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Statistical Analysis Plan

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A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF SCD-044 IN THE TREATMENT OF MODERATE TO SEVERE ATOPIC DERMATITIS

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LIST OF ABBREVIATIONS

Abbreviation	Explanation
ACLS	Advanced Cardiac Life Support
AD	Atopic dermatitis
AE	Adverse Event
ALC	Absolute Lymphocyte Counts
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
ANC	Absolute Neutrophil Count
AUC_{0-6}	Area under the concentration-time curve up to 6 hours
AUC_{0-last}	Area under the concentration-time curve up to the last observed quantifiable concentration
aPTT	Activated Partial Thromboplastin Time
AST	Aspartate Aminotransferase
ATWC	Active Treatment Worst Case
AV block	Atrioventricular block
BLQ	Below Limit of Quantification
BMI	Body Mass Index
BSA	Body Surface Area
C_{max}	Maximum concentration
CMH	Cochran-Mantel-Haenszel
COPD	Chronic Obstructive Pulmonary Disease
CRA	Clinical Research Associate
CRO	Contract Research Organization
C_{trough}	Lowest concentration reached by a drug before the next dose
CV	Coefficient of Variation
DLQI	Dermatology Life Quality Index
DSMB	Data Safety Monitoring Board
EASI	Eczema Area and Severity Index
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
EOT	End of Treatment
FEV	Forced Expiratory Volume
FVC	Forced Vital Capacity
GGT	Gamma Glutamyltransferase
HBsAg	Surface Antigen of The Hepatitis B Virus (HBV)
hCG	Human Chorionic Gonadotropin
HCV	Hepatitis C Virus
HDL	High-Density Lipoproteins
HEENT	Head, Eyes, Ears, Nose and Throat
HIV	Human Immunodeficiency Virus
INR	International Normalized Ratio

ITT	Intent to Treat
LDL	Low-Density Lipoprotein
LLN	Lower Level of Normal
LOCF	Last Observation Carried Forward
LS	Least Squares
MCV	Mean Corpuscular Volume
MedDRA	Medical Dictionary for Regulatory Activities
MM	Medical Monitor
MMRM	Mixed Model for Repeated Measures
OCT	Optical Coherence Tomography
PD	Pharmacodynamic
PFT	Pulmonary Function Tests
PGIC	Patient Global Impression of Change
PGIS	Patient Global Impression of Severity
PK	Pharmacokinetics
PML	Progressive Multifocal Leukoencephalopathy
POEM	Patient Oriented Eczema Measure
PP	Per Protocol
PP-NRS	Peak Pruritus Numeric Rating Scale
PRES	Posterior Reversible Encephalopathy Syndrome
PT	Prothrombin Time
QRS	A combination of the Q wave, R wave and S wave
QT	QT Interval (the time from the start of the Q wave to the end of the T wave)
QTcF	QT Corrected by Fridericia's Formula
S1P	Sphingosine-1-Phosphate
SAP	Statistical Analysis Plan
SCORAD	SCORing Atopic Dermatitis
SUSAR	Suspected Unexpected Serious Adverse Reactions
TEAE	Treatment Emergent Adverse Event
t_{max}	Time to maximum concentration
VAS	Visual Analogue Scale
vIGA	validated Investigator's Global Assessment
VZV	Varicella Zoster Virus
WBC	White Blood Cells

1. INTRODUCTION

The purpose of this statistical analysis plan (SAP) is to provide details of the statistical analyses that have been outlined within the protocol "A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of SCD-044 in the Treatment of Moderate to Severe Atopic Dermatitis", version 3.0, dated April 10, 2023.

Sun Pharmaceutical Industries Ltd. is developing a Sphingosine 1-phosphate (S1P) receptor agonist, SCD-044, to treat moderate to severe atopic dermatitis. The current study is a Phase IIb dose ranging study to assess the efficacy and safety of SCD-044 in the treatment of moderate to severe atopic dermatitis (AD).

2. OBJECTIVES AND ESTIMANDS

2.1 Primary Objective

The primary objective of this study is to determine the effect of SCD-044 treatment on moderate to severe atopic dermatitis, as measured by proportion of subjects showing at least 75% improvement in Eczema Area and Severity Index (EASI) at Week 16.

2.2 Primary Estimand

The primary estimand is defined as follows:

Population of interest	Subjects with moderate to severe atopic dermatitis
Outcome Measure/Endpoint	Achieving at least 75% improvement in EASI at Week 16
Treatment	SCD-044[redacted] and [redacted] mg once daily
Intercurrent Event	Use of rescue medication (systemic or topical), use of prohibited medications (as determined during blinded data review) and early treatment discontinuation. Composite strategy will be applied to these intercurrent events and the subjects with intercurrent events will be treated as non-responders.
Population-level Summary Measure	Difference in proportions between each the active treatment arms and placebo arm

2.3 Secondary Objectives

The secondary objectives of this study are:

- To evaluate the efficacy of SCD-044 as measured by validated Investigator's Global Assessment (vIGA) of disease severity
- To evaluate the efficacy of SCD-044 as measured by Peak Pruritus Numeric Rating Scale (PP-NRS)
- To evaluate the efficacy of SCD-044 as measured by SCORing Atopic Dermatitis (SCORAD)

- To evaluate the efficacy of SCD-044 as measured by Patient Oriented Eczema Measure (POEM)
- To evaluate the efficacy of SCD-044 as measured by change in body surface area (BSA) involvement over the treatment period
- To assess the effect of SCD-044 on quality of life, as measured by Dermatology Life Quality Index (DLQI)
- To assess the effect of SCD-044 on Patient Global Impression of Severity (PGIS)
- To assess the effect of SCD-044 on Patient Global Impression of Change (PGIC)
- To assess the safety and tolerability of SCD-044 in subjects with moderate to severe atopic dermatitis
- [redacted]

2.4 Key secondary estimand

The key secondary estimand is defined similar to the primary estimand as follows:

Population of interest	Subjects with moderate to severe atopic dermatitis
Outcome Measure/Endpoint	Achieving a vIGA of '0' or '1' with at least 2-point reduction from baseline at Week 16
Treatment	SCD-044 [redacted], [redacted] and [redacted] mg once daily
Intercurrent Event	Use of rescue medication (systemic or topical), use of prohibited medications (as determined during blinded data review) and early treatment discontinuation. Composite strategy will be applied to these intercurrent events and the subjects with intercurrent events will be treated as non-responders.
Population-level Summary Measure	Difference in proportions between each the active treatment arms and placebo arm

2.5 Exploratory Objectives

The exploratory objectives of this study are:

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

3. STUDY OVERVIEW

3.1 Study Design

Subjects in this randomized, double-blind, placebo controlled, parallel-group, multiple-center study will be assigned to treatment with the investigational products or placebo control according to a randomization scheme and [redacted] schedule.

- **Part I** (16 weeks): Subjects will be randomized to Placebo, Low dose ([redacted] mg), Intermediate dose ([redacted] mg) or High dose ([redacted] mg) of SCD-044 in 3:1:1:3 ratio [redacted] to assess primary and secondary endpoints at 16 weeks.
- [redacted]
- [redacted]

[redacted]

- [redacted]

- [redacted]

Phone or in person contacts may be scheduled for visits [redacted] visits to collect information on concomitant medication, compliance with the study drug use, health changes (AEs & AESI), queries for PML and PRES and to provide instructions.

[redacted]

Subjects will be admitted into the study after informed consent has been obtained. An Unscheduled Visit is allowed at any time, for any reason, if in the Investigator's opinion it is warranted. If a Subject is discontinued from the study during an Unscheduled Visit, the Unscheduled Visit will be referred to as an Early Discontinuation Visit and all procedures scheduled for Early Discontinuation will be performed. If the Unscheduled Visit is not an Early Discontinuation Visit (i.e., the Subject will continue to take part in the study), then all procedures scheduled for that Unscheduled Visit will be performed. Subjects who are discontinued early from the study must attend the Follow-up visit 4 weeks after the date of Early Discontinuation.

If necessary due to the COVID-19 pandemic, Visit 18 may have assessments done at home or remote visit. Remote visits must be discussed and consulted with the CRO's and the Sponsor's medical monitor before planning. Scheduled blood collection (for these visits only) may be waived if the individual subjects have not had a clinically significant changes or undesired trend in lab or chemistry values prior to visit 15. Remote assessments or delayed visit 18 will be recorded in the source documents and noted as a minor protocol deviation.

COVID-19 related protocol deviations will be analyzed to assess whether a protocol amendment or other modifications are needed. The Sponsor together with investigators plan to assess the COVID-19 situation to evaluate the benefit: risk of the study on an ongoing basis.

Changes in study visit schedules, missed visits, or subject discontinuations may lead to missing information (e.g., for protocol-specified procedures). It is important to capture specific information in the subject records that explains the basis of the missing data, including the relationship to COVID-19, for missing protocol-specified information (e.g., from missed study visits or study discontinuations due to COVID-19).

A subset of eligible subjects will participate in photographic evaluation.

Randomization and re-randomization will be stratified by three factors: [redacted] Approximately the same number of male and female subjects will be enrolled between treatment groups. [redacted]. Approximately the same number of subjects who have prior exposure to biologics therapy for atopic dermatitis will

be enrolled between treatment groups.

The assigned Investigational Product will be administered orally once a day. Subjects will be required to use diaries to document the date of study treatments, any missed treatments, and the occurrence of all adverse events.

The duration of each Subject's participation in the study will be approximately 40 weeks (280 days).

If the Principal Investigator or designee determines that the Subject's condition has worsened to the degree that it is unsafe for the Subject to continue in the study, the Subject may be discontinued from the study as a treatment failure and the Subject may be treated using the standard care.

Subjects with conditions or treatments that may affect cardiovascular safety (e.g. heart rate less than 55 bpm), history of uveitis or history of pulmonary conditions such as active severe respiratory disease (e.g. COPD, tuberculosis or pulmonary fibrosis, severe asthma or asthma requiring regular treatment with oral steroids) will be excluded due to the known mechanism-based AEs within this class which may expose such subjects to unwarranted excess risk for a condition with available alternatives.

[redacted]

[redacted]

3.3 Randomization and Unblinding Procedures

In order to maintain the study blind the randomization schedule will be generated by a third party. Randomization will be performed according to a computer-generated randomization scheme. [redacted]

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

[redacted]

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

[redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

4. STUDY ENDPOINTS/OUTCOMES

4.1 Primary endpoint

The primary endpoint of this study is the proportion of subjects who achieve ≥75% overall improvement in EASI score from Baseline to Week 16.

4.2 Key secondary endpoint

Key secondary endpoint of this study is the proportion of subjects who achieve score of '0' (clear) or '1' (almost clear) on a 5-point, vIGA scale and ≥2 point reduction from Baseline to Week 16.

4.3 Other secondary endpoints

The other (non-key) secondary endpoints of this study are:

[redacted]

[redacted]

[redacted]

- Proportion of subjects who achieve ≥4-point or ≥3-point improvement in PP-NRS from Baseline to Week [redacted], and 32
- [redacted]
- Proportion of subjects who achieve SCORAD 50 and SCORAD 75 response from Baseline to Week [redacted] 32
- Change from Baseline in quality of life measured by DLQI scores to Weeks [redacted] 32
- Proportion of subject s who achieve DLQI total score 0 or 1 at Weeks 16 and 32
- [redacted]
- Change from Baseline in percent BSA with atopic dermatitis measured to Weeks [redacted]
- Change from Baseline in POEM score to Weeks [redacted] 32
- Proportion of subjects who achieve ≥4-point improvement from Baseline in the frequency of itching recorded in PP-NRS to Weeks [redacted] 32
- Proportion of subjects with improvement in PGIC from Baseline to Weeks [redacted] and 32
- Change in PGIS of disease from Baseline to Weeks [redacted] 32

[redacted]

4.4 Exploratory endpoints

Exploratory endpoints include:

[redacted]

5. ANALYSIS POPULATIONS

5.1 Safety Population

The Safety Population will consist of all subjects who were randomized into the study and dispensed study drug. This population will be the primary population for the safety analysis. Subjects will be analyzed according to the actual treatment received.

5.2 Intent-to-Treat (ITT) Population

The Intent-to-Treat (ITT) Population will consist of all randomized subjects regardless of whether they received the investigational product. This population will be the main population for the efficacy analyses. Subjects will be analyzed according to the treatment they were randomized to receive.

5.3 Per-Protocol (PP) Population

The Per-Protocol (PP) Population will consist of all ITT subjects who meet all inclusion/exclusion criteria, complete part 1 of the study, and have no protocol violations that affect proper administration of the treatment or accurate evaluation of its effectiveness. For more information on protocol violations see section 6.7. This population will be the supportive population for the efficacy analyses. Subjects will be analyzed according to the treatment they were randomized to receive.

6. STATISTICAL METHODS OF ANALYSIS

6.1 General Principles

The statistical analyses will be performed by [redacted] with approval of the Sponsor, using SAS® Version 9.4 (or higher). All tables, figures and listings will be produced in landscape format.

In general, all data will be listed by subject and visit/time point where appropriate. The summary tables will be stratified by, or have columns corresponding to, treatment groups.

The total number of subjects in the treatment group (N) under the specified population will be displayed in the header of summary tables.

Data will be summarized using descriptive statistics for continuous variables. Unless otherwise specified, descriptive statistics will include number of subjects, mean, standard deviation, minimum, median, and maximum. Number of subjects with missing values will also be displayed, but only if non-zero. The minimum and maximum statistics will be presented to the same number of decimal places as the original data. The mean and median will be presented to one more decimal place than the original data. The standard deviation will be presented to two more decimal places than the original data.

In summary tables of categorical variables, counts and percentages will be displayed. The count [n] indicates the actual number of subjects in a particular category, which should always be less than or equal to the total number of subjects in the respective study group with known (non-missing) category [M]. Percentage will be obtained by: % = n/M*100. Unless otherwise specified, all percentages will be expressed to one decimal place.

All statistical tests will be two-sided at a significance level of $\alpha = 0.05$, unless otherwise indicated.

Baseline will be defined as the last assessment, scheduled or not, prior to the first dose of the study drug, unless otherwise specified. This notion of baseline will also be referred to as Part I baseline. Part II baseline will be defined as the last assessment, scheduled or not, prior to the first dose of the study drug in Part II. Part II baseline will be used in analysis of findings collected in Part II for subjects initially randomized to Placebo and re-randomized to SCD-044

([redacted] mg or [redacted] mg) in Part II. Throughout this SAP, if the word "baseline" is used without qualification "Part I" or "Part II", it will refer to Part I baseline.

In by-visit summaries, only data collected on scheduled visits/time points will be summarized. Data from unscheduled assessments will be included in listings and may be used in determination of baseline if applicable.

Relative days will be calculated relative to date of first dose of the study drug. Relative days will be calculated as follows only when the full assessment date is known (i.e., partial dates will have missing relative days).

For assessment on or after the day of first dose of the study drug:

Relative Day = Date of Assessment – Date of First Dose of Study Drug+1.

For assessment before the day of first dose of the study drug:

Relative Day = Date of Assessment – Date of First Dose of Study Drug.

All dates will be displayed in DDMMMYYYY format.

6.1.1 Treatment Groups

Data collected up to Week 16 visit will be analyzed by treatment groups based on the subject's treatment in Part I of the study:

- Placebo
- SCD-044 [redacted] mg
- SCD-044 [redacted] mg
- SCD-044 [redacted] mg

Data collected after Week 16 visit (i.e., Parts II) will be analyzed by treatment groups based on the subject's treatment in Part I and the subject's treatment in Part II of the study:

- Placebo/SCD-044 [redacted] mg
- Placebo/SCD-044 [redacted] mg
- SCD-044 [redacted] mg
- SCD-044 [redacted] mg
- SCD-044 [redacted] mg

Adverse events and concomitant medications will be additionally analyzed for the entire study. Details are provided in the sections 6.12.1 and 6.12.6.

6.1.2 Adjustment for multiplicity

No adjustment for multiplicity will be needed for the analysis of the primary and key secondary endpoints due to the step-down testing approach described in Section 6.9.1.1. P-values for other endpoints, if calculated, will be presented nominally, without multiplicity adjustment. No inferences will be drawn from these p-values.

6.1.3 Handling of Withdrawals and Missed Data

In the primary analysis of the primary and the key secondary endpoint subjects with missing endpoint will be treated as non-responders. For more details see section 6.9.1.1. Last Observation Carried Forward (LOCF) and Active Treatment Worst Case (ATWC)

imputations will be explored in the sensitivity analyses (see section 6.9.1.2). All other endpoints will be summarized as collected without imputations.

6.2 Subject Disposition

Disposition will be summarized for Part I, Part II, and the study overall.

For Part I, the number of subjects who were screened, were screen failures, were randomized to treatment, included in the Safety, ITT, and PP, completed Part I (i.e., attended Week 16 visit) and prematurely discontinued from the study during Part I (along with the reasons for discontinuation) will be presented.

For Part II, the summary will present the number and percentage of subjects who were re-randomized for Part II, completed Part II (i.e., attended Week 32 visit) and prematurely discontinued from the study during Part II (along with the reasons for discontinuation).

For the study overall, the summary will present the number of subjects who were screened, were screen failures, were randomized to treatment, included in the Safety, ITT, and PP, attended the visits at Weeks 16 and 32, completed the study (week 36) and prematurely discontinued from the study at any time (along with the reasons for discontinuation).

Subjects who discontinued from the study for reasons related to the COVID-19 pandemic will be identified through manual review. Their number and percentage will be summarized separately.

Number and percentage of subjects who did not attend a visit for reasons related to COVID-19 will be provided by visit and treatment group.

All disposition information will be listed. Also, a listing of enrollment details will provide the date of informed consent and inclusion/exclusion criteria not met, if any.

6.3 Demographic and Baseline Characteristics

Demographic and baseline characteristics will include:

- age
- sex
- race
- ethnicity
- baseline height, weight, and body mass index (BMI)
- Baseline vIGA score
- Baseline EASI score
- Baseline BSA (%)
- Baseline SCORAD score
- Baseline PP-NRS score
- time since atopic dermatitis diagnosis (years)

- whether the subject took any prior biologic therapy for atopic dermatitis

Descriptive statistics will be presented for continuous variables. Frequency counts and percentage will be presented for categorical variables. Height will be presented in centimeters, weight in kilograms and BMI in kg/m^2.

Age will be derived from Informed Consent Date and Date of Birth as the number of whole years between those two dates.

These analyses will be performed for the ITT populations.

All demographic parameters and baseline characteristics will be presented in the by-subject listings.

6.4 Medical History

Medical history will be summarized by Medical Dictionary of Regulatory Activities (MedDRA), Version 25.0, System Organ Class and Preferred Term. One subject will be counted once for each applicable Preferred Term and System Organ Class. This summary will be performed for the ITT population. All medical history information will be listed.

6.5 Atopic Dermatitis History

Time since diagnosis of atopic dermatitis in years will be calculated as the year of the screening visit minus the year of diagnosis. History of prior use of medications and types of medications for atopic dermatitis (includes biologics, JAK inhibitors, topical corticosteroids) will be derived from the prior medication data by a manual review. History of intolerance to topical corticosteroids will be derived from the medical history data by a manual review.

Time since diagnosis will be summarized descriptively. Number and percentage of subjects with history of prior use of each type of atopic dermatitis medications and with history of intolerance to topical corticosteroids will be presented.

6.6 Ophthalmological History

Number and percentage of subjects with each finding of past ocular history and each type of ocular surgery as collected at the Ophthalmological History eCRF will be presented by treatment group.

All ocular history conditions and surgeries will be listed.

6.7 Protocol Deviations

Protocol deviations will be derived algorithmically as well as reported by sites. A subset of protocol deviation will be classified as affecting proper administration of the treatment or accurate evaluation of its effectiveness and thus excluding from the PP population. Specific deviation, their severities and rules for their algorithmic detection are defined in the separate Protocol Deviations Specification document.

COVID-19 related protocol deviations will be identified through manual review and will be marked in the listing.

All reasons for exclusion from the PP population will be summarized by reason category and treatment group and listed. This analysis will be performed for the ITT population. The final

determination of which protocol deviations exclude subjects from the PP population will be made by the sponsor during the blinded data review prior to the database lock.

6.8 Study Drug Exposure and Compliance

Duration of exposure will be defined separately for each treatment group, by study parts and overall. Duration of exposure in each study part will be calculated as [redacted] – [redacted] The date of the last dose in the study will be collected at the IP Use Compliance eCRF. For subjects initially randomized to SCD-044 total duration of exposure in the study will be defined as the sum of their durations of exposure in Part I and Part II.

Total dose of SCD-044 will be calculated based on the number of tablets taken as collected at the Study Product Accountability eCRF. The strength of each tablet will be assumed to follow the protocol-defined [redacted] schedule. Average daily dose of SCD-044 will be calculated as Total dose taken / Duration of Exposure.

Compliance will be calculated for maintenance periods only and separately for Part I and Part II as [Total number of tablets of any strength taken] / [Planned number of tablets] *100%.

Planned number of tablets will be defined as follows:

- For Part I maintenance period:
  - [redacted]
- For Part II maintenance period:
  - [redacted]

Date of discontinuation will be defined as the date of early termination visit, if one occurred, otherwise the discontinuation date collected on the End of Study eCRF.

If Total number of tablets of any strength taken cannot be determined, the compliance will be missing.

Compliance in the maintenance periods will be classified as <75%, 75%-125% and >125%. Subjects with compliance <75% or >125% will be considered non-compliant with the study medication.

Duration of exposure, average daily dose and compliance will be summarized descriptively by treatment group for the Safety population.

Number and percentage of subjects who underwent re-[redacted] will be presented separately for Part I and Part II by treatment group for the Safety population. Number of missed doses in the [redacted] period will be summarized descriptively and also categorically (0, 1, 2, etc. missed doses) separately for Part I and Part II by treatment group for the Safety population.

6.9 Efficacy Analyses

6.9.1 Analysis of the primary and key secondary endpoints

6.9.1.1 Primary analysis

The primary analysis will be performed on the ITT population.

Subjects in the ITT population with missing EASI at Week 16 or missing baseline will be imputed as non-responders for the primary endpoint. Similarly, subjects in the ITT population with missing vIGA at Week 16 or missing baseline will be imputed as non-responders for the key secondary endpoint.

Additionally, the subjects with intercurrent events, i.e. those who took any rescue medications (systemic or topical) prior to Week 16, took any prohibited mediations prior to Week 16 (as determined by blinded data review) and discontinued the study drug prior to Week 16 will be considered non-responders for both the primary and key secondary endpoint. Subjects will be known to take systemic rescue medications prior to Week 16 if this is recorded at the "Rescue Medications" CRF or "Concomitant Medications" CRF or the subject attended any of "Systemic Rescue Medications Visits" 7 to 10. Topical rescue medications will be identified through a review of the "Concomitant Medications" CRF.

For both primary and key secondary endpoint the number and percentage of subjects achieving the endpoint will be provided. Comparisons between each active group and the placebo group will be performed pairwise. Each comparison will be done using Cochran-Mantel-Haenszel (CMH) test stratified [redacted]
If all strata have no subject in one of the treatment groups, a value of 0.1 will be added to all cells in the corresponding table in order to prevent dividing by 0, as suggested in Greenland and Robins (1985). The estimates of Mantel-Haenszel common risk (response rate) difference between each active dose group and placebo, along with 95% confidence interval, will be provided. The p-value from the Breslow-Day test for homogeneity of strata will also be provided. If the p-value of the Breslow-Day test is ≥ 0.05, the treatment-by-strata interaction is not significant. In the case of heterogeneity between the strata, in-depth analysis will be conducted to understand the source of the interaction; Fisher's exact test will be used instead of CMH.

Tests for superiority over placebo for the primary and the key secondary endpoint will be conducted using a hierarchical closed testing step-down approach to preserve the overall Type I error rate of 0.05. Testing would begin with the highest dose for the primary endpoint, and if statistically significant at alpha (α) 0.05, then move to the highest dose for the key secondary endpoint, followed by the middle dose for the primary endpoint, then the middle dose for the key secondary endpoint, and so on until the lowest dose for the key secondary endpoint is reached.

6.9.1.2 Sensitivity analyses

The following sensitivity analyses will be performed to explore the effects of missing data on the primary endpoint and the key secondary endpoint:

1. Analysis similar to the primary analysis on the ITT population, but with missing endpoints imputed using Last Observation Carried Forward (LOCF) approach. For this

analysis the latest available post-baseline assessment of EASI will be carried forward to impute missing Week 16 assessments. Subjects with missing baseline or no post-baseline assessment prior to Week 16 will be excluded from this analysis. Additionally for subjects with intercurrent events, i.e. those who took topical or systemic rescue medications prior to Week 16, took prohibited medications prior to Week 16 or discontinued treatment prior to Week 16 the last available post-baseline assessment obtained prior to the start of the rescue medication will be used to impute Week 16 assessment. If no post-baseline assessment obtained prior to the intercurrent event (start of rescue medication, start of prohibited medication, discontinuation of treatment) is available, such subject will be excluded from this analysis.

2. Analysis similar to the primary analysis on the ITT population, but with missing endpoints imputed using Active Treatment Worst Case (ATWC) approach. For this analysis any subjects in the Placebo group with missing response or with an intercurrent event will be imputed as responders, while any subjects in any active treatment group with missing response or with an intercurrent event will be imputed as non-responders.
3. Tipping point analysis. This analysis will consist of a series of analyses similar to the primary analysis of the primary and key secondary endpoints with varying proportions of subjects with missing endpoint value or with intercurrent events imputed as responders or non-responders. The analysis will be performed for each active treatment group vs. placebo and for each combination of X1, the percentage of subjects with missing endpoint value or with intercurrent events in the placebo group and X2, the percentage of subjects with missing endpoint value or with intercurrent events in the active group. Both X1 and X2 will range from 0% to 100% in steps of 25%.

   For each pair of (X1, X2), X1% of subjects will be randomly drawn from the subjects with missing values or intercurrent events in placebo group and X2% of subjects will be randomly drawn from the subjects with missing values or intercurrent events in the active group. These randomly selected X1% subjects in the placebo and X2% subjects in the active group will be imputed as responders. The remaining subjects with missing endpoint value or intercurrent events will be imputed as non-responders. Analysis then will be conducted using the combined observed data and imputed data for each treatment group using the CMH test as described for the primary analysis in section 6.9.1.1. The random draw procedure will be repeated 49 times for each pair of (X1, X2) and the median p-value for the active vs. placebo comparison will be used for the conclusion. The estimate of the CMH common risk (response rate) difference between the treatment groups associated with the p-value selected as median will also be shown. If the same median p-value is obtained in more than one of the 49 random draws, the largest difference will be selected. The random seed for the draw will be preset as 441916 to ensure the analysis is repeatable and amenable to validation via double programming. If one pair of X1 and X2 is found to reverse the study conclusion (i.e., median p-value > 0.05 [tipping point analysis will be performed only if the primary analysis reached p-value ≤ 0.05]), then these parameters will be the tipping points.

6.9.1.3 Supplementary analyses

The following supplementary analyses will be performed:

1. Analysis similar to the primary analysis, but on the Per Protocol population using observed cases only with no imputations.
2. Analysis similar to the primary analysis, but on the ITT population excluding the subjects with protocol deviations related to the COVID-19 pandemic. This analysis will be performed only if more than 5% of subjects have protocol deviations related to the COVID-19 pandemic.

6.9.1.4 Subgroup analyses

The primary analysis of the primary and key secondary endpoints will also be repeated by subgroups:

[redacted]

In case when subgrouping variable was used as the stratification factor for the primary analysis, this variable will not be used as a stratification variable for the analysis of this subgroup.

The Breslow-Day test will be performed for each subgrouping variables in order to verify the homogeneity of endpoints. In the case of sparse data Fisher's exact test will be used instead of CMH.

6.9.2 Analysis of other endpoints

All other endpoints will be summarized using the ITT population.

6.9.2.1 Continuous endpoints

Continuous endpoints such as change from baseline and/or percent change from baseline in EASI, DLQI score, SCORAD score, BSA involvement, POEM score will be summarized descriptively by visit and treatment group.

In the analyses of change from baseline and percent change from baseline above Part II baseline will be used for the groups Placebo/SCD-044 [redacted] mg and Placebo/SCD-044 [redacted] mg, while Part I baseline will be used for the other treatment groups.

Continuous endpoints will also be summarized with a Mixed Model for Repeated Measures (MMRM) that will include fixed effects for treatment, visit (time variable), treatment by visit interaction, baseline vIGA score, gender, prior biologic therapy (yes/no), and Baseline value as a covariate. Unstructured covariance matrix will be assumed and Kenward-Roger method for computing the denominator degrees of freedom will be used. If the model fails to converge with the unstructured covariance matrix, the following covariance matrix types will be tried in order until convergence is achieved: heterogeneous Toeplitz (TOEPH), heterogeneous first-order auto-regressive (ARH(1)), Toeplitz (TOEP), first-order auto-regressive (AR(1)), compound symmetry (CS). Data up to Week 16 will be used in this analysis. The model will

be used to estimate treatment LS Means of the endpoint at Week 16 as well as LS mean differences for each SCD-044 dose vs. Placebo with 95% confidence interval and p-value for the hypothesis of no difference. These analyses will be considered supportive.

Percent reduction from baseline in EASI will be presented graphically.

Notes of scoring:

1. EASI.
    a. Based on gross morphological findings, scores are assigned on a 4-point scale [‘0’ (absent), ‘1’ (mild), ‘2’ (moderate) and ‘3’ (severe)] for each clinical sign (erythema, induration/papulation, excoriation and lichenification) in four body regions (head/neck, trunk, upper extremities and lower extremities).
    b. The score of percent of body surface is affected with atopic dermatitis in each body region ranges from 0 to 6.
    c. Clinical sign scores are summed within each body region and the sum is multiplied by the affected body surface score to arrive at the body region score.
    d. The total EASI score is the weighted sum of the body region scores:

        Total EASI score = 0.1*head/neck + 0.3*trunk + 0.2*upper extremities + 0.4*lower extremities.

        It ranges from 0 to 72, with higher scores denoting more severe extent of atopic dermatitis.
2. DLQI. The scoring of each question is as follows: Very Much or Yes = 3, A lot = 2, A little = 1, Not relevant or Not at all or No = 0. The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.
3. SCORAD.
    a. Area (A): the extent affected by eczema is determined using the Rule of Nines as a percentage of the whole body, which has a possible maximum of 100%.
    b. Intensity (B): the intensity of each of the 6 signs is assessed as none (0), mild (1), moderate (2) or severe (3). Total intensity score (B) is calculated by summing the score of each sign resulting in a maximum of 18.
    c. Subjective symptoms (C): itch and sleeplessness scored by the patient or relative using a visual analogue scale where 0 is no itch (or no sleeplessness) and 10 is the worst imaginable itch (or sleeplessness). These scores are added to give total subjective symptoms score 'C' (maximum 20).
    d. The total SCORAD score is calculated as: [redacted]
4. POEM. Questionnaire consists of 7 items about their atopic dermatitis over the past week. Each of the seven questions carries equal weight and is scored from 0 to 4. The total score is the sum of all items scores (maximum 28), with higher POEM scores denoting more severe eczema. If one question is left unanswered this is scored 0 and the scores are summed and expressed as usual out of a maximum of 28. If two or more questions are left unanswered the questionnaire is not scored.

6.9.2.2 Binary endpoints

Binary endpoints include:

- EASI50, EASI75, EASI90, EASI100 responses (i.e., reduction of at least 50%, 75%, 90% and 100% from baseline in EASI)
- vIGA response (achieving vIGA score of "clear" or "almost clear" on a 5-point vIGA scale with at least two-grade reduction from baseline)
- achieving ≥ 4-point or ≥ 3-point improvement in the severity of itching recorded in PP-NRS from baseline
- SCORAD50 and SCORAD75 responses (i.e., reduction of at least 50% and 75% from baseline in total SCORAD score)
- achieving ≥ 4-point or ≥ 3-point improvement in the frequency of itching recorded in PP-NRS from baseline
- achieving PGIC improvement
- achieving DLQI total score 0 or 1 at Weeks 16 and 32

Note that for all binary endpoints above that involve change from baseline or percent change from baseline, Part II baseline will be used for the groups Placebo/SCD-044 [redacted] mg and Placebo/SCD-044 [redacted] mg, while Part I baseline will be used for the other treatment groups.

Number and percentage of subjects achieving these endpoints will be presented by treatment group along with 95% confidence interval for percentages based on binomial proportion.

The percentage of subjects achieving EASI75, EASI50, vIGA and SCORAD75, SCORAD50 responses will be presented graphically.

6.9.2.3 Categorical endpoints

Categorical endpoints include vIGA, PGIC, and PGIS. Number and percentage of subjects with each category of response will be presented by treatment group and visit. Additionally, for vIGA, PGIS shifts from baseline to each post-baseline visit will be presented.

6.9.2.4 Time to EASI75, EASI90, vIGA, and PP-NRS responses

Time to achieve EASI75 and EASI90, and time to achieve vIGA and PP-NRS responses will be summarized separately for the Part I of the study, for the Part II for subjects re-randomized at Week 16 and for the study overall for subjects assigned to SCD-044 at the Baseline.

In the analysis of Part I subjects will be analyzed by treatment groups based on the treatment that the subject received in Part I (see Section 6.1.1). Time to achieve EASI75 will be defined as the number of weeks from the day of the first dose of the study drug to the first EASI assessment in Part I (i.e., up to and including Week 16 visit) when EASI75 is achieved. For subjects who never achieve EASI75 in Part I the time will be censored at the last EASI assessment in Part I. Similar algorithm is used to define time to achieve EASI90.

Similarly, time to achieve vIGA response in Part I will be defined as the number of weeks from the day of the first dose of the study drug to the first vIGA assessment in Part I (i.e., up to and including Week 16 visit) when vIGA score of 'clear' or 'almost clear' with at least two-grade reduction from Baseline is achieved. For subjects who never achieve vIGA response in Part I the time will be censored at the last vIGA assessment in Part I.

Similarly, time to achieve PP-NRS response in the severity of itching in Part I will be defined as the number of weeks from the day of the first dose of the study drug to the first PP-NRS assessment in Part I (i.e., up to and including Week 16 visit) when severity of itching recorded in PP-NRS with at least four-point (or at least three-point) reduction from Baseline is achieved. For subjects who never achieve PP-NRS response in Part I the time will be censored at the last PP-NRS assessment in Part I.

The analysis for Part II will be conducted only for subjects who were initially randomized to placebo and switched to active treatment in Part II. In this analysis subjects will be analyzed by treatment groups based on their treatments in Part II (see Section 6.1.1). Times will be defined similarly to the analysis of Part I, except they will start at the time of the switch to a new treatment in Part II and will be censored at the last assessment in the study. Part II baseline will be used when determining EASI and vIGA responses.

The analysis for the study overall will be conducted only for subjects who were initially randomized to any dose of SCD-044 and thus did not switch treatments during the study. In this analysis subjects will be analyzed by treatment groups based on their treatments in Part I. Times will be defined similarly to the analysis of Part I, except then will be censored at the last assessment in the study.

Quartiles of time to achieve EASI75 and EASI90, and time to achieve vIGA and PP-NRS responses with their 95% confidence intervals will be calculated by treatment group.

6.9.2.5 Relationship between SCD-044 plasma concentrations and efficacy/PD endpoints

[redacted]

subjects with intercurrent events prior to the analysis timepoint will be excluded from the analysis.

[redacted]

6.11 Analyses of PD biomarkers

At the study visits 2, 9, 10, 17 (study weeks 0, 12, 16, and 32), and Early Discontinuation visits occurring before visit 17, a blood sample will be collected for testing of: cytokines in plasma/serum [redacted]

Additional biomarkers may be included during the study.

Biomarker concentrations and their changes from baseline will be summarized descriptively by visit and treatment group.

6.12 Safety Analyses

All safety analyses will be performed on the Safety population.

6.12.1 Adverse Events

Adverse events will be coded using MedDRA, Version 25.0, AE coding system for purposes of summarization.

An AE will be considered as treatment-emergent (TEAE) if the date of onset is on or after the date of the first study drug administration. AEs with unknown start dates will be counted as treatment-emergent unless the AE resolution date is prior to the study drug start date. If the start date is partially missing, the AE will be considered treatment-emergent, unless the month and year (when available) rule out the possibility that the event occurred post start of study drug dosing.

A TEAE is defined as treatment-related if its relationship to study medication is recorded as "Possible", "Probable" or "Definite" on the eCRF. In case the relatedness was not assessed, the most conservative result (related) will be chosen for the analysis.

Cardiovascular AEs will be defined as AEs with MedDRA system organ class "Cardiac disorders" or "Vascular disorders".

Adverse events that are of special interest, that represent signs/symptoms of Progressive Multifocal Leukoencephalopathy (PML) or of Posterior Reversible Encephalopathy Syndrome (PRES) and that are cardiac arrhythmias will be marked on the eCRF.

Events will be assigned to Part I or Part II of the study based on the date of onset, i.e. AEs that start prior to the first dose of the Part II treatment will be assigned to Part I and AEs that start on or after the date of the first Part II dose will be assigned to Part II.

In summaries of TEAEs a subject experiencing the same AE multiple times on the same treatment will only be counted once for that preferred term and treatment. Similarly, if a subject experiences multiple AEs within the same system organ class on the same treatment that subject will be counted only once in that system organ class and treatment. When summarizing AEs by severity, only the most severe occurrence within the preferred term or system organ class and treatment will be used. Similarly, when summarizing AEs by relationship to study drug, only the most related occurrence within the preferred term or system organ class and treatment will be selected for displays in summary tables.

All AE summaries will be presented in 3 ways:

1. For events in Part I only, using Part I treatment groups, with the additional groups SCD-044 Any Dose (including the three SCD-044 groups) and Total (including all subjects).
2. For events in Part II only, using Part II treatment groups, with the additional group Total.
3. For the entire study only for subjects initially randomized to SCD-044 and thus staying on the same treatment throughout the study, using the three active treatment groups with the additional group Total.

An overall summary for the Safety population will include, by treatment and overall, the number and percentage of subjects reporting at least 1 TEAE in the following categories:

- Any TEAE
- Treatment-related TEAE
- Serious TEAE
- Serious drug-related TEAE
- TEAE leading to discontinuation of the study medication
- Treatment-related TEAE leading to discontinuation of the study medication
- TEAE requiring temporary interruption of the study medication
- Treatment-related TEAE requiring temporary interruption of the study medication
- TEAE leading to death.
- TEAEs of special interest

Additional overall summary of cardiovascular TEAEs will include, by treatment and overall, the number and percentage of subjects reporting at least one cardiovascular TEAE in the following categories:

- Any cardiovascular TEAE
- Treatment-related cardiovascular TEAE
- Serious cardiovascular TEAE
- Cardiovascular TEAE leading to discontinuation of the study medication
- Cardiovascular TEAE leading to death.
- Cardiovascular TEAEs of special interest
- Cardiac arrhythmias

The following TEAE frequency tables will be prepared summarizing the number and percentage of subjects reporting at least one TEAE by MedDRA System Organ Class (SOC) and preferred term PT, by treatment group for the Safety population:

- All TEAEs
- Serious TEAEs
- Treatment-related TEAEs
- Serious treatment-related TEAEs
- TEAEs leading to discontinuation of the study medication
- Treatment-related TEAEs leading to discontinuation of the study medication
- TEAE requiring temporary interruption of the study medication
- Treatment-related TEAE requiring temporary interruption of the study medication
- TEAEs occurring in ≥2% in any treatment group
- TEAEs of special interest
- Cardiac arrhythmias
- TEAEs with onset during the [redacted] period in Part I and in Part II
- TEAEs by Severity
- TEAEs by Relationship to Study Drug.

The tables for the [redacted] periods will be separated into sections for Week 1, Week 2 and Week 3 of [redacted] where the weeks are defined by the dates of the [redacted] visits (Week 1, Week 2 and Week 3 for Part I and Week 16, Week 17 and Week 18 for Part II). Only events occurring in each week in the treatment groups still undergoing [redacted] (including the Placebo group in

Part I) will be included. In the Part II table three columns will be included: Placebo/SCD-044 [redacted] mg, Placebo/SCD-044 [redacted] mg and Total as only these groups actually undergo [redacted] in Part II.

All information pertaining to adverse events noted during the study will be listed by subject, detailing verbatim, preferred term, system organ class, start date and study day, stop date, intensity, outcome, action taken and causal relationship to the study drug. The adverse event onset will also be shown relative (in number of days) to the date of first administration of the study drug.

6.12.2 Laboratory tests

A central laboratory will be used for all assessments unless noted otherwise. Unscheduled laboratory assessments can be performed at discretion of the Investigator in response to AEs. The laboratory assessments include:

Hematology: at all on-site study visits a blood sample will be collected for total and differential WBC count, Absolute Neutrophil count (ANC), ALC, Platelet count, Hemoglobin, Hematocrit, Mean Corpuscular Volume (MCV) testing. Additionally, total WBC count with differential counts including ALC and ANC counts will be performed pre-dose and at 1h, 2h, 4h and 6h post-dose on Day 29 (Week 4).

Lipid profile: at the study visits 1, 2, 10 and 17 (Screening and study weeks 0, 16, and 32) a blood sample will be collected for LDL, HDL and total cholesterol and Triglycerides testing.

Clinical chemistry: at the study visits 1, 2, 7, 8, 10, 15, 16, and 17 (Screening and study weeks 0, 4, 8, 16, 20, 28, and 32) a blood sample will be collected for sodium, potassium, chloride, calcium, magnesium, bicarbonate, phosphate, blood urea nitrogen, random glucose, albumin, total protein, alkaline phosphatase, creatinine, ALT, AST, gamma glutamyl transferase (GGT), total bilirubin, conjugated bilirubin testing.

Coagulation profile: at the study visits 1, 2, 10, and 17 (Screening and study weeks 0, 4, 16, and 32) a blood sample will be collected for PT, INR, and aPTT testing.

Serology: at Screening visit a blood sample will be collected for: anti-VZV IgG, HIV antibodies, HBsAg, and HCV antibodies testing.

QuantiFERON Gold test: at Screening Visit a blood sample will be collected for TB antigens testing. A maximum of 2 QuantiFERON tests are allowed. A retest is permitted if the first is indeterminate; the result of the second test will be used. Chest X-ray should be performed for subjects with a positive or 2 successive indeterminate QuantiFERON test results; a chest X-ray is acceptable if performed within the past 3 months and available at a site along with an associated report.

Serum pregnancy test: at Screening Visit a blood sample will be collected for serum beta-hCG testing.

The following tests will be performed at a clinic site:

Urinalysis dipstick: at the study visits 1, 2, 10, and 17 (Screening and study weeks 0, 16, and 32) a urine sample will be collected for pH, specific gravity, protein, glucose, ketones, and blood testing.

Microscopic exam may be performed at the local or central laboratory at the discretion of the Investigator if the dipstick is positive (i.e., trace or above).

Urine Pregnancy Test: at the study visits 2, 7, 8, 9, 10, 15, 16, 17, 18 (study weeks 0, 4, 8, 12, 16, 20, 28, 32, and 36) a urine sample will be collected in women of childbearing potential for hCG testing.

A positive result should be confirmed by a serum beta-hCG test. A confirmed positive urine pregnancy test during the treatment periods of the study requires immediate interruption of study drugs and the subject must be discontinued from the study.

Labs need not be repeated at baseline if these assessments for screening visit are performed within 2 weeks prior to the Visit 2.

For Hematology, Chemistry, and Coagulation profile the labs, which were abnormal and clinically significant at EOT, need to be repeated at safety follow-up visit.

Hematology, chemistry (including lipid profile), coagulation and continuous urinalysis parameters and their changes from baseline will be summarized descriptively by visit and treatment group. For WBC and differentials (absolute counts and percentages) percent change from baseline will also be summarized.

Additionally, hematology (WBC and differentials) results obtained during Day 29 (Week 4) visit will be summarized by timepoint with changes and percent changes from baseline.

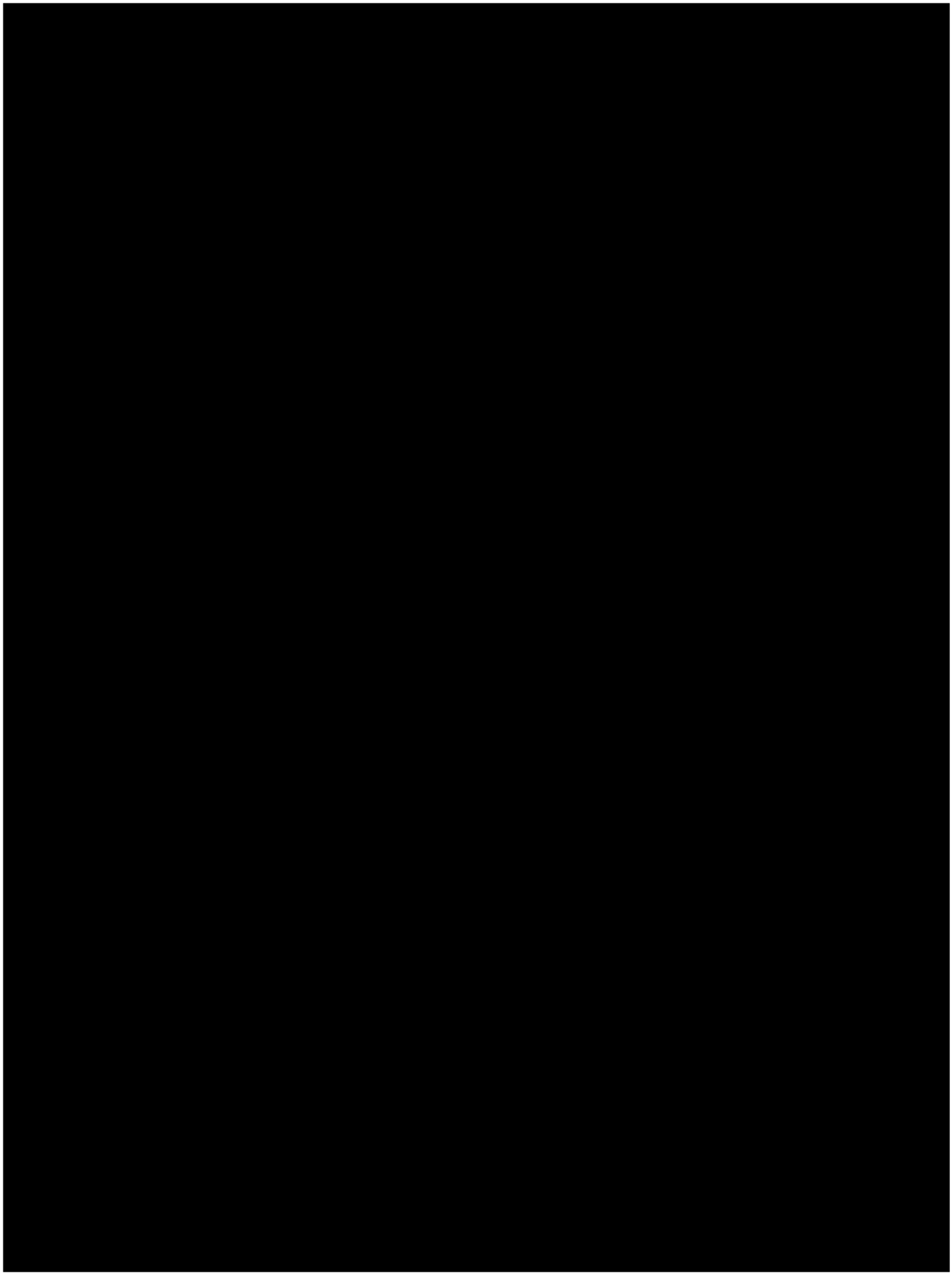
Shifts from baseline among the categories Normal (within the reference range), Low (below the reference range) and High (above the reference range) will be presented by visit.

In the analyses of change from baseline and shifts from baseline above, Part II baseline will be used for the groups Placebo/SCD-044 [redacted] mg and Placebo/SCD-044 [redacted] mg, while Part I baseline will be used for the other treatment groups.

All results will be listed.

[redacted]

[redacted]



6.12.5 Physical Examination

The investigator, sub-investigator or appropriately delegated designee will perform a physical examination, prior to the Subject starting study drug and at the end of treatment. Physical examinations may also be done at the discretion of the investigator. The physical examination will include, at a minimum, examination of the Subject's general appearance, comprehensive skin examination, HEENT (head, eyes, ears, nose and throat), heart, lungs, musculoskeletal system, neurological system, lymph nodes, abdomen and extremities.

Each body system will be classified as normal, abnormal not clinically significant or abnormal clinically significant.

Number and percentage of subjects with normal, abnormal not clinically significant or abnormal clinically significant findings will be presented by body system, visit and treatment group.

All results will be listed.

6.12.6 Prior and Concomitant Medication

Prior and concomitant medication will be coded according to the World Health Organization – Drug Dictionary version MAR 01, 2022 and the Anatomical Therapeutic Chemical (ATC) classification system. Prior medications are defined as those taken within 30 days before the first dose of the study drug (i.e., start and end date before the first dose of the study drug). Concomitant medications are defined as those taken at the time on or after the first dose of the study drug. Any medications that were started before the first dose of the study drug and continued after dosing will be considered a concomitant medication.

Medications concomitant with Part I will be defined as those taken at any time on or after the first study drug dose date in Part I and prior to the first study drug dose date in Part II. Medications concomitant with Part II will be defined as those taken at any time on or after the first study drug dose in Part II.

All previous and concomitant medication will be listed by subject. Concomitant medications in Part I, in Part II and in the study overall will be summarized by treatment group, ATC class (highest level available) and preferred name. The summary for the study overall will include only subjects initially randomized to SCD-044 and thus staying on the same treatment throughout the study. This analysis will be done for the Safety population.

All prior and concomitant medications will be listed.

6.12.7 Pulmonary Function Tests

At the study Visits 1 and 17 (Screening and study Week 32) pulmonary function tests (PFTs) will be performed, including assessment of FEV_1 and FVC. Spirometry will be performed in accordance with American Thoracic Society standards. The results will be compared to the predicted values based on factors such as age, gender, and ethnicity to the lower level of normal (LLN).

Additional pulmonary assessments will be done in case of clinically significant abnormal findings on the PFTs or physical examination and at the discretion of the Investigator in subjects with respiratory complaints like dyspnea, shortness of breath, chest tightness, wheezing etc.

Spirometry parameters such as FEV_1, FEV_1 Percent Predicted, FVC, FVC Percent Predicted and FEV_1/FVC Ratio as well as their changes from baseline to Week 32 will be summarized descriptively by visit.

6.12.8 Ophthalmological Examination

At the study Visits 1, 9 and 17 (Screening and study Weeks 12 and 32) a complete ophthalmologic examination will be performed by an ophthalmologist, including an ophthalmological history, best corrected visual acuity (Snellen chart), ophthalmoscopy (preferably slit-lamp) and Optical Coherence Tomography (OCT) assessment (measurement of central foveal thickness).

The following results of the ophthalmological examination will be summarized descriptively by eye (left or right), visit and treatment group:

- Best corrected visual acuity (Snellen denominator)
- OCT results: central fovea thickness

Number and percentage of subjects with presence of macular edema and/or uveitis will be presented by visit and overall across all visits (including both scheduled and unscheduled visits).

All ophthalmological examination data will be listed.

[redacted]

Number and percentage of subjects requiring monitoring beyond 6 hours will be provided along with reasons, treatment group and visit as well as overall across all visits.

7. TIMING OF ANALYSES

6.9.1.1Once the last subject completes Week 16 visit (or early termination prior to Week 16), statistical analysis will be conducted on all available data to evaluate the Part I results including the primary and key secondary efficacy outcomes. At this time all planned tables, listing and figures pertaining to Part I of the study will be created. This will be the final analysis for the primary efficacy endpoint. Investigational sites, subjects, and study team members directly involved in study activities will remain blinded to study treatment assignments until the last subject completes the follow-up period. The Interim Blinding Maintenance and Communication Plan provides further details related to unblinding of personnel involved in reporting activities for the analysis of Part I. Sharing of subject-level unblinded information for the Part I analysis will be confined to a designated unblinded study team.

When all subjects complete the study, the final analysis will be performed. At this time the randomization code will be released and the statistical and programming team that was blinded throughout the study will become unblinded. For the final analysis all planned tables, listings and figures will be created.

8. CHANGES FROM PROTOCOL-SPECIFIED ANALYSES

Handling of intercurrent events is expanded in this SAP. There are no other changes from the protocol-specified analyses.

9. LIST OF PLANNED TABLES, FIGURES, AND LISTINGS

See separate document with the table, figure and listing shells.

10. LITERATURE CITATIONS / REFERENCES

1. Study protocol: "A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of SCD-044 in the Treatment of Moderate to Severe Atopic Dermatitis", version 3.0, dated APR 10, 2023
2. Hwang IK, Shih WJ, De Cani JS. Group sequential designs using a family of type I error probability spending functions. Stat Med. 1990 Dec;9(12):1439-45.
3. Greenland S, Robins M. Estimation of a common effect parameter from sparse follow-up data. Biometrics. 1985;41(1):55-68.