[redacted]

Statistical Analysis Plan

Study Title:	**AN OPEN LABEL STUDY EVALUATING THE SAFETY, TOLERABILITY, AND EFFICACY OF EVO756 IN ADULTS WITH CHRONIC INDUCIBLE URTICARIA**
Protocol Number:	**EVO756-CIU001**
Protocol Version and Date:	**Final, V4.0 (Amendment 3), dated 10-Jan-2025**
Product:	**EVO756**
Sponsor:	**Evommune, Inc.** **841 Page Mill Road** **Suite 100** **Palo Alto, CA 94304** **USA**
Version:	**Final, V2.0**
Date:	**14-Apr-2025**
Prepared by:	[redacted]

Confidentiality Statement

This Statistical Analysis Plan is the confidential information of Evommune, Inc. and is intended solely for the guidance of the clinical investigation. This Statistical Analysis Plan may not be disclosed to parties not associated with the clinical investigation or used for any purpose without prior written consent for Evommune, Inc.

[redacted]

STATISTICAL ANALYSIS PLAN REVISION SUMMARY			
Version	**Version Date**	**Author**	**Summary of Changes**
Final V1.0	15-Nov-2024	[redacted]	Initial version
Final V2.0	14-Apr-2025	[redacted]	Changes to study details to align with Protocol V4.0 (Amendment 3), including but not limited to: • [redacted] •

[redacted]

SIGNATURE PAGE

AUTHOR

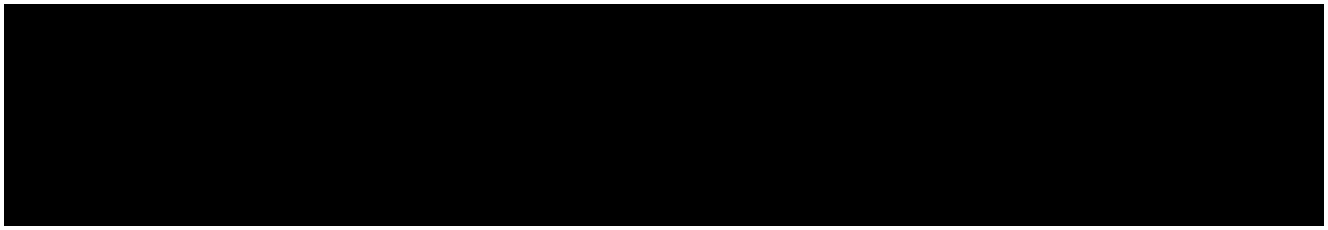
[redacted]

APPROVALS

[redacted]

This statistical analysis plan will be reviewed and revised as needed. The most recent version will replace the previous version in place.

TABLE OF CONTENT



ABBREVIATIONS

AE	adverse event
ATC	anatomical therapeutic chemical
BMI	body mass index
bpm	beats per minute
CI	confidence interval
CIndU	chronic inducible urticaria
DBP	diastolic blood pressure
ECG	electrocardiogram
eCRF	electronic case report form
ET	early termination
IA	interim analysis
ITT	intent-to-treat
LLT	lowest level term
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified intent-to-treat
n	number of subjects with non-missing data
NRS	numeric rating scale
PDMP	protocol deviation management plan
PP	per protocol
PK	pharmacokinetic
PT	preferred term
SAE	serious adverse event
SAP	statistical analysis plan
SAS	statistical analysis system®
SBP	systolic blood pressure
SD	standard deviation
SE	standard error
SOC	system organ class
TEAE	treatment-emergent adverse event
TLF	tables, listings, and figures
WHO-DD	World Health Organization Drug Dictionary

[redacted]

1 INTRODUCTION

This statistical analysis plan (SAP) describes the planned analysis and reporting for Evommune Inc. clinical protocol EVO756-CIU001. The analyses described in the SAP are based upon the protocol version 4.0 (Amendment 3), dated 10-Jan-2025.

The SAP v1.0 was developed and finalized prior to the database lock for the first interim analysis (IA). The SAP v2.0 was developed and finalized prior to the database lock for the final analysis.

2 STUDY OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS
Primary	**Primary safety endpoints:**
The primary objective of this study is to evaluate the safety and tolerability of EVO756 in subjects with chronic inducible urticaria (CIndU).	Safety will be assessed through an evaluation of treatment emergent adverse events (TEAEs), physical exams, vital signs, laboratory tests (serum chemistry, hematology, and urinalysis), and 12-lead ECGs.
Secondary	**Secondary efficacy endpoints:**
The secondary objectives of this study are: • To assess the efficacy of EVO756 in reducing wheal formation following a standardized provocation test in CIndU (cold urticaria or symptomatic dermographism). • To assess the efficacy of EVO756 in reducing pruritus at the site of the urticaria provocation tests.	**Key secondary efficacy endpoints:** Efficacy of EVO756 in reducing wheal formation following standardized provocation will be assessed by: • In subjects with cold urticaria, [redacted] • In subjects with symptomatic dermographism, [redacted] • Pruritus-Numeric Rating Scale (NRS) score at the provocation test site [redacted]

[redacted]

OBJECTIVES	ENDPOINTS
	[redacted]
Exploratory	**Exploratory endpoints**
[redacted]	[redacted]

3 STUDY DESIGN

3.1 Overall Design

This is a multi-center Phase 2a open label study evaluating the safety, tolerability, and efficacy of EVO756 in approximately 30 adult subjects with CIndU. During screening, subjects will be evaluated for cold urticaria or symptomatic dermographism by the TempTest or the FricTest to determine baseline sensitivity to a cold or pressure provocation, respectively. [redacted] Subjects will be evaluated for IgE levels at Screening and will be identified as either an IgE low subject [redacted] or an IgE high subject [redacted] Subjects will be seen on an outpatient basis at the study center at Screening, Day 1, Week 1, Week 2, Week 3, and Week 4 (End of Treatment). Subjects will return to the study center for a Study Exit visit at Week 6.

Efficacy will be assessed using a TempTest for subjects with cold urticaria or FricTest for subject with symptomatic dermographism, [redacted]

Safety will be assessed through an evaluation of treatment emergent adverse events (TEAEs), physical exams, vital signs, laboratory tests (serum chemistry, hematology, and urinalysis), and 12-lead ECGs.

[redacted]

[redacted]

The duration of participation for each subject is expected to be approximately 10 weeks (up to 30 days for screening, 4 weeks of treatment, and 2 weeks of follow-up).

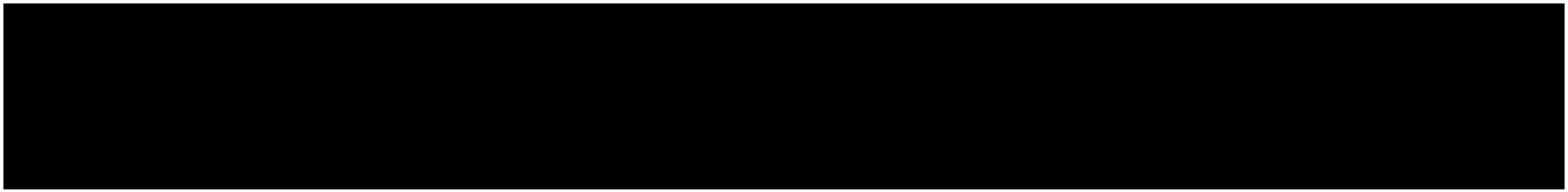
3.2 Schedule of Assessments

[redacted] provides a description of the procedures planned at each visit.

[redacted]

[redacted]

[redacted]



[redacted]

3.3 Treatment Group and Replacement

The treatment groups are:

- EVO756 300 mg, QD for 4 weeks [redacted]
- EVO756 50 mg, BID for 4 weeks [redacted]

No replacement will be made for discontinued subjects.

3.4 Changes from Planned Analyses Described in the Protocol

Table 2: Summary of Changes from Planned Analyses Described in the Protocol

[redacted]

[redacted]

4 PLANNED ANALYSES

4.1 Data Monitoring Committee

Not applicable.

4.2 Interim Analyses

[redacted]. Relevant efficacy and TEAE data will be source data verified. Ongoing subjects in the study will not be considered for this interim analysis. [redacted]

4.3 Final Analysis

Final analysis will be performed after signature of this SAP, clinical trial data are entered into the database, any discrepancies in the data are resolved, and database is locked.

5 ANALYSIS POPULATIONS

5.1 Screened Population

The screened population will include all subjects who signed an informed consent.

This population will be used to summarize disposition data.

5.2 Safety Population

The safety population will include all subjects who received at least one dose of study drug.

This population will be used to summarize demographic and other baseline characteristics, surgical and medical history, disease history, prior and concomitant medications, exposure to and compliance with study drug, and all safety data.

5.3 Pharmacokinetic Population

The Pharmacokinetic (PK) population will include all subjects who receive at least one dose of study drug and have at least one post-dose PK sample.

This population will be used to summarize all PK data.

[redacted]

5.4 Efficacy Population

The efficacy population will include all subjects who receive at least one dose of study drug and have at least one [redacted] provocation test.

This population will be used to summarize all efficacy data.

5.5 Per-Protocol Population

The per-protocol population will include all subjects who receive at least one dose of study drug, have at least one pre- and one post-treatment provocation test and have no protocol deviation with a Severity of Major potentially having an impact on efficacy data.

6 GENERAL CONSIDERATIONS

Table, listing, and figure (TLFs) Shells will be provided in a separate document. [redacted]

6.1 Baseline

[redacted]

6.2 Change and Percent Change from Baseline

[redacted]

[redacted]

6.3 Study Day

Study Day will be calculated from the first dose of study drug as follows and will be used to show start/end day of assessments or events:

> (Date of assessment/event – Date of first dose of study drug) if date of assessment/event is before the date of first dose of study drug.
>
> or
>
> (Date of assessment/event – Date of first dose of study drug) + 1 if date of assessment/event is on or after the date of first dose of study drug.

In the situation where the assessment/event date is partially or completely missing, the Study Day will be missing.

6.4 Windowing Conventions

For by-visit summary and analysis (when applicable), visits will be summarized and analyzed as scheduled [redacted] Retest, unscheduled, and early termination (ET) visits will only be considered if a scheduled measurement is not available and a retest, unscheduled, and/or ET measurement falls within protocol-adjusted analysis visit window for that scheduled measurement, as described in Table 3, 4, 5, 6 and 7.

For summary and analysis (when applicable) not presented by visit (e.g., worst post-baseline value), all data (scheduled, retest, unscheduled, and ET) will be considered.

All data collected during scheduled, retest, unscheduled, and ET visits will be listed.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

If more than one assessment falls within the same protocol-adjusted analysis visit windows and a scheduled measurement is not available, the measurement collected closest to the scheduled visit

target study day will be used for the by-visit summary. If two measurements or more are equidistant from a scheduled visit target study day, the measurement collected before the scheduled visit target study day will be used.

6.5 Software Version

All analyses will be performed using SAS® software Version 9.4 or higher.

7 STATISTICAL CONSIDERATIONS

7.1 Sample Size Determination

Approximately 30 adults with CIndU, having either cold urticaria or symptomatic dermographism, will be enrolled in this study.

7.2 Multicenter Studies

This study will be conducted by multiple investigators at multiple sites in the USA. Data from all sites will be pooled together in the summaries and analyses.

7.3 Handling of Dropouts or Missing data

Unless otherwise specified in the sections below, no missing data will be imputed.

7.3.1 Efficacy Data

7.3.1.1 Observed Cases

No missing data will be imputed, and the analysis will be based on observed data only.

7.3.2 Safety Data

Partially or completely missing medication and AE start and stop dates will be imputed as described in Appendix 2 and will only be used for the classification of each medication as prior or concomitant (refer to Section 11) and each AE as prior or treatment-emergent (refer to Section 14.1). That is, imputed dates will not be used to compute duration and will not be presented in subject data listings.

7.4 Descriptive Statistics

Unless otherwise indicated, continuous endpoints will be summarized using descriptive statistics i.e., number of subjects with non-missing data (n), mean, standard deviation (SD), median, minimum, and maximum.

[redacted]

Categorical endpoints will be summarized using frequencies and percentages.

7.5 Adjustment for Covariates and/or Fixed Effect

Not applicable.

7.6 Coverage of Confidence Intervals and Statistical Tests

Confidence intervals (CIs) will be two-sided with 95% coverage.

No statistical tests will be performed.

7.7 Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons/multiplicity will be made for this study.

7.8 Examination of Subgroups

[redacted]

8 STUDY SUBJECTS

8.1 Disposition of Subjects

All subjects who provide informed consent will be accounted for in this study. The number of subjects screened and rescreened will be presented. The number and percentage of subjects with screen failure will be presented for all screened subjects, except for those who were rescreened and did not fail the second screening. Reason for screen failure will be summarized similarly but for subjects with screen failure.

The number of subjects enrolled (i.e., who provide informed consent and are eligible to continue in the study) will be presented for each treatment group and overall. Number and percentage of subjects included in each population, who completed or discontinued early from study drug, and who completed or discontinued early from study will be presented for all enrolled subjects. Reason for discontinuation from study drug and/or reason for discontinuation from study will be presented similarly but for subjects who discontinued early from study drug and/or who discontinued early from study, respectively.

Number of days in the study will be calculated as follows and summarized overall:

(Date of completion/discontinuation – Date of first dose of study drug) +1

A listing of subject's disposition will be provided. Information on first screening for subjects who were rescreened, including the rescreened subject identifier, will be presented under the first screening subject identifier. A listing of subject's enrollment information and a listing of subjects included/excluded from each of the populations, with reason for exclusion, will also be provided.

8.2 Protocol Deviations

Protocol deviations are classified as Major or Minor. Classification will be based on the Protocol Deviation Management Plan (PDMP). The PDMP refers to Important/Non-Important classification and these will be considered as Major/Minor PDs for the purpose of the analysis, respectively.

The number of events and the number and percentage of subjects with at least one major protocol deviation will be summarized by treatment group and overall, deviation category and sub-category based on the safety population. Site-level protocol deviations will be reported once for each subject enrolled at that site.

A listing of all protocol deviations will be provided and major will be flagged.

9 DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Demographic and other baseline characteristics will be summarized using descriptive statistics by treatment group and overall based on the safety population. The list of demographic and baseline characteristics to be summarized includes:

- Age (years) as collected on electronic Case Report Form (eCRF)
- Sex at birth
- Ethnicity
- Race
- Baseline height (cm)
- Baseline weight (kg)
- Baseline body mass index (BMI) (kg/m^2), derived as the baseline weight (kg) divided by the square of the baseline height (m^2) i.e., baseline height (m) x baseline height (m)
- Disease history of symptomatic dermographism or cold urticaria

[redacted]

- Time since diagnosis of symptomatic dermographism or cold urticaria
- [redacted]

Subjects who reported more than one race will be counted once under each reported race.

The time since diagnosis of symptomatic dermographism or cold urticaria will be calculated as:

Time since diagnosis = (Date of first dose of study treatment – Date of diagnosis)/365.25.

Completely or partially missing dates for the date of diagnosis will be imputed as follows:

- Completely missing: Leave missing.
- Missing day and month: Impute to January 1st.
- Missing day: Impute to the 1st of the month.

A listing of all demographics and other baseline characteristics will be provided.

10 SURGICAL AND MEDICAL HISTORY

Surgical and medical history will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA), version 27.0.

Incidence of surgical and medical history will be summarized by system organ class (SOC) and preferred term (PT), by treatment group and overall based on the safety population. Subjects who experienced the same surgical and medical history multiple times within the same SOC will be counted only once for the corresponding SOC. Similarly, subjects who experienced the same surgical and medical history multiple times within the same PT will be counted only once for the corresponding PT. Surgical and medical history will be sorted alphabetically by SOC and within each SOC, PTs will be presented by decreasing order of overall frequency.

A listing of all surgical and medical history will be provided.

11 PRIOR AND CONCOMITANT MEDICATIONS

Medications will be coded according to the World Health Organization Drug Dictionary (WHO-DD), version B3 Mar 2024.

Prior medications are defined as any medication started and discontinued prior to the first dose of study drug. Concomitant medications are defined as any medication taken on or after the first dose

[redacted]

of study drug including those who started prior to the date of the first dose of study drug and continued past that date. [redacted]

Incidence of prior medications will be summarized by anatomical therapeutic chemical (ATC) class level 3 and preferred drug name, by treatment group and overall based on the safety population. Subjects with multiple medications within the same ATC class level 3 will be counted only once for that ATC class level 3. Similarly, subjects with multiple medications within the same preferred drug name will be counted only once for that preferred drug name. Prior medications will be sorted alphabetically by ATC class level 3 and within each ATC class level 3, the preferred drug name will be presented by decreasing order of overall frequency.

Concomitant medications will be summarized similarly.

Medications received for urticaria will be split into prior and concomitant medications similarly and summarized separately.

A listing of all medications (prior and concomitant) and a listing of all medications received for urticaria will be provided.

Furthermore, the use of antihistamines by the subjects, and whether the medication qualifies as a short-acting or long-acting antihistamine, will be reviewed, flagged, and confirmed by the Medical Monitor prior to database lock. This information will be used for the purpose of the sensitivity analysis as defined in section 13.4.

12 EXPOSURE TO AND COMPLIANCE WITH STUDY DRUG

Duration of exposure to study drug, in days, is defined as follows:

(Date of last dose of study drug – Date of first dose of study drug) + 1

Compliance with study drug (%) will be calculated as follows:

$$\frac{\textbf{Total number of doses taken}}{\textbf{Number of Expected Doses}} \textbf{ x 100}$$

[redacted]

The number of doses taken corresponds to the number of expected doses per day x duration of exposure (days), minus the number of doses missed between the first dose and last dose of study drug per eCRF reporting.

[redacted]

- [redacted]
- [redacted]

Duration of exposure to study drug (days), and compliance with study drug (%) will be summarized using descriptive statistics based on the safety population.

Study drug administration, accountability, exposure, and compliance will be listed.

13 EFFICACY ANALYSES

Unless otherwise specified, all efficacy endpoints will be summarized by visit, when applicable, and by treatment group based the efficacy population.

13.1 Definition of Efficacy Endpoints

13.1.1 TempTest

The TempTest is an instrument used to elicit symptoms of cold and heat urticaria. A positive response to the provocation test is defined as a palpable wheal at the test site. Approximately 10 minutes after completion of provocation (i.e., approximately 15 minutes from the start of the test), the resultant wheal will be outlined on the TempTest provided stencil. The critical threshold temperature (CTT), defined as the highest temperature that elicits a wheal response, will be determined and recorded.

[redacted]

[redacted]

The proportion of subjects who are complete responders [redacted] will be calculated at Weeks 1, 2, and 4.

The proportion of subjects categorized as at least partial responders will also be calculated at Weeks 1, 2 and 4. [redacted]

13.1.2 FricTest

The FricTest is an instrument used to diagnose symptomatic dermographism. The FricTest is a flat plastic comb (85 x 55 mm) with four round-ended plastic pins 3 mm in diameter, numbered 1 – 4, with length of 3.0, 3.5, 4.0, and 4.5 mm, respectively. For provocation, the comb is held perpendicular to the volar forearm and constant sufficient pressure is applied so that all pins make contact with the skin and are almost, but not completely, invisible. The instrument is then stroked across the skin across approximately 60 mm. After about 10 minutes, the resultant wheals are evaluated. A clearly visible and palpable linear wheal with a width of ≥3 mm (the diameter of the pins) is considered a positive response. The total number of linear wheals with a width of ≥3 mm is the Total Fric Score (TFS).

[redacted]

Additionally, the proportion of complete responders [redacted] will be calculated at Weeks 1, 2, and 4.

The proportion of subjects categorized as at least partial responders will also be calculated at Week 1, 2 and 4. [redacted]

13.1.3 Pruritus-NRS

Prior to and approximately 10 minutes after completion of the provocation test (right after the wheal evaluation), the subject will be asked to rate the severity of their pruritus at the site of the provocation test [redacted]

Overall change in pruritus after provocation will be calculated at Weeks 1, 2, and 4 and compared to baseline, such that:

[redacted]

[redacted]

[redacted]

Additionally, change from baseline after provocation will be calculated at Weeks 1, 2, and 4 and compared to the mean post-provocation scores at baseline, such that:

[redacted]

The proportion of at least partial responders, and complete responders will also be calculated at Weeks 1, 2 and 4. [redacted]

13.2 Main Analysis

For all analyses on the TempTest, only subjects with cold urticaria will be considered. For all analyses on the FricTest, only subjects with symptomatic dermographism will be considered.

Mean change from baseline in efficacy parameters will be summarized using descriptive statistics at each post-baseline visit. The 95% CI will be provided for the mean change and will be calculated using the t-distribution. Analysis will be performed on the observed cases (OC) only and no imputation will be made for missing data.

Proportions of subjects achieving efficacy parameter criteria will be summarized by frequency counts and percentages with 95% CIs at each post-baseline visit. The Clopper-Pearson method will be used for the calculation of the CIs. Analysis will be performed on the observed cases (OC) only and no imputation will be made for missing data. For proportion endpoints, percentages will be based on the number of subjects with a response at the specified visit.

Similarly, a combined analysis on the FricTest and TempTest (for both partial and complete responders) will be performed. In the at least partial responder analysis, a subject will be considered a partial responder if they meet the criteria for partial responder of either the TempTest or the FricTest. In the complete responder analysis, a subject will be considered a complete responder if they meet the criteria for complete responder of either the TempTest or the FricTest.

Subgroups analyses are defined in section 7.8.

[redacted]

13.3 Supportive Analyses

The main analysis for the change in TempTest, FricTest, and Pruritus-NRS will be repeated based on the per-protocol population.

13.4 Sensitivity Analyses

[redacted]

14 SAFETY ANALYSES

All safety endpoints will be summarized by visit, when applicable, by treatment group, and overall based the safety population.

14.1 Adverse Events

AEs will be coded according to the MedDRA, version 27.0.

Treatment emergent adverse events (TEAEs) are defined as any AEs with onset date, and time (if available), on or after the date, and time (if applicable) of the first dose of study drug. [redacted] In the case where it is not possible to define an AE as treatment emergent or not, the AE will be classified as treatment emergent.

An overall summary table for AEs will be provided. The number of events and the number and percentage of subjects who experienced at least one AE, TEAE, TEAE by greatest reported relationship to study drug, TEAE by worst reported severity, TEAE with an outcome of death, serious TEAE, non-serious TEAE, TEAE leading to discontinuation from study drug, and TEAE leading to discontinuation from study will be presented.

[redacted]

Incidence of TEAEs will be summarized by SOC and PT. Subjects experiencing multiple TEAEs within a SOC will be counted only once for that SOC. Similarly, subjects experiencing multiple TEAEs within a PT will be counted only once for that PT. TEAEs will be sorted alphabetically by SOC and within each SOC, PTs will be presented by decreasing order of total frequency.

Incidence of TEAEs will be further broken down by greatest reported relationship with study drug, where a treatment-related TEAE is defined as any TEAE that is assessed by the investigator as related to study drug while not treatment-related TEAE is defined as any TEAE that is assessed as not related to study drug. Subjects experiencing multiple TEAEs within the same SOC/PT but in different categories of relationship to study drug will be reported only once under the greatest reported relationship to study drug. A TEAE with an unknown relationship will be considered as treatment-related.

Incidence of TEAEs will also be further broken down by worst reported severity. A severe adverse event is defined as any AE with a toxicity grade of 3 or higher. Subjects experiencing multiple TEAEs within the same SOC/PT but in different categories of severity will be reported only once under the worst severity. A TEAE with an unknown severity will be considered as severe.

Similarly, incidence of TEAEs will also be further broken down by worst reported severity and greatest reported relationship. When summarizing TEAEs by severity and relationship, each subject will be counted once within a system organ class or a preferred term by using the event with the highest severity and greatest relationship within each classification.

Incidence of serious TEAEs, non-serious TEAEs, TEAEs leading to discontinuation from study drug, and TEAEs leading to discontinuation from study will be summarized separately by SOC and PT.

Listings of all AEs with an outcome death, all serious AEs, all TEAEs leading to discontinuation from study drug, and all TEAEs leading to discontinuation from study will be provided. A listing of all AEs will also be provided, detailing the verbatim term given by the Investigator or designee, PT, SOC, onset date, resolution/stabilization date, severity, seriousness, action taken, outcome and relationship to study drug. The event onset will also be shown relative (in number of days) to date of first dose.

14.2 Clinical Laboratory

Laboratory data will be presented in SI units.

[redacted]

Observed values and changes from baseline in chemistry, hematology, and quantitative urinalysis tests will be summarized using descriptive statistics. Frequencies and percentages will be presented for each category of qualitative urinalysis tests.

Shift tables from baseline to each post-baseline visit describing shifts to abnormality based on the central laboratory reference ranges (low, normal, high for chemistry, hematology, and quantitative urinalysis; normal, abnormal for qualitative urinalysis) will be provided. Only subjects with a baseline result and a result at the specified post-baseline visit will be considered.

Separate listings of all data for chemistry, hematology, urinalysis tests and pregnancy will be provided.

14.3 Vital Signs

Observed values and changes from baseline in vital signs (systolic blood pressure [SBP], diastolic blood pressure [DBP], heart rate, respiratory rate, and body temperature) will be summarized using descriptive statistics.

A listing of all vital sign assessments will be provided.

14.4 Electrocardiogram

Observed values and changes from baseline in ECG tests/intervals (heart rate, RR interval, PR interval, QRS interval, QT interval, QTcB interval, and QTcF interval) will be summarized using descriptive statistics at each visit.

RR interval (sec), QTcB interval (msec), and QTcF interval (msec) will be re-calculated and used in summaries as follows:

$RR = 60/HR$

$QTcB = QT\ interval / (RR^{1/2})$

$QTcF = QT\ interval / (RR^{1/3})$

For Investigator ECG overall interpretation, shift tables from baseline to each post-baseline visit describing shifts to abnormality will be provided. Only subjects with a baseline result and a result at the specified visit will be considered.

A listing of all ECG tests, intervals, and overall interpretation will be provided.

[redacted]

14.5 Physical Examination

Information for all physical examinations will be included in the source documents. Any significant change will be reported as an AE in the source document and eCRF.

15 PHARMACOKINETIC ANALYSIS

A listing of plasma concentrations data will be provided based on the pharmacokinetic population.

[redacted]

[redacted]

[redacted]

[redacted]

APPENDICES

APPENDIX 1

Output Conventions

TLF will be generated using SAS® and will be displayed on letter size paper with landscape orientation, 1 inch margin, and 9 pt Courier New font.

The header section will comprise the sponsor's name, protocol number, delivery description, data cut-off date or date of database lock, as applicable, and page number (Page X of Y).

TLF title section will include TLF number, TLF title, and population.

The footer section will include the source listing(s) (if applicable), list of abbreviations, TLF footnotes, name of the SAS program name, and date and time of the execution of the program.

For categorical summary tables, percentages will be reported to one decimal place. Percentages between 0 and 0.1 (both exclusive) will be displayed as "<0.1" and percentages between 99.9 and 100.0 (both exclusive) will be displayed as ">99.9". Percentages will be based on total number of subjects in the population, except for efficacy and laboratory data where the percentages will be based on the number of subjects with available data.

For descriptive statistics, the minimum and maximum values will keep the same number of decimal places as the original value; the mean and median will be displayed with one additional decimal place than the original value; and the SD, standard error (SE), and CI will be displayed with two additional decimal places than the original value. If derived endpoints are to be summarized, the number of decimals of the derived values is to be chosen on a case-by-case basis, but the rule above applies.

P-values between 0.001 and 0.999, both inclusive, will be reported to 3 decimal places, p-values less than 0.001 will be reported as "<0.001", and p-values greater than 0.999 will be reported as ">0.999".

Listings will be ordered by treatment group, subject number, endpoint/test, date of assessment/ collection/measurement, and time of assessment/collection/measurement, if applicable. Imputed dates and imputed missing data will not be presented in the listings. For visit names, nominal visit names will be presented followed by the analysis visit name when both are different (e.g., 'Unscheduled/Week X', etc.) Otherwise, only the nominal visit names will be presented.

[redacted]

Dates & Times Format

Date and time (if available) will be presented in the format yyyy-mm-dd/hh:mm.

Presentation of Treatment Group

When applicable, treatment group will be represented as follows:

Treatment Group Full Name	Treatment Group Short Name for TLFs
EVO756 300 mg, QD	EVO756 300 mg QD
EVO756 50 mg, BID	EVO756 50 mg BID

[redacted]

APPENDIX 2

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]