NCT 03339999

Study ID: 1957-201-001

Title: A Randomized, Double-Blind, Placebo-Controlled, Study to Assess the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of AGN-242428 in Patients With Plaque Psoriasis

Statistical Analysis Plan Date: May 16, 2018

1.0 TITLE PAGE

1957-201-001

A Randomized, Double-Blind, Placebo-Controlled, Study to Assess the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of AGN-242428 in Patients With Plaque Psoriasis

STATISTICAL ANALYSIS PLAN - Clinical Study Report

Draft 1.0: 16MAY2018

[redacted]

2.0 TABLE OF CONTENTS

3.0 LIST OF ABBREVIATIONS

AE	adverse event
AESI	adverse event of special interest
ANCOVA	analysis of covariance
BSA	Body Surface Area
CMH	Cochran-Mantel-Haenszel
CRF	case report form
ECG	electrocardiogram, electrocardiographic
mITT	modified intent to treat
MedDRA	Medical Dictionary for Regulatory Activities
PASI	Psoriasis Area and Severity Index
PGA	Physician's Global Assessment
PRO	Patient Reported Outcomes
PT	Preferred Term
QTc	QT interval corrected for heart rate
SAE	serious adverse event
SAP	statistical analysis plan
SOC	System Organ Class
TEAE	treatment-emergent adverse event

4.0 INTRODUCTION

This statistical analysis plan (SAP) provides a more technical and detailed elaboration of the statistical analyses of the efficacy and safety data as outlined and/or specified in the final protocol of Study 1957-201-001 (dated 29 Jun 2017) and the most recent amendment 2 (dated 21 Dec 2017). Specifications of tables, figures, and data listings are contained in a separate document. The SAP for pharmacokinetic/pharmacodynamic and health economics and outcomes research data will be prepared separately.

Study 1957-201-001 is a Phase 2b, double-blind, randomized, placebo-controlled trial to evaluate the efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics of AGN-242428 when administered once daily for 16 weeks to adults with moderate to severe plaque psoriasis.

Approximately 200 participants were planned to be randomly assigned (1:1:1:1) to once-daily study medication (50 participants to AGN-242428 225 mg, 50 participants to AGN-242428 350 mg, 50 participants to AGN-242428 450 mg and 50 participants to placebo) to provide an estimated total of 160 evaluable participants who will complete the study. The study consists of 3 periods, as described below.

Screening Period: The purpose of the Screening period is to evaluate potential study participants and to qualify them for enrollment into the study. This period begins at the point of informed consent and ends when the participant is randomized to treatment. The screening period will be up to 4 weeks (≤ 28 days) in duration.

Treatment Period: Participation in the study begins at the point the participant is randomized. The treatment starts after his/her first dose of study medication and ends after 16 weeks of treatment or at the point of permanent study medication withdrawal should the participant discontinue treatment prior to completion of Week 16.

On Day 1 of the treatment period, qualified participants will be randomly assigned to receive 16 weeks of once-daily oral treatment with [redacted] AGN-242428, [redacted] AGN-242428, [redacted] AGN-242428, or placebo. Baseline data for evaluation of participant efficacy and safety will be obtained on Day 1, prior to receiving the first dose. Participants will complete study visits on the first day of treatment and following 2, 4, 6, 8, 10, 12, and 16 weeks of treatment for evaluation of efficacy, safety, and tolerability assessments.

Any participant who exhibits a predefined change in clinical laboratory parameters may be required to complete unscheduled visits to further monitor abnormal safety laboratory test results. Investigators may complete unscheduled study visits at any point they feel necessary to

monitor and ensure participant safety. [redacted]

Follow-up Period: Participants will return for a follow-up visit 14 ± 3 days after completion of study medication or after early withdrawal for end-of-study assessments.

The schedule of evaluations for Study 1957-201-001 is presented in Table 4-1.

[redacted]

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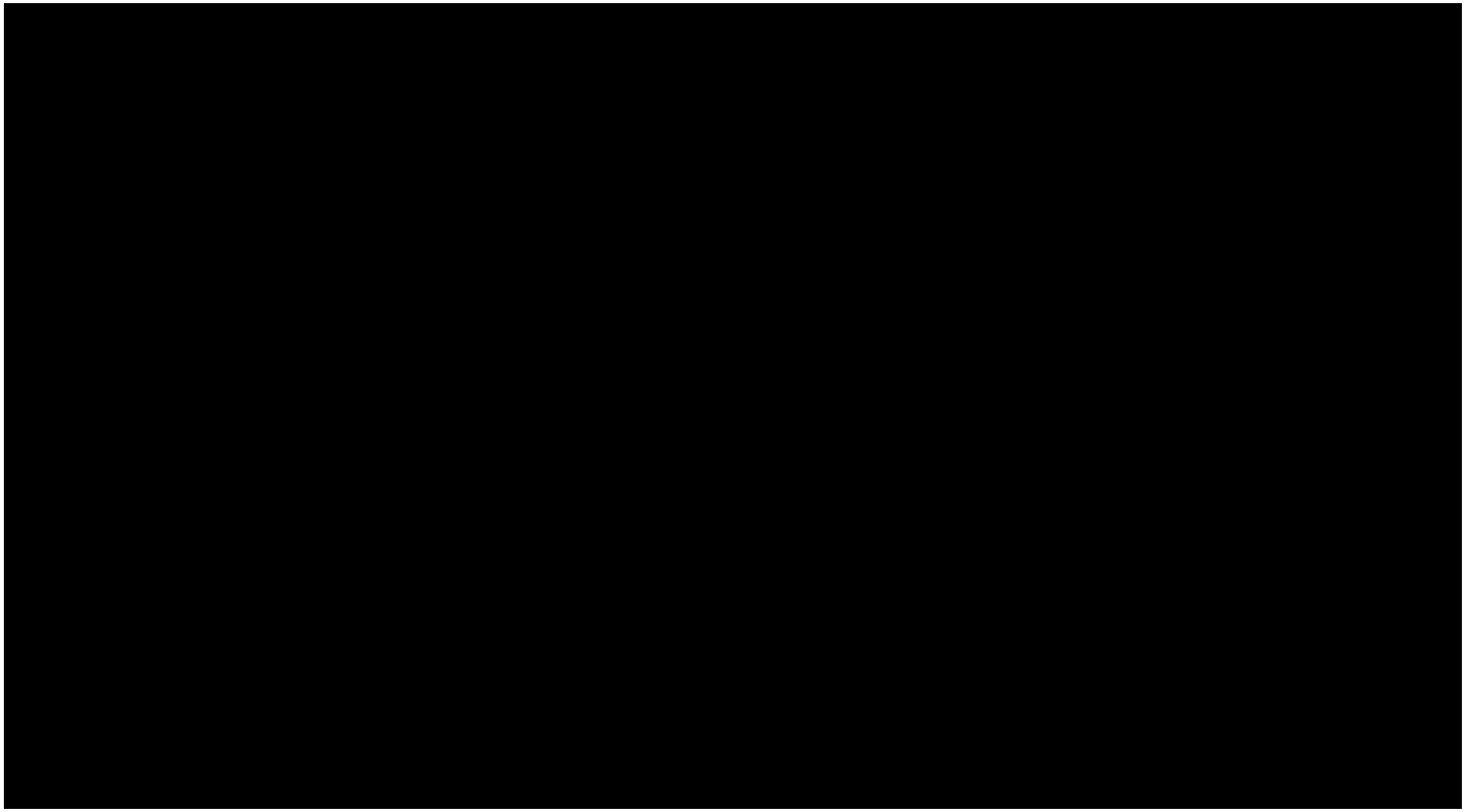
[redacted]

[redacted]

[redacted]



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[redacted]

[redacted]

[redacted]

5.0 OBJECTIVES

The objectives of this study are:

- To compare the efficacy of AGN-242428 with placebo, with respect to Psoriasis Area and Severity Index (PASI) score and Physician's Global Assessment (PGA) score, in participants with moderate to severe plaque psoriasis
- To assess the safety and tolerability of AGN-242428 in participants with moderate to severe plaque psoriasis
- To characterize the pharmacokinetics of AGN-242428 in participants with moderate to severe plaque psoriasis

6.0 PATIENT POPULATIONS

The patient populations will be summarized in total and by treatment group for all randomized or treated participants.

6.1 MODIFIED INTENT-TO-TREAT POPULATION

The modified Intent-to-Treat (mITT) Population will consist of all randomized participants with at least 1 postbaseline PASI assessment.

6.2 SAFETY POPULATION

The Safety Population will consist of all participants who received at least 1 administration of study treatment.

7.0 PATIENT DISPOSITION

Participant disposition encompasses the distribution of participants screened, randomized, treated, and who completed or discontinued the study (along with reasons for withdrawal/discontinuation). Participant disposition will be summarized for all screened participants in total and by treatment group.

8.0 DEMOGRAPHICS AND OTHER BASELINE CHARACTERISTICS

8.1 DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Demographic parameters (age; age group; sex; race; ethnicity), baseline characteristics (weight; height; body mass index, calculated as weight [kg]/(height [m])^2; Fitzpatrick skin phototype [Table 8-1], baseline PASI, % Body Surface Area (BSA), and PGA) will be summarized descriptively for the mITT Population by treatment group and in total. Continuous variables will be summarized by number of participants and mean, SD, median, minimum, and maximum values. Categorical variables will be summarized by number and percentage of participants.

Table 8-1 Fitzpatrick Skin Phototype

Type	Description
I	Always burns easily; never tans (sensitive)
II	Always burns easily; tans minimally (sensitive)
III	Burns moderately; tans gradually (light brown) (normal)
IV	Burns minimally; always tans well (moderate brown) (normal)
V	Rarely burns; tans profusely (dark brown) (insensitive)
VI	Never burns; deeply pigmented (insensitive)

Source: Federal Register 1999

8.2 MEDICAL HISTORY

Medical history, encompassing abnormalities and surgeries reported as occurring before Day 1, will be coded using the Medical Dictionary for Regulatory Activities (MedDRA), version 20.1 or newer. Unique participants who report medical history events will be summarized by MedDRA system organ class (SOC) and preferred term (PT) for the mITT Population by treatment group. Medical history will be summarized separately for those ongoing at Day 1 and those not ongoing at Day 1.

8.3 PRIOR AND CONCOMITANT MEDICATIONS

Medications will be coded using the World Health Organization (WHO) Drug Dictionary. Prior medications are medications taken ≥ 1 time before the study treatment start date, regardless of medication end date. Concomitant medications are medications taken ≥ 1 time on or after the study treatment start date, regardless of medication start date. Unique participants who reported medications will be summarized by WHO Drug class and preferred drug name for the mITT Population by treatment group. Prior and concomitant medications will be summarized separately.

9.0 EXTENT OF EXPOSURE AND TREATMENT COMPLIANCE

9.1 EXTENT OF EXPOSURE

Exposure to the investigational product for the Safety Population during the double-blind treatment period will be summarized in terms of treatment duration, calculated as the number of days from the date of the first dose of double-blind investigational product to the date of the last dose of double-blind investigational product during the double-blind treatment period, inclusive. Descriptive statistics (number of participants, mean, SD, median, minimum, and maximum) will be presented by treatment group.

Patient-years, defined as total exposure to double-blind investigational product in years will be summarized by treatment group for the Safety Population.

9.2 MEASUREMENT OF TREATMENT COMPLIANCE

Dosing compliance for the study period is defined as the total number of capsules (Row 1 + Row 2) actually taken by a participant during the study (from first treatment start date until the last treatment end date) divided by the number of capsules prescribed (2 capsules a day) for the same period multiplied by 100. If the total number of capsules for any week is missing, that week will be excluded from the compliance calculation. This information will be obtained from study treatment record of the participant's eCRF.

Descriptive statistics for study drug compliance will be presented by treatment group for the whole double-blind treatment period, for the Safety Population.

10.0 EFFICACY ANALYSES

The efficacy analyses will be based on the mITT Population, defined as randomized participants with at least 1 postbaseline PASI assessment. *Baseline* for efficacy is defined as the last non-missing efficacy assessment before the first dose of study treatment. All efficacy analyses will be conducted using observed data. All statistical tests will be 2-sided hypothesis tests performed at the 5% level of significance for main effects. All confidence intervals will be 2-sided 95% confidence intervals, unless stated otherwise.

10.1 PRIMARY EFFICACY PARAMETER

The primary efficacy endpoint will be percentage of participants achieving a reduction (improvement) in PASI score of ≥ 75% from baseline to Week 16.

The null hypothesis is that the population responder rates of the AGN-242428 and placebo groups are the same. The alternative hypothesis is that the rates differ:

- H_0: $r_v = r_p$
- H_a: $r_v \neq r_p$

where r_v and r_p are the population rates in the AGN-242428 and placebo groups, respectively.

Frequency counts of participants achieving a ≥ 75% reduction in PASI score relative to baseline will be tabulated by treatment at each postbaseline visit. The difference between each of the AGN-242428 groups and placebo in the proportion of participants with a reduction in PASI of ≥ 75% from baseline, will be analyzed using a Chi-Square test.

10.2 SECONDARY EFFICACY PARAMETERS

The following are considered secondary endpoints of the study:

- Percentage of participants achieving ≥ 2-point improvement in PGA score at Week 16
- Percentage of participants achieving a clear (0) or almost clear (1) score in PGA at Week 16

- Percentages of participants achieving reductions of 50% from baseline in PASI score at Week 16
- Percentages of participants achieving reductions of 90% from baseline in PASI score at Week 16

Frequency counts of participants achieving ≥ 2-point improvement in PGA score will be tabulated by treatment at each postbaseline visit. Frequency counts of participants who achieve a PGA score of clear or almost clear will be tabulated by treatment at each postbaseline visit. Frequency counts of participants achieving a 50% and 90% reduction in PASI score relative to baseline will be tabulated by treatment at each postbaseline visit.

The difference between each of the AGN-242428 groups and placebo in the proportion of participants achieving each of the secondary endpoints above will be analyzed using a Chi-Square test.

[redacted]

11.0 SAFETY ANALYSES

The safety analysis will be performed using the Safety Population. The safety parameters will include adverse events (AEs) and clinical laboratory, vital sign, and electrocardiographic (ECG) parameters. For each safety parameter of the clinical laboratory, vital sign, and ECG parameters, the last nonmissing safety assessment before the first dose of study treatment will be used as the baseline for all analyses of that safety parameter. Continuous variables will be summarized by number of participants and mean, SD, median, minimum, and maximum values. Categorical variables will be summarized by number and percentage of participants.

11.1 ADVERSE EVENTS

Adverse events will be coded by SOC and PT using the MedDRA, version 20.1 or newer.

An AE will be considered a treatment-emergent adverse event (TEAE) if the AE began or worsened (increased in severity or became serious) on or after the date of the first dose of study intervention. Per case report form instructions, a new AE record will be created for any AE that worsens; therefore, TEAEs can be identified as those AEs with recorded onset date on or after the date of the first dose of study intervention

The number and percentage of participants reporting TEAEs will be summarized by treatment group using MedDRA PT nested within SOC. Events will be in alphabetic order of SOC and by descending frequency of PTs within each SOC. Treatment-related TEAEs will be tabulated by descending frequency of PTs within the SOC. If more than 1 AE is coded to the same PT for the same patient, the patient will be counted only once for that PT using the greatest severity and strictest causality for the summarization by severity and causal relationship.

The number and percentage of participants who have treatment emergent serious adverse events (TESAEs) will be summarized by PT and treatment group.

The number and percentage of participants in the Safety Population who have TEAEs leading to premature discontinuation of the study treatment will be summarized by PT and treatment.

11.1.1 Adverse Events of Special Interest

The following adverse events of special interest (AESI) will be summarized by treatment group:

- aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) ≥ 5 x upper limit of normal (ULN)
- AST and/or ALT ≥ 3 x ULN AND total bilirubin (TBL) ≥ 2 x ULN or international normalized ratio (INR) > 1.5
- AST and/or ALT ≥ 3 x ULN with symptoms believed to be related to liver injury (eg, fatigue, nausea, vomiting, right upper quadrant pain or tenderness or jaundice) or hypersensitivity (such as fever, rash, or eosinophilia > 5%)
- Changes in hepatic laboratory test results that meet potential Hy's Law
  - ALT and/or AST ≥ 3 x ULN AND
  - TBL ≥ 2 x ULN AND
  - Alkaline phosphatase < 2 x ULN

Potential Hy's Law criteria within a 24-hour window is defined by a postbaseline elevation of ALT and/or AST ≥ 3x ULN, along with TBL ≥ 2 x ULN and a non-elevated alkaline phosphatase (ALP) < 2 x ULN, all based on blood draws collected within a 24-hour period.

A graphical representation of liver function, known as eDISH, will be generated by plotting the maximum postbaseline TBL elevation at any timepoint during the study vs maximum postbaseline ALT elevation at any timepoint. Note that the maximum ALT may be from a different visit than when the maximum TBL was observed. A plot of maximum TBL vs maximum AST will be generated separately.

11.2 CLINICAL LABORATORY PARAMETERS

Descriptive statistics (mean, SD, median, Q1, Q3, minimum, and maximum) for clinical laboratory values (in SI units) and changes from the baseline values at each assessment timepoint will be presented by treatment group for the following laboratory parameters:

Table 11.2-1 Clinical Laboratory Tests

Category[a]	Parameters
Hematology and Coagulation[a]	Hematocrit (HCT), hemoglobin (HGB), red blood cell (RBC) count, RBC indices, total leukocyte (or white blood cell [WBC]) count including differential, and platelet count with mean platelet volume, activated partial thromboplastin time (aPTT), prothrombin time (PT), international normalized ratio (INR)
Serum Chemistry	
Electrolytes	Sodium (Na), potassium (K), chloride, bicarbonate
Renal function	Blood urea nitrogen (BUN), creatinine (Cr)
Liver function[a]	ALT, AST, ALP, total, direct, and indirect bilirubin (TBL, DBL, IBL), gamma-glutamyl transferase (GGT), lactate dehydrogenase (LDH)
Pancreatic function	Lipase and amylase
Other[a] (selected tests at Week 6 and Week 10)	Calcium (Ca), magnesium (Mg), phosphorus (P), total protein[a], albumin[a], globulins, glucose, uric acid, creatine phosphokinase (CK)[a], cholesterol (total and fractionated) and triglycerides
Urinalysis	Appearance, bilirubin, color, ketones, glucose, leukocyte esterase, nitrites, pH, blood, protein

[a] Visits on Week 6 and Week 10 need random blood draws. Participants can be fasting or non-fasting and only the following laboratory tests will be performed at those visits: Hematology and Coagulation, Liver function, and Other (Total protein, albumin, and CK)

Clinical laboratory test values will be considered potentially clinically significant (PCS) if they meet either the lower-limit or higher-limit PCS criteria listed in Table 11.2-2. A listing of patients with PCS postbaseline values will be provided, including the participant identification (PID) number, baseline, and all postbaseline (including non-PCS) values.

Table 11.2-2 Criteria for Potentially Clinically Significant Laboratory Results

Parameter	***Unit***	***Lower Limit***	***Higher Limit***
CHEMISTRY			
Albumin	g/dL	≤ 2.0	≥ 7.1
Alanine aminotransferase	U/L	—	≥ 3 x ULN
Alkaline phosphatase	U/L	—	> 2 x ULN

Table 11.2-2 Criteria for Potentially Clinically Significant Laboratory Results

Parameter	*Unit*	*Lower Limit*	*Higher Limit*
Amylase	U/L	—	> 1.5 x ULN
Aspartate aminotransferase	U/L	—	≥ 3 x ULN
Bicarbonate	mEq/L	≤ 15	≥ 40
Bilirubin, total	mg/dL	—	≥ 2.75 x ULN
Calcium	mg/dL	< 7.0	> 12.5
Chloride	mEq/L	≤ 74	≥ 131
Cholesterol	mg/dL	—	> 400
CPK	U/L	—	> 2.5 x ULN
Creatinine	mg/dL	—	≥ 2 x ULN
GGT	U/L	—	≥ 2.5xULN
Glucose	mg/dL	< 55	> 250
LDH	U/L	—	≥ 2 x ULN
Lipase	U/L	—	> 2 x ULN
Magnesium	mEq/L	< 1.0	> 2.5
Potassium	mEq/L	< 3.0	> 6.0
Phosphorus	mg/dL	< 2.0	≥ 9.4
Protein, total	g/dL	≤ 3.9	≥ 10.1
Sodium	mEq/L	< 130	> 155
Triglycerides	mg/dL	—	> 300
BUN	mg/dL	—	> 31
Uric acid	mg/dL	—	> ULN
HEMATOLOGY			
Eosinophils, absolute cell count	x10E3/uL	—	> ULN
Eosinophils	%	—	> ULN
Neutrophils, absolute cell count	x10E3/uL	< 1.5	≥ 2 x ULN
Neutrophils	%	< LLN	> ULN

Table 11.2-2 Criteria for Potentially Clinically Significant Laboratory Results

Parameter	*Unit*	*Lower Limit*	*Higher Limit*
Lymphocytes, absolute count	x10E3/uL	< 0.8	> 4
Lymphocytes	%	< LLN	> ULN
Haematocrit	%	< 20	> 60
Haemoglobin	g/dL	< 8.0	≥ 19
INR	—	—	> 1.5
Platelet count	x10E3/uL	< 100	> 999
White blood cell count	x10E3/uL	< 3.0	≥ 22
URINALYSIS			
pH	—	< LLN	> ULN
Specific gravity	—	< LLN	> ULN
Blood	—	—	≥ 2+
Protein	—	—	≥ 2+
Glucose	—	—	≥ 2+

LLN = lower limit of normal value provided by the laboratory; ULN = upper limit of normal value provided by the laboratory.

11.3 VITAL SIGNS

Descriptive statistics (mean, SD, median, Q1, Q3, minimum, and maximum) for vital signs (systolic and diastolic blood pressures, pulse rate, and weight) and changes from baseline values at each visit and at the end of study will be presented by treatment group.

Vital sign values will be considered PCS if they meet both the observed-value criteria and the change-from-baseline criteria listed in Table 11.3-1. A listing of patients with PCS postbaseline values will be provided, including the PID number, baseline and all postbaseline (including non-PCS) values.

Table 11.3–1 Criteria for Potentially Clinically Significant Vital Signs

Parameter	***Flag***	***Criteria***[a]	
		Observed Value	*Change From Baseline*
Sitting systolic blood pressure, mm Hg	High	≥ 180	Increase of ≥ 20
	Low	≤ 90	Decrease of ≥ 20
Sitting diastolic blood pressure, mm Hg	High	≥ 105	Increase of ≥ 15
	Low	≤ 50	Decrease of ≥ 15
Sitting pulse rate, bpm	High	≥ 120	Increase of ≥ 15
	Low	≤ 50	Decrease of ≥ 15
Weight, kg	High	—	Increase of ≥ 7%
	Low	—	Decrease of ≥ 7%

a A postbaseline value is considered potentially clinically significant if it meets both the observed-value and the change-from-baseline criteria.
bpm = beats per minute.

11.4 ELECTROCARDIOGRAM

Descriptive statistics (mean, SD, median, Q1, Q3, minimum, and maximum) for ECG parameters (heart rate, RR interval, PR interval, QRS interval, QT interval, and QTc) and changes from baseline values at each assessment timepoint to the end of study will be presented by treatment group.

Electrocardiographic parameter values are considered PCS if they meet or exceed the higher-limit PCS criteria listed in Table 11.4–1. A listing of patients with PCS postbaseline values will be provided, including the PID number, baseline, all postbaseline (including non-PCS) values, and change from baseline.

Table 11.4–1 Criteria for Potentially Clinically Significant Electrocardiograms

Parameter	***Unit***	***Higher Limit***
QRS interval	msec	≥ 150
PR interval	msec	≥ 250
QTc	msec	>500 or Change from baseline (increase of > 60)

QTc = QT interval corrected for heart rate.

[redacted]

[redacted]

[redacted]

[redacted].

13.0 INTERIM ANALYSIS

No formal interim analyses are planned for this study.

14.0 DETERMINATION OF SAMPLE SIZE

A responder is a participant with ≥ 75% reduction in PASI from baseline to Week 16. The sample size of 200 participants (50 per treatment arm) was selected to provide 90% power to detect a response rate difference of 27% between each AGN-242428 and placebo group at Week 16, with an assumed response rate of 6% in the placebo group, a 5% type 1 error rate, and 20% dropout rate.

15.0 STATISTICAL SOFTWARE

Statistical analyses will be performed using [redacted].

16.0 DATA HANDLING CONVENTIONS

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

If the assessment date is on or after the date of the first dose of study treatment, the study day is calculated by assessment date – date of the first dose of study treatment + 1. If the assessment date is before the date of the first dose of study treatment, the study day is calculated by assessment date – date of the first dose of study treatment. Therefore, a negative day indicates a day before the start of the study treatment. If the assessment date is unavailable, use the visit date instead.

If a participant has 2 or more visits within the same window, the last visit with a nonmissing value will be used for analysis.

16.2 DERIVED VARIABLES

Not applicable.

16.3 REPEATED OR UNSCHEDULED ASSESSMENTS OF SAFETY PARAMETERS

If a participant has repeated assessments before the start of the first treatment, the results from the final nonmissing assessment made prior to the start of the study treatment will be used as baseline. If end-of-study assessments are repeated or if unscheduled visits occur, the last nonmissing postbaseline assessment will be used as the end-of-study assessment for generating summary statistics. If more than one lab assessment is conducted on the same day during the study, the last nonmissing value on that day will be used for analysis. If more than one ECG assessment is conducted on the same day during the study, the value corresponding to the scheduled visit on the CRF will be used for analysis as the valid reading will be assigned the scheduled visit label as opposed to being labeled as an unscheduled visit.

16.4 MISSING SEVERITY ASSESSMENT FOR ADVERSE EVENTS

If severity is missing for an AE that started before the date of the first dose of study treatment, an intensity of mild will be assigned. If severity is missing for an AE that started on or after the date of the first dose of study treatment (based on date, and time if known), an intensity of severe will be assigned. The imputed values for severity assessment will be used for the incidence summary; the values will be shown as missing in the data listings.

16.5 MISSING CAUSAL RELATIONSHIP TO STUDY TREATMENT FOR ADVERSE EVENTS

If the causal relationship to study treatment is missing for an AE that started before first dose of study treatment, a causality of no will be assigned. If the causal relationship to the study treatment (per the investigator) is missing for an AE that started on or after the date of the first dose of study treatment (based on date, and time if known), a causality of yes will be assigned. The imputed values for causal relationship to study treatment will be used for the incidence summary; the values will be shown as missing in the data listings.

16.6 MISSING DATE INFORMATION FOR ADVERSE EVENTS

Missing/incomplete AE start dates will be imputed on a case by case basis.

Imputed partial AE dates will only be used to determine if an AE is a TEAE. All partial dates will be listed "as is" in the data listings.

16.7 MISSING DATE INFORMATION FOR PRIOR OR CONCOMITANT MEDICATIONS

For prior or concomitant medications, including incomplete (ie, partly missing) start dates and/or stop dates will not be imputed.

If start or stop dates for medications are only partially reported but can be classified as prior to Day 1, then the medications will be included as prior medications.

If start or stop dates for medications are only partially reported and cannot be definitively classified as having stopped prior to Day 1, then the medications will be included as concomitant medications.

16.8 CHARACTER VALUES OF CLINICAL LABORATORY PARAMETERS

If the reported value of a clinical laboratory parameter cannot be used in a statistical summary table because, for example, a character string is reported for a parameter of the numeric type, a coded value must be appropriately determined for use in the statistical analyses. The actual values, however, as reported in the database will be presented in the data listings.

Table 16.8–1 shows examples of how some possible laboratory results should be coded for the analysis.

Table 16.8–1 Examples of Coding Special Character Values for Clinical Laboratory Parameters

Laboratory Test, SI Unit	***Possible Laboratory Results***	***Coded Value for Analysis***
CHEMISTRY		
ALT, U/L	< 5	5
AST, U/L	< 5	5
Bilirubin, total, µmol/L	< 2	2
URINALYSIS		
Glucose, mmol/L	= OR > 55, ≥ 55, > 0	Positive
	≤ 0, negative	Negative
pH	> 8.0, ≥ 8.0	8.0
	≥ 8.5	8.5
Protein	= OR > 3.0, ≥ 3.0, > 0	Positive
	≤ 0	Negative

ALT = alanine aminotransferase; AST = aspartate aminotransferase; SI = *Le Système International d'Unités* (International System of Units).

17.0 REFERENCES

Federal Register 1999: Volume 64(98); Friday, May 21, 1999
https://www.gpo.gov/fdsys/pkg/FR-1999-05-21/html/99-12643.htm

ALLERGAN

1957-201-001 Statistical Analysis Plan

Date (DD/MMM/YYYY)/Time (PT)	Signed by:	Justification
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]