal NCS	5 (2.5)	1 (0.5)	0	6 (3.0)
			Abnormal CS	0	0	0	0
			Total	193 (98.0)	4 (2.0)	0	197 (100)
	D71	Placebo (N=69)	Normal	61 (93.8)	2 (3.1)	0	63 (96.9)
			Abnormal NCS	0	2 (3.1)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	4 (6.2)	0	65 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Pulse Rate (beats/min)	D71	GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	0	2 (2.9)	0	2 (2.9)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (96.9)	1 (1.5)	0	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	64 (98.5)	1 (1.5)	0	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	0	0	60 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	189 (96.4)	1 (0.5)	0	190 (96.9)
			Abnormal NCS	3 (1.5)	3 (1.5)	0	6 (3.1)
			Abnormal CS	0	0	0	0
			Total	192 (98.0)	4 (2.0)	0	196 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Pulse Rate (beats/min)	D85	Placebo (N=69)	Normal	59 (92.2)	3 (4.7)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (97.0)	1 (1.5)	0	66 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (97.0)	2 (3.0)	0	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	2 (3.0)	0	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	0	0	59 (93.7)
			Abnormal NCS	3 (4.8)	1 (1.6)	0	4 (6.3)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Pulse Rate (beats/min)	D85	Combined GS1-144 (N=207)	Normal	187 (95.4)	2 (1.0)	0	189 (96.4)
			Abnormal NCS	5 (2.6)	2 (1.0)	0	7 (3.6)
			Abnormal CS	0	0	0	0
			Total	192 (98.0)	4 (2.0)	0	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	58 (90.6)	4 (6.3)	0	62 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	60 (93.8)	4 (6.3)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	66 (97.1)	1 (1.5)	0	67 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	66 (97.1)	2 (2.9)	0	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	64 (97.0)	1 (1.5)	0	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	65 (98.5)	1 (1.5)	0	66 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Pulse Rate (beats/min)	Safety Follow-up	GS1-144 30 mg BID (N=68)	Normal	62 (98.4)	0	0	62 (98.4)
			Abnormal NCS	0	1 (1.6)	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	1 (1.6)	0	63 (100)
		Combined GS1-144 (N=207)	Normal	192 (97.5)	2 (1.0)	0	194 (98.5)
			Abnormal NCS	1 (0.5)	2 (1.0)	0	3 (1.5)
			Abnormal CS	0	0	0	0
			Total	193 (98.0)	4 (2.0)	0	197 (100)
Systolic Blood Pressure (mmHg)	D15	Placebo (N=69)	Normal	63 (91.3)	2 (2.9)	0	65 (94.2)
			Abnormal NCS	4 (5.8)	0	0	4 (5.8)
			Abnormal CS	0	0	0	0
			Total	67 (97.1)	2 (2.9)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (91.4)	3 (4.3)	0	67 (95.7)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.4)	0	2 (2.9)	3 (4.3)
			Total	65 (92.9)	3 (4.3)	2 (2.9)	70 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Systolic Blood Pressure (mmHg)	D15	GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	3 (4.4)	1 (1.5)	64 (94.1)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	64 (94.1)	3 (4.4)	1 (1.5)	68 (100)
		GS1-144 30 mg BID (N=68)	Normal	66 (97.1)	0	0	66 (97.1)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	67 (98.5)	0	1 (1.5)	68 (100)
		Combined GS1-144 (N=207)	Normal	190 (92.2)	6 (2.9)	1 (0.5)	197 (95.6)
			Abnormal NCS	4 (1.9)	0	0	4 (1.9)
			Abnormal CS	2 (1.0)	0	3 (1.5)	5 (2.4)
			Total	196 (95.1)	6 (2.9)	4 (1.9)	206 (100)
	D29	Placebo (N=69)	Normal	63 (94.0)	2 (3.0)	0	65 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	65 (97.0)	2 (3.0)	0	67 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Systolic Blood Pressure (mmHg)	D29	GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	2 (2.9)	1 (1.4)	66 (95.7)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	1 (1.4)	0	1 (1.4)	2 (2.9)
			Total	64 (92.8)	3 (4.3)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	3 (4.5)	1 (1.5)	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	3 (4.5)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	65 (97.0)	0	0	65 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	66 (98.5)	0	1 (1.5)	67 (100)
		Combined GS1-144 (N=207)	Normal	191 (94.1)	5 (2.5)	2 (1.0)	198 (97.5)
			Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
			Abnormal CS	1 (0.5)	0	2 (1.0)	3 (1.5)
			Total	193 (95.1)	6 (3.0)	4 (2.0)	203 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Systolic Blood Pressure (mmHg)	D43	Placebo (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (89.9)	2 (2.9)	2 (2.9)	66 (95.7)
			Abnormal NCS	2 (2.9)	1 (1.4)	0	3 (4.3)
			Abnormal CS	0	0	0	0
			Total	64 (92.8)	3 (4.3)	2 (2.9)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	63 (94.0)	3 (4.5)	1 (1.5)	67 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	63 (94.0)	3 (4.5)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	62 (96.9)	0	0	62 (96.9)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.6)	0	1 (1.6)	2 (3.1)
			Total	63 (98.4)	0	1 (1.6)	64 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Systolic Blood Pressure (mmHg)	D43	Combined GS1-144 (N=207)	Normal	187 (93.5)	5 (2.5)	3 (1.5)	195 (97.5)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	190 (95.0)	6 (3.0)	4 (2.0)	200 (100)
	D57	Placebo (N=69)	Normal	63 (95.5)	1 (1.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	0	0
			Total	64 (97.0)	2 (3.0)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	2 (2.9)	1 (1.5)	65 (95.6)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (2.9)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (92.6)	3 (4.4)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	61 (92.4)	3 (4.5)	1 (1.5)	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Systolic Blood Pressure (mmHg)	D57	GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	1 (1.6)	62 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	62 (98.4)	0	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	184 (93.4)	5 (2.5)	3 (1.5)	192 (97.5)
			Abnormal NCS	3 (1.5)	1 (0.5)	0	4 (2.0)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	187 (94.9)	6 (3.0)	4 (2.0)	197 (100)
	D71	Placebo (N=69)	Normal	61 (93.8)	2 (3.1)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	63 (96.9)	2 (3.1)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	3 (4.4)	1 (1.5)	66 (97.1)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (92.6)	3 (4.4)	2 (2.9)	68 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Systolic Blood Pressure (mmHg)	D71	GS1-144 60 mg QD (N=69)	Normal	60 (92.3)	3 (4.6)	1 (1.5)	64 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	61 (93.8)	3 (4.6)	1 (1.5)	65 (100)
		GS1-144 30 mg BID (N=68)	Normal	61 (96.8)	0	0	61 (96.8)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.6)	0	1 (1.6)	2 (3.2)
			Total	62 (98.4)	0	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	183 (93.4)	6 (3.1)	2 (1.0)	191 (97.4)
			Abnormal NCS	2 (1.0)	0	0	2 (1.0)
			Abnormal CS	1 (0.5)	0	2 (1.0)	3 (1.5)
			Total	186 (94.9)	6 (3.1)	4 (2.0)	196 (100)
	D85	Placebo (N=69)	Normal	60 (93.8)	1 (1.6)	0	61 (95.3)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	0	0	0	0
			Total	62 (96.9)	2 (3.1)	0	64 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Systolic Blood Pressure (mmHg)	D85	GS1-144 30 mg QD (N=70)	Normal	61 (91.0)	2 (3.0)	1 (1.5)	64 (95.5)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	62 (92.5)	3 (4.5)	2 (3.0)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	59 (93.7)	0	0	59 (93.7)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	2 (3.2)	0	1 (1.6)	3 (4.8)
			Total	62 (98.4)	0	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	182 (92.9)	5 (2.6)	2 (1.0)	189 (96.4)
			Abnormal NCS	2 (1.0)	1 (0.5)	0	3 (1.5)
			Abnormal CS	2 (1.0)	0	2 (1.0)	4 (2.0)
			Total	186 (94.9)	6 (3.1)	4 (2.0)	196 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Systolic Blood Pressure (mmHg)	Safety Follow-up	Placebo (N=69)	Normal	62 (96.9)	1 (1.6)	0	63 (98.4)
			Abnormal NCS	1 (1.6)	0	0	1 (1.6)
			Abnormal CS	0	0	0	0
			Total	63 (98.4)	1 (1.6)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	3 (4.4)	2 (2.9)	66 (97.1)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (92.6)	3 (4.4)	2 (2.9)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	62 (93.9)	3 (4.5)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	60 (95.2)	0	1 (1.6)	61 (96.8)
			Abnormal NCS	0	0	0	0
			Abnormal CS	2 (3.2)	0	0	2 (3.2)
			Total	62 (98.4)	0	1 (1.6)	63 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Systolic Blood Pressure (mmHg)	Safety Follow-up	Combined GS1-144 (N=207)	Normal	183 (92.9)	6 (3.0)	4 (2.0)	193 (98.0)
			Abnormal NCS	1 (0.5)	0	0	1 (0.5)
			Abnormal CS	3 (1.5)	0	0	3 (1.5)
			Total	187 (94.9)	6 (3.0)	4 (2.0)	197 (100)
Diastolic Blood Pressure (mmHg)	D15	Placebo (N=69)	Normal	61 (88.4)	3 (4.3)	0	64 (92.8)
			Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.2)
			Abnormal CS	0	0	0	0
			Total	64 (92.8)	5 (7.2)	0	69 (100)
		GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	1 (1.4)	1 (1.4)	67 (95.7)
			Abnormal NCS	1 (1.4)	0	0	1 (1.4)
			Abnormal CS	0	0	2 (2.9)	2 (2.9)
			Total	66 (94.3)	1 (1.4)	3 (4.3)	70 (100)
		GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	1 (1.5)	1 (1.5)	62 (91.2)
			Abnormal NCS	5 (7.4)	1 (1.5)	0	6 (8.8)
			Abnormal CS	0	0	0	0
			Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Diastolic Blood Pressure (mmHg)	D15	GS1-144 30 mg BID (N=68)	Normal	62 (91.2)	1 (1.5)	0	63 (92.6)
			Abnormal NCS	2 (2.9)	1 (1.5)	0	3 (4.4)
			Abnormal CS	1 (1.5)	0	1 (1.5)	2 (2.9)
			Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)
		Combined GS1-144 (N=207)	Normal	187 (90.8)	3 (1.5)	2 (1.0)	192 (93.2)
			Abnormal NCS	8 (3.9)	2 (1.0)	0	10 (4.9)
			Abnormal CS	1 (0.5)	0	3 (1.5)	4 (1.9)
			Total	196 (95.1)	5 (2.4)	5 (2.4)	206 (100)
	D29	Placebo (N=69)	Normal	61 (91.0)	5 (7.5)	0	66 (98.5)
			Abnormal NCS	0	0	0	0
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	62 (92.5)	5 (7.5)	0	67 (100)
		GS1-144 30 mg QD (N=70)	Normal	63 (91.3)	1 (1.4)	2 (2.9)	66 (95.7)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	1 (1.4)	1 (1.4)
			Total	65 (94.2)	1 (1.4)	3 (4.3)	69 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Diastolic Blood Pressure (mmHg)	D29	GS1-144 60 mg QD (N=69)	Normal	61 (91.0)	1 (1.5)	1 (1.5)	63 (94.0)
			Abnormal NCS	3 (4.5)	1 (1.5)	0	4 (6.0)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	63 (94.0)	1 (1.5)	0	64 (95.5)
			Abnormal NCS	1 (1.5)	1 (1.5)	0	2 (3.0)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		Combined GS1-144 (N=207)	Normal	187 (92.1)	3 (1.5)	3 (1.5)	193 (95.1)
			Abnormal NCS	6 (3.0)	2 (1.0)	0	8 (3.9)
			Abnormal CS	0	0	2 (1.0)	2 (1.0)
			Total	193 (95.1)	5 (2.5)	5 (2.5)	203 (100)
	D43	Placebo (N=69)	Normal	61 (92.4)	4 (6.1)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Diastolic Blood Pressure (mmHg)	D43	GS1-144 30 mg QD (N=70)	Normal	65 (94.2)	0	3 (4.3)	68 (98.6)
			Abnormal NCS	0	1 (1.4)	0	1 (1.4)
			Abnormal CS	0	0	0	0
			Total	65 (94.2)	1 (1.4)	3 (4.3)	69 (100)
		GS1-144 60 mg QD (N=69)	Normal	62 (92.5)	1 (1.5)	1 (1.5)	64 (95.5)
			Abnormal NCS	2 (3.0)	1 (1.5)	0	3 (4.5)
			Abnormal CS	0	0	0	0
			Total	64 (95.5)	2 (3.0)	1 (1.5)	67 (100)
		GS1-144 30 mg BID (N=68)	Normal	58 (90.6)	1 (1.6)	0	59 (92.2)
			Abnormal NCS	2 (3.1)	1 (1.6)	0	3 (4.7)
			Abnormal CS	1 (1.6)	0	1 (1.6)	2 (3.1)
			Total	61 (95.3)	2 (3.1)	1 (1.6)	64 (100)
		Combined GS1-144 (N=207)	Normal	185 (92.5)	2 (1.0)	4 (2.0)	191 (95.5)
			Abnormal NCS	4 (2.0)	3 (1.5)	0	7 (3.5)
			Abnormal CS	1 (0.5)	0	1 (0.5)	2 (1.0)
			Total	190 (95.0)	5 (2.5)	5 (2.5)	200 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Diastolic Blood Pressure (mmHg)	D57	Placebo (N=69)	Normal	61 (92.4)	4 (6.1)	0	65 (98.5)
			Abnormal NCS	0	1 (1.5)	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	61 (92.4)	5 (7.6)	0	66 (100)
		GS1-144 30 mg QD (N=70)	Normal	64 (94.1)	1 (1.5)	3 (4.4)	68 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	64 (94.1)	1 (1.5)	3 (4.4)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	1 (1.5)	1 (1.5)	61 (92.4)
			Abnormal NCS	4 (6.1)	1 (1.5)	0	5 (7.6)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	57 (90.5)	2 (3.2)	1 (1.6)	60 (95.2)
			Abnormal NCS	3 (4.8)	0	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	2 (3.2)	1 (1.6)	63 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Diastolic Blood Pressure (mmHg)	D57	Combined GS1-144 (N=207)	Normal	180 (91.4)	4 (2.0)	5 (2.5)	189 (95.9)
			Abnormal NCS	7 (3.6)	1 (0.5)	0	8 (4.1)
			Abnormal CS	0	0	0	0
			Total	187 (94.9)	5 (2.5)	5 (2.5)	197 (100)
	D71	Placebo (N=69)	Normal	58 (89.2)	5 (7.7)	0	63 (96.9)
			Abnormal NCS	2 (3.1)	0	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	60 (92.3)	5 (7.7)	0	65 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (89.7)	1 (1.5)	2 (2.9)	64 (94.1)
			Abnormal NCS	3 (4.4)	0	0	3 (4.4)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	64 (94.1)	1 (1.5)	3 (4.4)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	57 (87.7)	2 (3.1)	1 (1.5)	60 (92.3)
			Abnormal NCS	5 (7.7)	0	0	5 (7.7)
			Abnormal CS	0	0	0	0
			Total	62 (95.4)	2 (3.1)	1 (1.5)	65 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Diastolic Blood Pressure (mmHg)	D71	GS1-144 30 mg BID (N=68)	Normal	58 (92.1)	2 (3.2)	1 (1.6)	61 (96.8)
			Abnormal NCS	2 (3.2)	0	0	2 (3.2)
			Abnormal CS	0	0	0	0
			Total	60 (95.2)	2 (3.2)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	176 (89.8)	5 (2.6)	4 (2.0)	185 (94.4)
			Abnormal NCS	10 (5.1)	0	0	10 (5.1)
			Abnormal CS	0	0	1 (0.5)	1 (0.5)
			Total	186 (94.9)	5 (2.6)	5 (2.6)	196 (100)
	D85	Placebo (N=69)	Normal	58 (90.6)	4 (6.3)	0	62 (96.9)
			Abnormal NCS	1 (1.6)	1 (1.6)	0	2 (3.1)
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	60 (89.6)	1 (1.5)	1 (1.5)	62 (92.5)
			Abnormal NCS	3 (4.5)	0	1 (1.5)	4 (6.0)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	63 (94.0)	1 (1.5)	3 (4.5)	67 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline: Normal n (%)	Baseline: Abnormal NCS n (%)	Baseline: Abnormal CS n (%)	Baseline: Total n (%)
Diastolic Blood Pressure (mmHg)	D85	GS1-144 60 mg QD (N=69)	Normal	62 (93.9)	2 (3.0)	1 (1.5)	65 (98.5)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	1 (1.6)	1 (1.6)	58 (92.1)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	2 (3.2)	0	0	2 (3.2)
			Total	60 (95.2)	2 (3.2)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	178 (90.8)	4 (2.0)	3 (1.5)	185 (94.4)
			Abnormal NCS	6 (3.1)	1 (0.5)	1 (0.5)	8 (4.1)
			Abnormal CS	2 (1.0)	0	1 (0.5)	3 (1.5)
			Total	186 (94.9)	5 (2.6)	5 (2.6)	196 (100)
	Safety Follow-up	Placebo (N=69)	Normal	59 (92.2)	5 (7.8)	0	64 (100)
			Abnormal NCS	0	0	0	0
			Abnormal CS	0	0	0	0
			Total	59 (92.2)	5 (7.8)	0	64 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.1
Shift of Vital Signs by Visit
SS

Test	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Diastolic Blood Pressure (mmHg)	Safety Follow-up	GS1-144 30 mg QD (N=70)	Normal	62 (91.2)	1 (1.5)	2 (2.9)	65 (95.6)
			Abnormal NCS	2 (2.9)	0	0	2 (2.9)
			Abnormal CS	0	0	1 (1.5)	1 (1.5)
			Total	64 (94.1)	1 (1.5)	3 (4.4)	68 (100)
		GS1-144 60 mg QD (N=69)	Normal	59 (89.4)	2 (3.0)	1 (1.5)	62 (93.9)
			Abnormal NCS	4 (6.1)	0	0	4 (6.1)
			Abnormal CS	0	0	0	0
			Total	63 (95.5)	2 (3.0)	1 (1.5)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	56 (88.9)	1 (1.6)	1 (1.6)	58 (92.1)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	2 (3.2)	0	0	2 (3.2)
			Total	60 (95.2)	2 (3.2)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	177 (89.8)	4 (2.0)	4 (2.0)	185 (93.9)
			Abnormal NCS	8 (4.1)	1 (0.5)	0	9 (4.6)
			Abnormal CS	2 (1.0)	0	1 (0.5)	3 (1.5)
			Total	187 (94.9)	5 (2.5)	5 (2.5)	197 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.6.2.2
Shift of Vital Signs by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	Placebo (N=69)	Normal	65 (94.2)	0	0	65 (94.2)
		Abnormal NCS	2 (2.9)	2 (2.9)	0	4 (5.8)
		Abnormal CS	0	0	0	0
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	66 (94.3)	2 (2.9)	0	68 (97.1)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	68 (97.1)	2 (2.9)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	57 (83.8)	1 (1.5)	0	58 (85.3)
		Abnormal NCS	7 (10.3)	3 (4.4)	0	10 (14.7)
		Abnormal CS	0	0	0	0
		Total	64 (94.1)	4 (5.9)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	59 (86.8)	1 (1.5)	0	60 (88.2)
		Abnormal NCS	6 (8.8)	2 (2.9)	0	8 (11.8)
		Abnormal CS	0	0	0	0
		Total	65 (95.6)	3 (4.4)	0	68 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.6.2.2
Shift of Vital Signs by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Ear Temperature (C)	Combined GS1-144 (N=207)	Normal	182 (88.3)	4 (1.9)	0	186 (90.3)
		Abnormal NCS	15 (7.3)	5 (2.4)	0	20 (9.7)
		Abnormal CS	0	0	0	0
		Total	197 (95.6)	9 (4.4)	0	206 (100)
Pulse Rate (beats/min)	Placebo (N=69)	Normal	57 (82.6)	2 (2.9)	0	59 (85.5)
		Abnormal NCS	7 (10.1)	2 (2.9)	0	9 (13.0)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	65 (94.2)	4 (5.8)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	65 (92.9)	0	0	65 (92.9)
		Abnormal NCS	3 (4.3)	2 (2.9)	0	5 (7.1)
		Abnormal CS	0	0	0	0
		Total	68 (97.1)	2 (2.9)	0	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	59 (86.8)	1 (1.5)	0	60 (88.2)
		Abnormal NCS	8 (11.8)	0	0	8 (11.8)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.6.2.2
Shift of Vital Signs by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Pulse Rate (beats/min)	GS1-144 30 mg BID (N=68)	Normal	60 (88.2)	0	0	60 (88.2)
		Abnormal NCS	7 (10.3)	1 (1.5)	0	8 (11.8)
		Abnormal CS	0	0	0	0
		Total	67 (98.5)	1 (1.5)	0	68 (100)
	Combined GS1-144 (N=207)	Normal	184 (89.3)	1 (0.5)	0	185 (89.8)
		Abnormal NCS	18 (8.7)	3 (1.5)	0	21 (10.2)
		Abnormal CS	0	0	0	0
		Total	202 (98.1)	4 (1.9)	0	206 (100)
Systolic Blood Pressure (mmHg)	Placebo (N=69)	Normal	62 (89.9)	1 (1.4)	0	63 (91.3)
		Abnormal NCS	4 (5.8)	1 (1.4)	0	5 (7.2)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	67 (97.1)	2 (2.9)	0	69 (100)
	GS1-144 30 mg QD (N=70)	Normal	59 (84.3)	1 (1.4)	0	60 (85.7)
		Abnormal NCS	5 (7.1)	2 (2.9)	0	7 (10.0)
		Abnormal CS	1 (1.4)	0	2 (2.9)	3 (4.3)
		Total	65 (92.9)	3 (4.3)	2 (2.9)	70 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.6.2.2
Shift of Vital Signs by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Systolic Blood Pressure (mmHg)	GS1-144 60 mg QD (N=69)	Normal	58 (85.3)	3 (4.4)	1 (1.5)	62 (91.2)
		Abnormal NCS	5 (7.4)	0	0	5 (7.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	64 (94.1)	3 (4.4)	1 (1.5)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	63 (92.6)	0	0	63 (92.6)
		Abnormal NCS	2 (2.9)	0	0	2 (2.9)
		Abnormal CS	2 (2.9)	0	1 (1.5)	3 (4.4)
		Total	67 (98.5)	0	1 (1.5)	68 (100)
	Combined GS1-144 (N=207)	Normal	180 (87.4)	4 (1.9)	1 (0.5)	185 (89.8)
		Abnormal NCS	12 (5.8)	2 (1.0)	0	14 (6.8)
		Abnormal CS	4 (1.9)	0	3 (1.5)	7 (3.4)
		Total	196 (95.1)	6 (2.9)	4 (1.9)	206 (100)
Diastolic Blood Pressure (mmHg)	Placebo (N=69)	Normal	59 (85.5)	3 (4.3)	0	62 (89.9)
		Abnormal NCS	4 (5.8)	2 (2.9)	0	6 (8.7)
		Abnormal CS	1 (1.4)	0	0	1 (1.4)
		Total	64 (92.8)	5 (7.2)	0	69 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.6.2.2
Shift of Vital Signs by Worst Abnormality
SS

Test	Treatment Group	Worst Abnormality Post-Baseline	Baseline			
			Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Diastolic Blood Pressure (mmHg)	GS1-144 30 mg QD (N=70)	Normal	59 (84.3)	0	1 (1.4)	60 (85.7)
		Abnormal NCS	7 (10.0)	1 (1.4)	0	8 (11.4)
		Abnormal CS	0	0	2 (2.9)	2 (2.9)
		Total	66 (94.3)	1 (1.4)	3 (4.3)	70 (100)
	GS1-144 60 mg QD (N=69)	Normal	50 (73.5)	1 (1.5)	1 (1.5)	52 (76.5)
		Abnormal NCS	15 (22.1)	1 (1.5)	0	16 (23.5)
		Abnormal CS	0	0	0	0
		Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	55 (80.9)	1 (1.5)	0	56 (82.4)
		Abnormal NCS	8 (11.8)	1 (1.5)	0	9 (13.2)
		Abnormal CS	2 (2.9)	0	1 (1.5)	3 (4.4)
		Total	65 (95.6)	2 (2.9)	1 (1.5)	68 (100)
	Combined GS1-144 (N=207)	Normal	164 (79.6)	2 (1.0)	2 (1.0)	168 (81.6)
		Abnormal NCS	30 (14.6)	3 (1.5)	0	33 (16.0)
		Abnormal CS	2 (1.0)	0	3 (1.5)	5 (2.4)
		Total	196 (95.1)	5 (2.4)	5 (2.4)	206 (100)

Data Source: Listing 16.2.8.3.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per test.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Skin, Mucous Membranes	Placebo (N=69)	Normal	53 (79.1)	0	0	53 (79.1)
		Abnormal NCS	0	13 (19.4)	0	13 (19.4)
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	54 (80.6)	13 (19.4)	0	67 (100)
	GS1-144 30 mg QD (N=70)	Normal	53 (76.8)	0	0	53 (76.8)
		Abnormal NCS	0	14 (20.3)	0	14 (20.3)
		Abnormal CS	0	0	2 (2.9)	2 (2.9)
		Total	53 (76.8)	14 (20.3)	2 (2.9)	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	58 (85.3)	0	0	58 (85.3)
		Abnormal NCS	0	9 (13.2)	0	9 (13.2)
		Abnormal CS	0	1 (1.5)	0	1 (1.5)
		Total	58 (85.3)	10 (14.7)	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	47 (71.2)	0	1 (1.5)	48 (72.7)
		Abnormal NCS	0	16 (24.2)	0	16 (24.2)
		Abnormal CS	1 (1.5)	0	1 (1.5)	2 (3.0)
		Total	48 (72.7)	16 (24.2)	2 (3.0)	66 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Skin, Mucous Membranes	Combined GS1-144 (N=207)	Normal	158 (77.8)	0	1 (0.5)	159 (78.3)
		Abnormal NCS	0	39 (19.2)	0	39 (19.2)
		Abnormal CS	1 (0.5)	1 (0.5)	3 (1.5)	5 (2.5)
		Total	159 (78.3)	40 (19.7)	4 (2.0)	203 (100)
Lymph Nodes	Placebo (N=69)	Normal	65 (97.0)	0	0	65 (97.0)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	2 (3.0)	2 (3.0)
		Total	65 (97.0)	0	2 (3.0)	67 (100)
	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	67 (98.5)	0	0	67 (98.5)
		Abnormal NCS	0	0	0	0
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	68 (100)	0	0	68 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Lymph Nodes	GS1-144 30 mg BID (N=68)	Normal	66 (100)	0	0	66 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	66 (100)	0	0	66 (100)
	Combined GS1-144 (N=207)	Normal	202 (99.5)	0	0	202 (99.5)
		Abnormal NCS	0	0	0	0
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	203 (100)	0	0	203 (100)
Head	Placebo (N=69)	Normal	67 (100)	0	0	67 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	67 (100)	0	0	67 (100)
	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Head	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	66 (100)	0	0	66 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	66 (100)	0	0	66 (100)
	Combined GS1-144 (N=207)	Normal	203 (100)	0	0	203 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	203 (100)	0	0	203 (100)
Neck	Placebo (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
		Abnormal NCS	0	0	0	0
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Neck	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	67 (100)	0	0	67 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	67 (100)	0	0	67 (100)
	GS1-144 30 mg BID (N=68)	Normal	65 (98.5)	0	0	65 (98.5)
		Abnormal NCS	0	0	0	0
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	66 (100)	0	0	66 (100)
	Combined GS1-144 (N=207)	Normal	201 (99.5)	0	0	201 (99.5)
		Abnormal NCS	0	0	0	0
		Abnormal CS	1 (0.5)	0	0	1 (0.5)
		Total	202 (100)	0	0	202 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Chest	Placebo (N=69)	Normal	67 (100)	0	0	67 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	67 (100)	0	0	67 (100)
	GS1-144 30 mg QD (N=70)	Normal	67 (97.1)	0	0	67 (97.1)
		Abnormal NCS	1 (1.4)	1 (1.4)	0	2 (2.9)
		Abnormal CS	0	0	0	0
		Total	68 (98.6)	1 (1.4)	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	66 (100)	0	0	66 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	66 (100)	0	0	66 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Chest	Combined GS1-144 (N=207)	Normal	201 (99.0)	0	0	201 (99.0)
		Abnormal NCS	1 (0.5)	1 (0.5)	0	2 (1.0)
		Abnormal CS	0	0	0	0
		Total	202 (99.5)	1 (0.5)	0	203 (100)
Abdomen	Placebo (N=69)	Normal	60 (89.6)	0	0	60 (89.6)
		Abnormal NCS	0	7 (10.4)	0	7 (10.4)
		Abnormal CS	0	0	0	0
		Total	60 (89.6)	7 (10.4)	0	67 (100)
	GS1-144 30 mg QD (N=70)	Normal	60 (87.0)	0	0	60 (87.0)
		Abnormal NCS	0	9 (13.0)	0	9 (13.0)
		Abnormal CS	0	0	0	0
		Total	60 (87.0)	9 (13.0)	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	60 (88.2)	0	0	60 (88.2)
		Abnormal NCS	0	8 (11.8)	0	8 (11.8)
		Abnormal CS	0	0	0	0
		Total	60 (88.2)	8 (11.8)	0	68 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Abdomen	GS1-144 30 mg BID (N=68)	Normal	60 (90.9)	0	0	60 (90.9)
		Abnormal NCS	0	6 (9.1)	0	6 (9.1)
		Abnormal CS	0	0	0	0
		Total	60 (90.9)	6 (9.1)	0	66 (100)
	Combined GS1-144 (N=207)	Normal	180 (88.7)	0	0	180 (88.7)
		Abnormal NCS	0	23 (11.3)	0	23 (11.3)
		Abnormal CS	0	0	0	0
		Total	180 (88.7)	23 (11.3)	0	203 (100)
Muscle and bone/limbs	Placebo (N=69)	Normal	66 (98.5)	0	0	66 (98.5)
		Abnormal NCS	0	0	0	0
		Abnormal CS	1 (1.5)	0	0	1 (1.5)
		Total	67 (100)	0	0	67 (100)
	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Muscle and bone/limbs	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	66 (100)	0	0	66 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	66 (100)	0	0	66 (100)
	Combined GS1-144 (N=207)	Normal	203 (100)	0	0	203 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	203 (100)	0	0	203 (100)
Nervous System	Placebo (N=69)	Normal	67 (100)	0	0	67 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	67 (100)	0	0	67 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.7
Shift of Physical Examination by Worst Abnormality
SS

Body System	Treatment Group	Worst Abnormality Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Nervous System	GS1-144 30 mg QD (N=70)	Normal	69 (100)	0	0	69 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	69 (100)	0	0	69 (100)
	GS1-144 60 mg QD (N=69)	Normal	68 (100)	0	0	68 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	68 (100)	0	0	68 (100)
	GS1-144 30 mg BID (N=68)	Normal	66 (100)	0	0	66 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	66 (100)	0	0	66 (100)
	Combined GS1-144 (N=207)	Normal	203 (100)	0	0	203 (100)
		Abnormal NCS	0	0	0	0
		Abnormal CS	0	0	0	0
		Total	203 (100)	0	0	203 (100)

Data Source: Listing 16.2.8.4.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Summarizing the worst abnormality including all post-baseline data after first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and post-baseline per body system.

Table 14.3.8.1
Summary of Endometrial Thickness and Endometrial Biopsy
SS

Visit		Placebo N = 69 n(%)	GS1-144 30 mg QD N = 70 n(%)	GS1-144 60 mg QD N = 69 n(%)	GS1-144 30 mg BID N = 68 n(%)	Combined GS1-144 N = 207 n(%)	Overall N = 276 n(%)
Baseline	Endometrial Thickness[1]	64 (100)	67 (100)	66 (100)	65 (100)	198 (100)	262 (100)
	<=4mm	60 (93.8)	63 (94.0)	61 (92.4)	61 (93.8)	185 (93.4)	245 (93.5)
	>4mm	4 (6.3)	4 (6.0)	5 (7.6)	4 (6.2)	13 (6.6)	17 (6.5)
	Endometrial Biopsy [2]						
	Normal	3 (75.0)	1 (25.0)	1 (20.0)	1 (25.0)	3 (23.1)	6 (35.3)
	Abnormal NCS	0	1 (25.0)	4 (80.0)	2 (50.0)	7 (53.8)	7 (41.2)
	Abnormal CS	0	1 (25.0)	0	0	1 (7.7)	1 (5.9)
D85	Endometrial Thickness[1]	61 (100)	66 (100)	62 (100)	59 (100)	187 (100)	248 (100)
	<=4mm	57 (93.4)	54 (81.8)	57 (91.9)	55 (93.2)	166 (88.8)	223 (89.9)
	>4mm	4 (6.6)	12 (18.2)	5 (8.1)	4 (6.8)	21 (11.2)	25 (10.1)
	Endometrial Biopsy [2]						
	Normal	0	7 (58.3)	2 (40.0)	0	9 (42.9)	9 (36.0)
	Abnormal NCS	2 (50.0)	1 (8.3)	0	2 (50.0)	3 (14.3)	5 (20.0)
	Abnormal CS	0	0	1 (20.0)	0	1 (4.8)	1 (4.0)

Data Source: Listing 16.2.8.5.1 and Listing 16.2.8.5.2
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
[1] Endometrial Thickness were summarized based on number of subjects who had available measurement value at specific visit.
[2] Endometrial Biopsy were summarized based on number of subjects with Endometrial Thickness >4 mm.

Table 14.3.8.2
Shift of Transvaginal Ultrasound by Visit
SS

Body System/Organ	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Uterus	D85	Placebo (N=69)	Normal	18 (29.5)	3 (4.9)	0	21 (34.4)
			Abnormal NCS	3 (4.9)	17 (27.9)	0	20 (32.8)
			Abnormal CS	3 (4.9)	2 (3.3)	15 (24.6)	20 (32.8)
			Total	24 (39.3)	22 (36.1)	15 (24.6)	61 (100)
		GS1-144 30 mg QD (N=70)	Normal	14 (21.2)	2 (3.0)	2 (3.0)	18 (27.3)
			Abnormal NCS	2 (3.0)	25 (37.9)	1 (1.5)	28 (42.4)
			Abnormal CS	2 (3.0)	2 (3.0)	16 (24.2)	20 (30.3)
			Total	18 (27.3)	29 (43.9)	19 (28.8)	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	13 (21.0)	1 (1.6)	2 (3.2)	16 (25.8)
			Abnormal NCS	6 (9.7)	18 (29.0)	2 (3.2)	26 (41.9)
			Abnormal CS	0	6 (9.7)	14 (22.6)	20 (32.3)
			Total	19 (30.6)	25 (40.3)	18 (29.0)	62 (100)
		GS1-144 30 mg BID (N=68)	Normal	19 (30.6)	2 (3.2)	0	21 (33.9)
			Abnormal NCS	6 (9.7)	19 (30.6)	2 (3.2)	27 (43.5)
			Abnormal CS	1 (1.6)	1 (1.6)	12 (19.4)	14 (22.6)
			Total	26 (41.9)	22 (35.5)	14 (22.6)	62 (100)

Data Source: Listing 16.2.8.5.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.8.2
Shift of Transvaginal Ultrasound by Visit
SS

Body System/Organ	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Uterus	D85	Combined GS1-144 (N=207)	Normal	46 (24.2)	5 (2.6)	4 (2.1)	55 (28.9)
			Abnormal NCS	14 (7.4)	62 (32.6)	5 (2.6)	81 (42.6)
			Abnormal CS	3 (1.6)	9 (4.7)	42 (22.1)	54 (28.4)
			Total	63 (33.2)	76 (40.0)	51 (26.8)	190 (100)
Appendages	D85	Placebo (N=69)	Normal	46 (74.2)	1 (1.6)	2 (3.2)	49 (79.0)
			Abnormal NCS	2 (3.2)	4 (6.5)	0	6 (9.7)
			Abnormal CS	1 (1.6)	1 (1.6)	5 (8.1)	7 (11.3)
			Total	49 (79.0)	6 (9.7)	7 (11.3)	62 (100)
		GS1-144 30 mg QD (N=70)	Normal	54 (80.6)	2 (3.0)	0	56 (83.6)
			Abnormal NCS	5 (7.5)	3 (4.5)	0	8 (11.9)
			Abnormal CS	0	0	3 (4.5)	3 (4.5)
			Total	59 (88.1)	5 (7.5)	3 (4.5)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	55 (85.9)	4 (6.3)	0	59 (92.2)
			Abnormal NCS	2 (3.1)	2 (3.1)	0	4 (6.3)
			Abnormal CS	0	0	1 (1.6)	1 (1.6)
			Total	57 (89.1)	6 (9.4)	1 (1.6)	64 (100)

Data Source: Listing 16.2.8.5.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.8.2
Shift of Transvaginal Ultrasound by Visit
SS

Body System/Organ	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Appendages	D85	GS1-144 30 mg BID (N=68)	Normal	50 (80.6)	0	2 (3.2)	52 (83.9)
			Abnormal NCS	3 (4.8)	6 (9.7)	0	9 (14.5)
			Abnormal CS	1 (1.6)	0	0	1 (1.6)
			Total	54 (87.1)	6 (9.7)	2 (3.2)	62 (100)
		Combined GS1-144 (N=207)	Normal	159 (82.4)	6 (3.1)	2 (1.0)	167 (86.5)
			Abnormal NCS	10 (5.2)	11 (5.7)	0	21 (10.9)
			Abnormal CS	1 (0.5)	0	4 (2.1)	5 (2.6)
			Total	170 (88.1)	17 (8.8)	6 (3.1)	193 (100)

Data Source: Listing 16.2.8.5.1
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.9.1
Summary of BI-RADS Category
SS

Visit	Placebo N = 69 n(%)	GS1-144 30 mg QD N = 70 n(%)	GS1-144 60 mg QD N = 69 n(%)	GS1-144 30 mg BID N = 68 n(%)	Combined GS1-144 N = 207 n(%)	Overall N = 276 n(%)
Baseline	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)
<4	69 (100)	70 (100)	69 (100)	68 (100)	207 (100)	276 (100)
>=4	0	0	0	0	0	0
D85	64 (100)	67 (100)	66 (100)	63 (100)	196 (100)	260 (100)
<4	64 (100)	66 (98.5)	65 (98.5)	62 (98.4)	193 (98.5)	257 (98.8)
>=4	0	1 (1.5)	1 (1.5)	1 (1.6)	3 (1.5)	3 (1.2)

Data Source: Listing 16.2.8.6
BI-RADS = Breast Imaging Reporting and Data System.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
BI-RADS were summarized based on number of subjects who had available measurement value at specific visit.

Table 14.3.9.2
Shift of Breast Ultrasound by Visit
SS

Body System/Organ	Visit	Treatment Group	Post-Baseline	Baseline Normal n (%)	Baseline Abnormal NCS n (%)	Baseline Abnormal CS n (%)	Baseline Total n (%)
Bilateral breasts	D85	Placebo (N=69)	Normal	18 (28.1)	2 (3.1)	1 (1.6)	21 (32.8)
			Abnormal NCS	4 (6.3)	18 (28.1)	0	22 (34.4)
			Abnormal CS	0	1 (1.6)	20 (31.3)	21 (32.8)
			Total	22 (34.4)	21 (32.8)	21 (32.8)	64 (100)
		GS1-144 30 mg QD (N=70)	Normal	20 (29.9)	4 (6.0)	2 (3.0)	26 (38.8)
			Abnormal NCS	2 (3.0)	17 (25.4)	1 (1.5)	20 (29.9)
			Abnormal CS	2 (3.0)	1 (1.5)	18 (26.9)	21 (31.3)
			Total	24 (35.8)	22 (32.8)	21 (31.3)	67 (100)
		GS1-144 60 mg QD (N=69)	Normal	21 (31.8)	2 (3.0)	1 (1.5)	24 (36.4)
			Abnormal NCS	2 (3.0)	20 (30.3)	0	22 (33.3)
			Abnormal CS	0	0	20 (30.3)	20 (30.3)
			Total	23 (34.8)	22 (33.3)	21 (31.8)	66 (100)
		GS1-144 30 mg BID (N=68)	Normal	19 (30.2)	1 (1.6)	3 (4.8)	23 (36.5)
			Abnormal NCS	1 (1.6)	18 (28.6)	0	19 (30.2)
			Abnormal CS	3 (4.8)	1 (1.6)	17 (27.0)	21 (33.3)
			Total	23 (36.5)	20 (31.7)	20 (31.7)	63 (100)

Data Source: Listing 16.2.8.6
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.9.2
Shift of Breast Ultrasound by Visit
SS

Body System/Organ	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Bilateral breasts	D85	Combined GS1-144 (N=207)	Normal	60 (30.6)	7 (3.6)	6 (3.1)	73 (37.2)
			Abnormal NCS	5 (2.6)	55 (28.1)	1 (0.5)	61 (31.1)
			Abnormal CS	5 (2.6)	2 (1.0)	55 (28.1)	62 (31.6)
			Total	70 (35.7)	64 (32.7)	62 (31.6)	196 (100)
Bilateral axillae	D85	Placebo (N=69)	Normal	56 (88.9)	4 (6.3)	0	60 (95.2)
			Abnormal NCS	2 (3.2)	1 (1.6)	0	3 (4.8)
			Abnormal CS	0	0	0	0
			Total	58 (92.1)	5 (7.9)	0	63 (100)
		GS1-144 30 mg QD (N=70)	Normal	61 (92.4)	3 (4.5)	0	64 (97.0)
			Abnormal NCS	1 (1.5)	0	0	1 (1.5)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	63 (95.5)	3 (4.5)	0	66 (100)
		GS1-144 60 mg QD (N=69)	Normal	54 (81.8)	5 (7.6)	1 (1.5)	60 (90.9)
			Abnormal NCS	4 (6.1)	1 (1.5)	0	5 (7.6)
			Abnormal CS	1 (1.5)	0	0	1 (1.5)
			Total	59 (89.4)	6 (9.1)	1 (1.5)	66 (100)

Data Source: Listing 16.2.8.6
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.3.9.2
Shift of Breast Ultrasound by Visit
SS

Body System/Organ	Visit	Treatment Group	Post-Baseline	Baseline			
				Normal n (%)	Abnormal NCS n (%)	Abnormal CS n (%)	Total n (%)
Bilateral axillae	D85	GS1-144 30 mg BID (N=68)	Normal	54 (85.7)	3 (4.8)	1 (1.6)	58 (92.1)
			Abnormal NCS	3 (4.8)	2 (3.2)	0	5 (7.9)
			Abnormal CS	0	0	0	0
			Total	57 (90.5)	5 (7.9)	1 (1.6)	63 (100)
		Combined GS1-144 (N=207)	Normal	169 (86.7)	11 (5.6)	2 (1.0)	182 (93.3)
			Abnormal NCS	8 (4.1)	3 (1.5)	0	11 (5.6)
			Abnormal CS	2 (1.0)	0	0	2 (1.0)
			Total	179 (91.8)	14 (7.2)	2 (1.0)	195 (100)

Data Source: Listing 16.2.8.6
NCS = not clinically significant; CS = clinically significant.
Baseline values were defined as the last available measurement value prior to the first study drug administration.
Percentages were based on subjects with non-missing values at both baseline and specific visit per test.

Table 14.4.1.1
Exposure
SS

Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Week 4	Duration of Treatments (days)						
	n	69	70	69	68	207	276
	Mean (SD)	27.7 (1.56)	27.8 (1.67)	27.5 (2.95)	28.0 (0)	27.8 (1.96)	27.8 (1.87)
	Median	28.0	28.0	28.0	28.0	28.0	28.0
	Q1 - Q3	28.0 - 28.0	28.0 - 28.0	28.0 - 28.0	28.0 - 28.0	28.0 - 28.0	28.0 - 28.0
	Min - Max	17 - 28	14 - 28	7 - 28	28 - 28	7 - 28	7 - 28
	Actual Cumulative Dose (mg)						
	n	NA	70	69	68	207	NA
	Mean (SD)		831.2 (54.32)	1644.8 (181.90)	1676.0 (20.01)	1379.9 (408.40)	
	Median		840.0	1680.0	1680.0	1680.0	
	Q1 - Q3		840.0 - 840.0	1680.0 - 1680.0	1680.0 - 1680.0	840.0 - 1680.0	
	Min - Max		405 - 855	390 - 1680	1530 - 1680	390 - 1680	
	Average Daily Dose (mg/day)						
	n	NA	70	69	68	207	NA
	Mean (SD)		29.89 (0.609)	59.75 (1.179)	59.86 (0.715)	49.69 (14.211)	
	Median		30.00	60.00	60.00	60.00	
	Q1 - Q3		30.00 - 30.00	60.00 - 60.00	60.00 - 60.00	30.00 - 60.00	
	Min - Max		25.2 - 30.5	51.4 - 60.0	54.6 - 60.0	25.2 - 60.0	

Data Source: Listing 16.2.5.3
Week 4 were from first study drug administration up to Day 28.
Week 12 were from first study drug administration up to day of last treatment.

Table 14.4.1.1
Exposure
SS

Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68	Combined GS1-144 N = 207	Overall N = 276
Week 12	Duration of Treatments (days)						
	n	69	70	69	68	207	276
	Mean (SD)	80.7 (13.14)	81.9 (10.62)	81.1 (13.11)	80.0 (14.48)	81.0 (12.78)	80.9 (12.85)
	Median	84.0	84.0	84.0	84.0	84.0	84.0
	Q1 - Q3	84.0 - 84.0	84.0 - 84.0	84.0 - 84.0	84.0 - 84.0	84.0 - 84.0	84.0 - 84.0
	Min - Max	17 - 85	14 - 85	7 - 85	28 - 85	7 - 85	7 - 85
	Actual Cumulative Dose (mg)						
	n	NA	70	69	68	207	NA
	Mean (SD)		2452.9 (321.07)	4850.4 (788.04)	4793.2 (880.56)	4020.9 (1324.57)	
	Median		2520.0	5040.0	5040.0	5040.0	
	Q1 - Q3		2520.0 - 2520.0	5040.0 - 5040.0	5040.0 - 5040.0	2520.0 - 5040.0	
	Min - Max		405 - 2535	390 - 5100	1530 - 5100	390 - 5100	
	Average Daily Dose (mg/day)						
	n	NA	70	69	68	207	NA
	Mean (SD)		29.92 (0.250)	59.76 (0.887)	59.83 (0.683)	49.69 (14.180)	
	Median		30.00	60.00	60.00	60.00	
	Q1 - Q3		30.00 - 30.00	60.00 - 60.00	60.00 - 60.00	30.00 - 60.00	
	Min - Max		28.4 - 30.2	54.6 - 60.0	54.6 - 60.0	28.4 - 60.0	

Data Source: Listing 16.2.5.3
Week 4 were from first study drug administration up to Day 28.
Week 12 were from first study drug administration up to day of last treatment.

Table 14.4.1.2
Compliance
FAS

Week	Statistic	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Week 4	Compliance (%)				
	n	69	70	69	68
	Mean (SD)	99.48 (2.168)	99.64 (2.030)	99.59 (1.964)	99.76 (1.191)
	Median	100.00	100.00	100.00	100.00
	Q1 - Q3	100.00 - 100.00	100.00 - 100.00	100.00 - 100.00	100.00 - 100.00
	Min - Max	83.9 - 100.0	83.9 - 101.8	85.7 - 100.0	91.1 - 100.0
	Compliance Category, n (%)				
	< 80%	0	0	0	0
	80% - 120%	69 (100)	70 (100)	69 (100)	68 (100)
	> 120%	0	0	0	0
Week 12	Compliance (%)				
	n	69	70	69	68
	Mean (SD)	99.46 (1.878)	99.74 (0.834)	99.59 (1.478)	99.71 (1.138)
	Median	100.00	100.00	100.00	100.00
	Q1 - Q3	100.00 - 100.00	100.00 - 100.00	100.00 - 100.00	100.00 - 100.00
	Min - Max	87.5 - 100.0	94.6 - 100.6	91.1 - 100.0	91.1 - 100.0
	Compliance Category, n (%)				
	< 80%	0	0	0	0
	80% - 120%	69 (100)	70 (100)	69 (100)	68 (100)
	> 120%	0	0	0	0

Data Source: Listing 16.2.5.3
Week 4 were from first study drug administration up to Day 28.
Week 12 were from first study drug administration up to day of last treatment.

Table 14.4.2.1.1
Summary of GS1-144 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D1	Pre-dose	70	2	0.04	0.278			0	2.3		
	1.5h	68	66	269.34	141.159	52.4	265.50	3.4	677.0	216.03	105.7
	4h	68	66	111.34	56.882	51.1	104.00	5.5	381.0	97.08	64.8
D15	Pre-dose	68	54	20.22	87.885			0.5	649.0		
	1.5h	2	2	609.50	622.961	102.2	609.50	169.0	1050.0	421.25	207.4
	4h	2	2	127.85	68.094	53.3	127.85	79.7	176.0	118.44	60.7
D29	Pre-dose	69	53	10.66	23.909			0.6	159.0		
	1.5h	67	65	283.87	128.906	45.4	258.00	0.4	577.0	228.39	137.9
	4h	67	64	131.40	69.079	52.6	119.00	2.2	337.0	110.94	80.9

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.2 ng/mL.

Table 14.4.2.1.1
Summary of GS1-144 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D43	Pre-dose	69	55	15.69	43.759			0.3	273.0		
	1.5h	2	2	377.00	329.512	87.4	377.00	144.0	610.0	296.38	135.5
	4h	2	2	348.35	449.225	129.0	348.35	30.7	666.0	142.99	1061.9
D57	Pre-dose	68	58	12.86	34.431			0.4	199.0		
	1.5h	68	67	241.38	126.567	52.4	220.00	0.2	588.0	180.23	178.0
	4h	67	65	116.50	62.611	53.7	107.00	1.7	324.0	94.86	99.8
D71	Pre-dose	68	53	11.64	53.176			0.5	390.0		
	4h	1	1	230.00			230.00	230.0	230.0	230.00	
D85		67	42					0.2	364.0		

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.2 ng/mL.

Table 14.4.2.1.1
Summary of GS1-144 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 60 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D1	Pre-dose	69	1	2.17	18.058			0	150.0		
	1.5h	67	65	549.73	289.625	52.7	541.00	18.1	1290.0	449.47	88.4
	4h	67	65	254.85	151.689	59.5	235.00	15.3	857.0	205.37	87.4
D15	Pre-dose	66	48	69.19	239.202			0.5	1130.0		
	1.5h	2	2	621.50	70.004	11.3	621.50	572.0	671.0	619.53	11.3
	4h	2	2	339.50	234.052	68.9	339.50	174.0	505.0	296.43	87.4
D29	Pre-dose	67	52	17.97	28.715			0.3	162.0		
	1.5h	66	64	519.40	253.336	48.8	519.50	8.1	1070.0	419.54	105.5
	4h	66	64	253.38	138.174	54.5	233.50	4.3	719.0	207.22	90.6

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.2 ng/mL.

Table 14.4.2.1.1
Summary of GS1-144 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 60 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D43	Pre-dose	67	51	15.90	23.223			0.3	109.0		
	1.5h	1	1	485.00			485.00	485.0	485.0	485.00	
	4h	1	1	461.00			461.00	461.0	461.0	461.00	
D57	Pre-dose	65	46	23.49	55.753			0.3	367.0		
	1.5h	65	64	517.50	234.406	45.3	496.50	1.2	1320.0	417.78	133.3
	4h	65	64	283.01	186.045	65.7	257.00	0.3	1210.0	210.76	157.4
D71	Pre-dose	65	50	12.07	12.093			0.3	58.6		
	1.5h	1	1	657.00			657.00	657.0	657.0	657.00	
	4h	1	1	248.00			248.00	248.0	248.0	248.00	
D85		66	38					0.5	882.0		

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.2 ng/mL.

Table 14.4.2.1.1
Summary of GS1-144 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg BID

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D1	Pre-dose	68	0	0	0			0	0		
	1.5h	65	61	288.61	146.967	50.9	293.00	8.9	754.0	240.06	85.7
	4h	65	61	111.81	63.037	56.4	106.00	3.6	401.0	94.73	75.4
D15	Pre-dose	67	58	36.99	38.362			0.8	194.0		
	1.5h	3	3	443.70	299.563	67.5	590.00	99.1	642.0	334.83	143.0
	4h	3	3	273.63	202.211	73.9	358.00	42.9	420.0	186.15	201.6
D29	Pre-dose	67	55	44.25	61.207			0.8	421.0		
	1.5h	63	59	290.67	135.503	46.6	266.00	43.4	802.0	261.27	51.4
	4h	63	59	142.42	72.625	51.0	132.00	30.5	398.0	125.43	56.7

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.2 ng/mL.

Table 14.4.2.1.1
Summary of GS1-144 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg BID

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D43	Pre-dose	64	56	37.82	32.735			0.8	185.0		
	1.5h	3	3	402.33	183.364	45.6	301.00	292.0	614.0	377.90	44.0
	4h	3	3	209.00	47.624	22.8	227.00	155.0	245.0	205.04	24.9
D57	Pre-dose	63	56	40.58	40.602			0.2	169.0		
	1.5h	59	56	308.30	133.040	43.2	300.00	70.3	703.0	278.90	50.2
	4h	59	56	160.38	88.600	55.2	139.00	32.8	528.0	140.65	55.7
D71	Pre-dose	63	57	44.70	46.411			0.2	282.0		
	1.5h	4	4	279.00	161.210	57.8	259.50	103.0	494.0	241.94	71.9
	4h	4	4	170.00	88.348	52.0	143.00	96.0	298.0	155.43	50.2
D85		62	47	30.30	33.951	112.1	17.90	0.2	141.0	12.14	417.5

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.2 ng/mL.

Table 14.4.2.1.2
Summary of M1 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D1	Pre-dose	70	1	0.02	0.176			0	1.5		
	1.5h	68	66	244.72	116.414	47.6	243.50	3.1	639.0	200.16	102.5
	4h	68	66	208.62	54.181	26.0	199.00	12.6	331.0	197.67	43.1
D15	Pre-dose	68	56	48.09	37.564			3.0	221.0		
	1.5h	2	2	274.50	136.472	49.7	274.50	178.0	371.0	256.98	55.6
	4h	2	2	329.00	175.362	53.3	329.00	205.0	453.0	304.74	60.8
D29	Pre-dose	69	58	46.67	55.414			0.6	380.0		
	1.5h	67	65	318.61	127.236	39.9	288.00	0.6	612.0	263.51	127.5
	4h	67	64	260.64	82.323	31.6	248.50	3.9	492.0	238.94	64.1

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.5 ng/mL.

Table 14.4.2.1.2
Summary of M1 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D43	Pre-dose	69	58	47.86	48.721			2.7	243.0		
	1.5h	2	2	404.50	89.803	22.2	404.50	341.0	468.0	399.48	22.7
	4h	2	2	501.50	457.498	91.2	501.50	178.0	825.0	383.21	149.7
D57	Pre-dose	68	59	46.95	49.847			6.2	313.0		
	1.5h	68	66	300.06	113.332	37.8	297.00	5.8	594.0	264.70	73.5
	4h	67	65	241.09	79.736	33.1	233.00	5.8	441.0	216.78	70.0
D71	Pre-dose	68	56	35.97	27.330			0.7	201.0		
	4h	1	1	275.00			275.00	275.0	275.0	275.00	
D85		67	49	56.66	80.160	141.5	33.20	0.6	412.0	27.03	253.4

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.5 ng/mL.

Table 14.4.2.1.2
Summary of M1 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 60 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D1	Pre-dose	69	1	11.55	95.948			0	797.0		
	1.5h	67	65	511.51	244.208	47.7	477.00	10.4	1160.0	414.03	101.6
	4h	67	65	421.62	143.293	34.0	435.00	21.8	859.0	383.62	58.8
D15	Pre-dose	66	49	103.40	162.977			5.5	853.0		
	1.5h	2	2	557.00	329.512	59.2	557.00	324.0	790.0	505.92	69.8
	4h	2	2	410.00	123.037	30.0	410.00	323.0	497.0	400.66	31.2
D29	Pre-dose	67	52	86.00	59.939			9.6	270.0		
	1.5h	66	64	593.09	205.768	34.7	607.00	5.8	1120.0	506.10	104.6
	4h	66	64	503.73	168.509	33.5	486.00	6.0	1240.0	458.58	68.3

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.5 ng/mL.

Table 14.4.2.1.2
Summary of M1 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 60 mg QD

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D43	Pre-dose	67	51	82.66	54.051			29.1	303.0		
	1.5h	1	1	601.00			601.00	601.0	601.0	601.00	
	4h	1	1	713.00			713.00	713.0	713.0	713.00	
D57	Pre-dose	65	48	95.14	79.347			1.6	374.0		
	1.5h	65	65	565.33	275.952	48.8	556.00	2.2	1280.0	423.08	171.1
	4h	65	65	502.19	228.963	45.6	503.00	2.8	1180.0	385.65	163.7
D71	Pre-dose	65	51	77.91	39.581			11.5	206.0		
	1.5h	1	1	539.00			539.00	539.0	539.0	539.00	
	4h	1	1	487.00			487.00	487.0	487.0	487.00	
D85		66	43					2.3	958.0		

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.5 ng/mL.

Table 14.4.2.1.2
Summary of M1 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg BID

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D1	Pre-dose	68	0	0	0			0	0		
	1.5h	65	61	249.38	97.972	39.3	247.00	9.8	452.0	218.12	73.7
	4h	65	61	211.75	54.200	25.6	217.00	7.3	341.0	197.73	53.7
D15	Pre-dose	67	58	139.84	64.210			35.5	344.0		
	1.5h	3	3	493.67	88.325	17.9	453.00	433.0	595.0	488.69	17.3
	4h	3	3	400.00	61.587	15.4	432.00	329.0	439.0	396.63	16.3
D29	Pre-dose	67	56	142.20	93.183			16.4	633.0		
	1.5h	63	59	381.85	145.691	38.2	371.00	57.5	876.0	351.80	46.7
	4h	63	59	304.27	83.749	27.5	291.00	144.0	633.0	293.64	27.4

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.5 ng/mL.

Table 14.4.2.1.2
Summary of M1 (ng/mL) Plasma Concentrations
PKAS

Treatment Group: GS1-144 30 mg BID

Visit	Planned Time Point	n	NALQ	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
D43	Pre-dose	64	57	136.95	63.797			3.4	332.0		
	1.5h	3	3	429.00	53.113	12.4	410.00	388.0	489.0	426.88	12.1
	4h	3	3	356.00	94.715	26.6	330.00	277.0	461.0	347.99	26.3
D57	Pre-dose	63	57	143.56	125.448			4.7	917.0		
	1.5h	59	57	373.87	139.291	37.3	367.00	6.7	791.0	328.81	77.7
	4h	59	57	313.25	105.012	33.5	297.00	4.2	673.0	283.60	70.5
D71	Pre-dose	63	57	150.61	96.815			6.1	675.0		
	1.5h	4	4	321.50	107.785	33.5	294.00	224.0	474.0	309.25	32.3
	4h	4	4	309.75	66.204	21.4	313.50	228.0	384.0	304.21	22.5
D85		62	51	112.89	88.242	78.2	117.00	0.8	446.0	65.51	235.9

Data Source: Listing 16.2.5.4
n = number of observations; NALQ = Number of observations Above Lower limit of Quantification; SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Summary Statistic are calculated by setting concentration values of BQL (below the lower limit of quantification) to zero prior to the first study drug administration and setting to missing after the first study drug administration.
The lower limit of quantification is 0.5 ng/mL.

Figure 14.4.2.2.1
Mean (±SD) GS1-144 Plasma Concentrations
PKAS

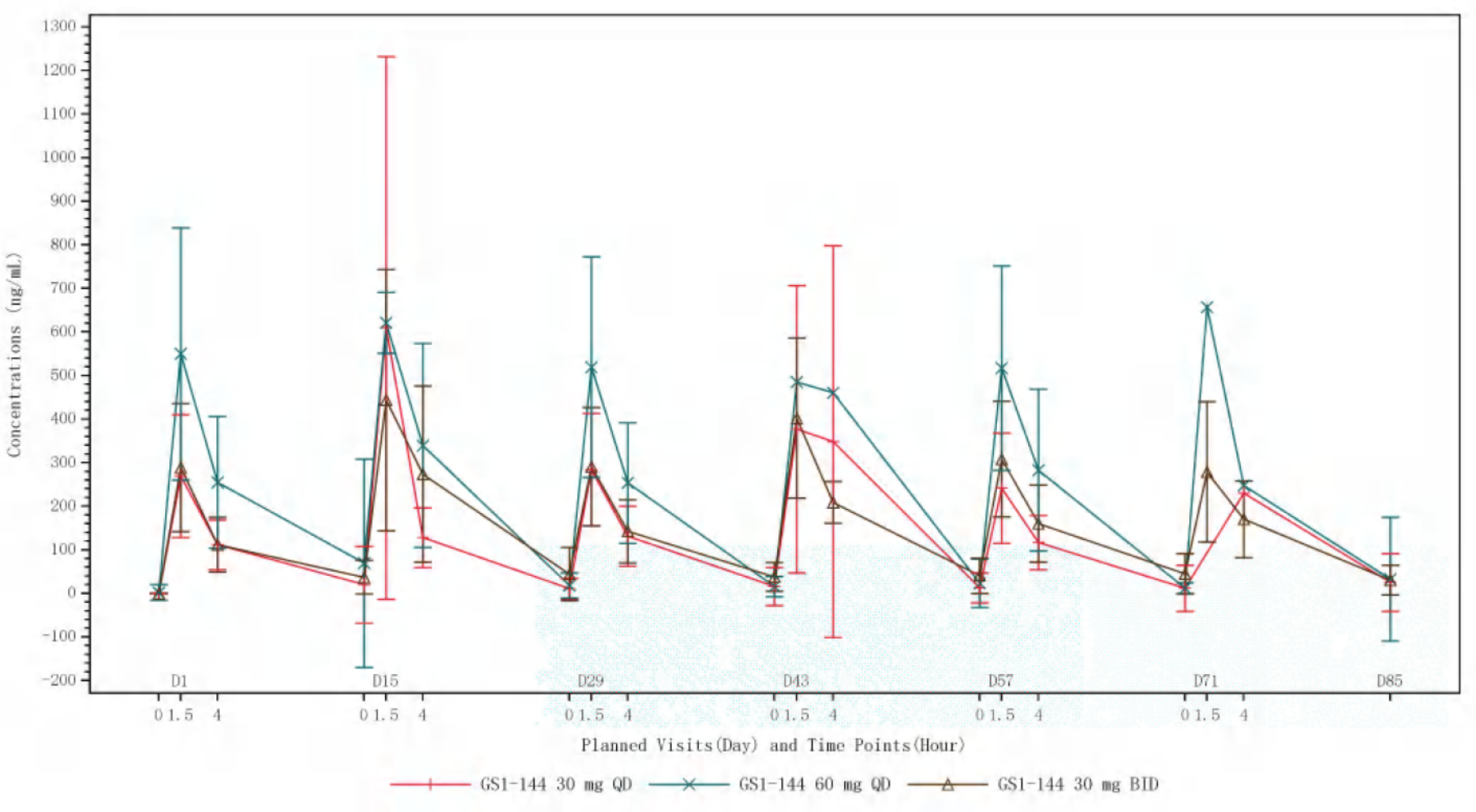


Figure 14.4.2.2.2
Mean (±SD) M1 Plasma Concentrations
PKAS

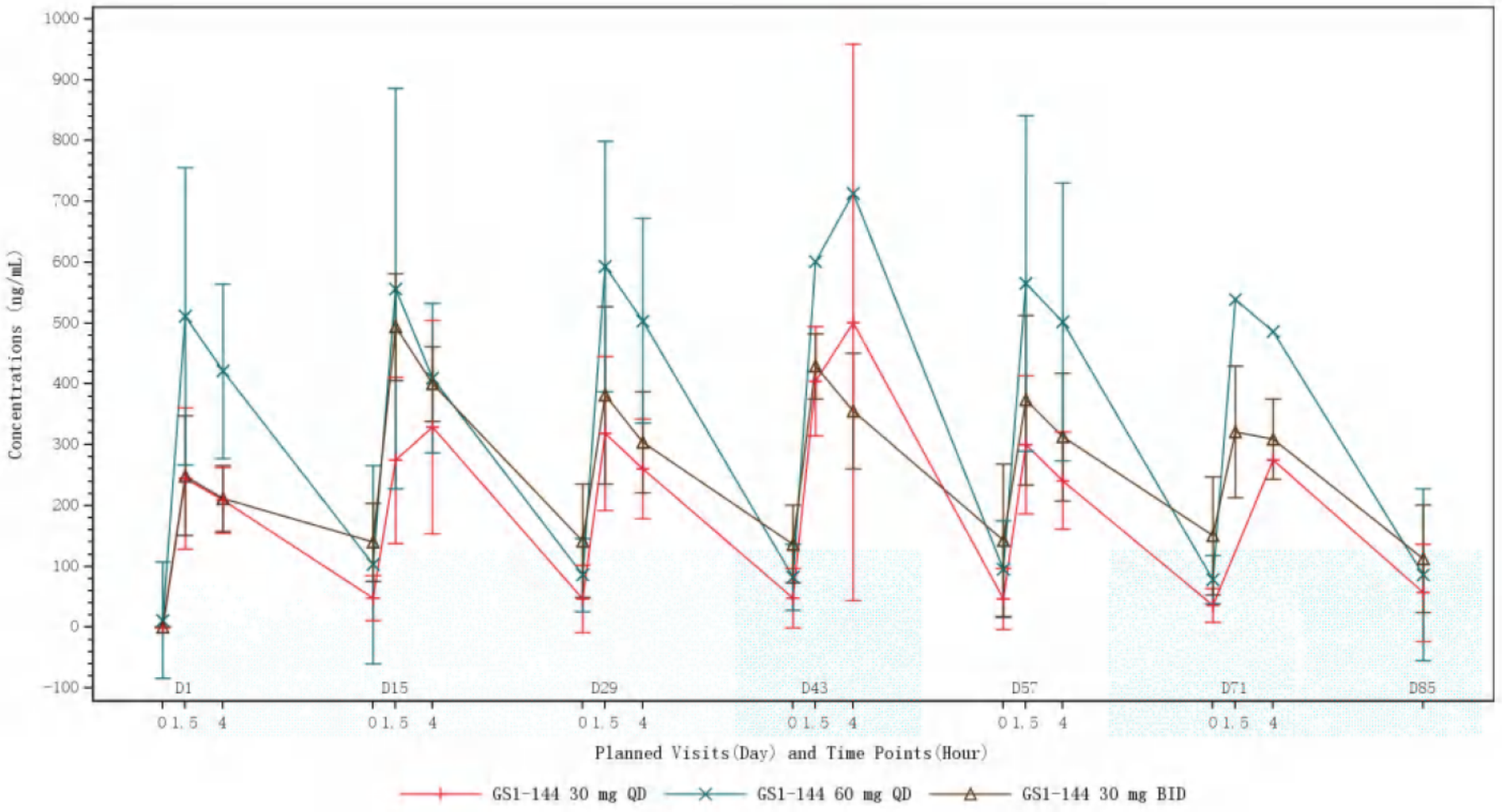


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

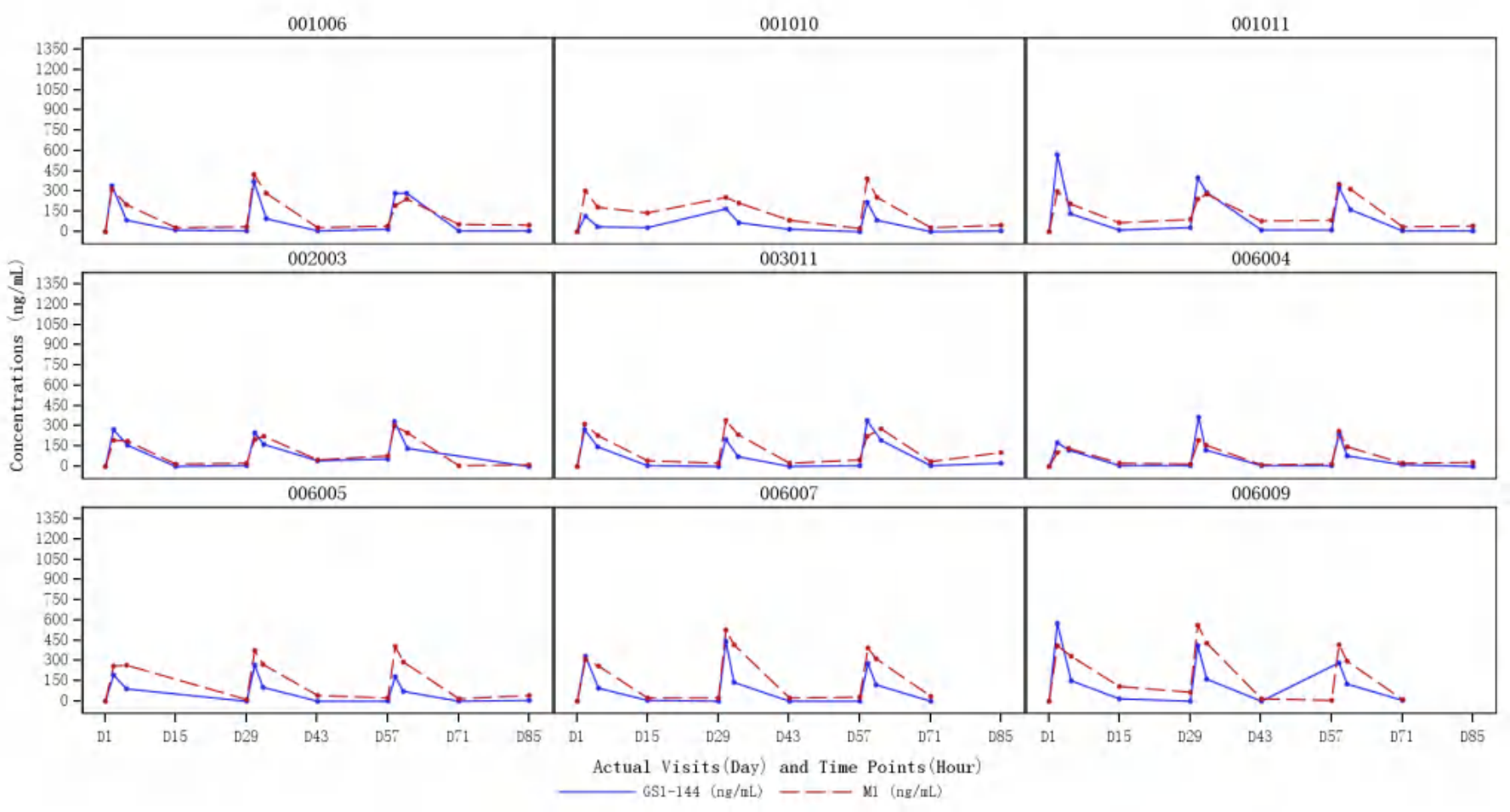


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

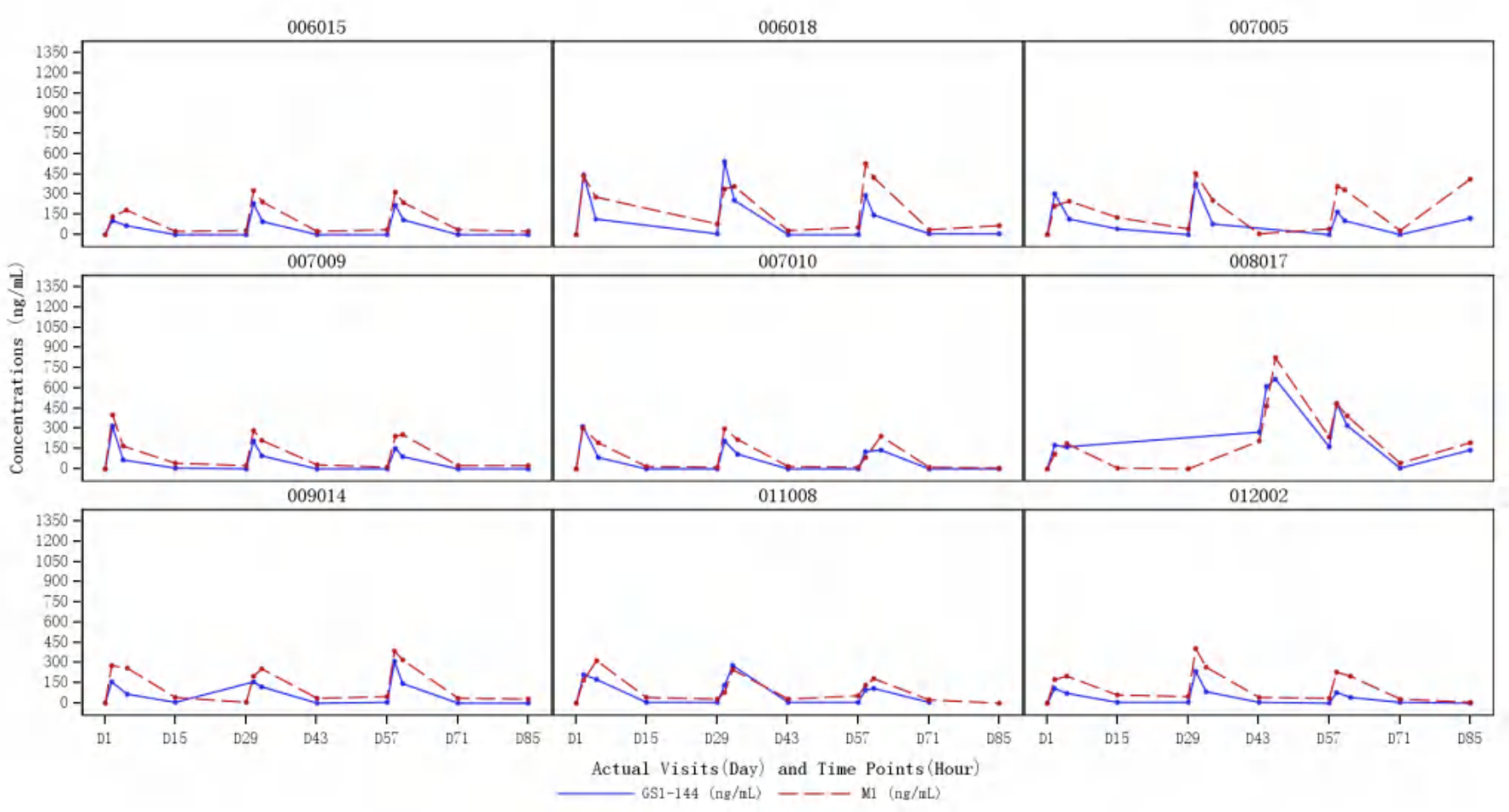


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

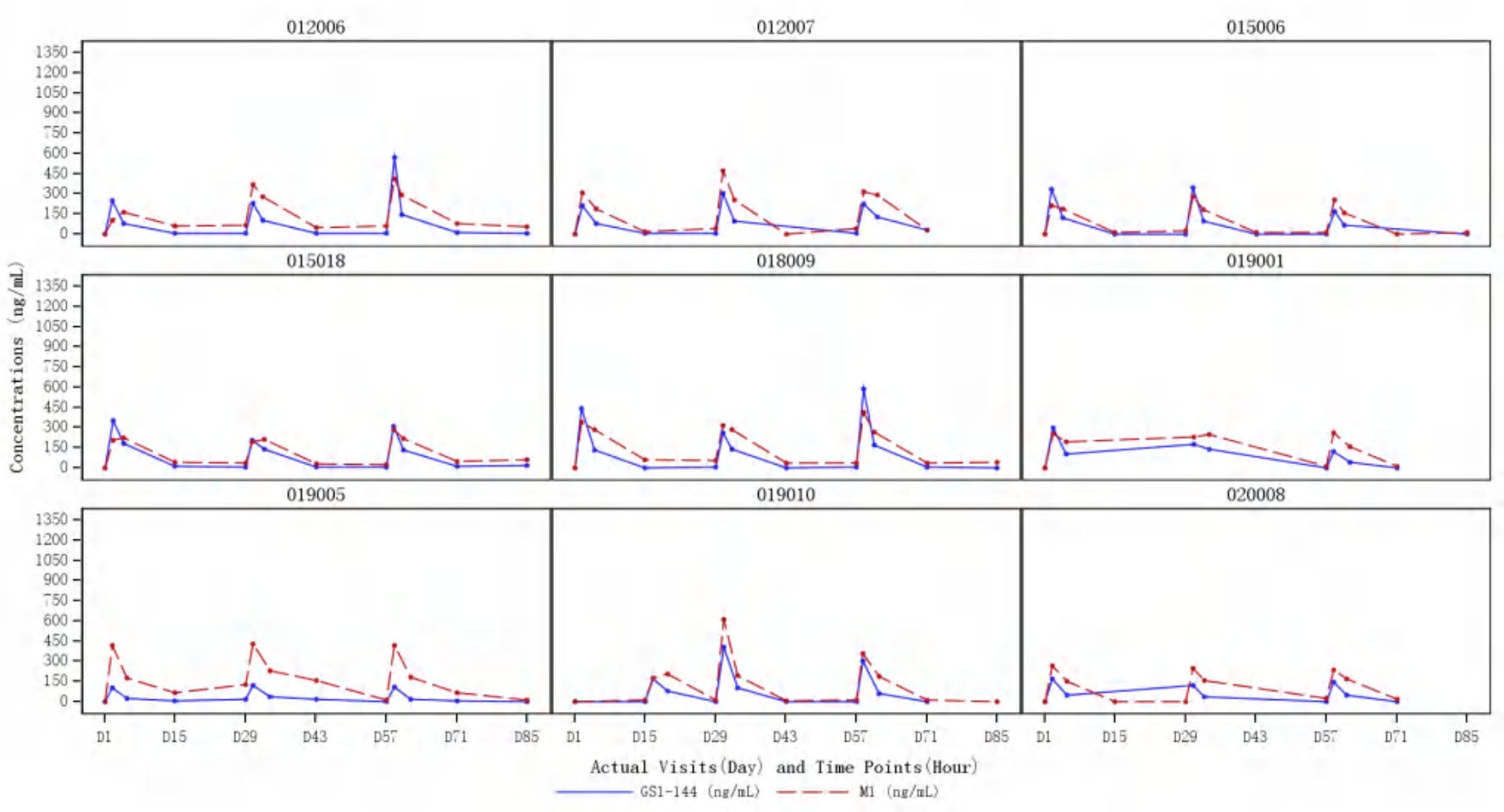


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

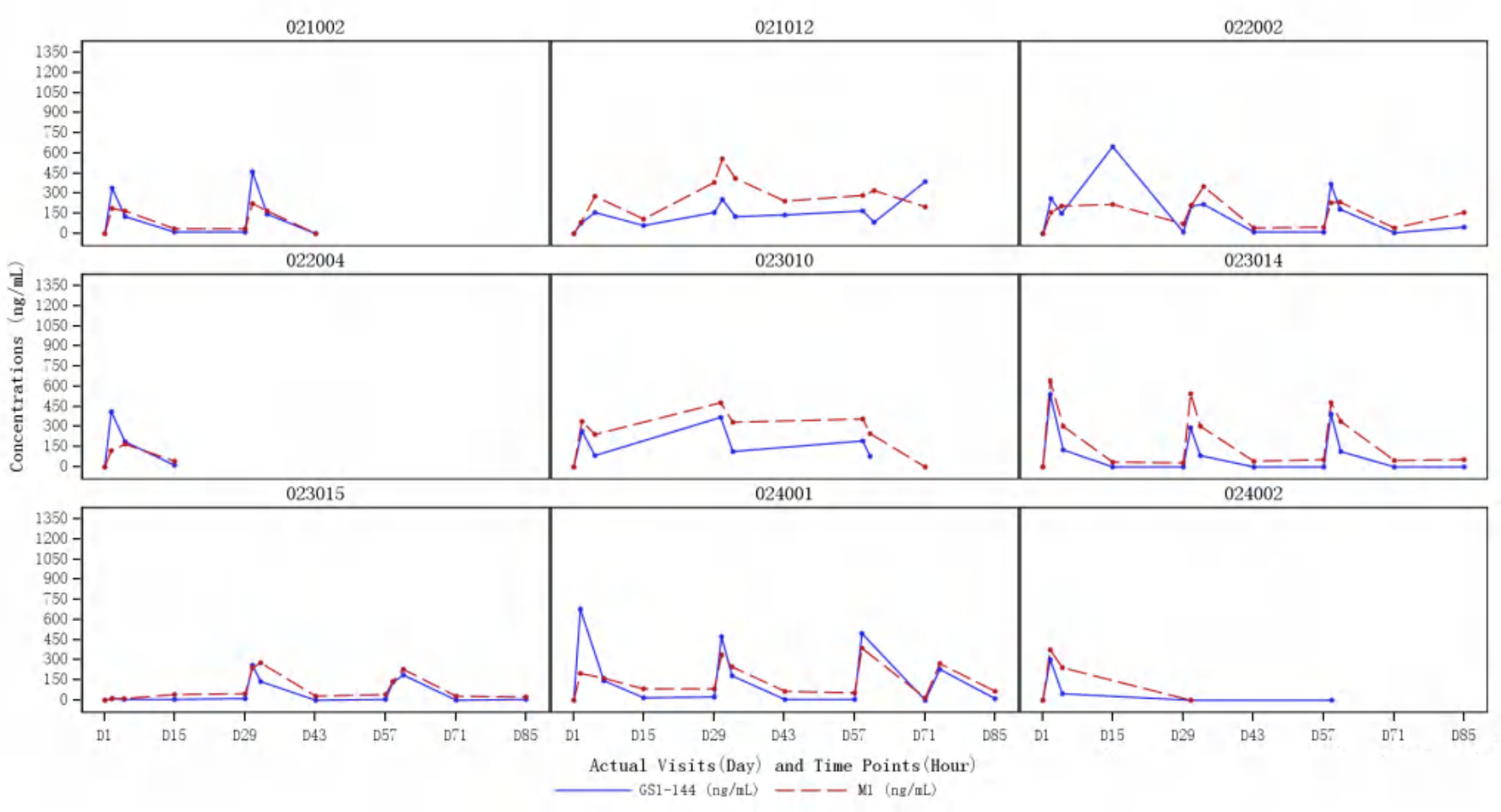


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

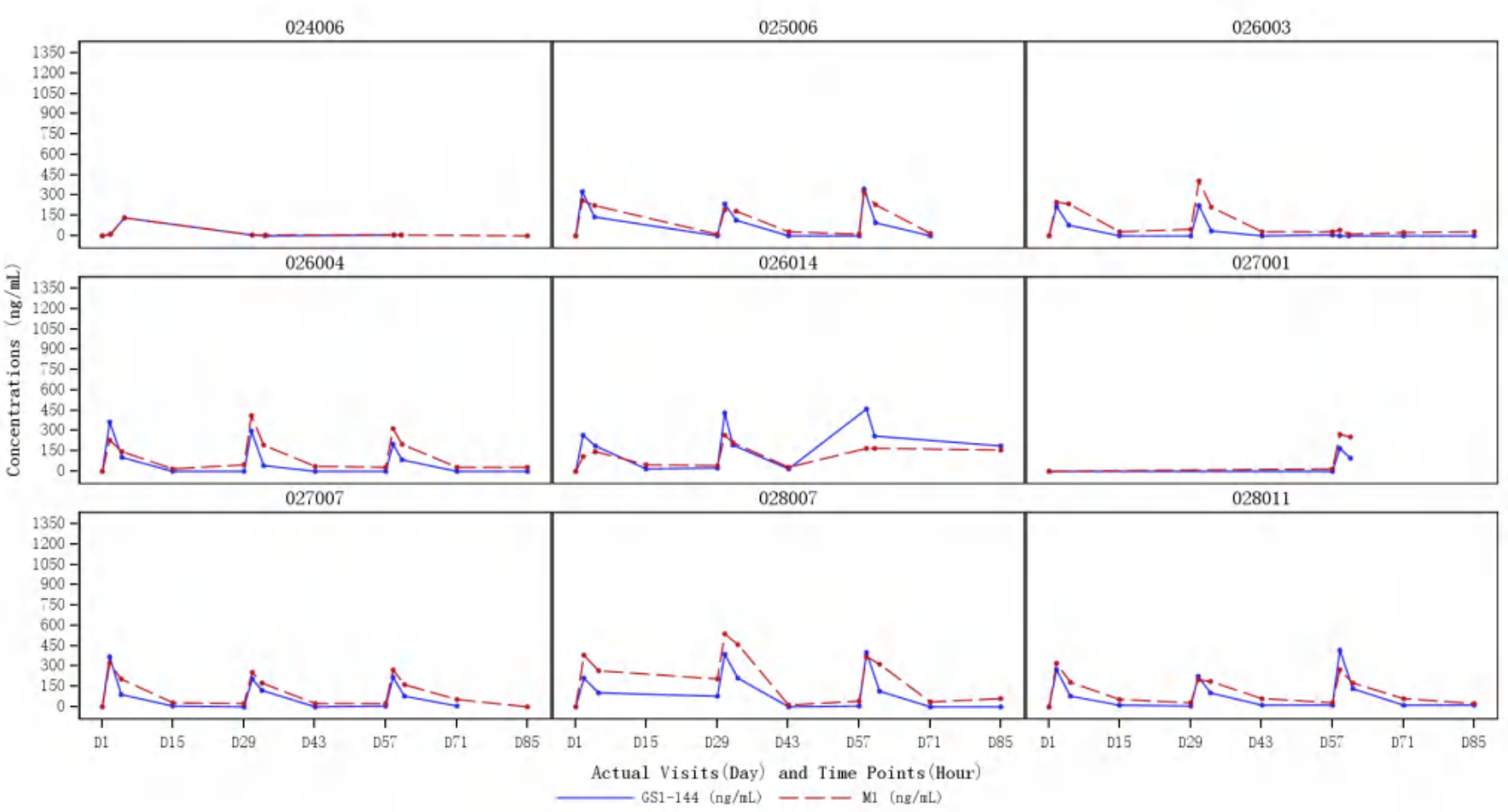


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

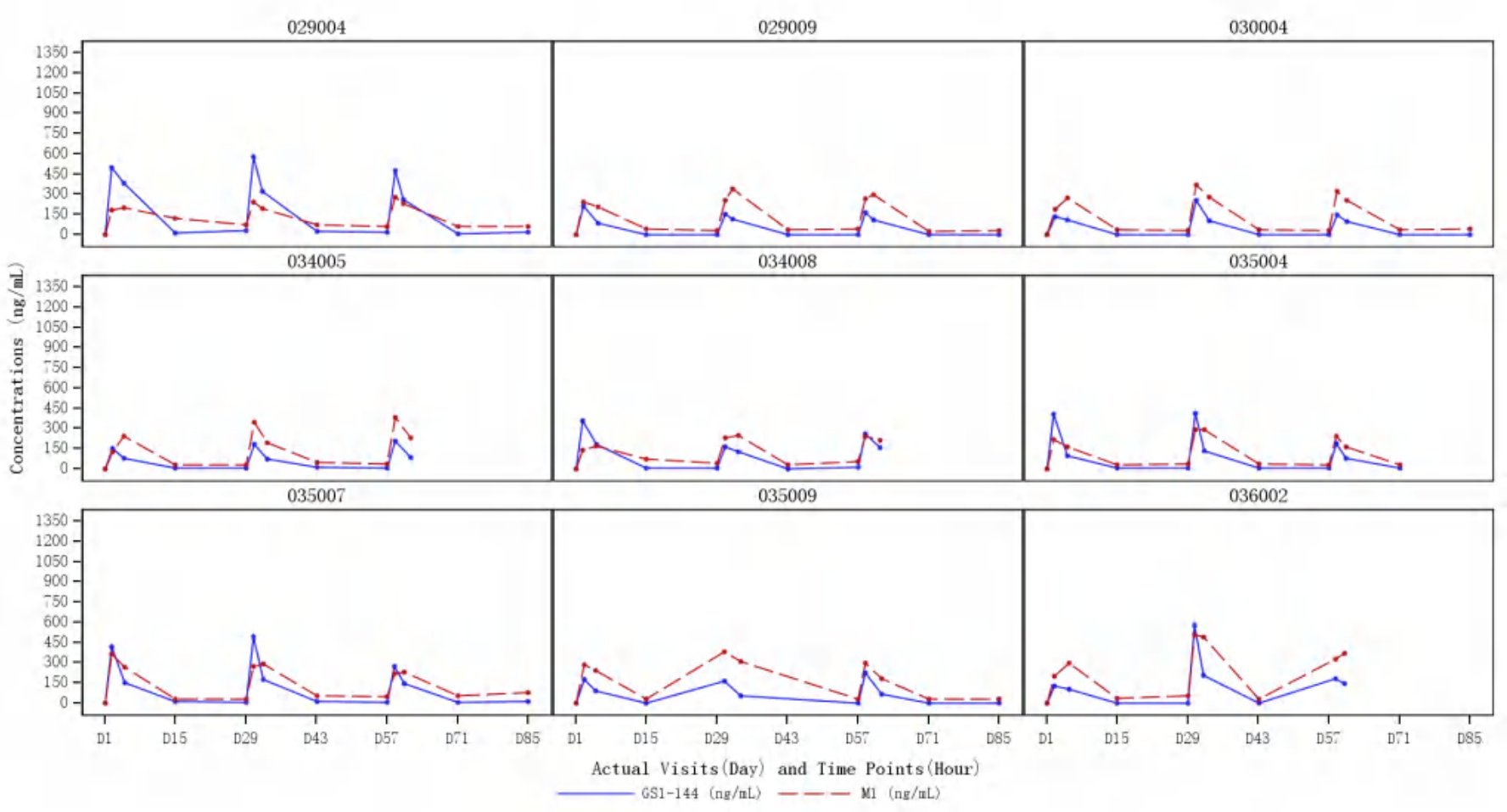


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

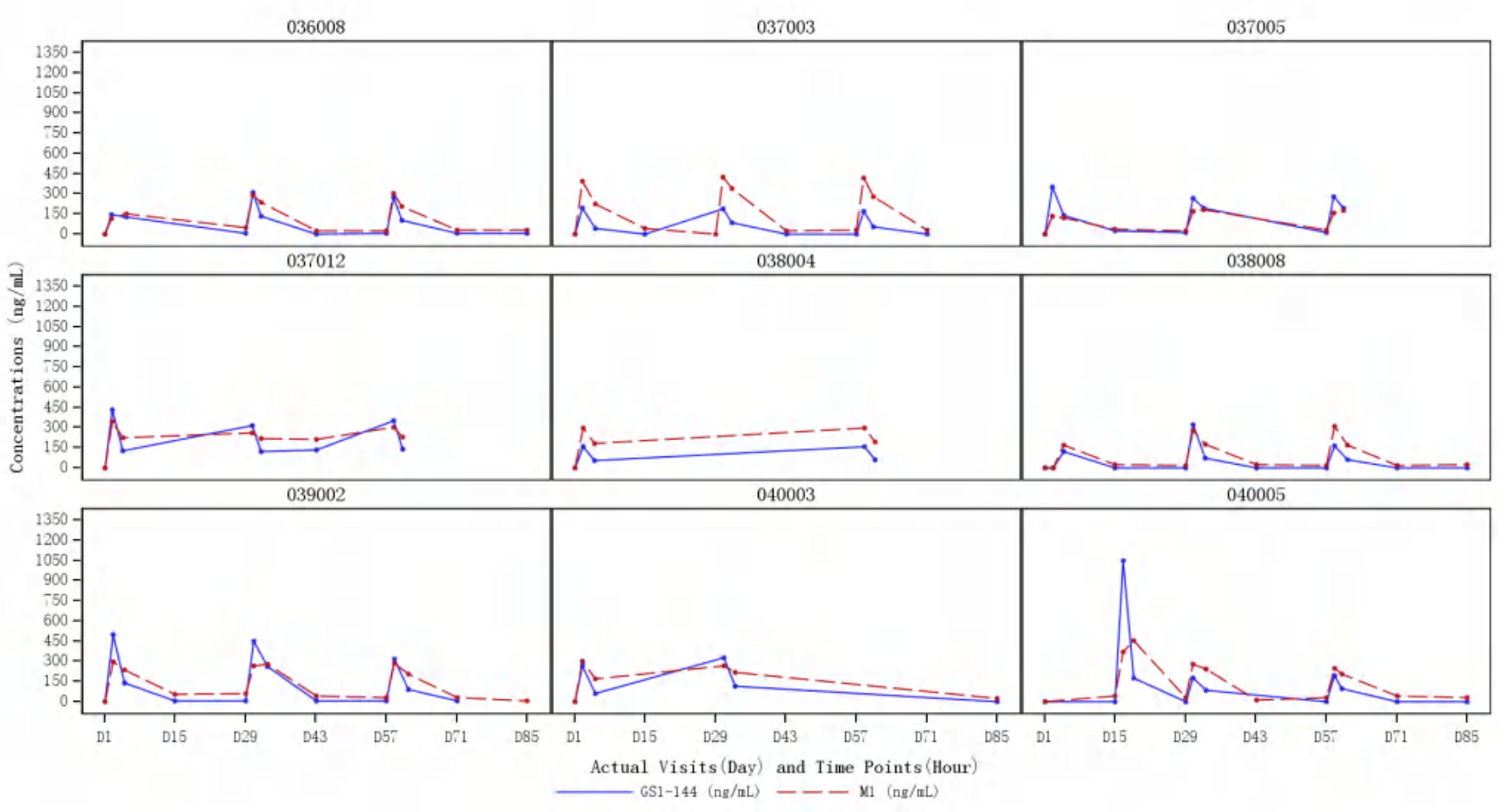


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg QD

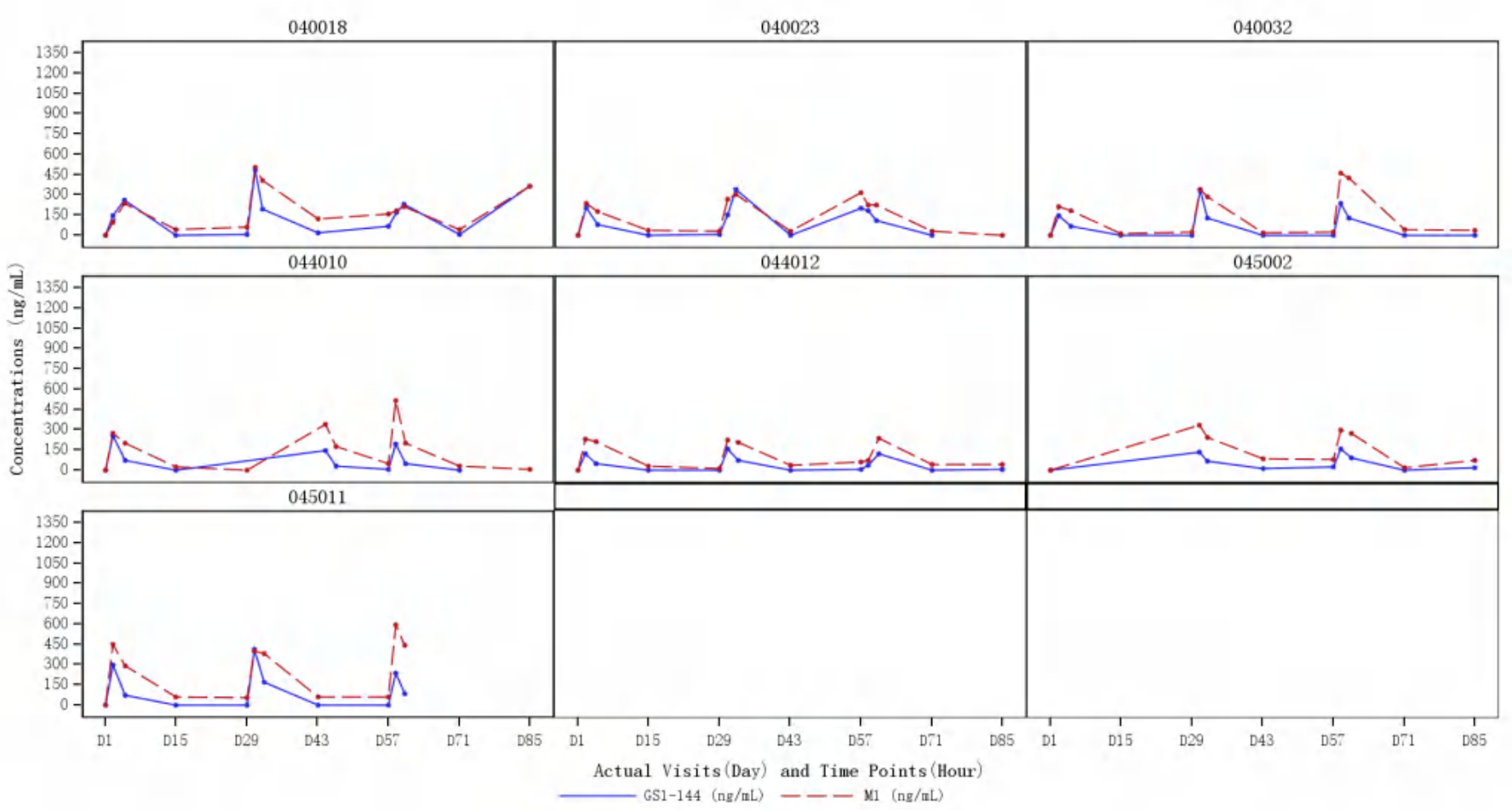


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

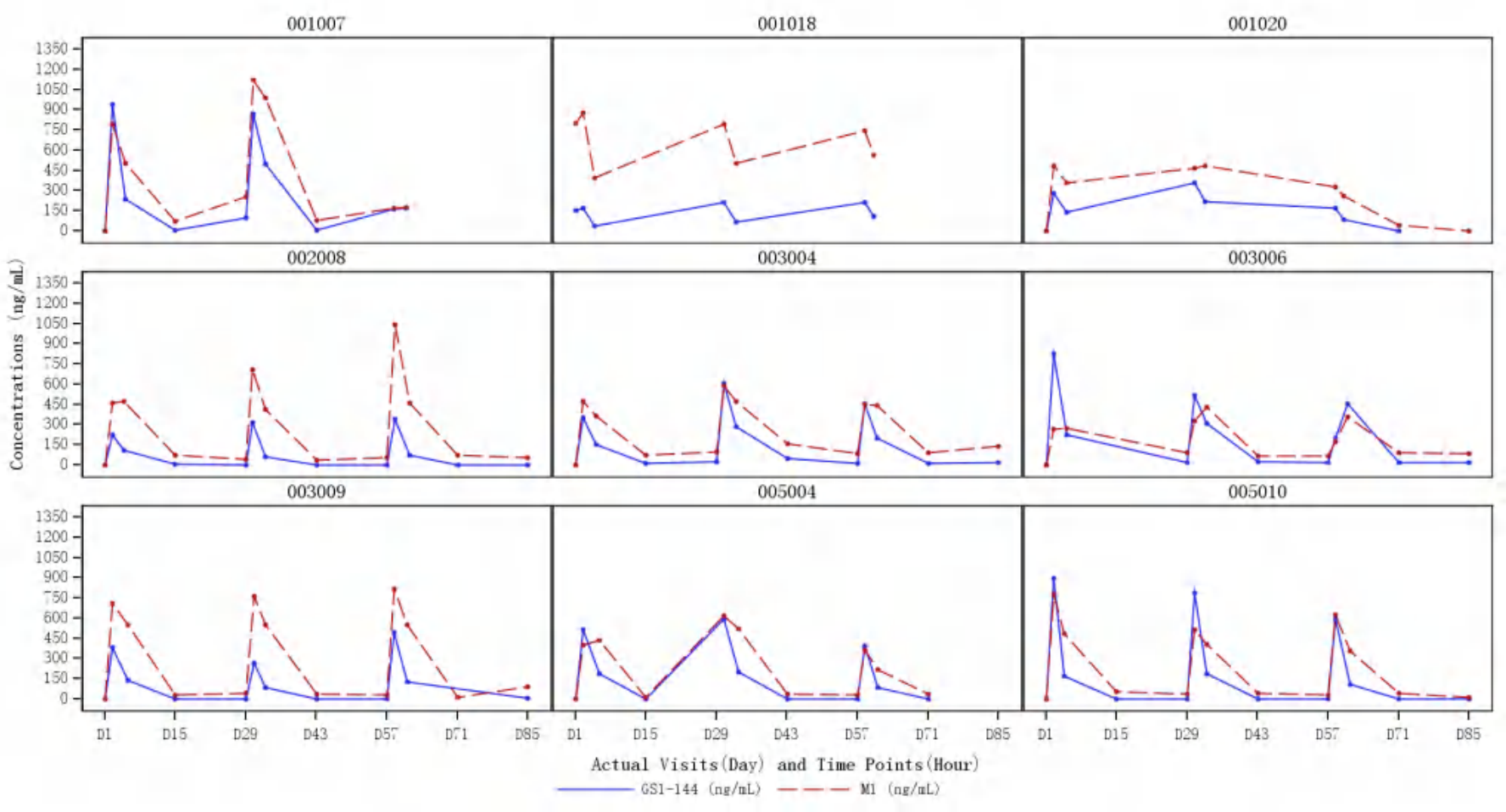


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

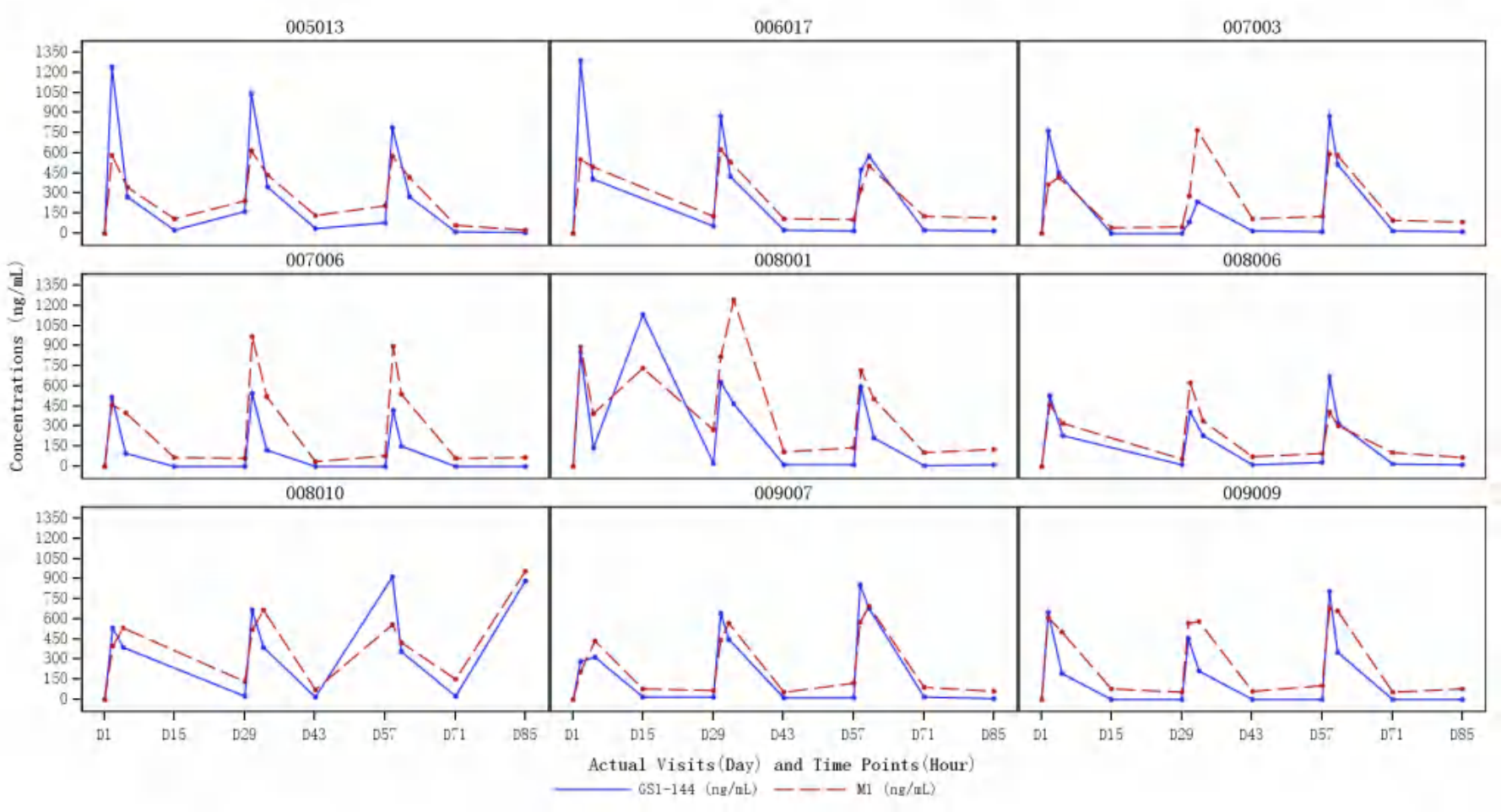


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

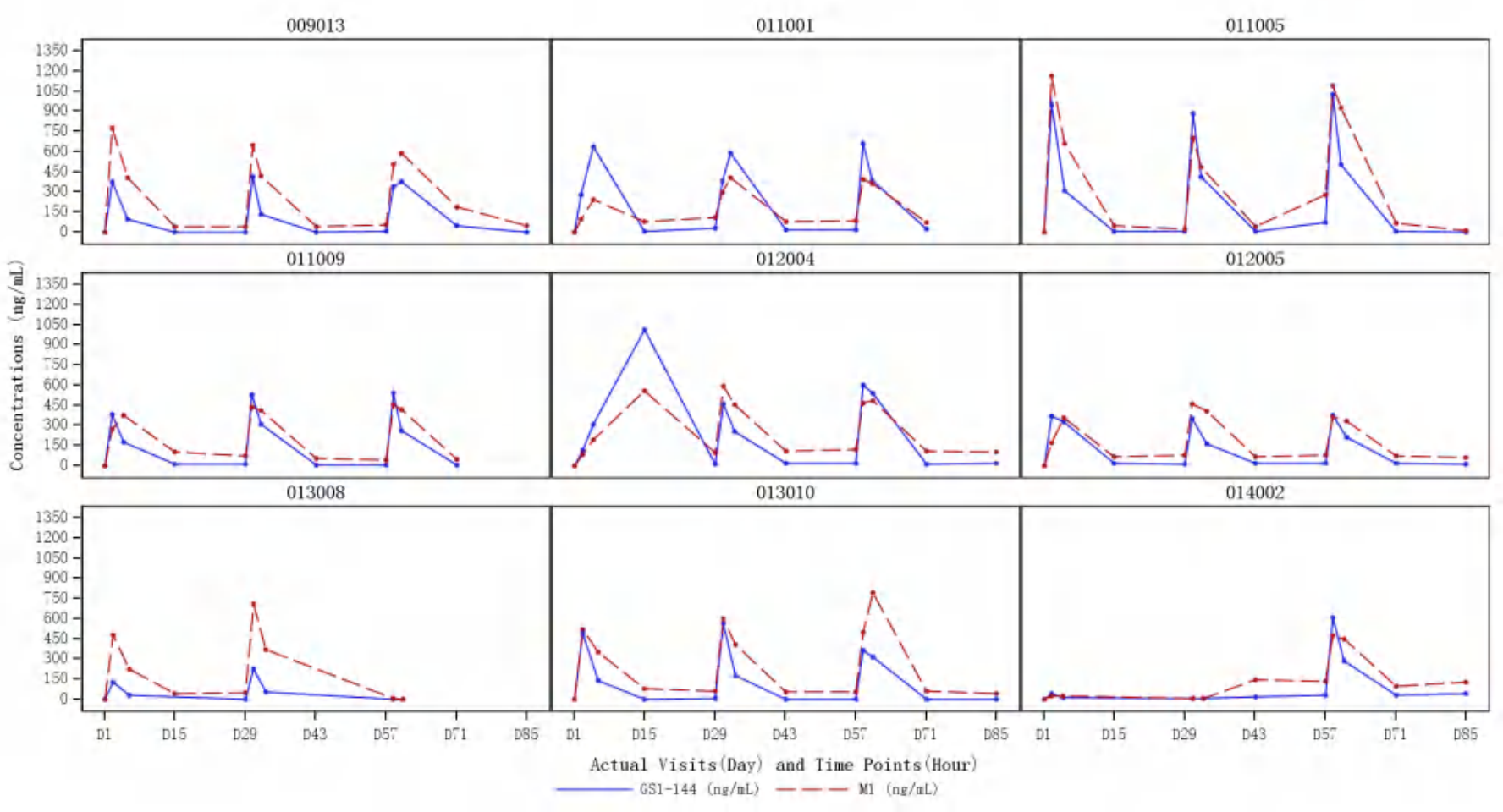


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

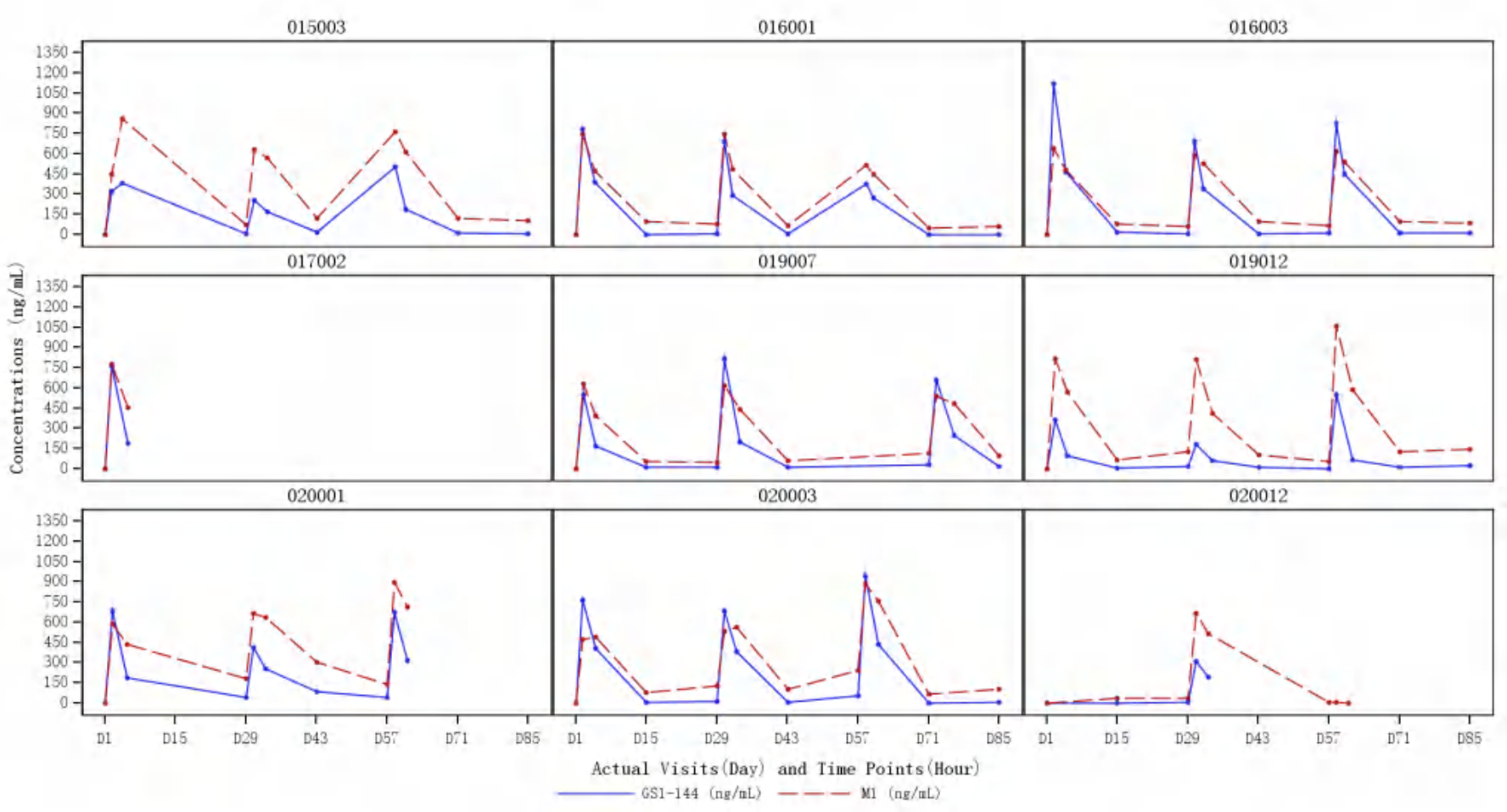


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

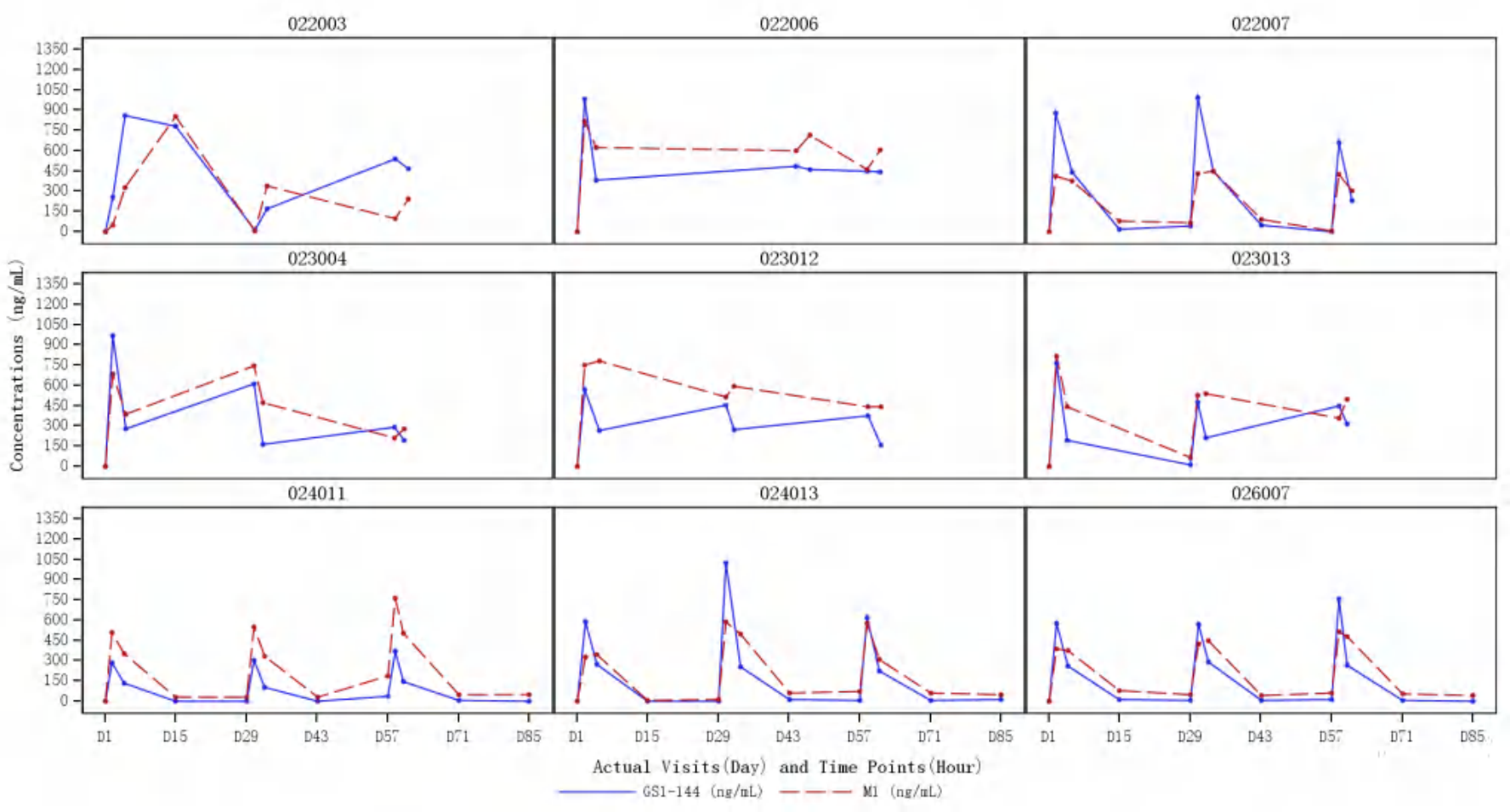


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

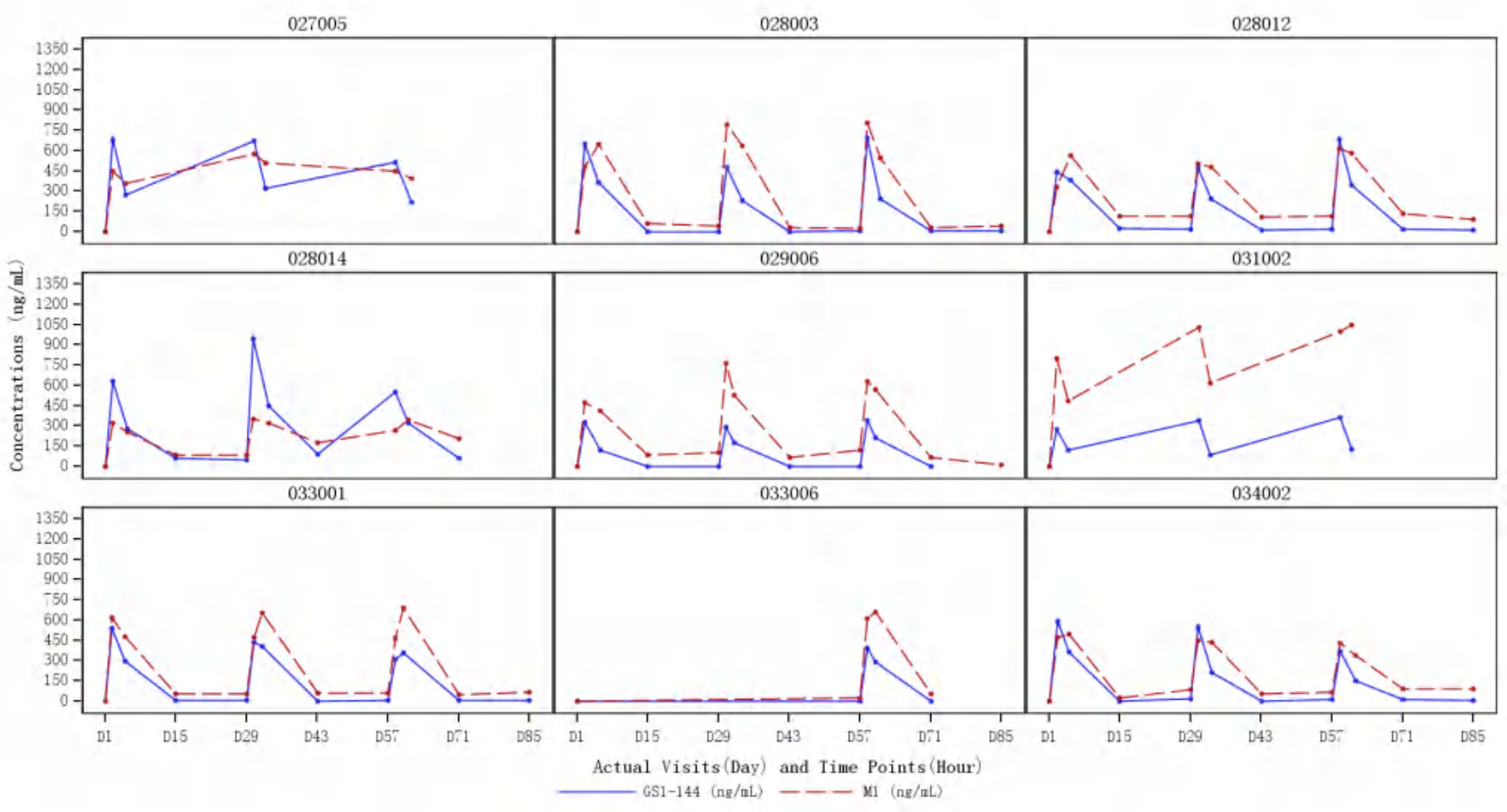


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

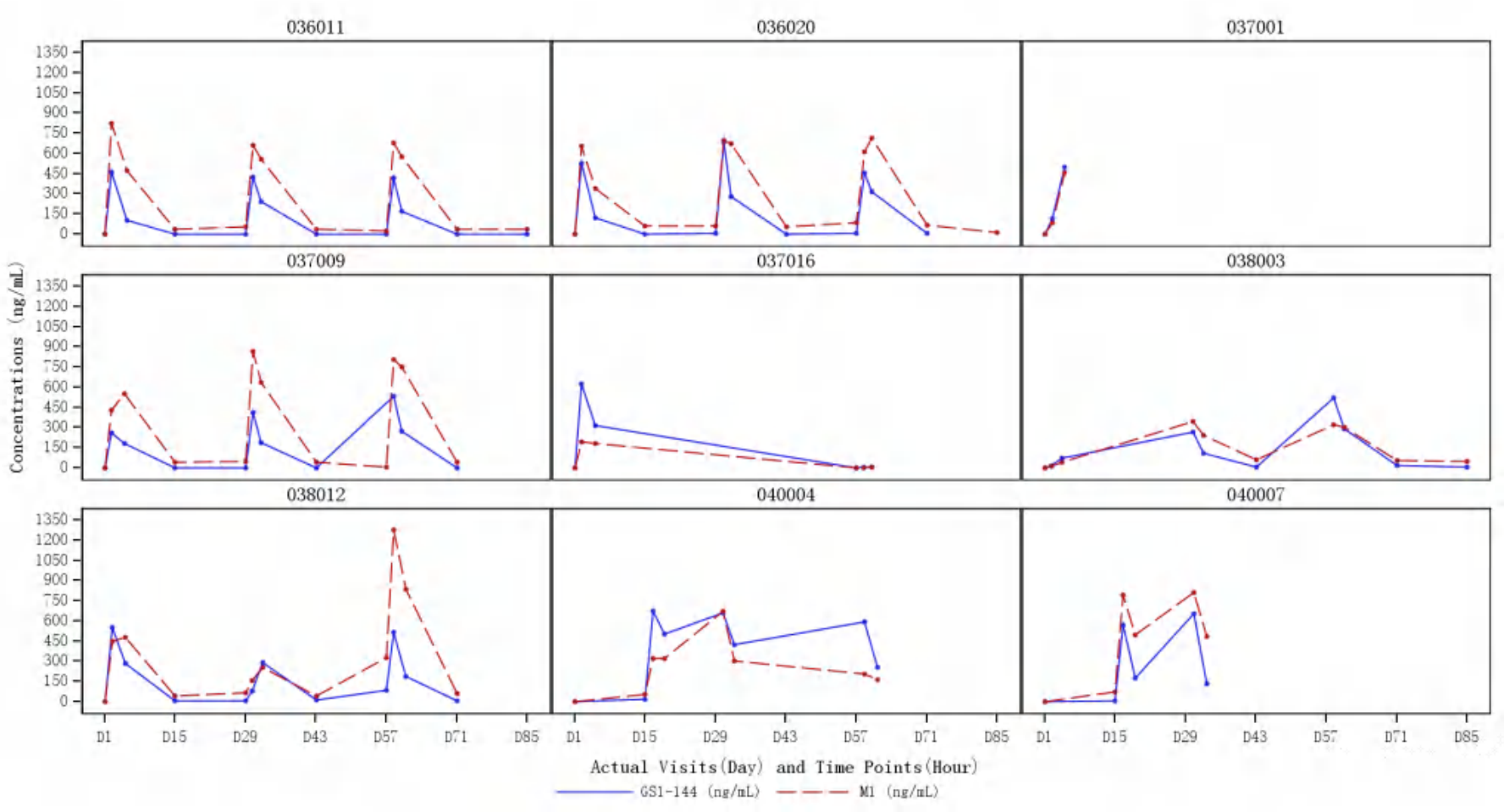


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 60 mg QD

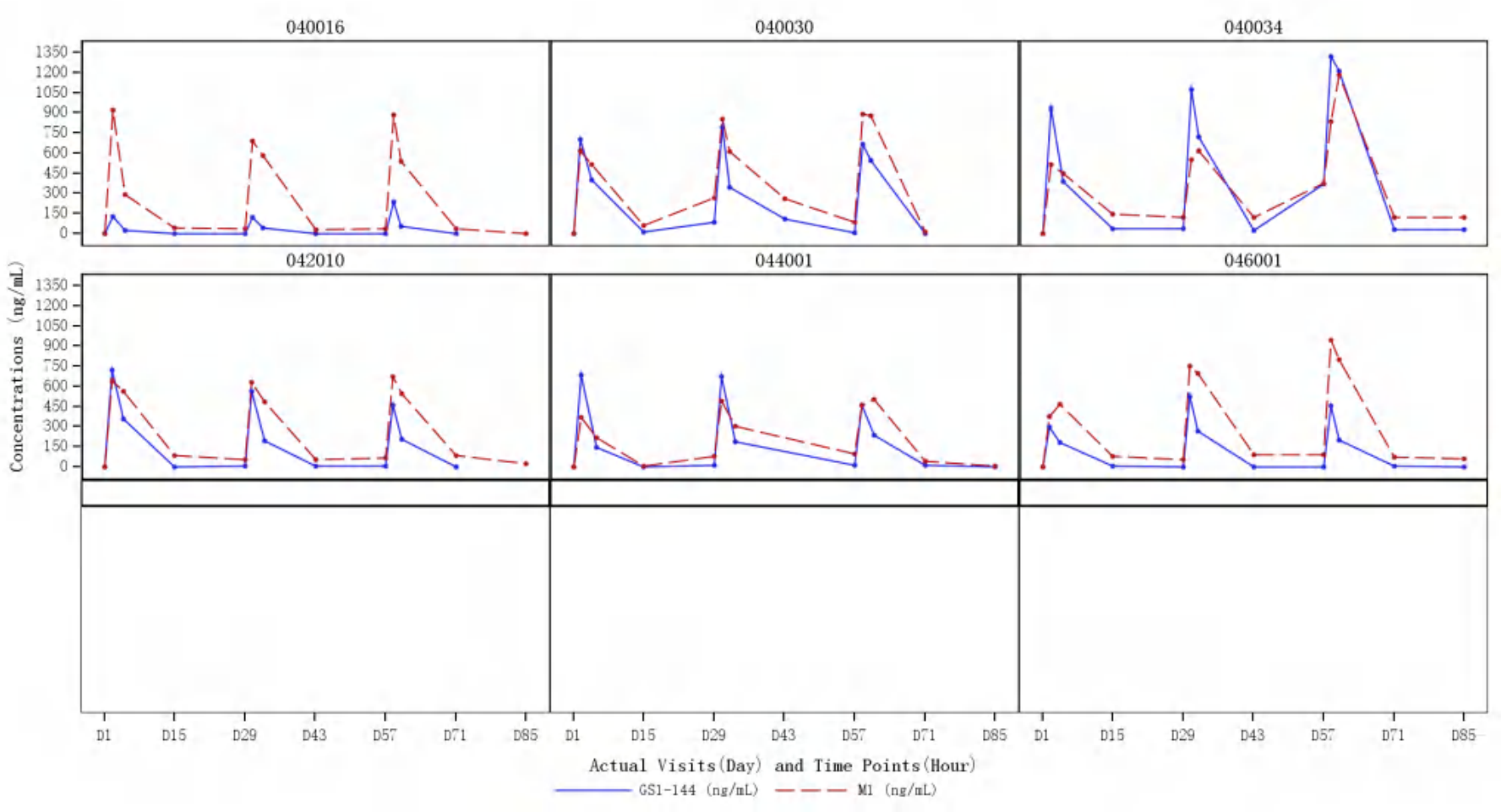


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

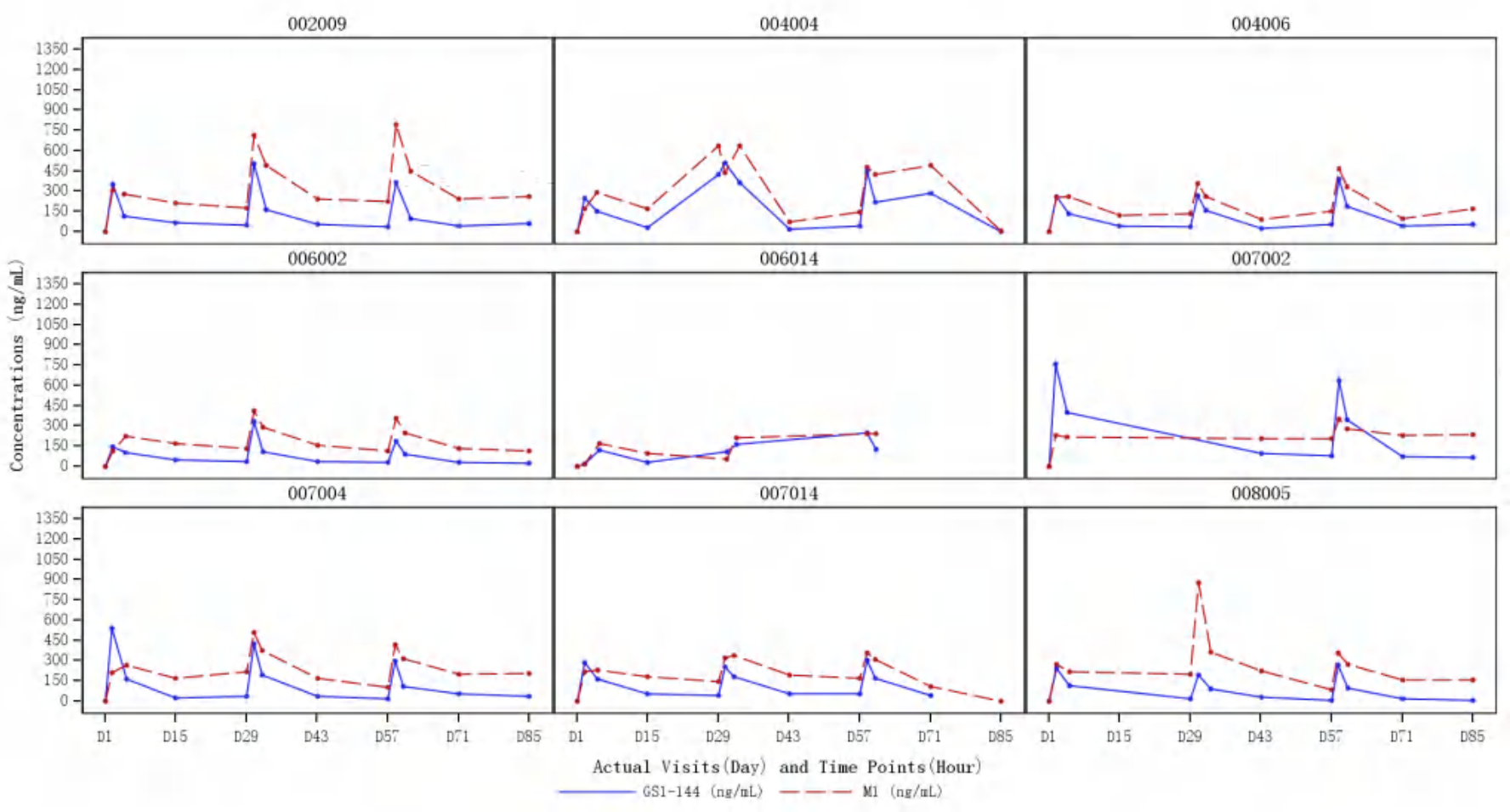


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

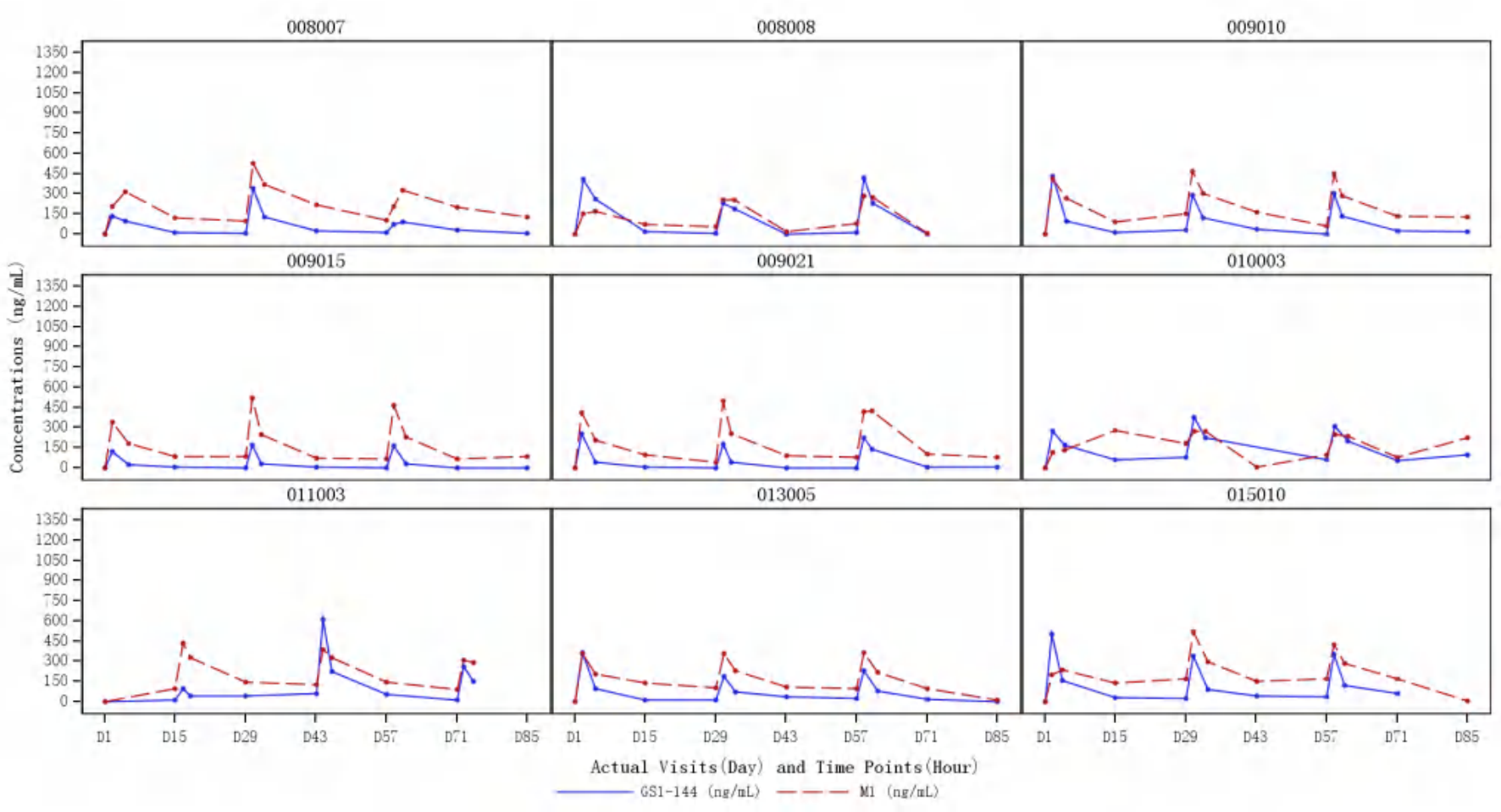


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

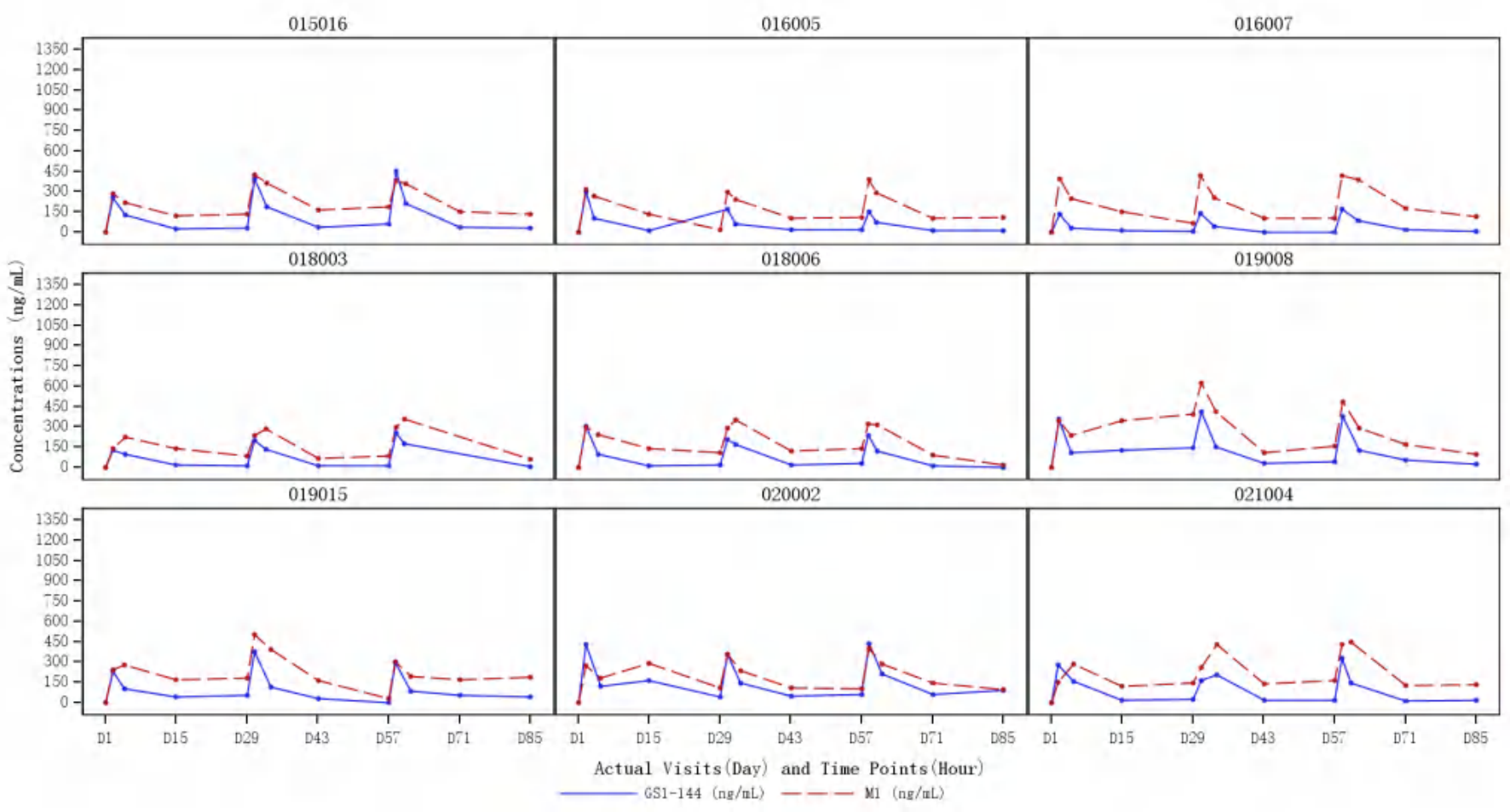


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

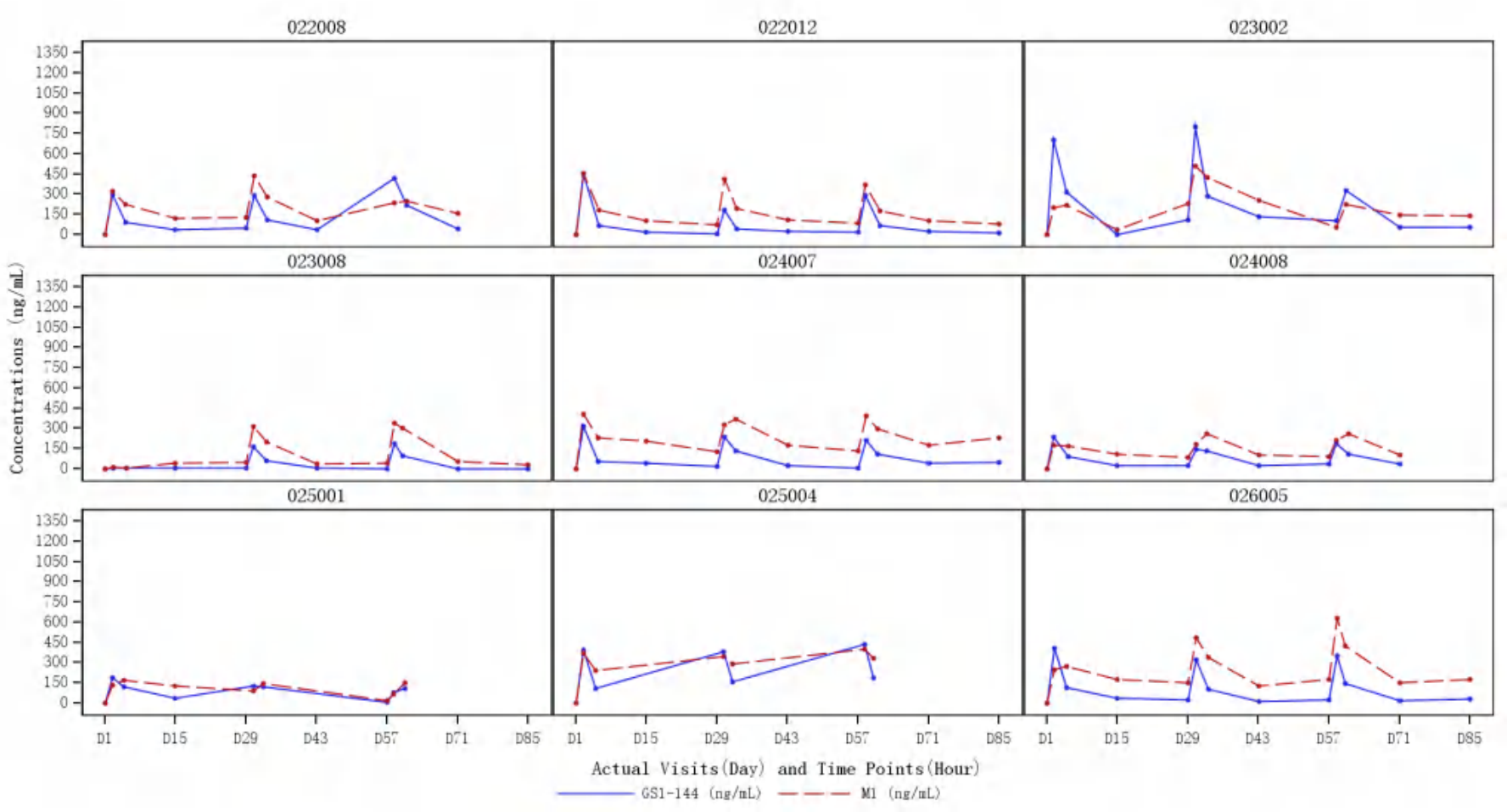


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

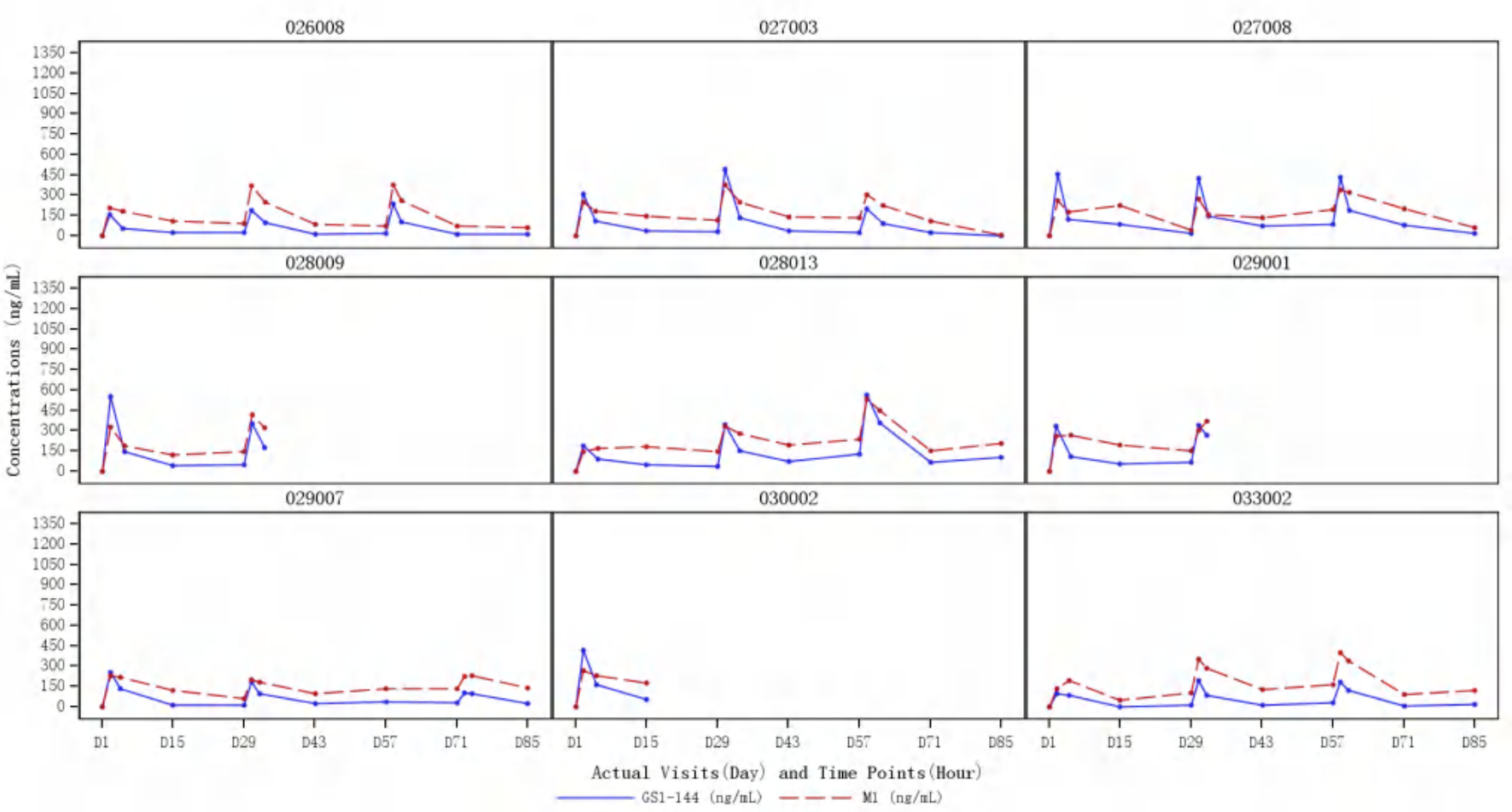


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

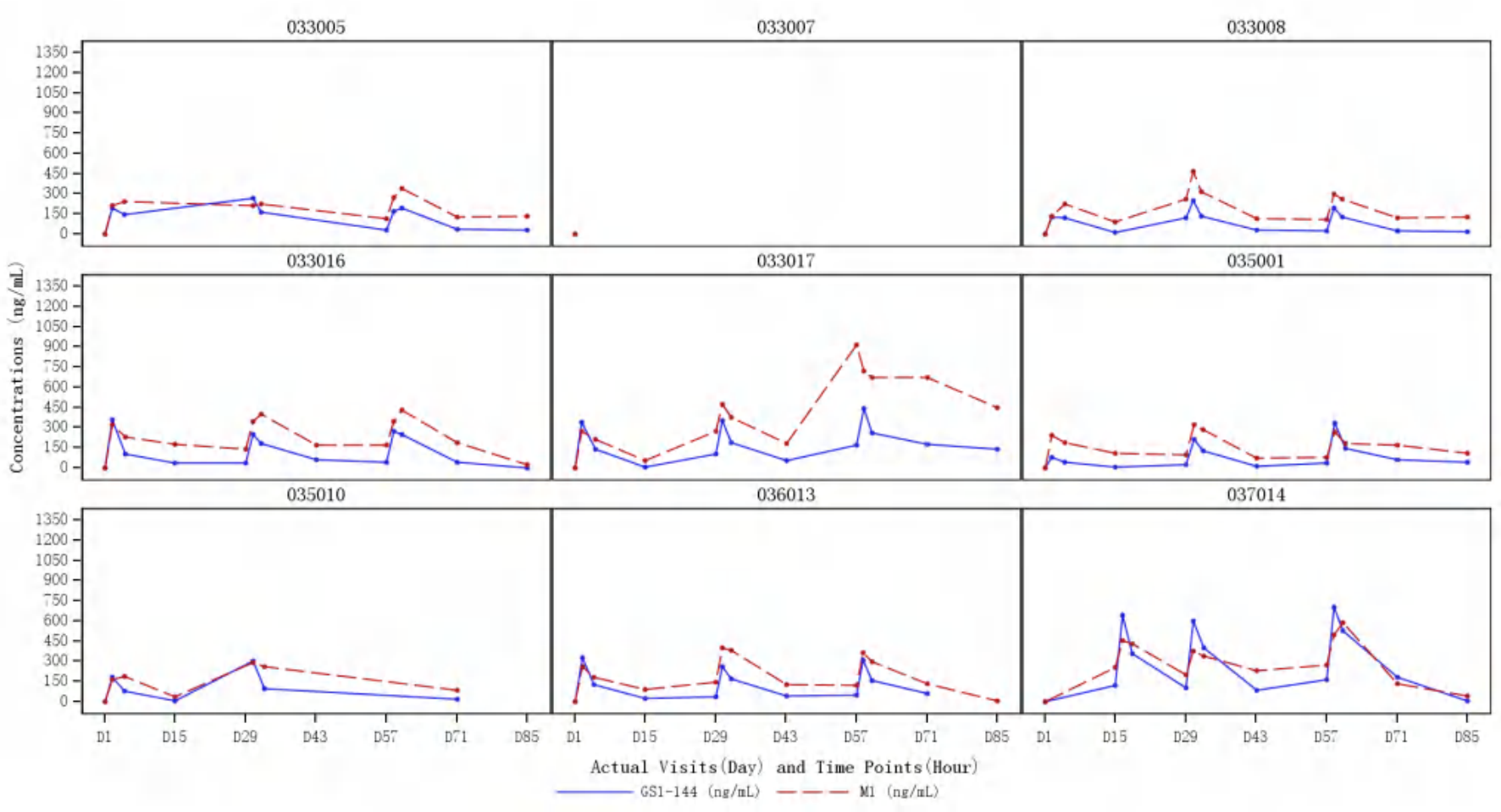


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

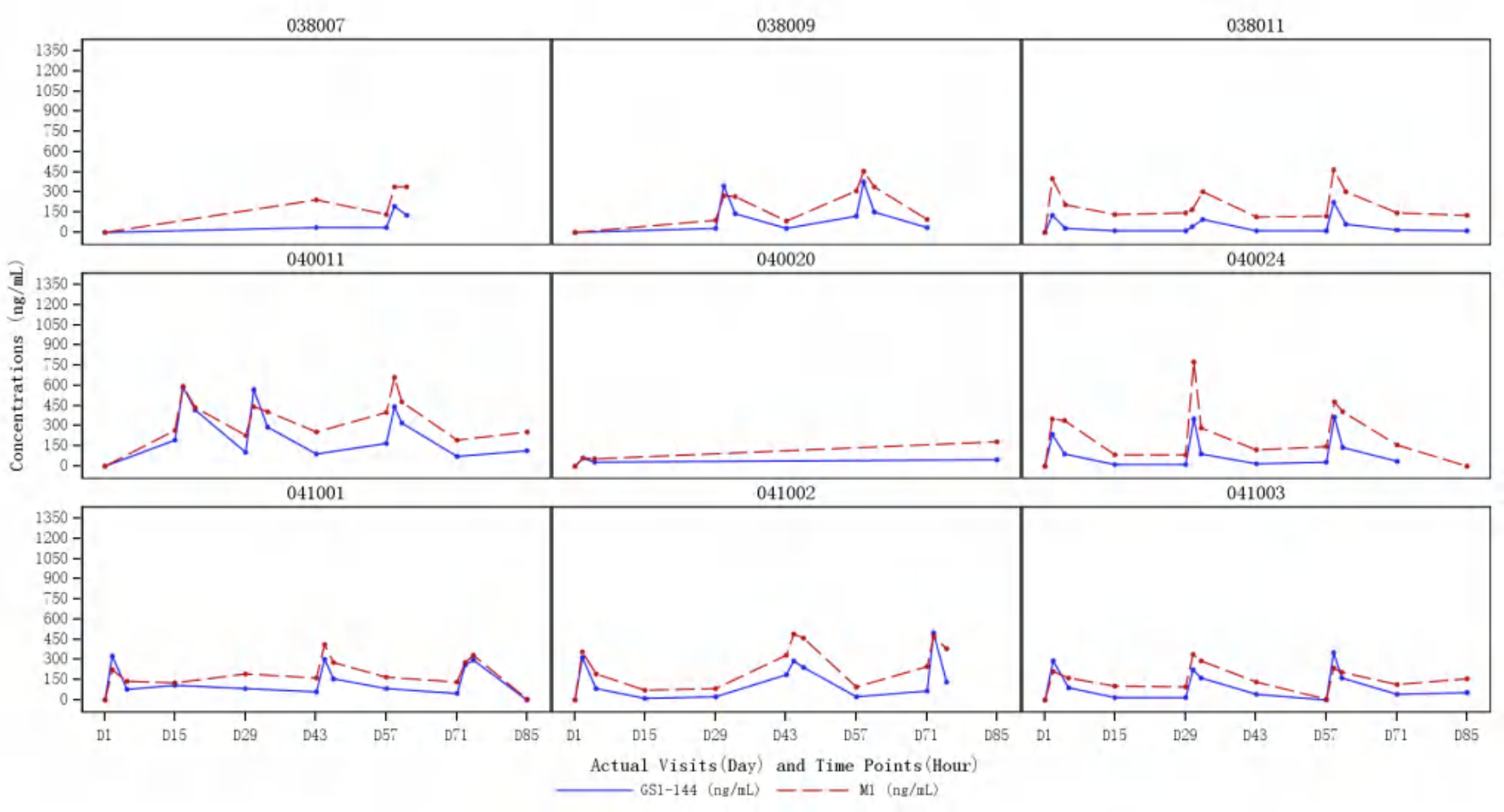


Figure 14.4.2.3
GS1-144 and M1 Plasma Concentrations by Subject
PKAS

Treatment Group: GS1-144 30 mg BID

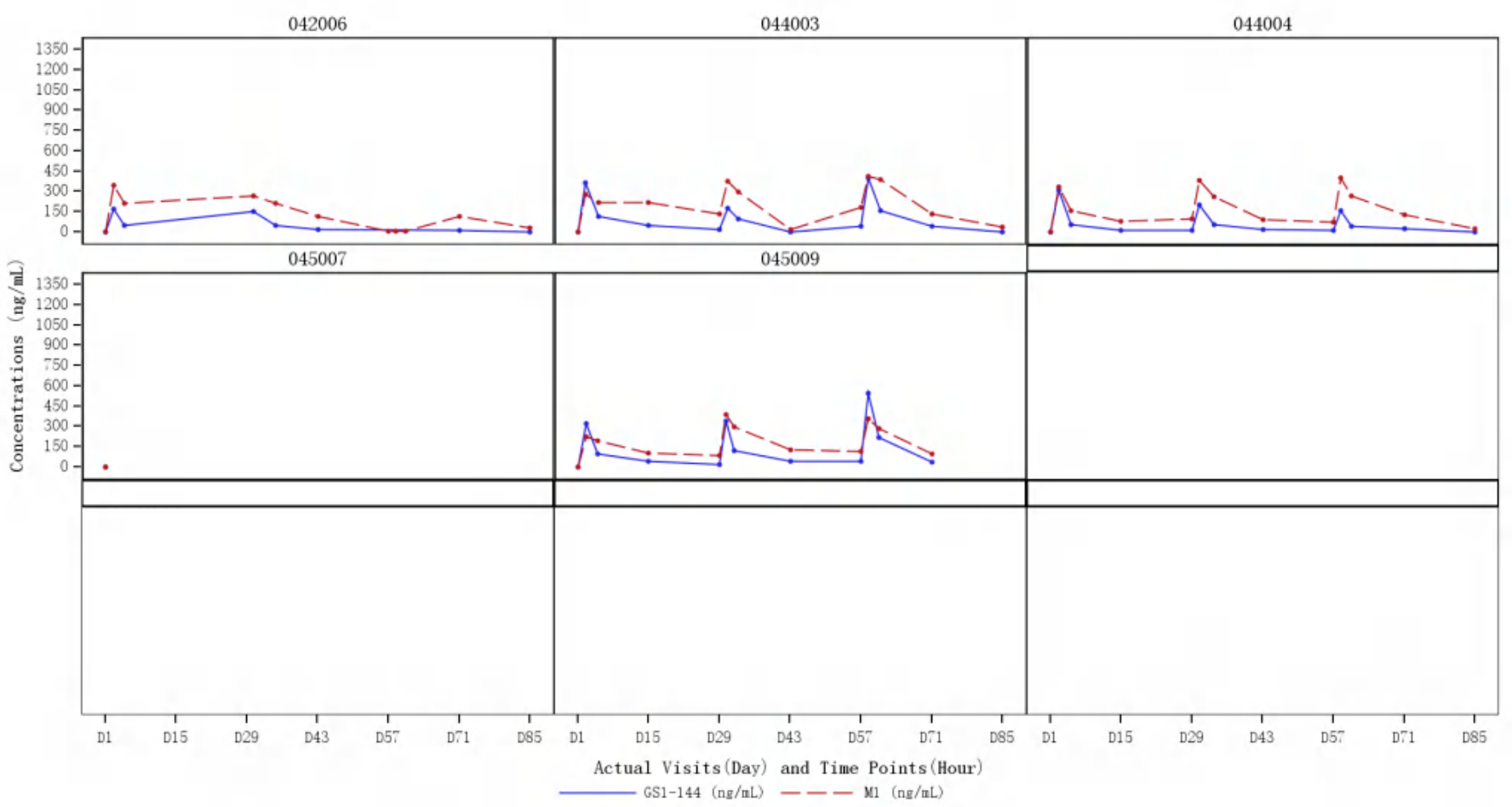


Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: Placebo

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Observed Value	D1	Pre-dose	69	37.65	13.464	35.8	35.63	10.0	80.0	35.33	38.4
		1.5h	64	37.35	14.030	37.6	35.27	7.3	79.2	34.87	40.0
		4h	63	37.41	12.899	34.5	36.68	10.9	78.4	35.29	36.2
	D15	Pre-dose	69	36.87	14.101	38.2	35.32	8.7	78.8	34.05	44.3
		1.5h	5	27.36	18.391	67.2	21.59	7.7	56.5	22.48	84.3
		4h	6	27.10	15.143	55.9	26.11	10.6	54.8	23.93	59.4
	D29	Pre-dose	66	36.66	13.868	37.8	35.39	8.8	80.0	33.91	44.0
		1.5h	63	34.52	12.776	37.0	33.54	7.6	65.6	31.94	44.2
		4h	63	34.74	13.083	37.7	33.14	6.0	65.9	32.06	45.4
	D43	Pre-dose	65	36.16	13.349	36.9	35.35	4.3	74.6	33.25	48.1
		1.5h	3	42.08	23.013	54.7	33.22	24.8	68.2	38.31	55.8
		4h	3	41.94	24.636	58.7	31.67	24.1	70.1	37.67	60.0
	D57	Pre-dose	65	37.01	14.960	40.4	34.32	6.2	77.7	33.52	52.6
		1.5h	62	35.59	13.957	39.2	33.94	5.9	68.8	32.52	48.9
		4h	62	36.13	13.503	37.4	34.06	7.2	72.2	33.44	44.0
	D71	Pre-dose	65	36.33	14.546	40.0	35.72	8.5	81.8	33.24	47.5
		1.5h	3	30.96	13.352	43.1	30.69	17.8	44.5	28.93	48.8
		4h	3	27.16	12.195	44.9	27.12	15.0	39.4	25.20	51.7
	D85		64	37.57	13.131	35.0	37.25	8.5	74.9	35.04	41.9

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: Placebo

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Change from Baseline	D1	1.5h	64	-1.01	4.524		-0.79	-14.5	10.0		
		4h	63	-1.10	5.036		-0.67	-20.5	11.7		
	D15	Pre-dose	69	-0.78	7.009		-0.13	-29.7	12.7		
		1.5h	5	-1.20	7.116		-0.79	-10.4	9.2		
		4h	6	-1.46	4.476		-3.42	-4.1	7.4		
	D29	Pre-dose	66	-0.06	8.155		0.26	-26.2	22.0		
		1.5h	63	-1.49	7.948		-1.31	-27.1	18.4		
		4h	63	-1.27	7.773		-2.15	-23.4	21.8		
	D43	Pre-dose	65	-0.61	9.152		-0.78	-34.0	34.1		
		1.5h	3	-9.62	6.378		-11.81	-14.6	-2.4		
		4h	3	-9.77	6.507		-9.97	-16.2	-3.2		
	D57	Pre-dose	65	0.14	10.553		-1.45	-32.1	39.0		
		1.5h	62	-1.69	9.505		-2.18	-32.5	40.3		
		4h	62	-1.15	8.383		-1.85	-17.4	30.0		
	D71	Pre-dose	65	-0.54	8.544		-0.71	-23.3	34.5		
		1.5h	3	2.45	1.522		3.23	0.7	3.4		
		4h	3	-1.35	1.051		-1.84	-2.1	-0.1		
	D85		64	0.66	7.900		0.30	-22.7	27.4		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: Placebo

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Percentage Change from Baseline	D1	1.5h	64	-2.95	11.739		-2.08	-36.7	23.2		
		4h	63	-1.89	13.314		-1.48	-53.4	29.9		
	D15	Pre-dose	69	-1.21	18.679		-0.43	-77.4	32.4		
		1.5h	5	-10.34	23.138		-3.91	-35.1	19.4		
		4h	6	-8.14	11.798		-12.21	-15.4	15.7		
	D29	Pre-dose	66	0.54	22.195		0.87	-68.4	66.8		
		1.5h	63	-4.02	20.566		-4.90	-70.6	55.4		
		4h	63	-3.78	21.094		-6.35	-61.1	66.3		
	D43	Pre-dose	65	2.58	47.671		-2.79	-88.7	341.0		
		1.5h	3	-18.09	11.183		-14.76	-30.6	-9.0		
		4h	3	-19.28	12.579		-12.46	-33.8	-11.6		
	D57	Pre-dose	65	0.90	29.657		-3.78	-83.8	136.9		
		1.5h	62	-3.61	27.827		-5.65	-84.6	141.4		
		4h	62	-2.74	23.218		-5.19	-36.9	105.4		
	D71	Pre-dose	65	-1.72	21.563		-1.74	-70.1	72.8		
		1.5h	3	8.17	4.249		7.84	4.1	12.6		
		4h	3	-5.69	5.880		-4.46	-12.1	-0.5		
	D85		64	2.52	19.492		0.96	-32.2	57.5		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 30 mg QD

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Observed Value	D1	Pre-dose	70	38.64	15.219	39.4	37.12	3.1	83.4	34.67	59.2
		1.5h	68	28.85	12.011	41.6	28.70	2.7	64.0	25.59	62.2
		4h	68	26.84	14.634	54.5	23.61	1.7	65.2	22.26	78.8
	D15	Pre-dose	68	39.94	14.712	36.8	39.90	6.3	85.1	36.73	47.9
		1.5h	2	28.26	8.351	29.6	28.26	22.4	34.2	27.63	30.7
		4h	2	27.58	10.734	38.9	27.58	20.0	35.2	26.52	41.6
	D29	Pre-dose	69	38.59	15.232	39.5	38.13	6.4	85.0	35.32	47.9
		1.5h	67	27.41	10.823	39.5	26.62	3.9	56.9	24.96	50.4
		4h	67	28.37	14.836	52.3	28.25	2.6	88.2	24.50	64.0
	D43	Pre-dose	69	37.12	14.608	39.4	36.48	4.4	82.8	33.38	56.9
		1.5h	2	12.24	6.908	56.5	12.24	7.4	17.1	11.22	65.6
		4h	2	12.69	9.892	78.0	12.69	5.7	19.7	10.58	107.7
	D57	Pre-dose	68	38.44	14.416	37.5	36.94	6.3	76.9	35.31	47.8
		1.5h	68	26.24	10.368	39.5	25.07	3.9	65.5	24.08	47.2
		4h	67	27.76	13.872	50.0	27.56	2.8	68.2	23.84	67.5
	D71	Pre-dose	68	36.92	14.676	39.8	36.51	10.2	89.7	34.02	44.5
		4h	1	16.79			16.79	16.8	16.8	16.79	
	D85		67	37.88	14.536	38.4	38.72	3.7	88.0	34.40	53.8

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 30 mg QD

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Change from Baseline	D1	1.5h	68	-9.56	6.090		-9.45	-24.1	8.3		
		4h	68	-11.56	10.492		-13.26	-33.2	19.9		
	D15	Pre-dose	68	1.01	5.911		1.13	-21.5	20.4		
		1.5h	2	-18.48	7.439		-18.48	-23.7	-13.2		
		4h	2	-19.16	9.822		-19.16	-26.1	-12.2		
	D29	Pre-dose	69	-0.08	6.701		-0.17	-15.3	30.5		
		1.5h	67	-11.69	8.679		-13.11	-29.4	27.7		
		4h	67	-10.73	11.130		-10.50	-34.4	27.9		
	D43	Pre-dose	69	-1.55	6.000		-0.14	-17.6	20.3		
		1.5h	2	-12.02	5.657		-12.02	-16.0	-8.0		
		4h	2	-11.57	2.673		-11.57	-13.5	-9.7		
	D57	Pre-dose	68	-0.31	8.035		-0.91	-20.2	30.5		
		1.5h	68	-12.51	8.982		-12.01	-32.6	27.7		
		4h	67	-11.05	11.439		-9.01	-42.3	27.3		
	D71	Pre-dose	68	-1.84	9.342		-0.44	-45.8	26.8		
		4h	1	-18.12			-18.12	-18.1	-18.1		
	D85		67	-0.95	10.256		-0.81	-28.2	45.9		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 30 mg QD

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Percentage Change from Baseline	D1	1.5h	68	-24.32	14.228		-26.43	-59.4	37.8		
		4h	68	-30.33	28.184		-39.48	-69.0	90.1		
	D15	Pre-dose	68	13.29	81.728		2.62	-40.4	662.7		
		1.5h	2	-39.70	16.692		-39.70	-51.5	-27.9		
		4h	2	-41.20	21.820		-41.20	-56.6	-25.8		
	D29	Pre-dose	69	14.40	120.488		-0.38	-45.2	989.6		
		1.5h	67	-16.20	114.669		-33.07	-60.5	899.4		
		4h	67	-14.92	116.767		-30.44	-69.5	906.5		
	D43	Pre-dose	69	2.20	53.461		-0.31	-71.5	410.1		
		1.5h	2	-50.26	2.715		-50.26	-52.2	-48.3		
		4h	2	-51.80	15.814		-51.80	-63.0	-40.6		
	D57	Pre-dose	68	15.02	122.114		-2.27	-42.2	990.9		
		1.5h	68	-18.42	113.594		-34.77	-53.3	898.4		
		4h	67	-15.87	114.537		-26.41	-69.5	887.0		
	D71	Pre-dose	68	11.84	110.002		-1.17	-78.4	869.5		
		4h	1	-51.90			-51.90	-51.9	-51.9		
	D85		67	18.95	143.731		-2.16	-76.2	1087.0		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 60 mg QD

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Observed Value	D1	Pre-dose	69	38.35	14.093	36.7	35.35	13.7	74.1	35.81	39.4
		1.5h	67	28.47	10.348	36.4	27.21	10.1	54.9	26.54	40.4
		4h	67	21.68	11.972	55.2	17.80	6.0	60.4	18.98	55.2
	D15	Pre-dose	66	38.90	13.402	34.5	37.36	16.5	79.1	36.62	36.9
		1.5h	2	16.80	9.977	59.4	16.80	9.7	23.9	15.24	70.2
		4h	2	9.82	4.320	44.0	9.82	6.8	12.9	9.33	48.0
	D29	Pre-dose	67	38.27	14.662	38.3	36.29	7.7	75.5	35.25	45.3
		1.5h	66	26.22	10.443	39.8	23.65	6.4	51.7	24.12	44.6
		4h	66	23.16	12.453	53.8	21.20	6.2	59.1	20.04	59.9
	D43	Pre-dose	67	37.83	14.876	39.3	35.13	8.7	78.2	34.67	46.9
		1.5h	1	41.19			41.19	41.2	41.2	41.19	
		4h	1	34.28			34.28	34.3	34.3	34.28	
	D57	Pre-dose	65	38.28	14.895	38.9	35.18	13.9	82.7	35.33	43.5
		1.5h	65	27.05	11.893	44.0	23.50	8.7	76.3	24.72	45.3
		4h	65	22.49	13.243	58.9	18.30	6.2	64.9	19.44	57.5
	D71	Pre-dose	65	38.72	14.170	36.6	36.17	13.5	74.4	36.07	40.6
		1.5h	1	34.08			34.08	34.1	34.1	34.08	
		4h	1	31.38			31.38	31.4	31.4	31.38	
	D85		66	38.01	16.142	42.5	33.75	10.5	106.9	34.91	44.2

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 60 mg QD

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Change from Baseline	D1	1.5h	67	-10.21	6.623		-10.29	-32.9	6.9		
		4h	67	-17.00	11.259		-16.26	-45.6	10.6		
	D15	Pre-dose	66	0.62	6.585		1.22	-24.6	19.2		
		1.5h	2	-10.65	1.082		-10.65	-11.4	-9.9		
		4h	2	-17.63	4.575		-17.63	-20.9	-14.4		
	D29	Pre-dose	67	-0.17	8.331		0.48	-32.7	16.5		
		1.5h	66	-11.69	6.854		-10.46	-28.1	0.7		
		4h	66	-14.74	10.786		-13.98	-46.1	7.2		
	D43	Pre-dose	67	-0.62	8.870		1.49	-42.7	13.8		
		1.5h	1	-32.90			-32.90	-32.9	-32.9		
		4h	1	-39.81			-39.81	-39.8	-39.8		
	D57	Pre-dose	65	-0.49	7.966		0.42	-22.8	23.4		
		1.5h	65	-11.72	7.924		-9.92	-44.4	12.3		
		4h	65	-16.29	11.398		-15.52	-48.4	18.9		
	D71	Pre-dose	65	-0.07	8.148		0.66	-20.0	32.1		
		1.5h	1	-0.24			-0.24	-0.2	-0.2		
		4h	1	-2.94			-2.94	-2.9	-2.9		
	D85		66	-0.70	8.869		-0.61	-27.5	42.9		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 60 mg QD

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Percentage Change from Baseline	D1	1.5h	67	-25.75	11.232		-27.41	-51.2	14.3		
		4h	67	-44.27	21.723		-52.10	-66.4	23.9		
	D15	Pre-dose	66	3.97	16.358		4.24	-33.2	73.6		
		1.5h	2	-41.62	17.435		-41.62	-53.9	-29.3		
		4h	2	-64.94	4.380		-64.94	-68.0	-61.8		
	D29	Pre-dose	67	0.85	20.902		0.86	-71.0	49.2		
		1.5h	66	-30.33	14.468		-31.03	-75.7	4.0		
		4h	66	-39.31	23.853		-48.06	-76.5	21.4		
	D43	Pre-dose	67	0.01	21.340		3.03	-79.6	35.6		
		1.5h	1	-44.41			-44.41	-44.4	-44.4		
		4h	1	-53.73			-53.73	-53.7	-53.7		
	D57	Pre-dose	65	-0.32	20.212		1.57	-53.4	76.1		
		1.5h	65	-30.37	13.577		-31.72	-61.5	19.1		
		4h	65	-42.81	22.184		-50.25	-71.2	41.0		
	D71	Pre-dose	65	2.45	26.934		0.97	-55.7	157.7		
		1.5h	1	-0.70			-0.70	-0.7	-0.7		
		4h	1	-8.57			-8.57	-8.6	-8.6		
	D85		66	-1.36	18.967		-2.16	-68.7	67.0		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 30 mg BID

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Observed Value	D1	Pre-dose	68	38.07	11.669	30.6	36.15	15.4	69.3	36.31	32.3
		1.5h	65	29.01	8.896	30.7	28.11	12.6	50.6	27.66	32.4
		4h	65	28.48	13.926	48.9	28.21	7.4	71.2	25.20	54.7
	D15	Pre-dose	67	38.21	11.355	29.7	38.22	12.7	69.7	36.32	34.8
		1.5h	3	31.99	10.509	32.9	31.36	21.8	42.8	30.82	34.7
		4h	3	34.33	17.741	51.7	28.24	20.4	54.3	31.53	53.1
	D29	Pre-dose	67	36.53	11.240	30.8	37.09	12.3	65.6	34.56	36.6
		1.5h	63	25.62	8.115	31.7	26.06	9.1	49.0	24.26	35.7
		4h	63	28.26	12.255	43.4	27.01	6.8	59.3	25.46	51.2
	D43	Pre-dose	64	36.05	10.697	29.7	34.38	11.2	63.3	34.35	33.7
		1.5h	3	19.70	9.558	48.5	25.14	8.7	25.3	17.66	68.1
		4h	3	22.68	20.296	89.5	15.59	6.9	45.6	16.97	120.7
	D57	Pre-dose	63	35.92	11.923	33.2	34.81	4.4	61.8	33.41	45.1
		1.5h	59	25.03	8.267	33.0	24.75	3.5	42.0	23.32	44.1
		4h	59	27.53	11.036	40.1	28.13	3.2	47.4	24.72	56.0
	D71	Pre-dose	63	36.70	12.031	32.8	34.66	12.9	71.6	34.68	36.2
		1.5h	4	24.69	8.727	35.3	22.23	17.4	36.9	23.65	34.1
		4h	4	26.91	12.357	45.9	24.57	15.5	43.0	24.88	48.2
	D85		62	35.20	10.249	29.1	33.98	7.8	62.8	33.56	34.0

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 30 mg BID

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Change from Baseline	D1	1.5h	65	-8.99	5.832		-9.34	-22.8	5.8		
		4h	65	-9.52	10.061		-7.94	-30.4	5.3		
	D15	Pre-dose	67	0.04	7.110		0.15	-21.4	17.5		
		1.5h	3	-7.65	9.756		-12.23	-14.3	3.6		
		4h	3	-5.32	8.976		-0.72	-15.7	0.4		
	D29	Pre-dose	67	-1.56	8.959		-1.41	-32.0	23.1		
		1.5h	63	-12.45	9.551		-12.46	-42.9	10.8		
		4h	63	-9.81	11.086		-9.09	-38.7	11.4		
	D43	Pre-dose	64	-1.63	8.713		0.31	-29.7	22.1		
		1.5h	3	-16.53	13.455		-17.72	-29.4	-2.5		
		4h	3	-13.55	5.413		-12.22	-19.5	-8.9		
	D57	Pre-dose	63	-2.07	8.741		-1.05	-27.2	23.2		
		1.5h	59	-12.64	8.111		-13.76	-32.1	9.4		
		4h	59	-10.15	11.199		-8.76	-40.6	13.3		
	D71	Pre-dose	63	-1.29	8.640		-1.17	-23.5	19.3		
		1.5h	4	-17.95	14.571		-16.98	-34.8	-3.0		
		4h	4	-15.72	7.527		-15.58	-24.5	-7.3		
	D85		62	-2.67	8.439		-2.57	-26.8	16.1		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.1
Summary of LH (IU/L) Serum Concentrations
PDAS

Treatment Group: GS1-144 30 mg BID

	Visit	Planned Time Point	n	Mean	SD	CV%	Median	Min	Max	Geo Mean	Geo CV%
Percentage Change from Baseline	D1	1.5h	65	-22.58	13.548		-24.92	-44.4	18.1		
		4h	65	-25.83	25.686		-24.52	-62.4	23.3		
	D15	Pre-dose	67	2.57	23.879		0.47	-59.7	113.8		
		1.5h	3	-16.34	26.658		-22.22	-39.6	12.8		
		4h	3	-14.38	25.161		-1.31	-43.4	1.5		
	D29	Pre-dose	67	-0.91	28.856		-3.40	-59.8	150.3		
		1.5h	63	-29.73	23.337		-33.28	-72.4	70.1		
		4h	63	-24.11	29.010		-22.10	-77.8	74.2		
	D43	Pre-dose	64	-0.72	27.561		0.76	-58.2	143.5		
		1.5h	3	-43.37	30.444		-53.86	-67.2	-9.1		
		4h	3	-44.74	28.783		-43.94	-73.9	-16.4		
	D57	Pre-dose	63	-2.73	30.301		-3.48	-86.1	150.6		
		1.5h	59	-31.65	21.733		-33.80	-88.8	60.9		
		4h	59	-24.58	30.043		-23.12	-89.8	86.3		
	D71	Pre-dose	63	-0.75	27.385		-2.73	-59.3	125.7		
		1.5h	4	-37.30	21.822		-37.24	-63.9	-10.8		
		4h	4	-36.78	9.044		-37.34	-44.9	-27.5		
	D85		62	-3.76	25.827		-7.86	-68.0	104.8		

Data Source: Listing 16.2.5.5
LH = Luteinizing Hormone; n = number of observations;SD = Standard Deviation; CV% = Coefficient of Variation (percent); Geo = Geometric.
Baseline value were defined as the D1 pre-dose concentration prior to the first study drug administration.

Table 14.4.3.2
Summary of LH Change from Baseline
PDAS

	Statistics	Placebo N = 69	GS1-144 30 mg QD N = 70	GS1-144 60 mg QD N = 69	GS1-144 30 mg BID N = 68
Maximum Change from Baseline of LH (IU/L)	Analysis Value				
	n	68	70	69	68
	Mean (SD)	-8.52 (6.480)	-19.57 (8.544)	-21.33 (8.847)	-19.27 (9.047)
	Median	-6.84	-18.24	-20.69	-18.00
	Q1 - Q3	-10.37 - -4.23	-24.72 - -14.86	-25.32 - -14.93	-24.43 - -12.78
	Min - Max	-34.0 - -0.2	-45.8 - -0.2	-48.4 - -7.7	-42.9 - -0.6
Maximum Percentage Change from Baseline of LH (%)	Analysis Value				
	n	68	70	69	68
	Mean (SD)	23.37 (15.810)	50.73 (12.903)	55.93 (10.438)	49.78 (16.177)
	Median	21.33	51.95	56.95	50.74
	Q1 - Q3	12.13 - 31.44	41.85 - 58.66	50.27 - 61.84	39.19 - 60.85
	Min - Max	0.5 - 88.7	6.5 - 78.4	24.6 - 79.6	3.0 - 89.8

Data Source: Listing 16.2.5.5
Baseline values were defined as the D1 pre-dose concentration prior to the first study drug administration.

Figure 14.4.3.3
Mean (±SD) LH Serum Concentrations
PDAS

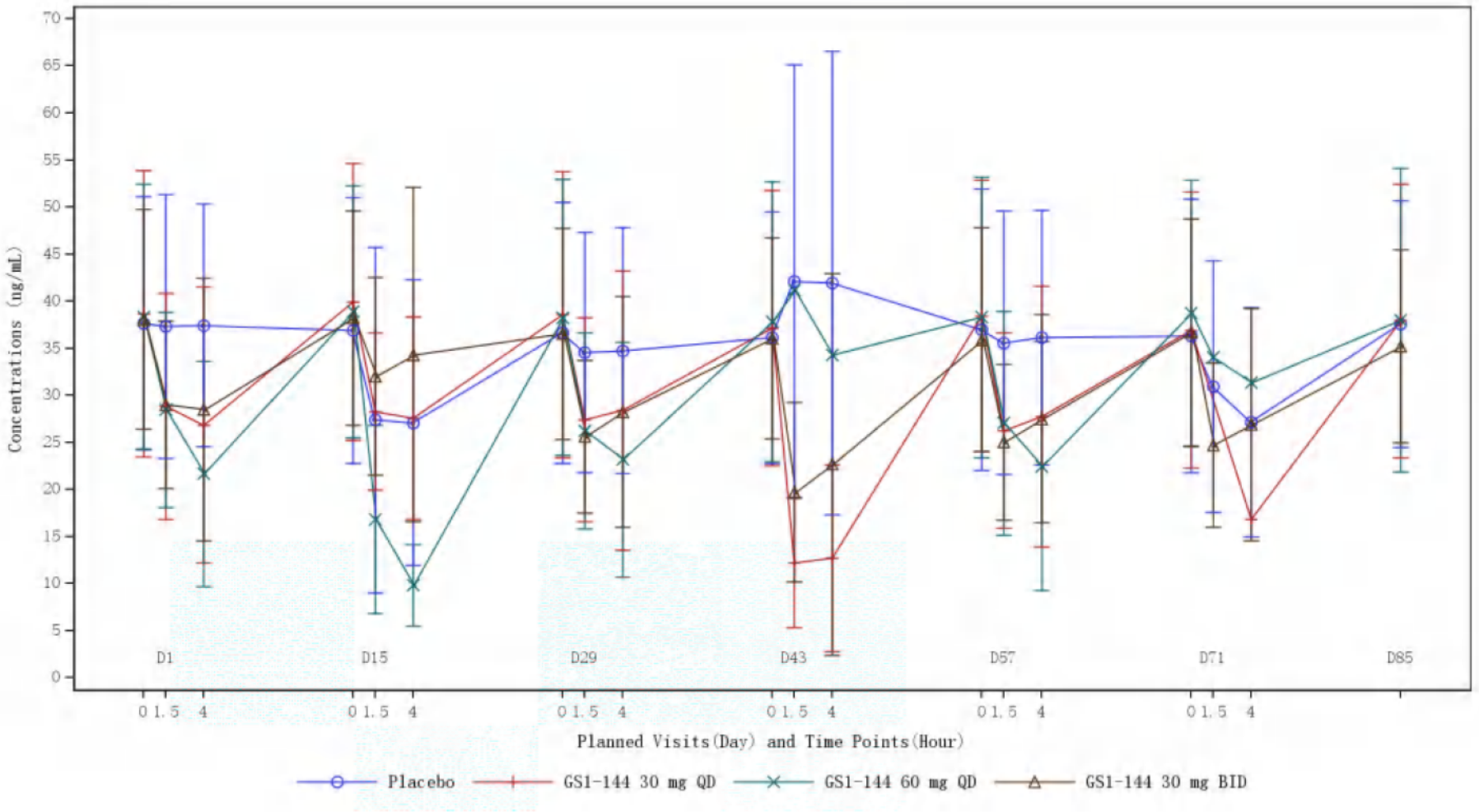


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

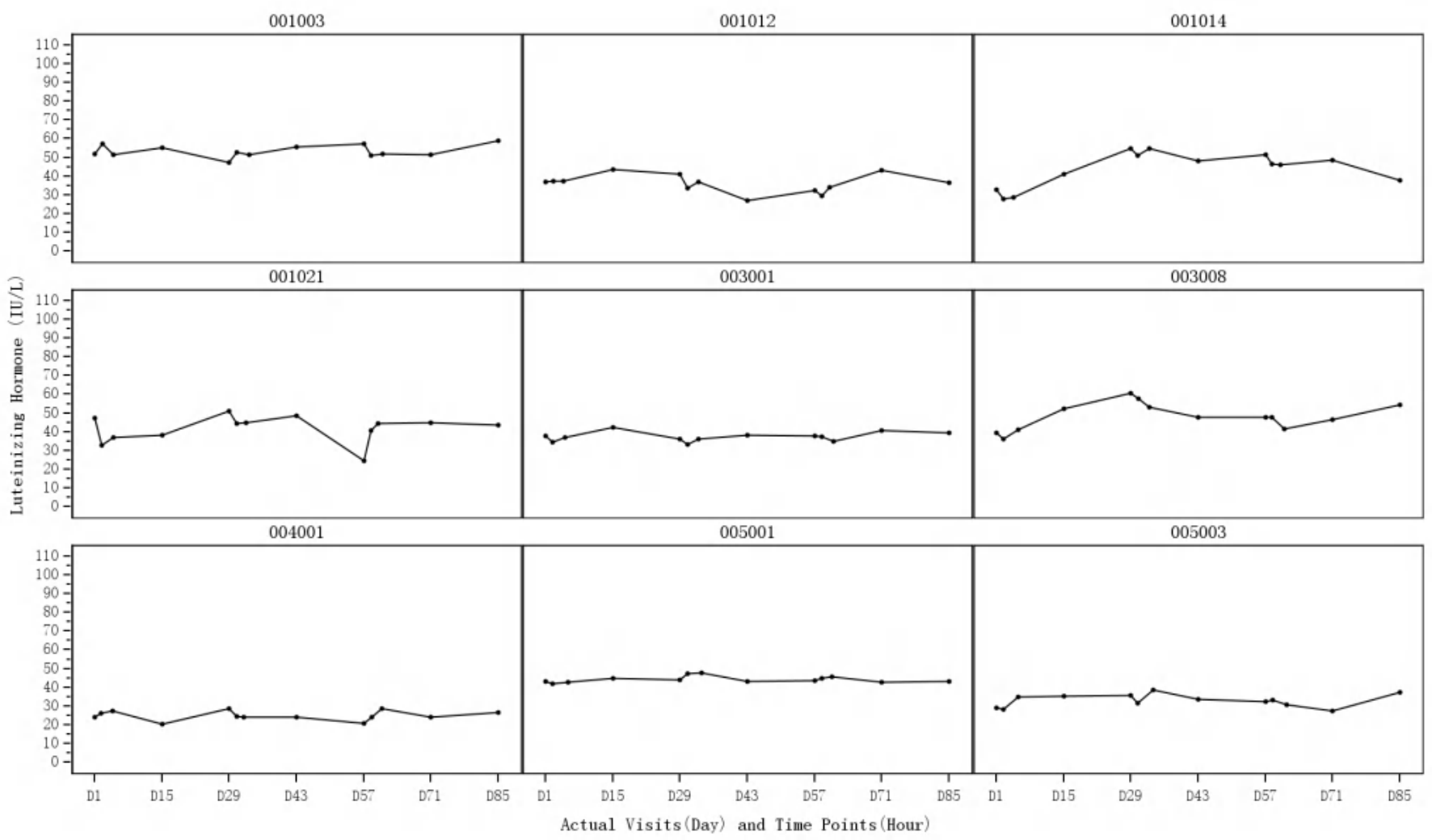


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

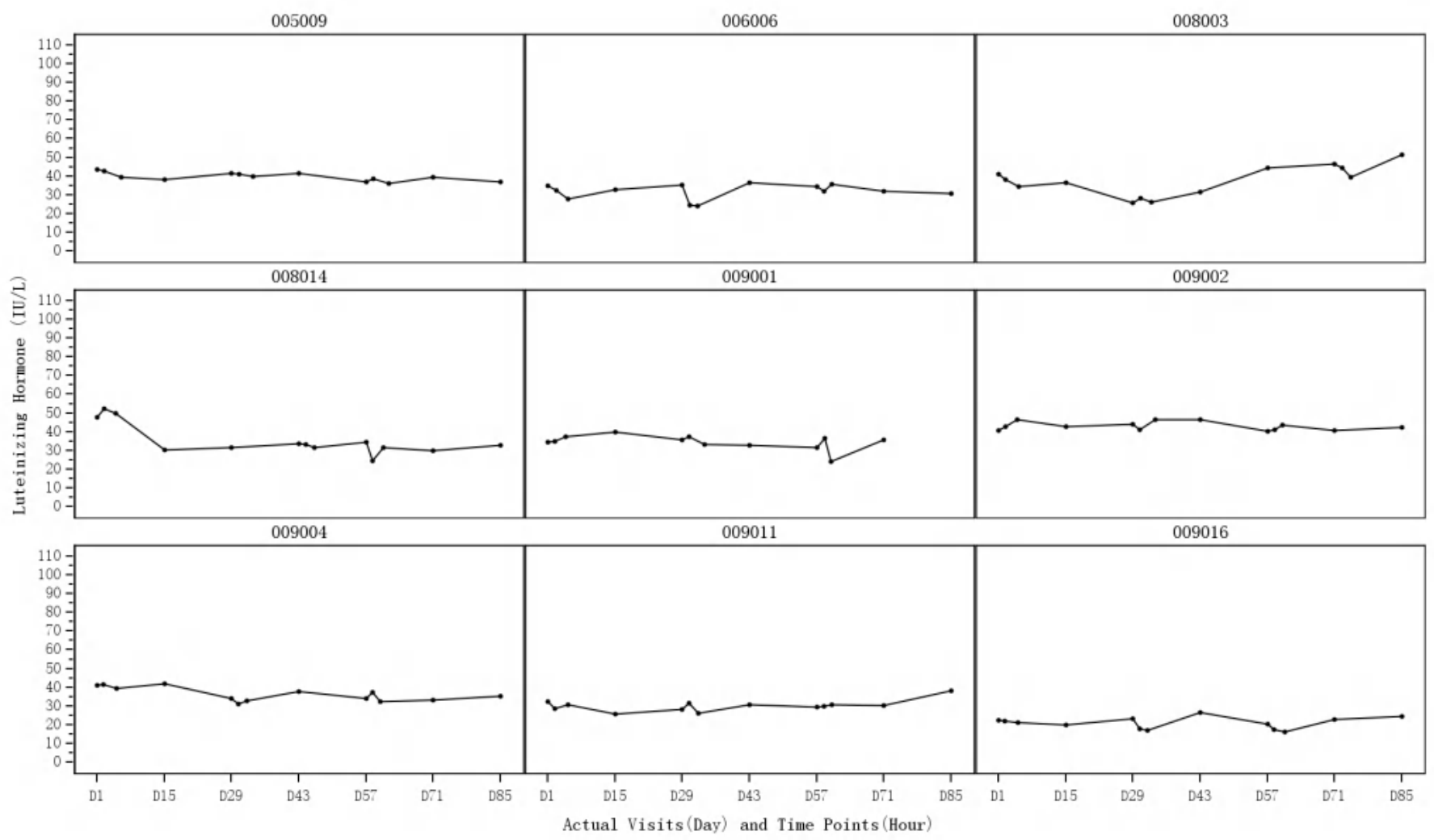


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

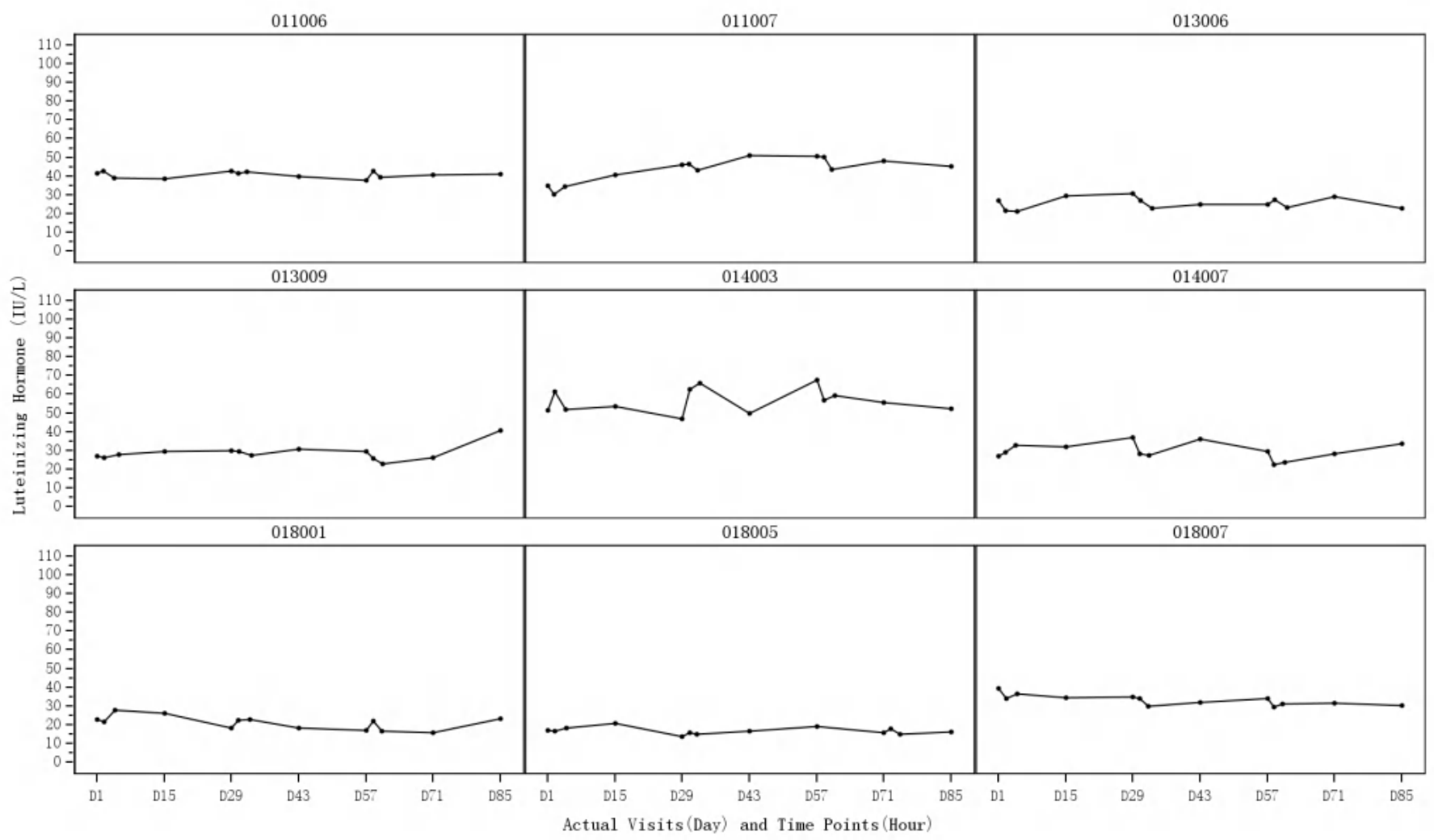


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

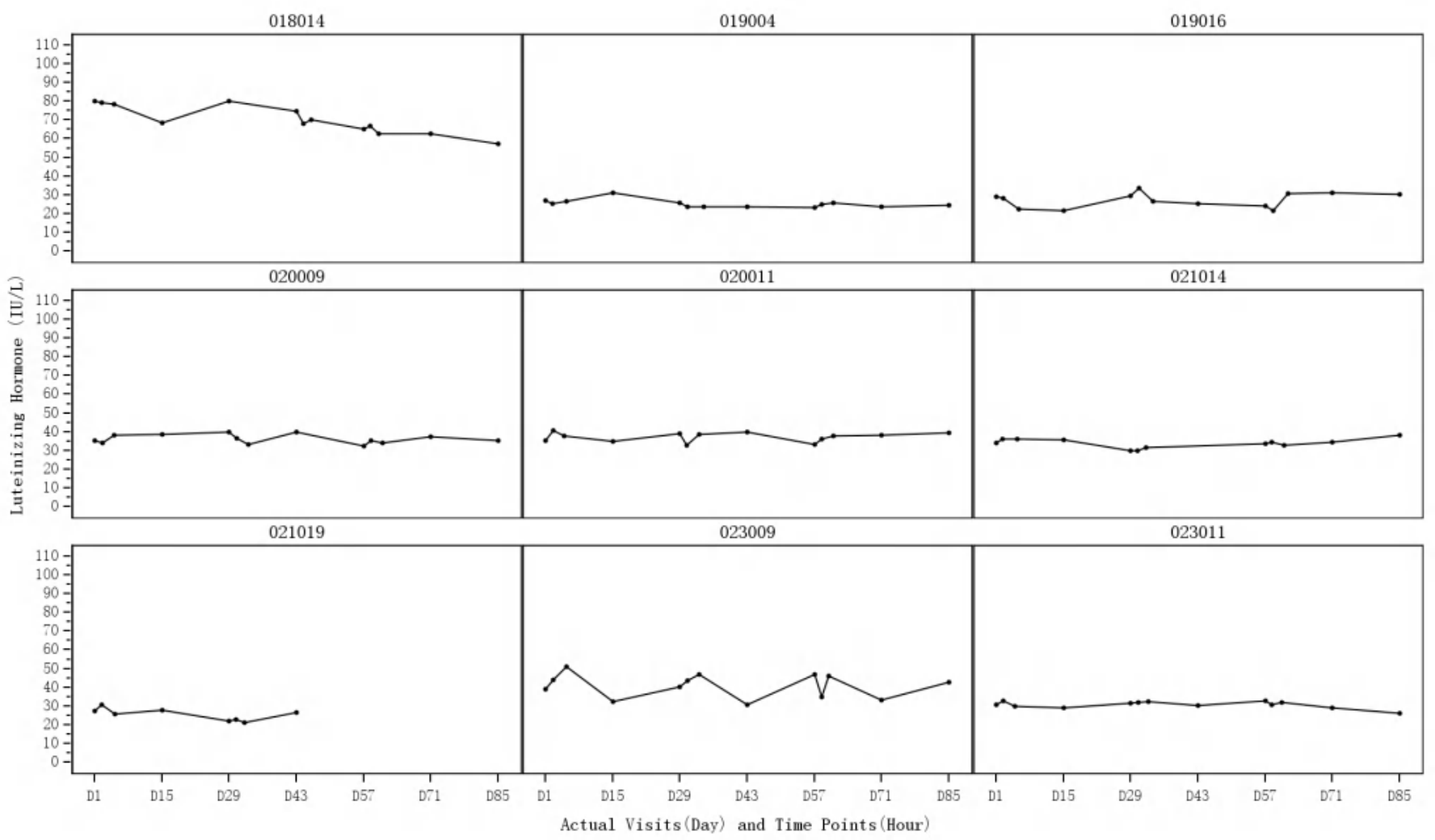


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

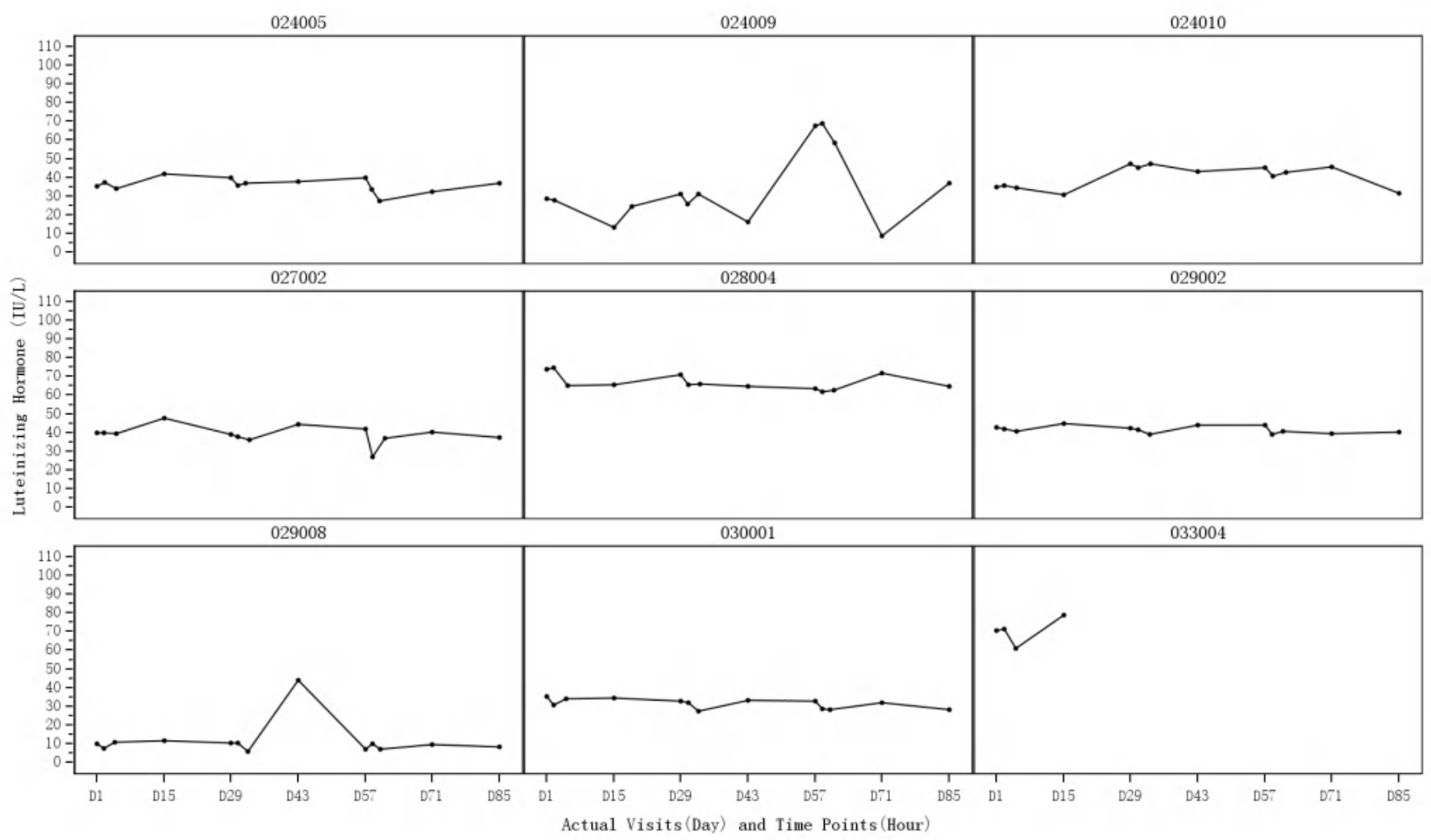


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

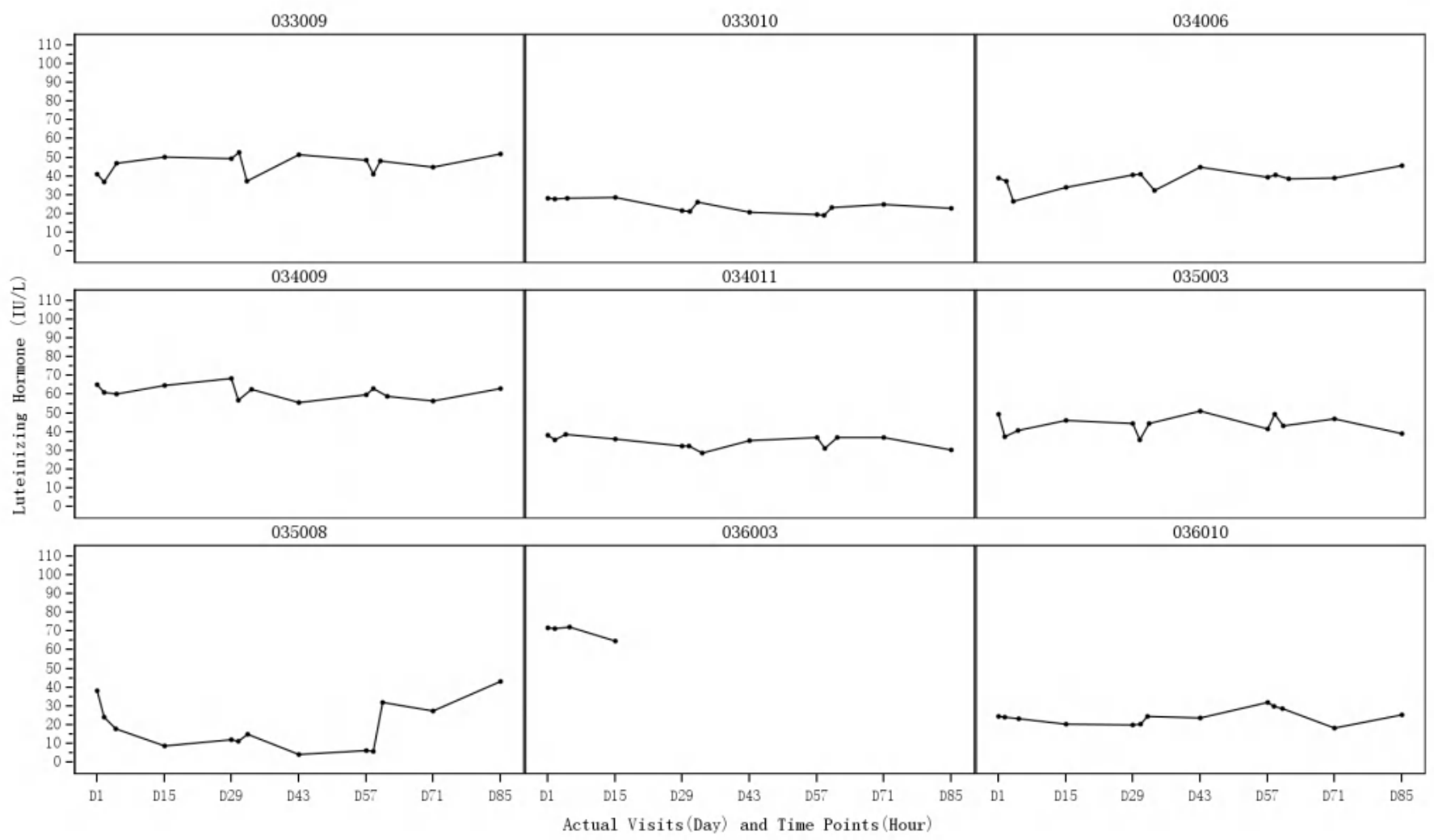


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

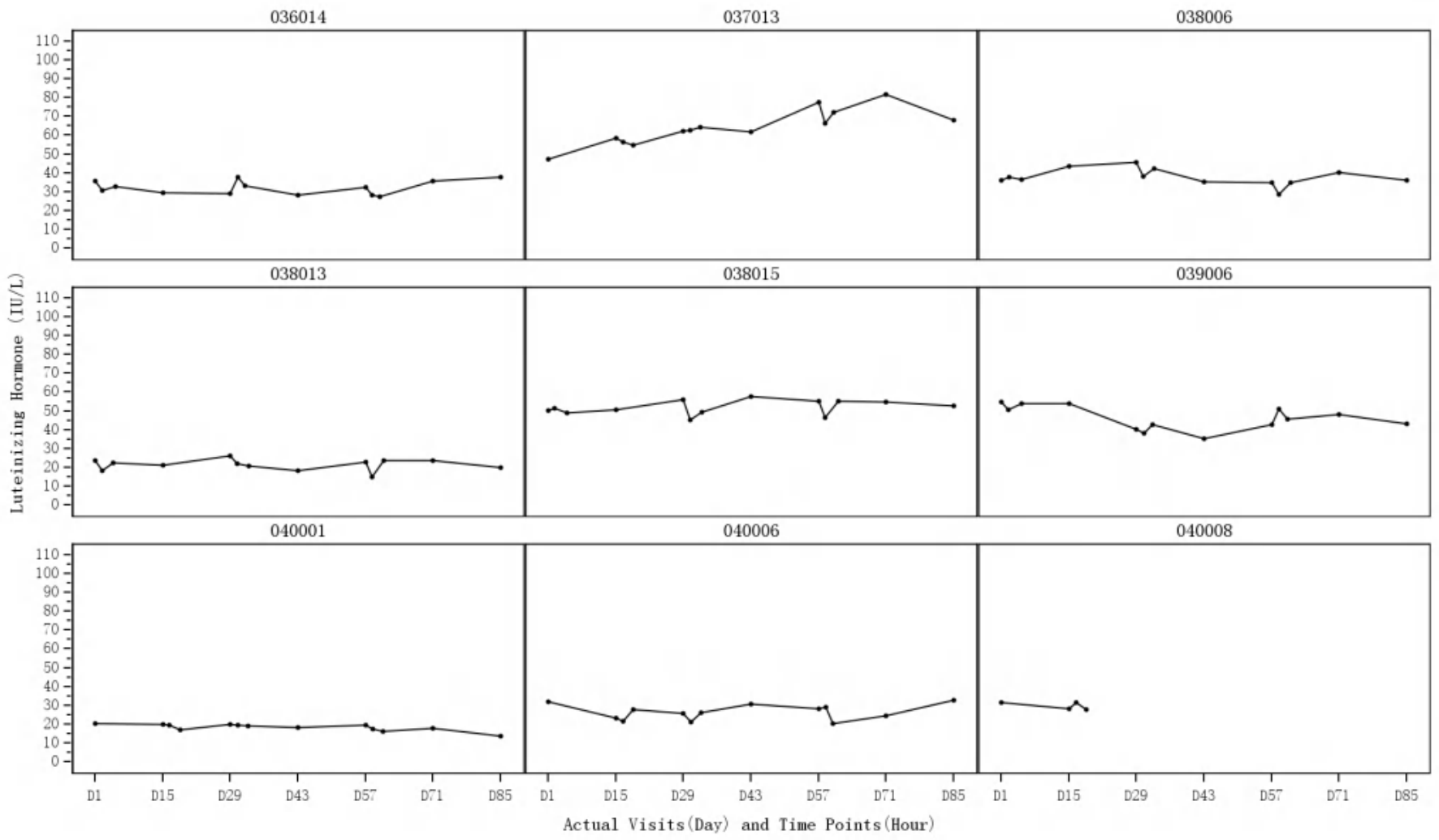


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: Placebo

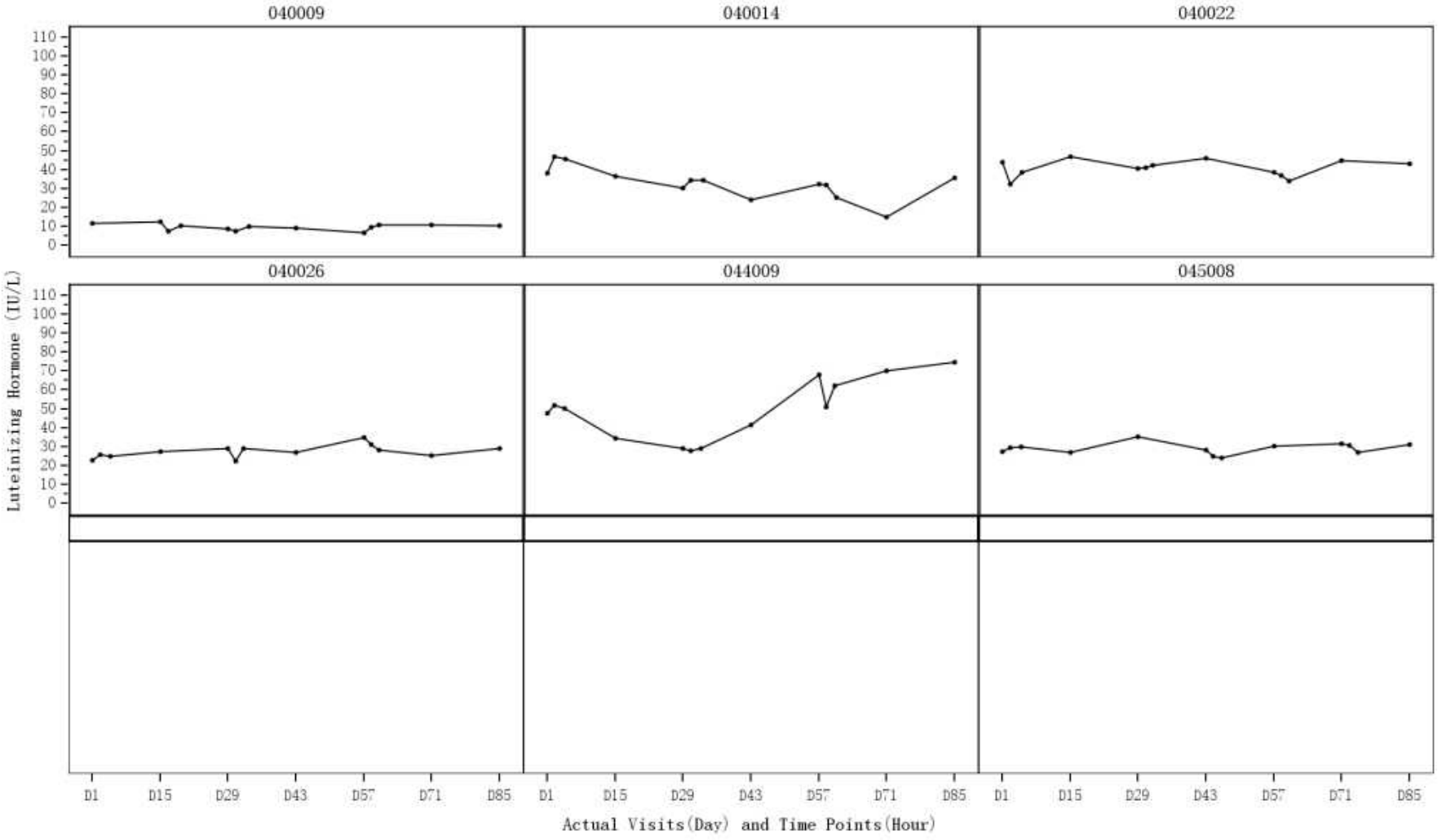


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

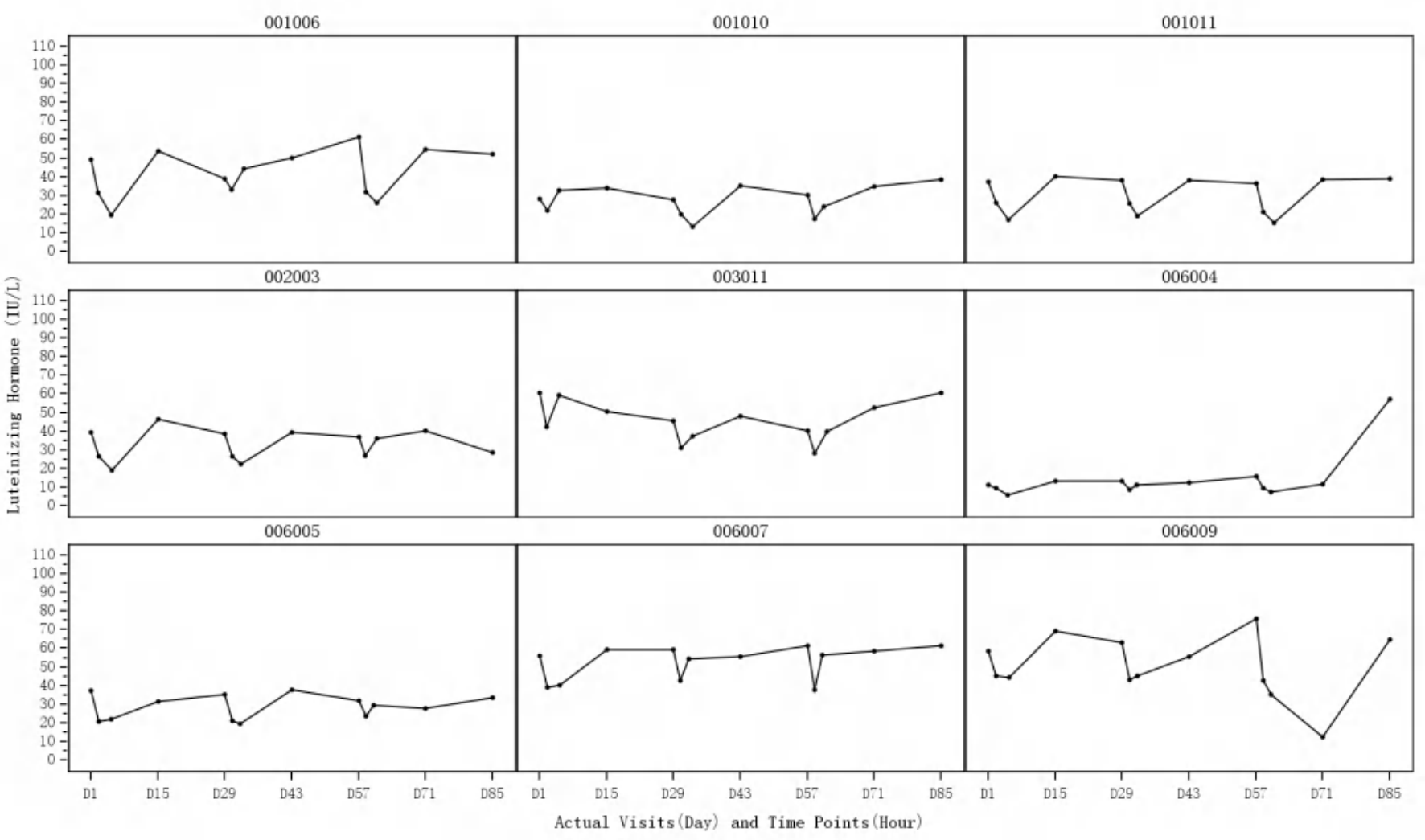


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

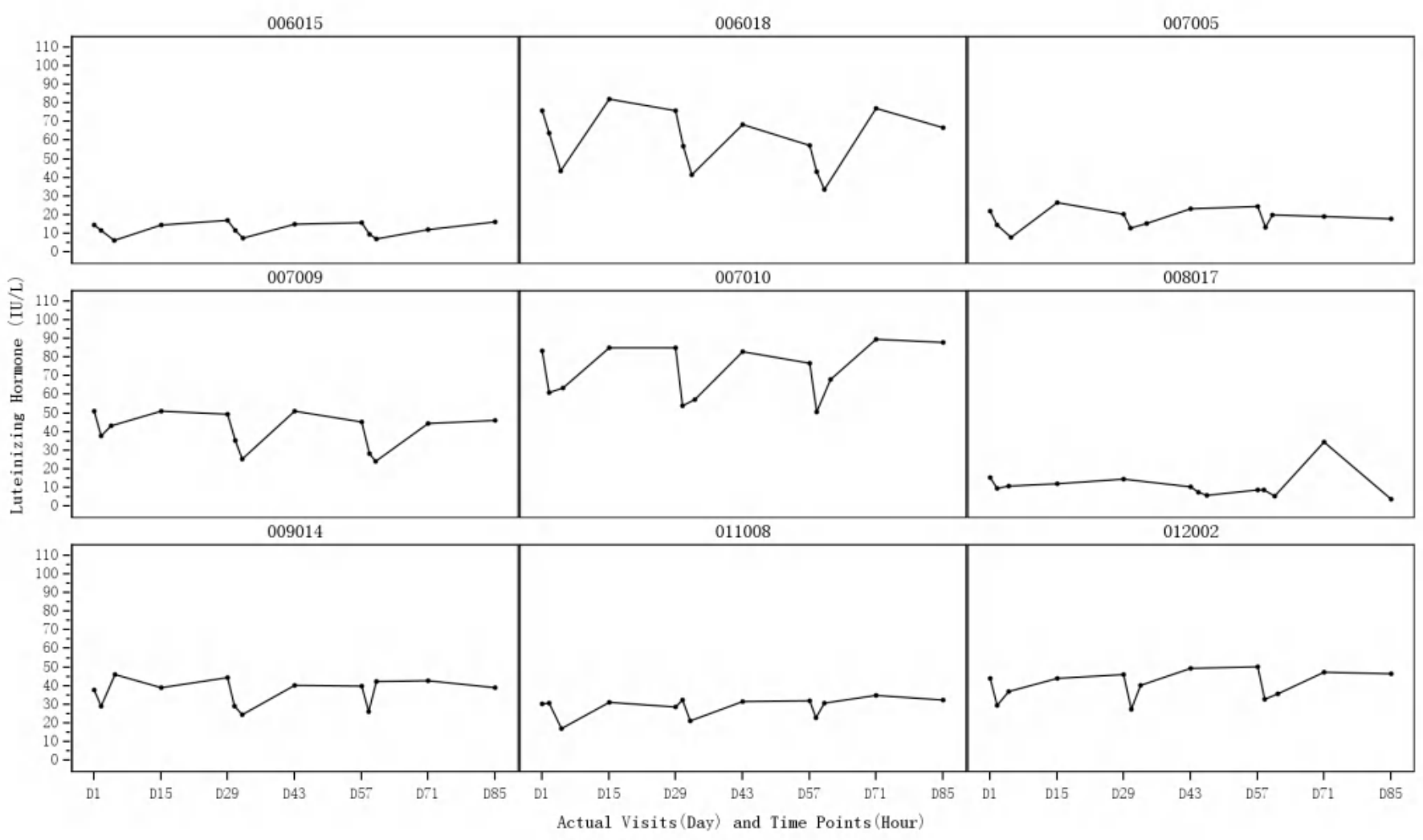


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

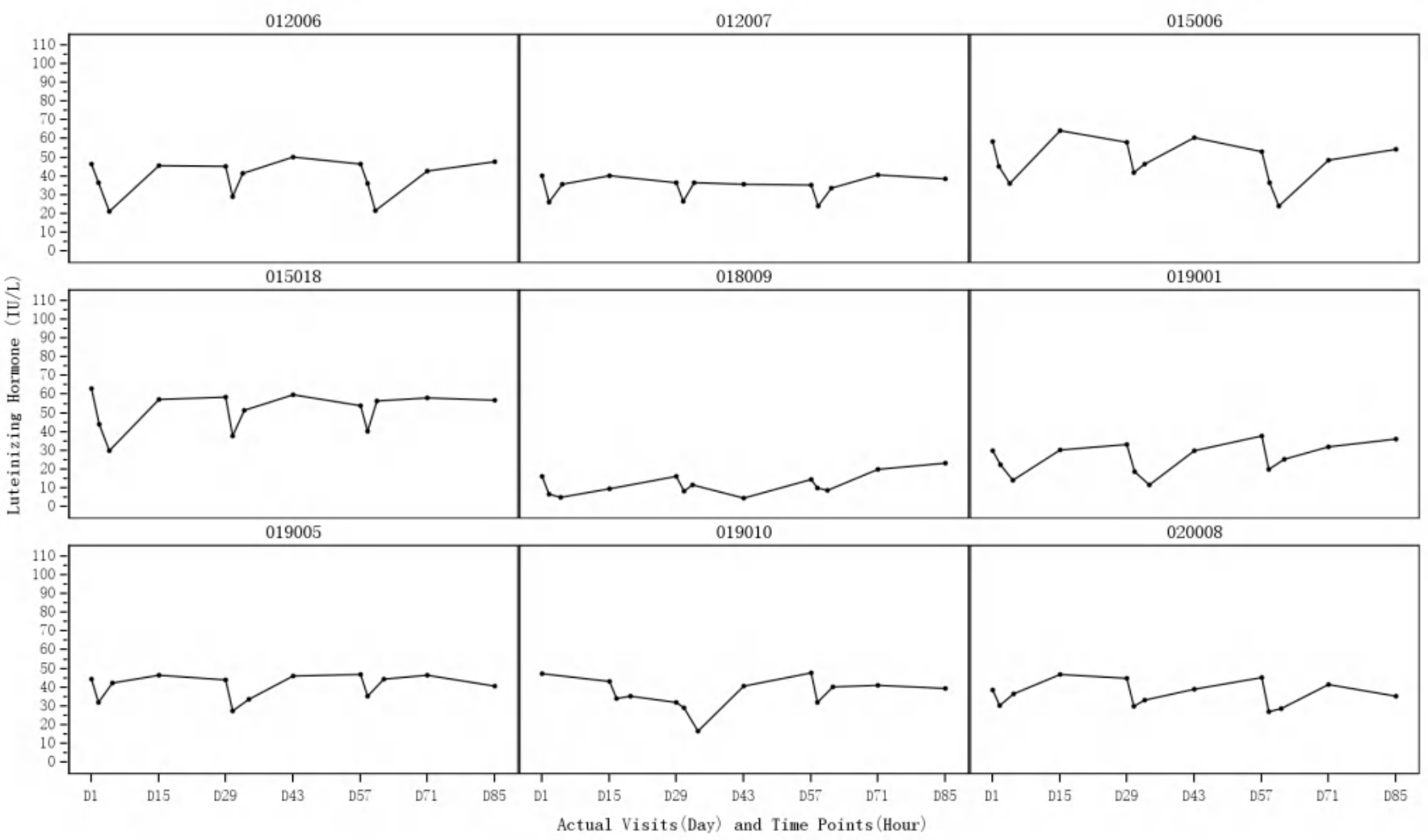


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

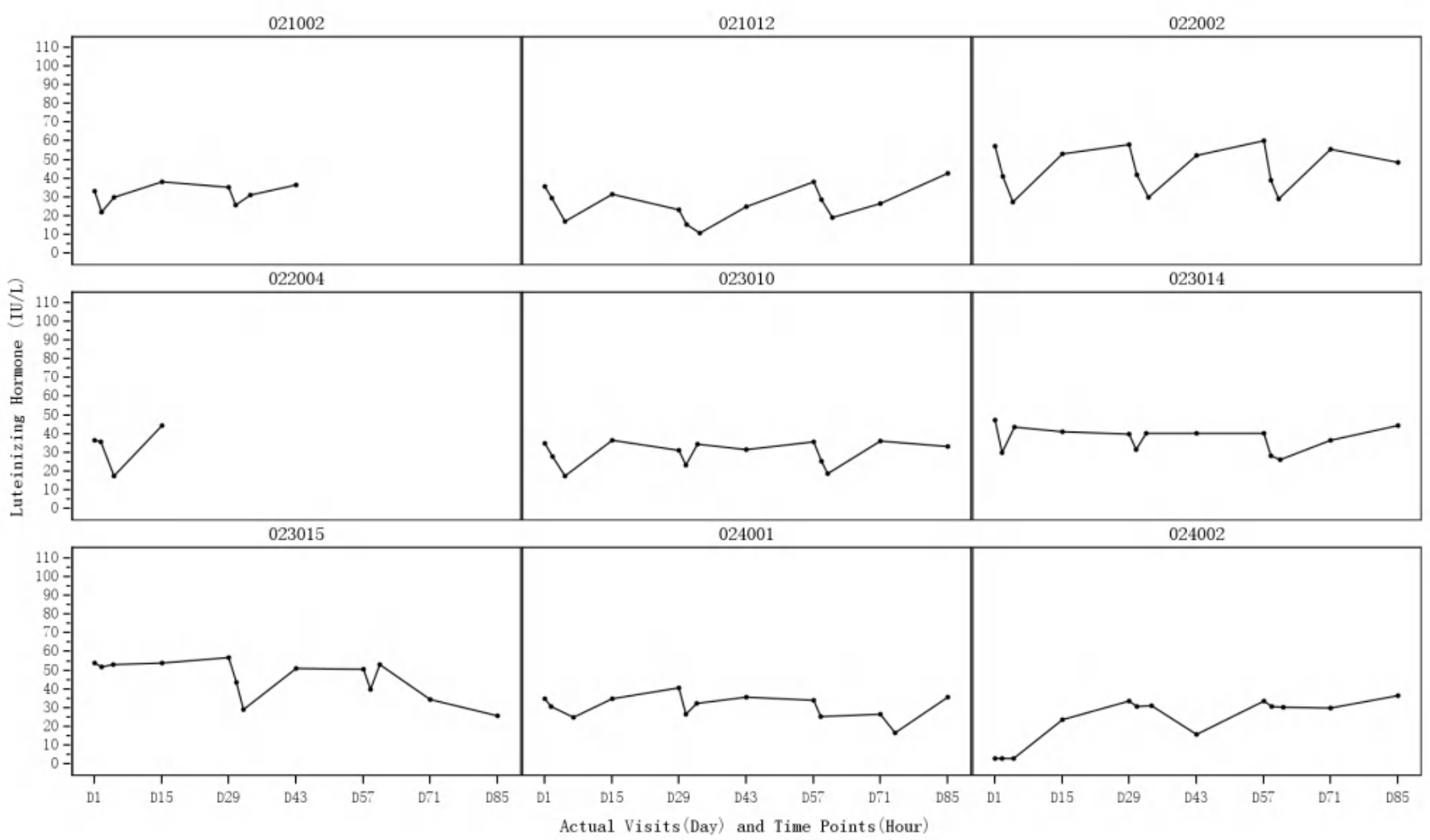


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

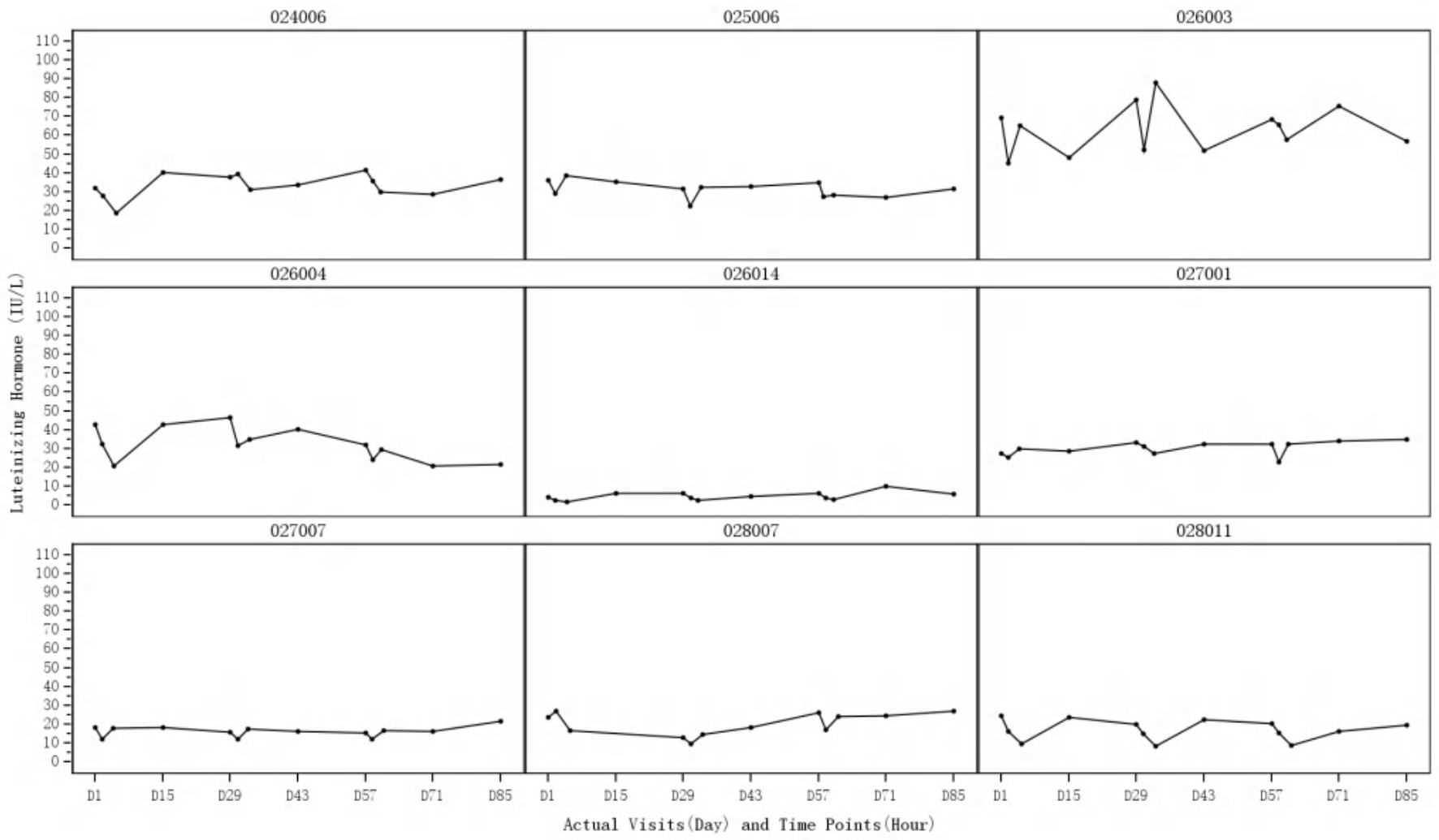


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

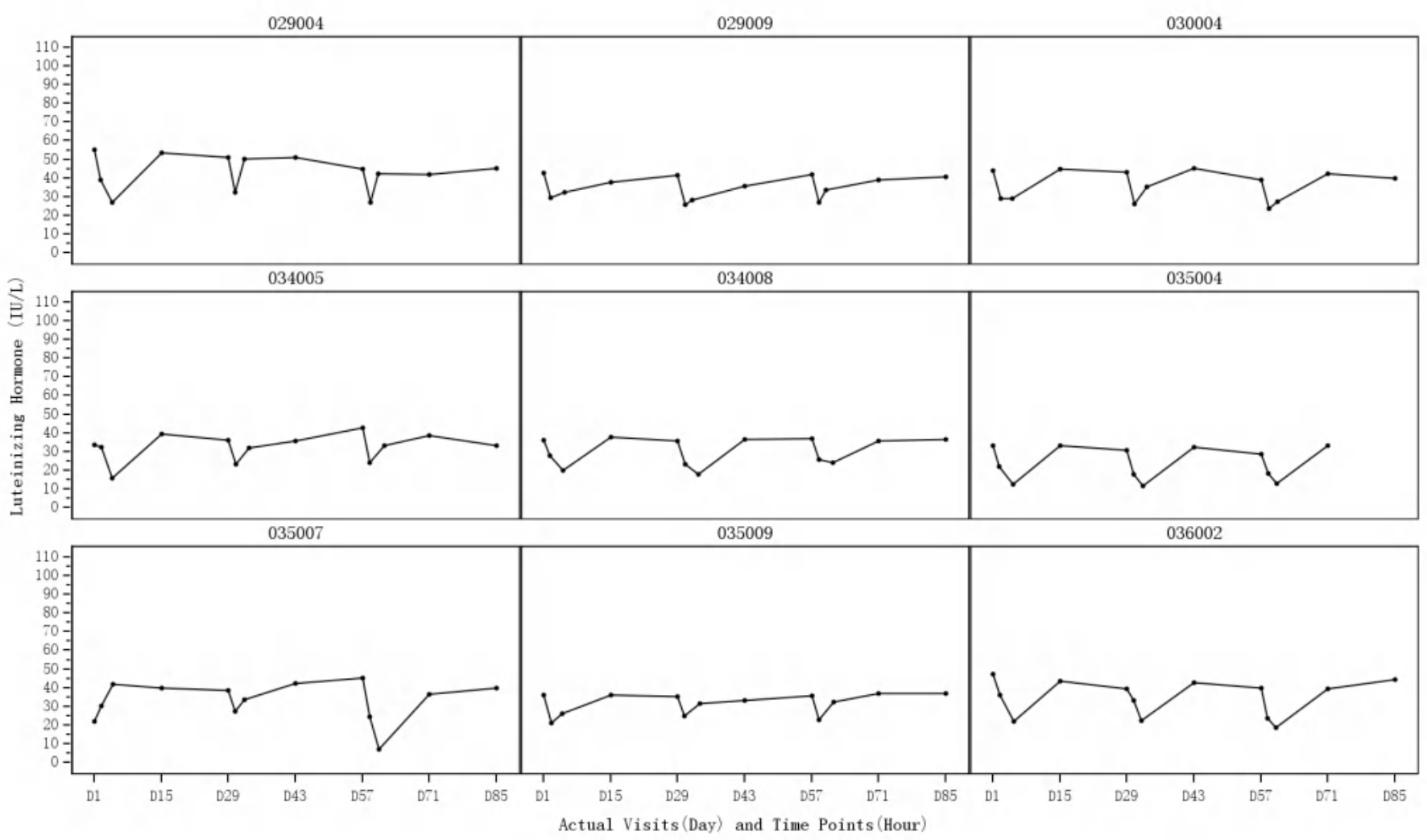


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

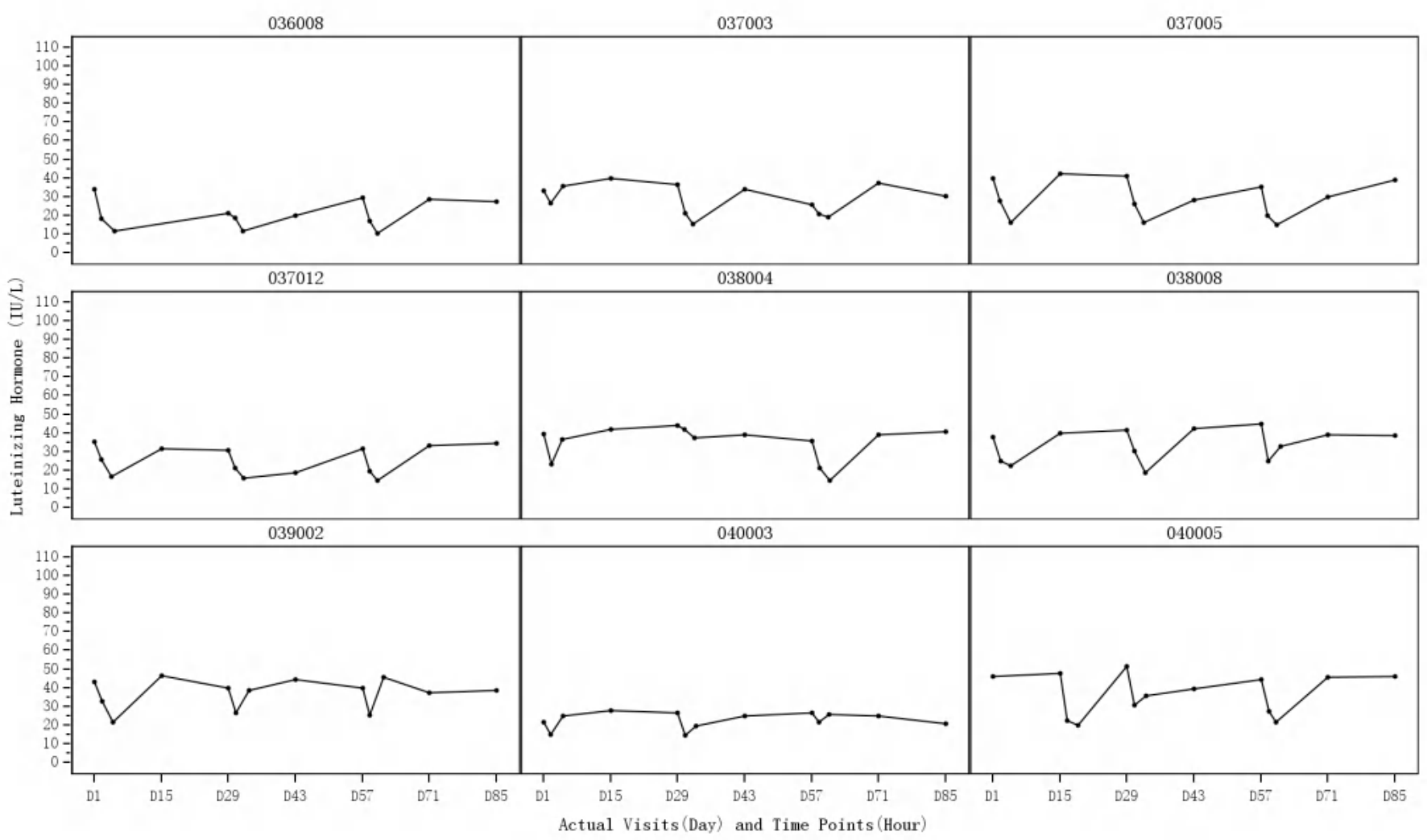


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg QD

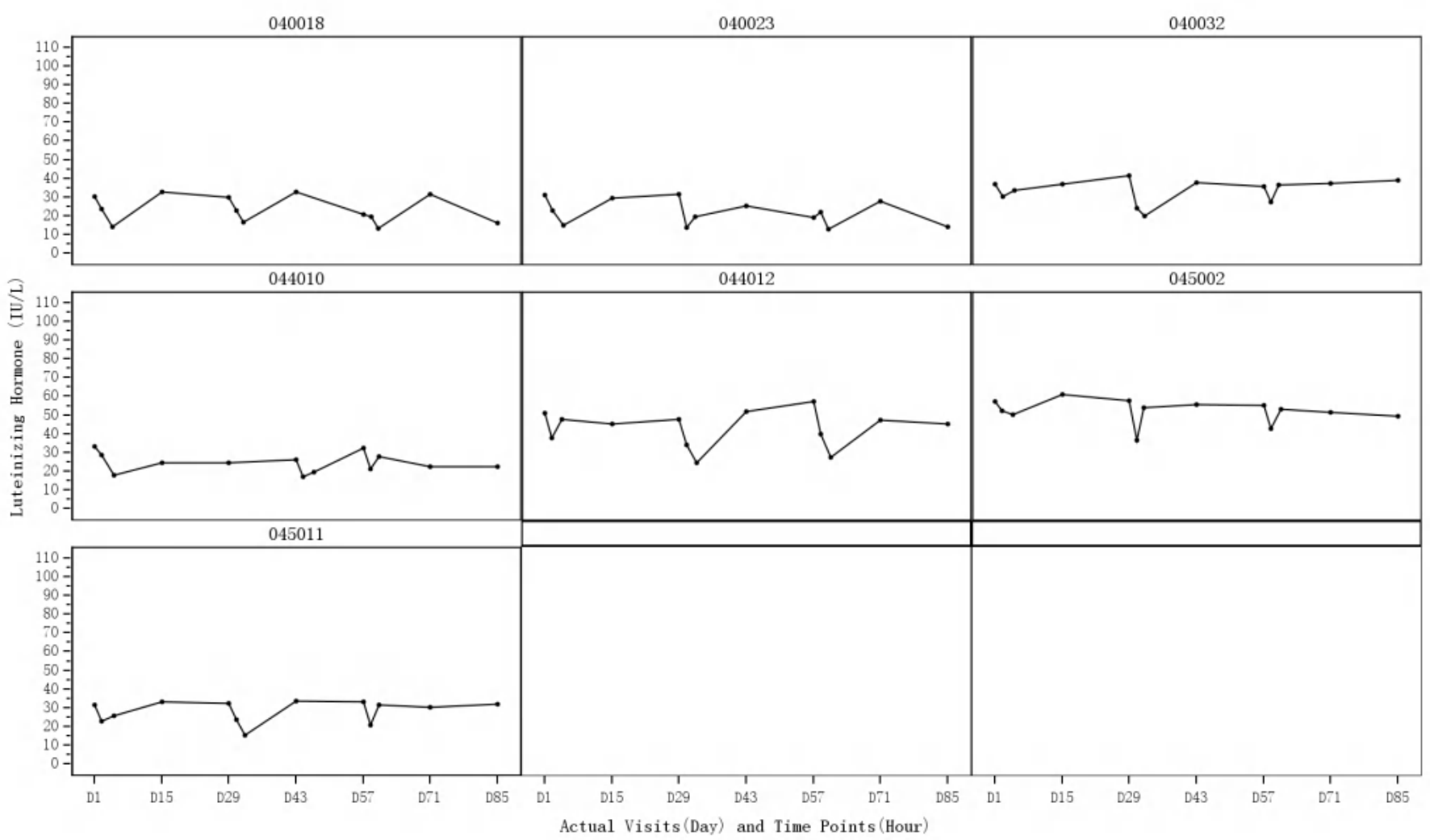


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

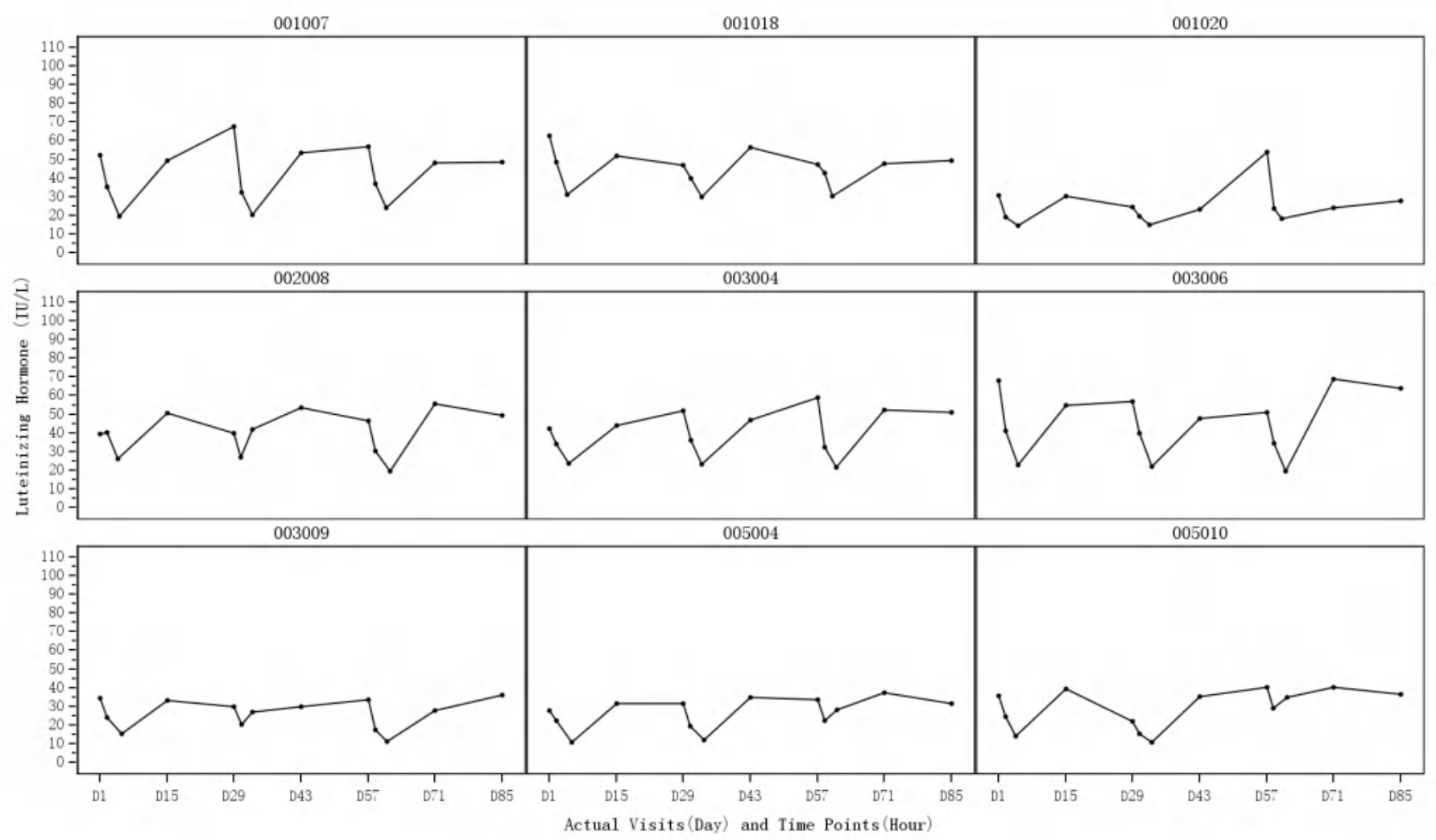


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

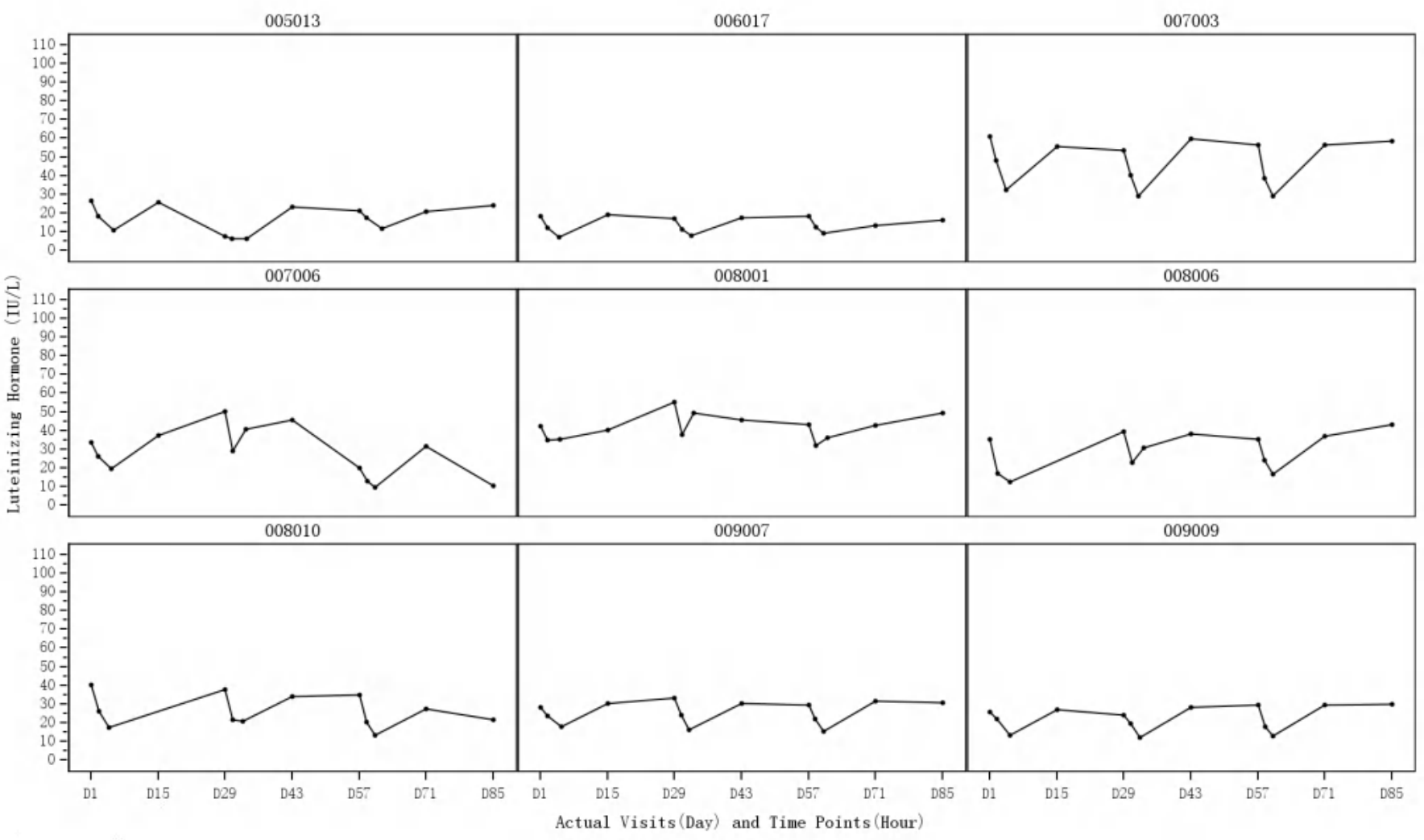


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

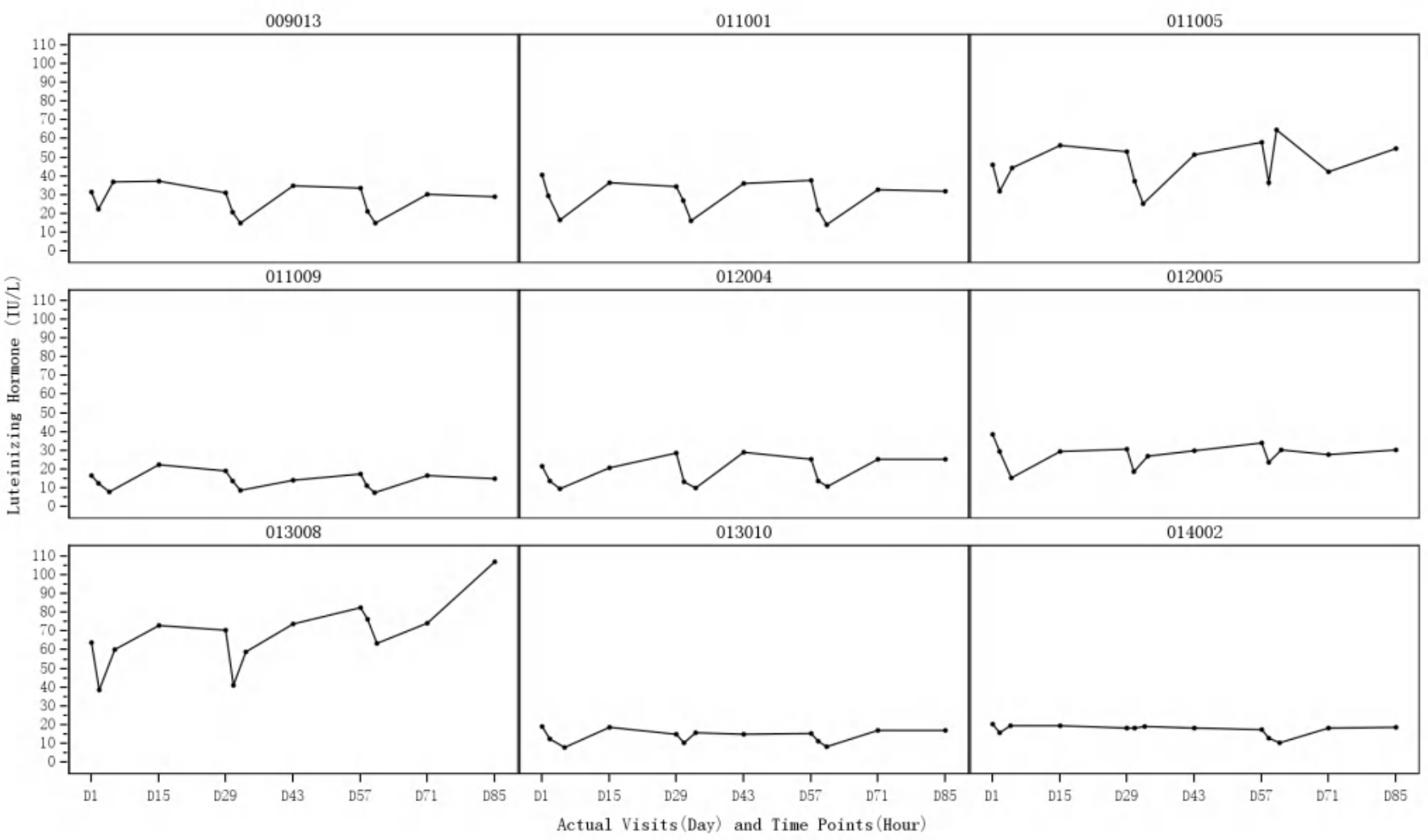


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

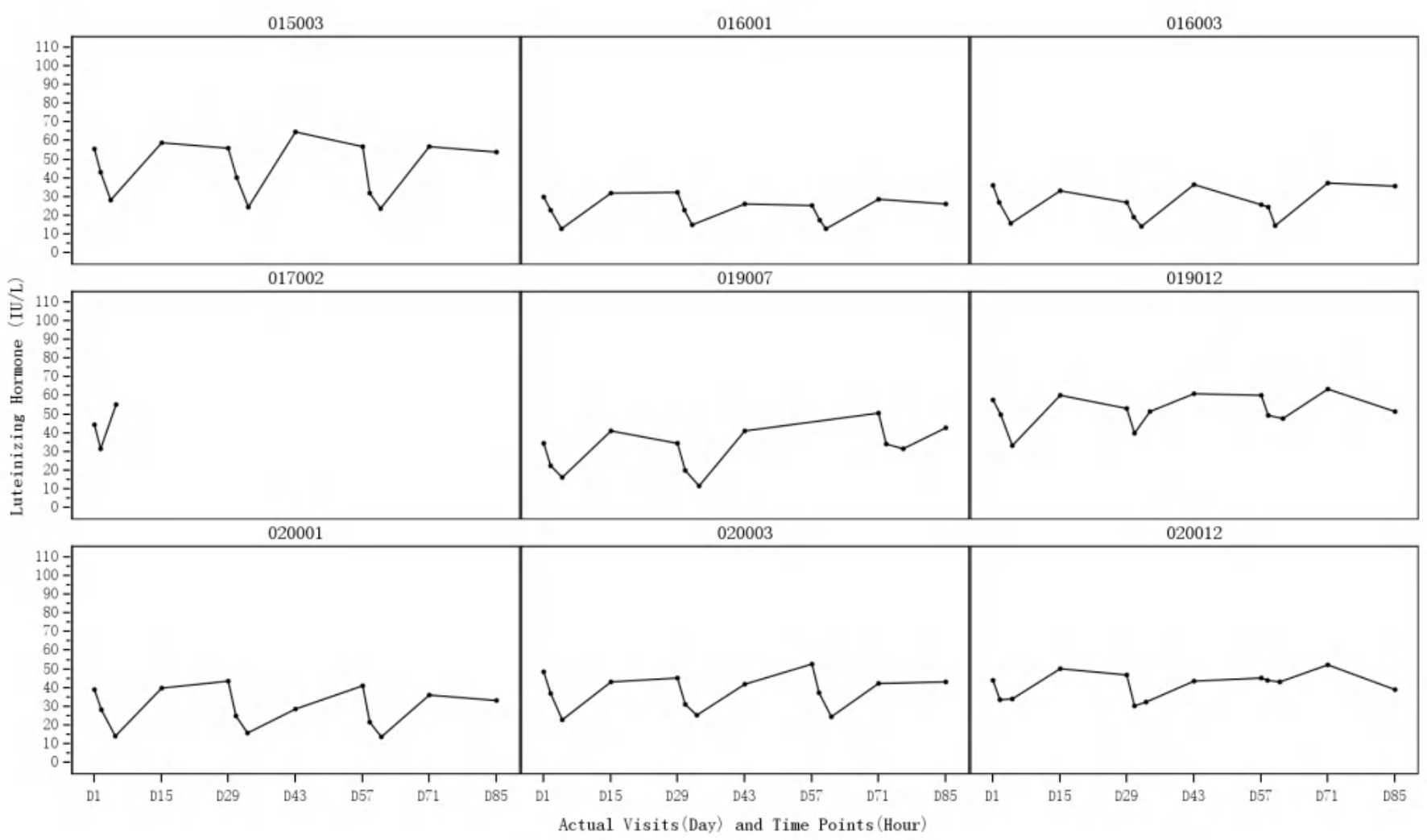


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

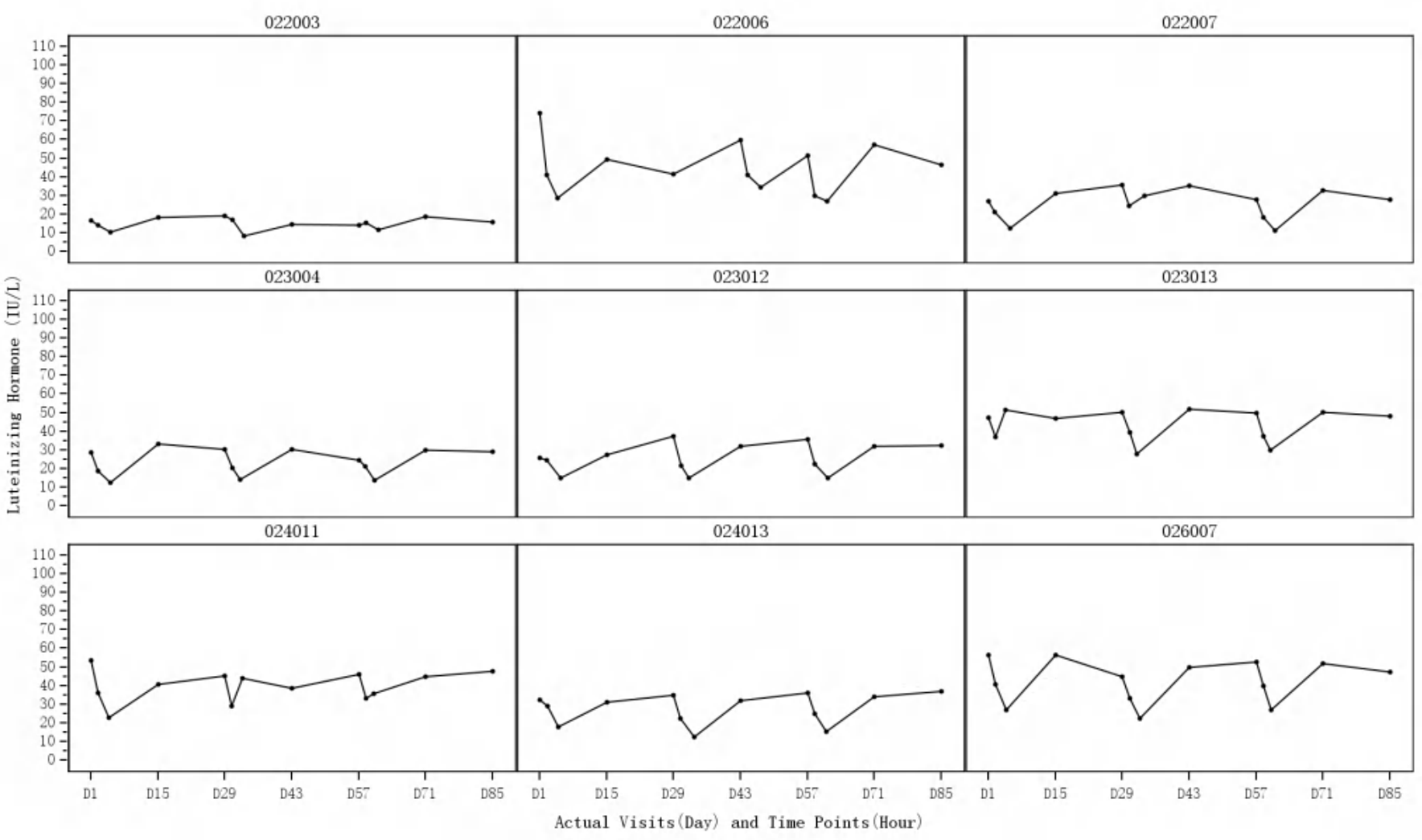


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

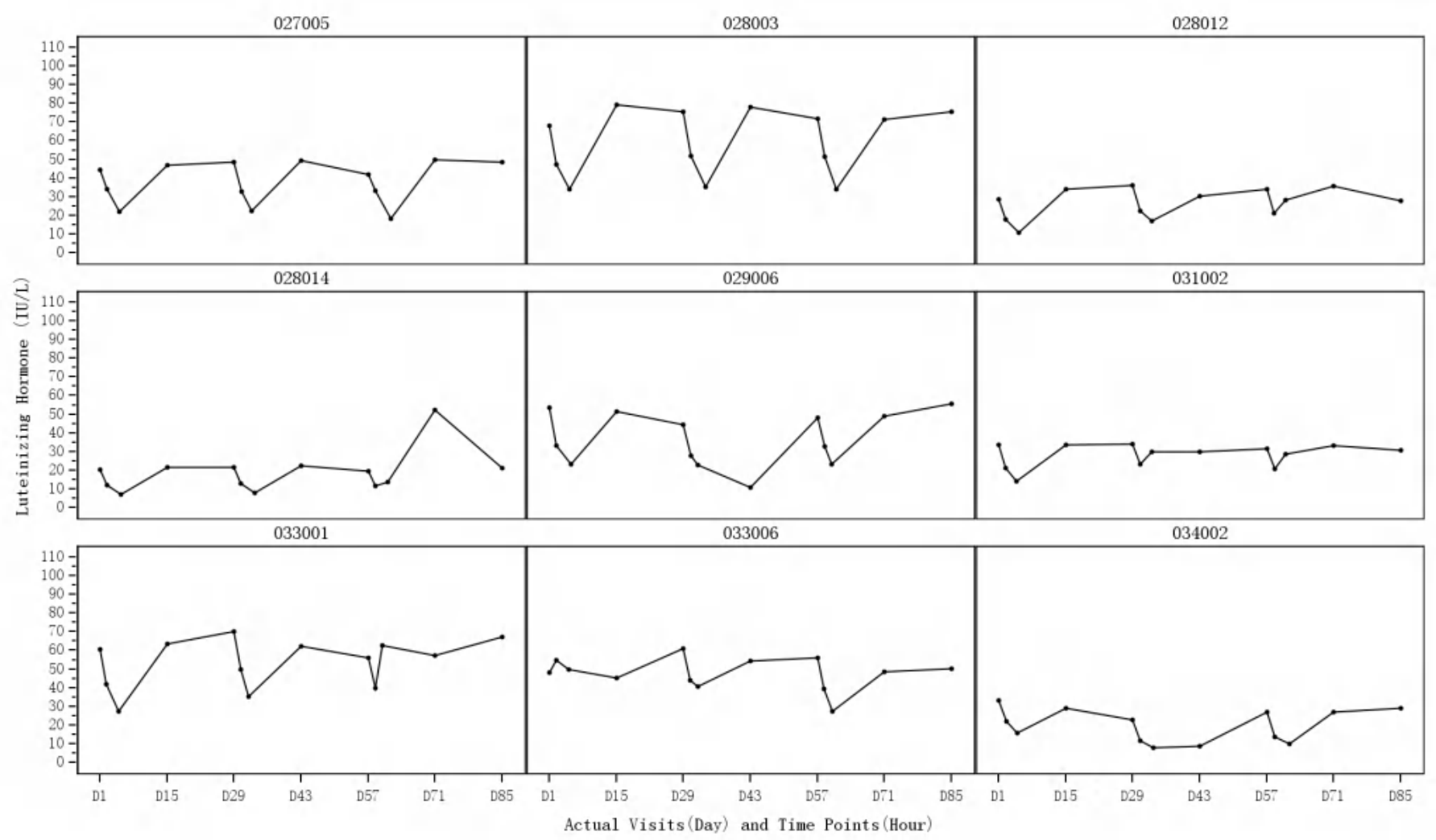


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

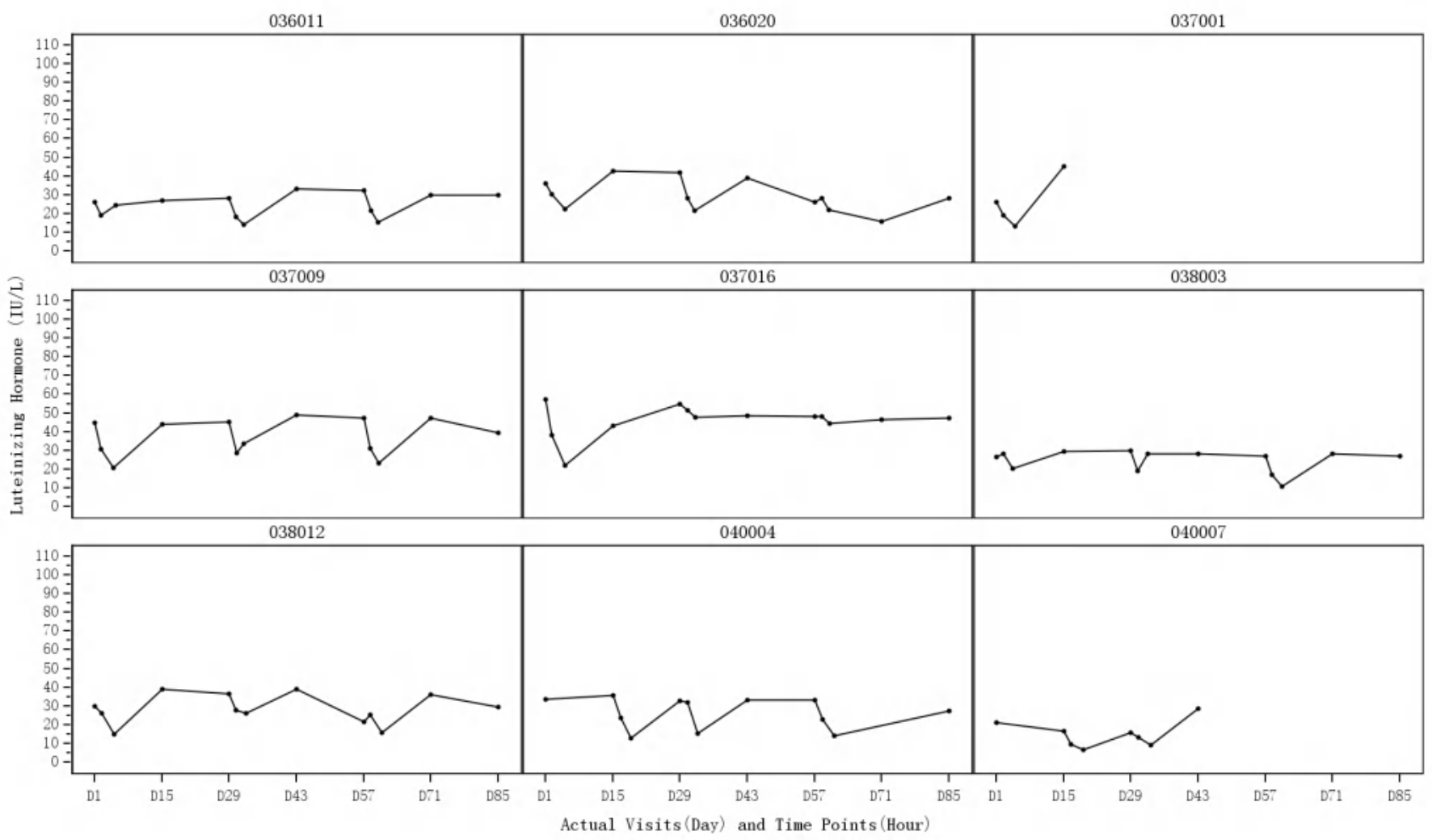


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 60 mg QD

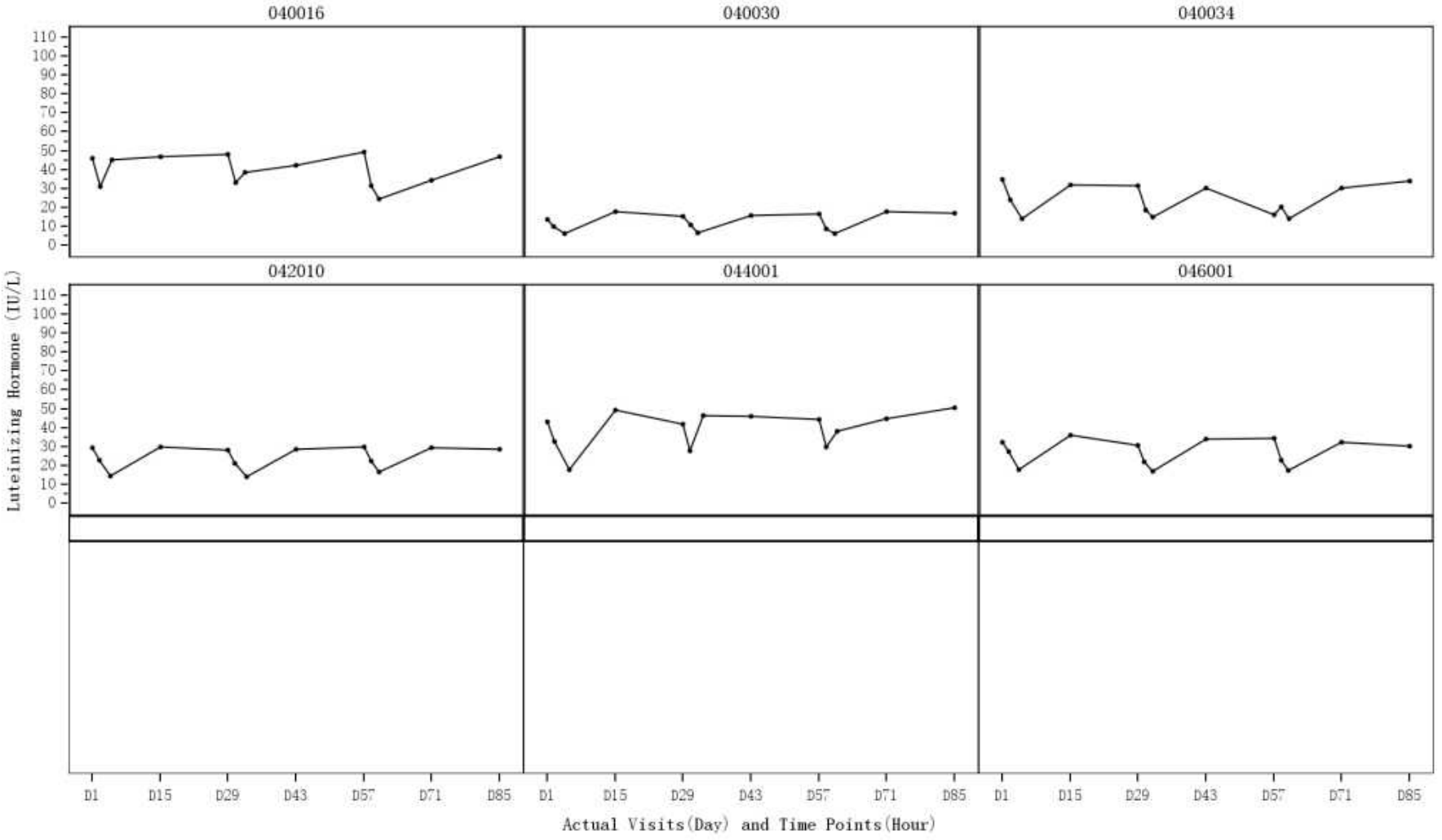


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID

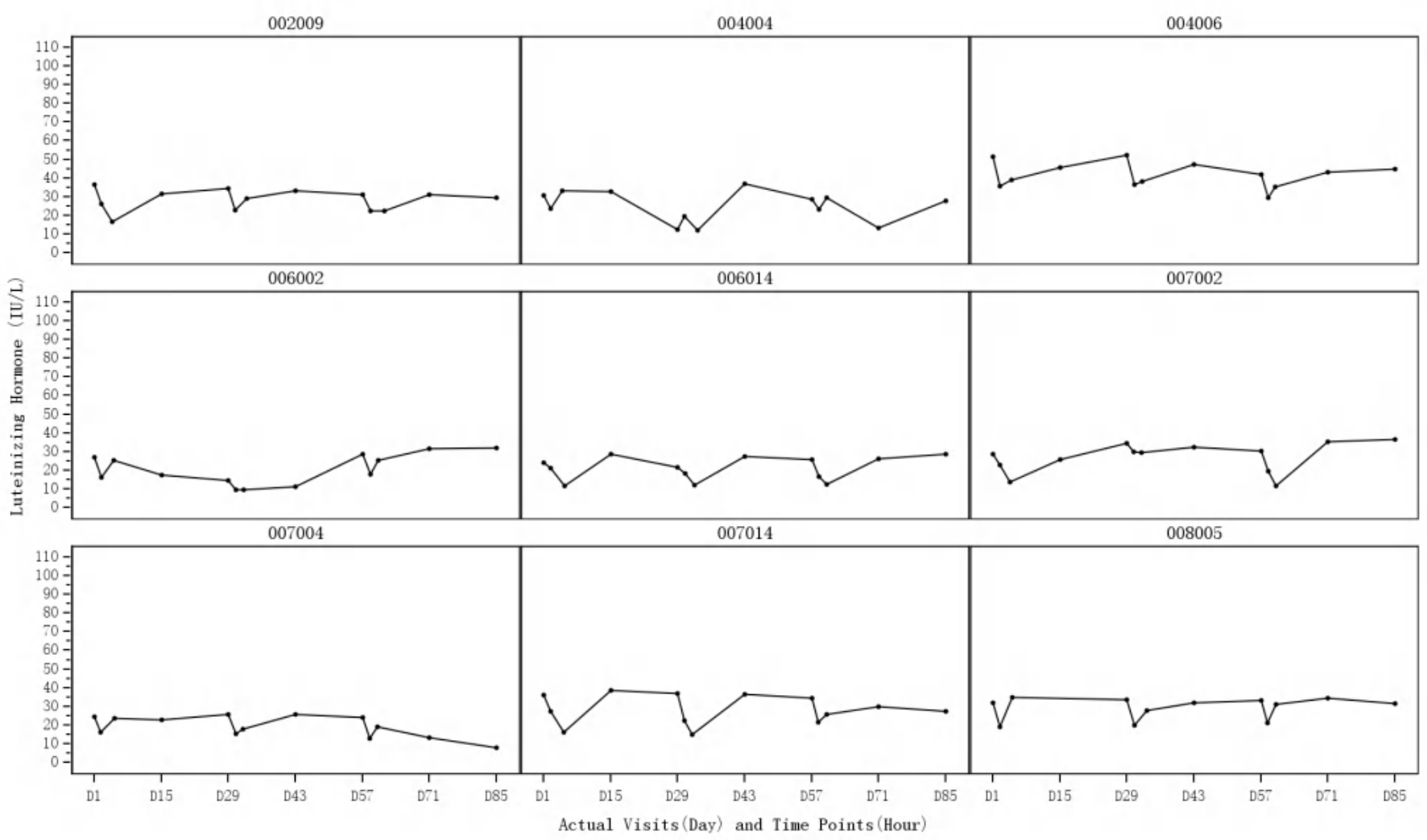


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID

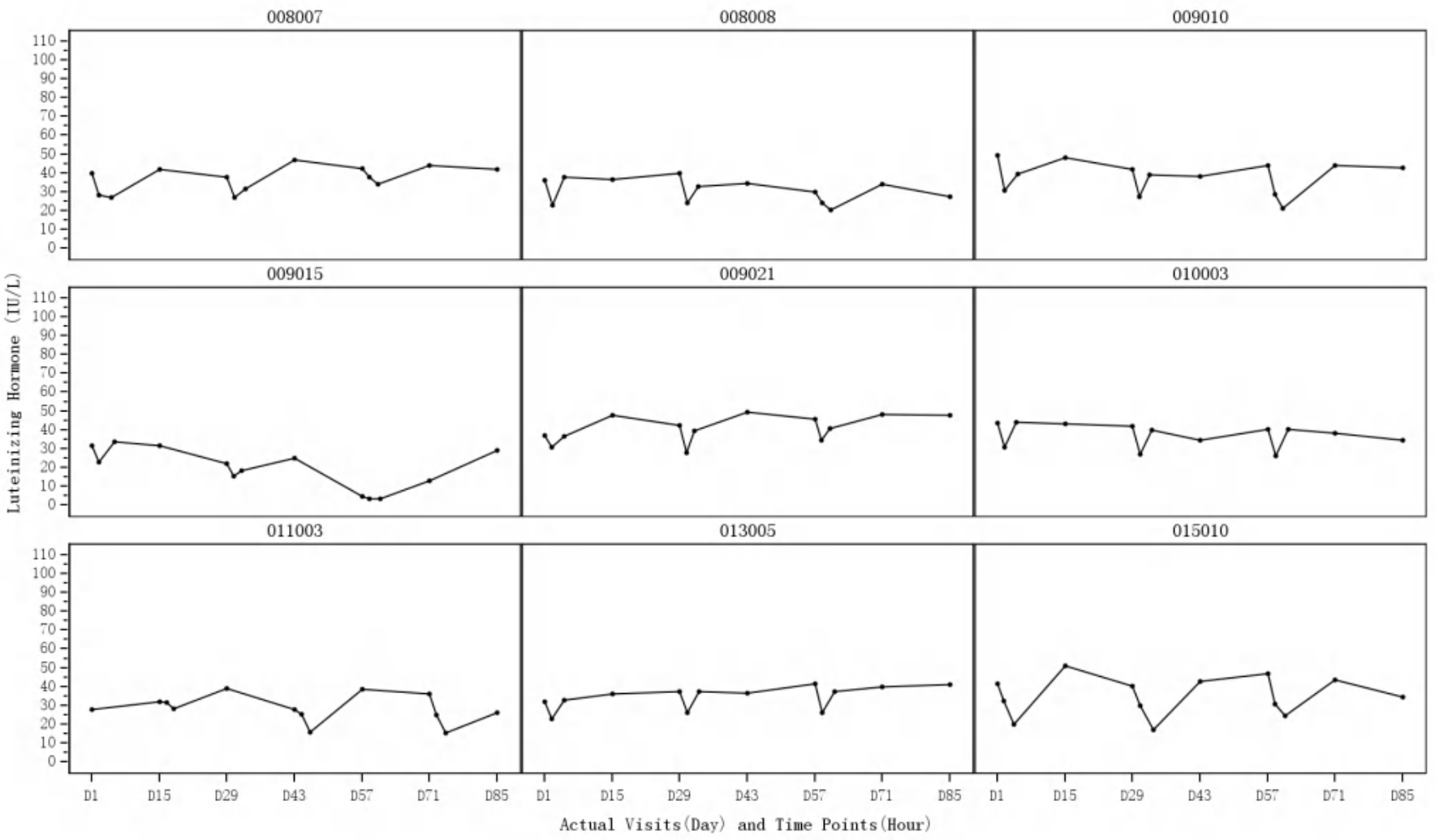


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID

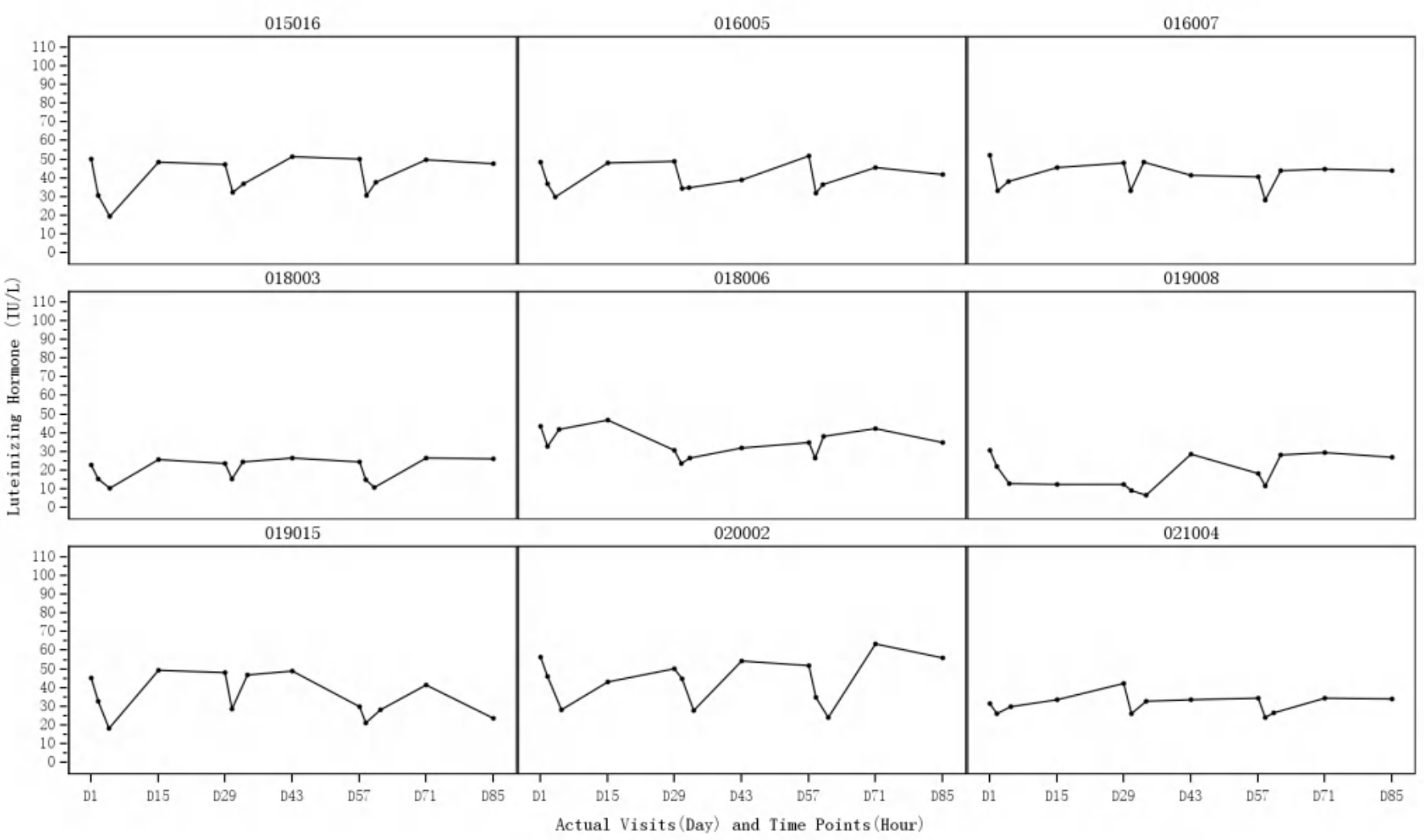


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID

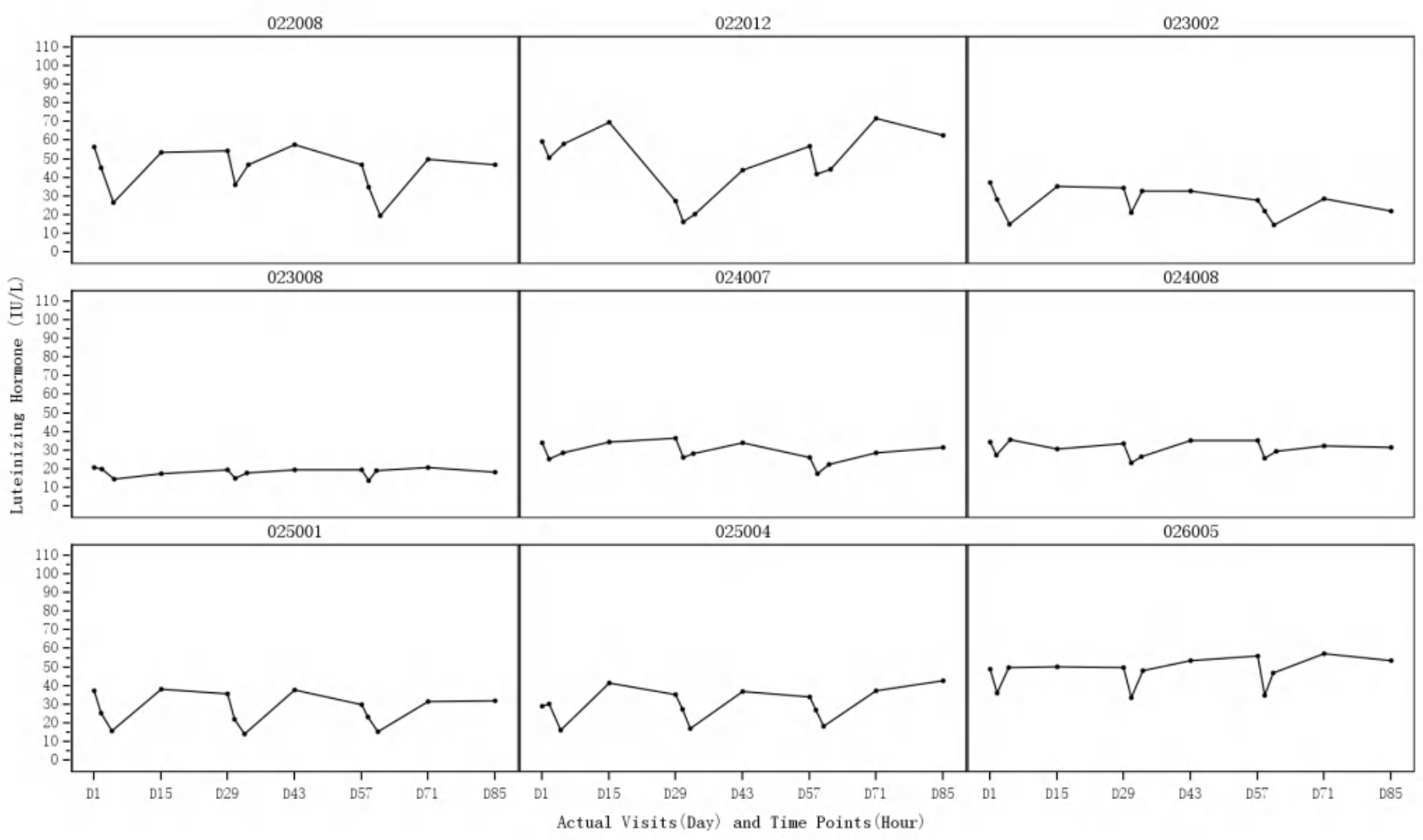


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID

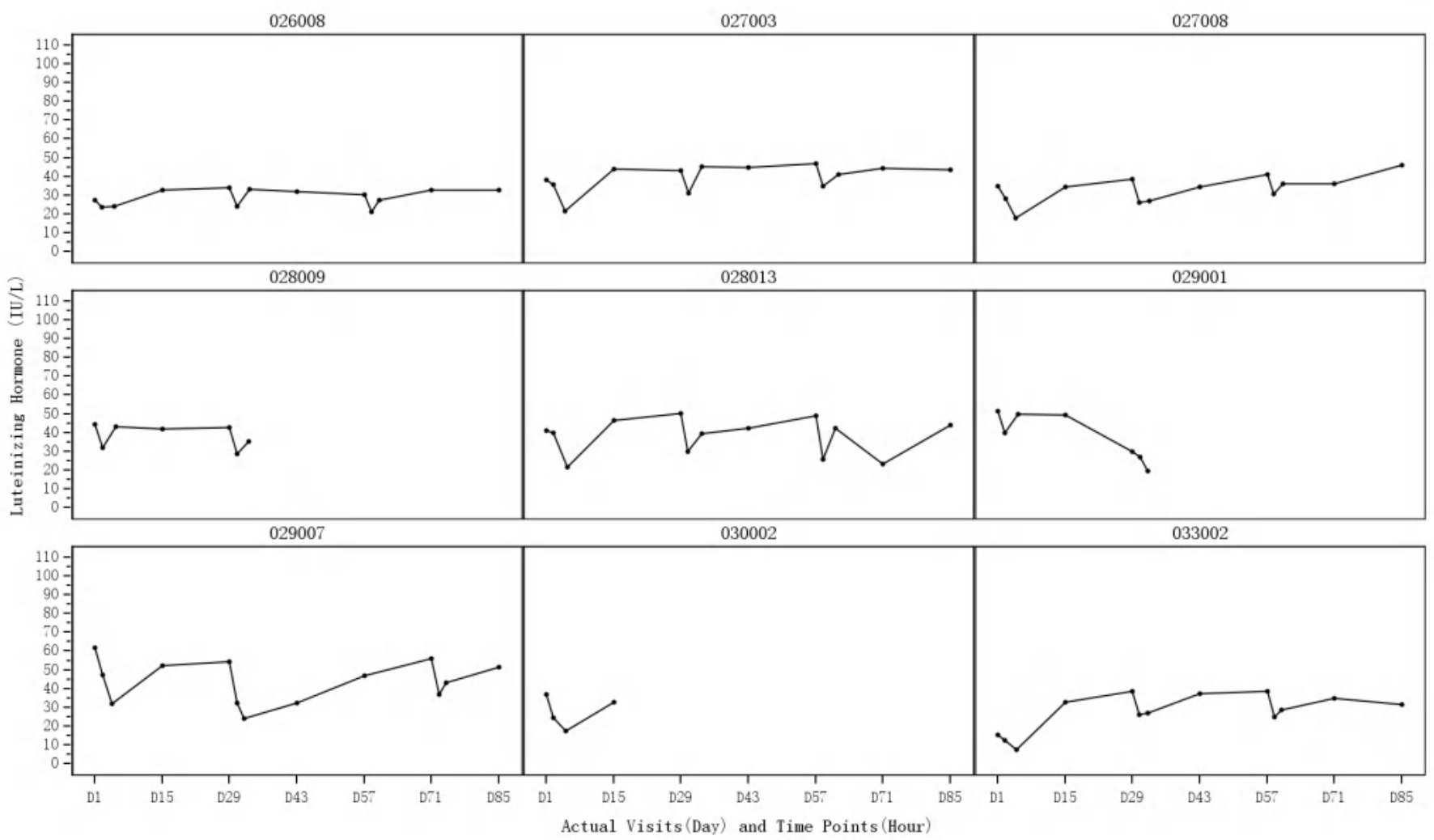


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID

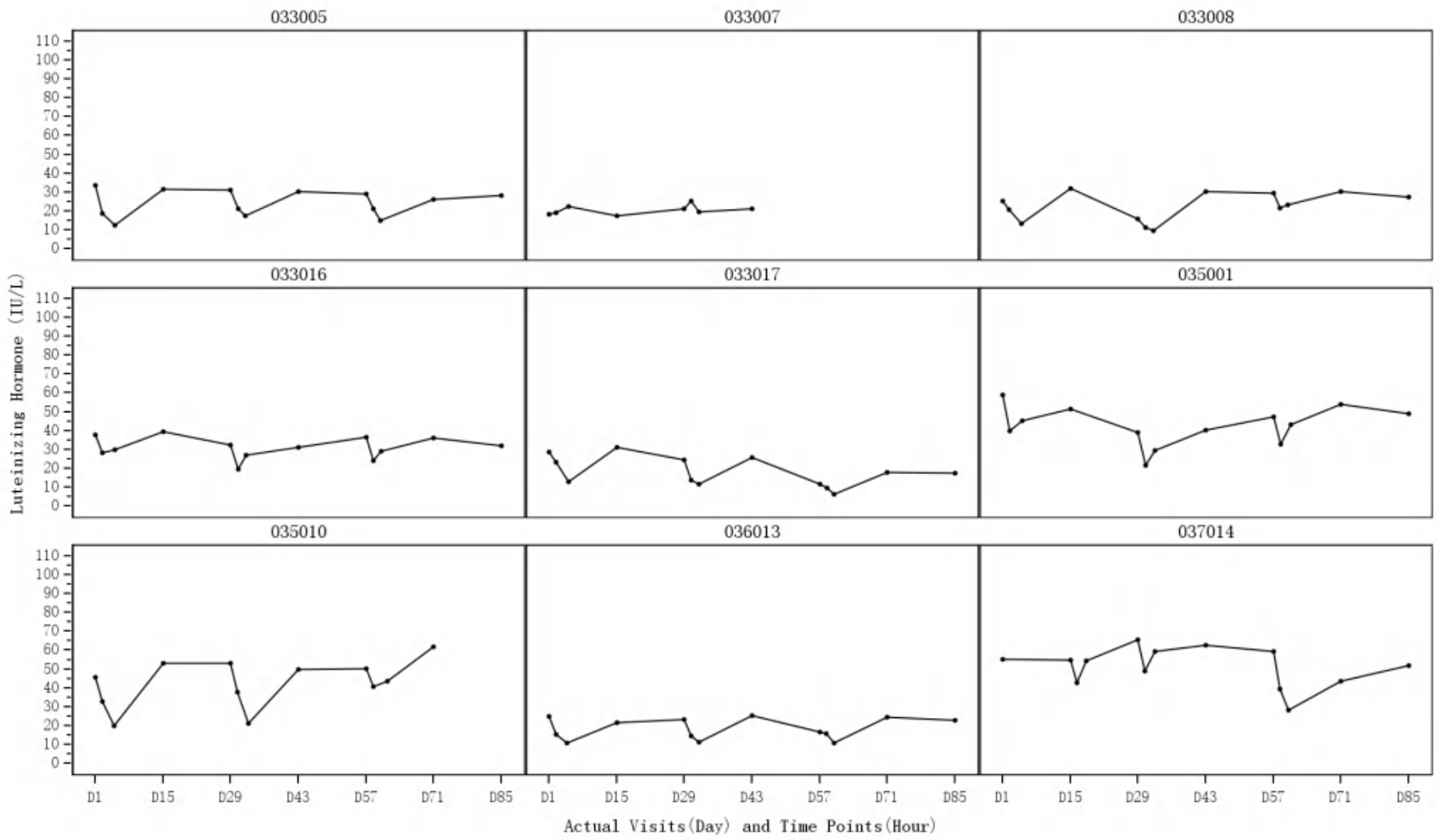


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID

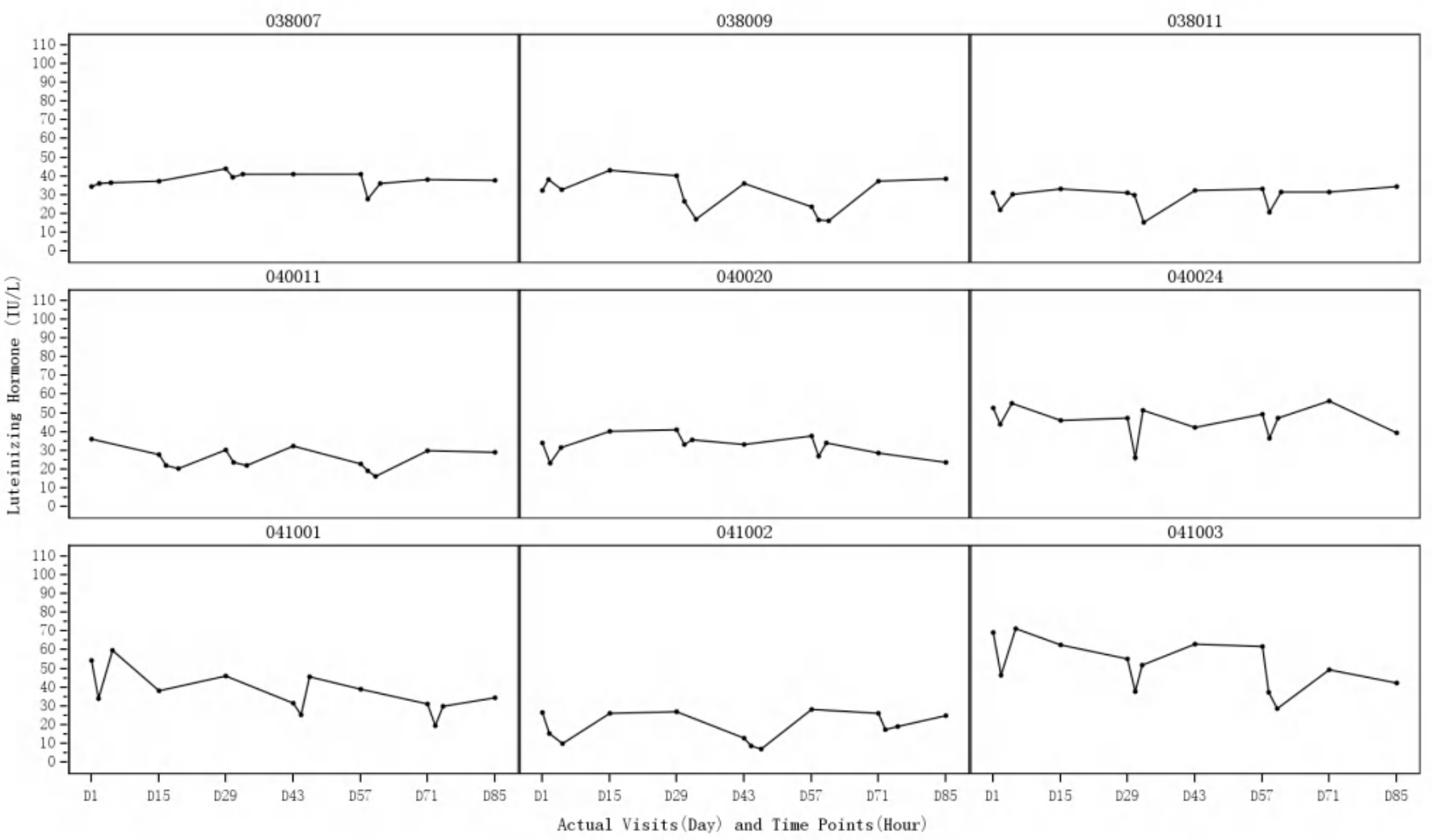


Figure 14.4.3.4
LH Serum Concentrations by Subject
PDAS

Treatment Group: GS1-144 30 mg BID