Official Title: A Phase 3, Open-Label, One-Year Safety Study of Ruxolitinib Cream in Adolescents (Ages ≥ 12 Years to < 18 Years) With Atopic Dermatitis

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Statistical Analysis Plan

INCB 18424-315

A Phase 3, Open-Label, One-Year Safety Study of Ruxolitinib Cream in Adolescents (Ages ≥ 12 Years to < 18 Years) With Atopic Dermatitis

IND Number:	**77101**
EudraCT Number:	**2021-006626-44**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803** **United States**
Protocol Version:	**Protocol Amendment 1 dated 30 NOV 2022**
CRF Approval Date:	**12 JUN 2023**
SAP Version:	**Original**
SAP Author:	[redacted], **Biostatistics**
Date of Plan:	**10 MAY 2024**

This study is being conducted in compliance with Good Clinical Practice, including the archiving of essential documents.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

Abbreviation	Term
AD	atopic dermatitis
AE	adverse event
ASR	application site reaction
BID	twice daily
BSA	body surface area
CI	confidence interval
CRF	case report form
CT	continuous treatment
CTCAE	Common Terminology Criteria for Adverse Events
EASI	Eczema Area and Severity Index
EASI75	≥ 75% improvement in EASI score
eCRF	electronic case report form
EOT	end of treatment
ET	early termination
FAS	full analysis set
FDA	Food and Drug Administration
IGA	Investigator's Global Assessment
IGA-TS	Investigator's Global Assessment Treatment Success (IGA score of 0 or 1 with ≥ 2 grade improvement from baseline)
ITCH4	≥ 4-point improvement in ITCH score
LTS	long-term safety
LTS-EV	long-term safety evaluable
MedDRA	Medical Dictionary for Regulatory Activities
MPV	mean platelet volume
NCI	National Cancer Institue
NRS	numerical rating scale
PK	pharmacokinetic(s)
PT	preferred term
SAP	Statistical Analysis Plan
SOC	system organ class
TEAE	treatment-emergent adverse event
WHO	World Health Organization

1. INTRODUCTION

This is an open-label, 1-year safety study with an LTS period. Adolescents aged ≥ 12 to < 18 years with AD for at least 2 years and affecting 3% to 20% BSA (excluding the scalp) plus a total IGA score of 2 or 3. The primary purpose of this study is to collect additional long-term safety data regarding the types, severity, and frequencies of TEAEs occurring in adolescents with AD who are treated with ruxolitinib 1.5% cream BID.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the INCB 18424-315 Protocol. The scope of this plan includes the final analyses that are planned and will be executed by the Department of Biostatistics or designee and the Department of Clinical Pharmacokinetics or designee will execute the analysis of PK.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 18424-315 Protocol Amendment 1 dated 30 NOV 2022 and CRFs approved12 JUN 2023. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and eCRF versions.

2.2. Study Objectives and Endpoints

Table 1 presents the objectives and endpoints.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
To evaluate the long-term safety and tolerability of ruxolitinib cream in adolescents with AD.	Incidence of TEAEs, assessed by monitoring the type, frequency, and severity of AEs.
Secondary	
To further evaluate the long-term safety and tolerability of ruxolitinib cream in adolescents with AD.	Changes in vital signs, height, weight, and laboratory data for hematology and serum chemistry.
To characterize the PK of ruxolitinib cream in adolescents with AD.	Trough concentrations of ruxolitinib at each postbaseline visit.
Exploratory	
[redacted]	

3. STUDY DESIGN

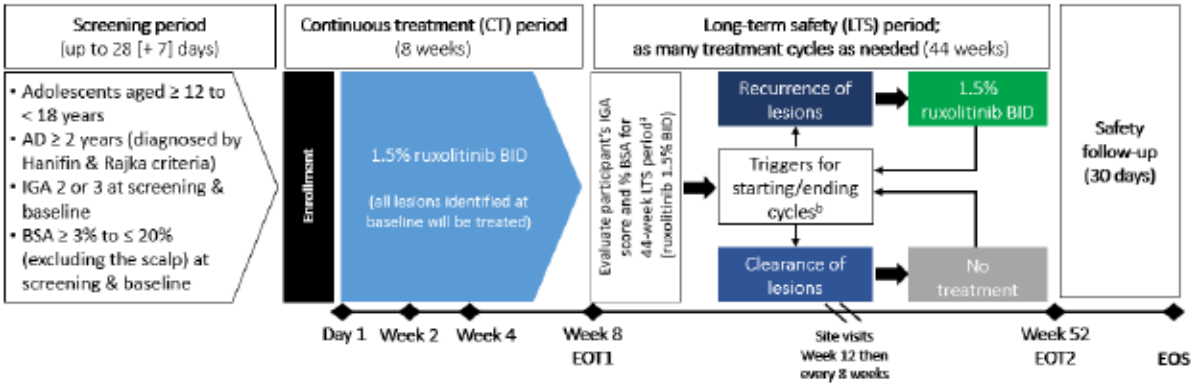
This is a Phase 3, open-label, 1-year safety study of ruxolitinib cream in adolescents (ages ≥ 12 years to < 18 years) with AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

All participants will apply ruxolitinib cream at the FDA-approved strength (1.5%) BID using the same treatment paradigm as the INCB 18424-303 and -304 Phase 3 AD studies, namely starting with an 8-week CT period during which participants will treat all baseline AD lesions, regardless of whether or not the lesion(s) improve, followed by a 44-week LTS period during which participants will only treat active AD lesions with the same treatment regimen. Participants who complete the Week 8 assessments with no safety concerns and with %BSA affected by AD no greater than 20% will continue into the LTS period.

Participants will have a safety follow-up visit 30 to 37 days following the end of treatment (Week 52/EOT2 or ET) to evaluate safety and duration of response except for participants who have been in an observation/no treatment cycle with a total IGA score of 0 from Week 48 or earlier until Week 52, for whom the Week 52/EOT2 visit will also count as the safety follow-up visit.

The study schema is presented below in Figure 1.

Figure 1: Study Design Schema



[a] At Week 8, to qualify for the LTS period, an IGA score of 0 to 4 and %BSA affected by AD of 0% to ≤ 20% will be required.
[b] Treatment is ceased 3 days after clearing of AD lesions. Treatment is restarted if AD lesions recur. There is no limit to the number of treatment cycles during the 44-week LTS period.

3.1. Randomization

Not applicable.

3.2. Control of Type I Error

All statistical analyses for efficacy are exploratory in nature; therefore, no alpha control will be implemented in this study. Unless otherwise specified, all CIs provided will be at the 95% confidence level.

3.3. Sample Size Considerations

The sample size is based on the evaluation of safety and is not based on statistical power calculations.

3.4. Schedule of Assessments

Refer to Protocol Amendment 1 dated 30 NOV 2022 for a full description of all study procedures and assessment schedules for this study.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1

Day 1 is the date that the first dose of study drug (ruxolitinib) is applied to the participants.

4.1.2. Study Day

If a visit/reporting date is on or after Day 1, then the study day at the visit/reporting date will be calculated as

Day # = (visit/reporting date – Day 1 date + 1).

If the visit/reporting date is before Day 1, then the study day at the visit/reporting date will be calculated as

Day # = (visit/reporting date – Day 1 date).

A study day of –1 indicates 1 day before Day 1.

4.1.3. Baseline Value

Baseline is the last nonmissing measurement obtained before the first application of ruxolitinib cream, unless otherwise defined.

When scheduled assessments and unscheduled assessments occur on the same day and the time of the assessment or time of first application is not available, use the following convention to determine baseline:

- If both a scheduled and an unscheduled visit are available on the day of the first application and the time is missing, use the scheduled assessment as baseline.
- If all scheduled assessments are missing on the day of the first application and an unscheduled assessment is available, use the unscheduled assessment as baseline.

4.1.4. Handling of Missing and Incomplete Dates

In general, values for missing dates will not be handled unless methods for handling missing dates are specified in this section or relevant sections. The following rules will be used for handling partial dates for analyses requiring dates:

- If only the day is missing, then the 15th of the month will be used.
- If both the month and day are missing, then 01 JUL of the year will be used.
- If the diagnosis date is completely missing, then the time since diagnosis will not be calculated.

4.2. Variable Definitions

The following variables will only be calculated if not reported on the eCRF.

4.2.1. Body Mass Index

Body mass index will be calculated as follows:

Body mass index (kg/m^2) = [weight (kg)] / [height (m)]^2.

4.2.2. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first application of ruxolitinib cream.

Concomitant medication is defined as any nonstudy medication that is started accordingly:

- Before the date of first application of ruxolitinib cream and is ongoing throughout the study or ends on/after the date of first study drug application.
- On/after the date of first application of ruxolitinib cream and is ongoing or ends during the course of study.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first application of ruxolitinib cream. In the listing, it will be indicated whether a medication is only prior, only concomitant, or both prior and concomitant.

For the purposes of analysis, all medications will be considered concomitant medications unless the medications can unequivocally be defined as not concomitant.

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9 or later) will be used for the generation of all tables, graphs, and statistical analyses. Descriptive summaries for continuous variables will include but not be limited to the number of observations, mean, standard deviation, median, minimum, and maximum. Descriptive summaries for categorical variables will include the number and percentage of participants in each category.

5.2. Treatment Groups

This is an open-label, single treatment group study. Participants will be summarized overall by total only.

5.3. Analysis Populations

5.3.1. Full Analysis Set

The FAS will include all participants who applied ruxolitinib cream at least once.

The FAS will be used for the summary of demographics, baseline characteristics, participant disposition, analyses of all efficacy data, and safety for the CT period and for the whole study as well.

5.3.2. Pharmacokinetic/Hematology Lab Evaluable Population

The PK-evaluable population will include all participants who applied ruxolitinib cream at least once and provided at least 1 postbaseline PK sample (1 PK measurement).

The hematology lab evaluable population will include all participants who applied ruxolitinib cream at least once, provided the baseline hematology blood sample, and at least 1 postbaseline hematology blood sample (1 hematology measurement).

The PK/hematology lab evaluable population will include all participants who are both PK evaluable and hematology lab evaluable.

5.3.3. Long-Term Safety Evaluable Population

All participants who applied ruxolitinib cream at least once during the LTS period will constitute the LTS-EV population. All safety analyses for the LTS period will be conducted with the LTS-EV population.

6. BASELINE, EXPOSURE, AND DISPOSITION

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

6.1. Demographics, Baseline Characteristics, and Disease History

6.1.1. Demographics and Baseline Characteristics

The following demographics and baseline characteristics will be summarized for the FAS: age, sex, race, ethnicity, weight, height, and BMI.

6.1.2. Baseline Disease Characteristics

The following baseline disease characteristics will be summarized for the FAS:

- Baseline IGA score (2 or 3)
- Baseline facial IGA score
- Baseline EASI score
- Baseline Itch NRS (by-visit, daily)
- Time (years) since first onset of AD
- Prior history of asthma (no/yes)
- Prior allergies (food, environmental; no/yes)
- History of contact dermatitis (no/yes)
- Common complications of AD
- Time since onset of current AD episode
- Number of AD episodes/flare over the last 12 months
- Prior therapy for AD given in the past 12 months (no/yes)
- Total %BSA involvement in current AD episode
- Facial and/or neck involvement during past episodes/flares (no/yes)
- Average duration of episodes/flares

6.1.3. Prior Therapy for Atopic Dermatitis

Prior therapies for AD, including medication and other types of therapies, during the past 12 months will be coded using the WHO Drug Dictionary and summarized. The type of treatment and reason for discontinuation will be summarized as well.

6.1.4. Medical History

For participants in the FAS, medical history will be summarized. This summation will include the number and percentage of participants with medical history event for each body system/organ class as documented on the eCRF.

6.2. Disposition of Participant

The number and percentage of participants who were treated, who completed CT period, who discontinued study treatment, or who withdraw from the study during the CT period with a primary reason for discontinuation will be summarized and listed for the FAS population during the CT period.

The number and percentage of participants who were treated, who completed LTS period, who discontinued study treatment, or who withdraw from the study during the LTS period with a primary reason for discontinuation will be summarized and listed for the LTS-EV population during the LTS period.

6.3. Protocol Deviations

Protocol deviations will be summarized and listed for the CT and LTS periods separately.

6.4. Exposure

For participants in the FAS and LTS-EV populations, descriptive statistics will be provided for duration of treatment (ie, the average daily amount of cream applied [g], and the total amount of cream applied [g]), respectively. Duration of treatment with ruxolitinib cream is defined as the number of days from Day 1 to the date of last record of ruxolitinib cream application.

6.5. Study Drug Compliance

Overall compliance (%) for the application of ruxolitinib cream during the CT and LTS period will be calculated as follows:

> Overall compliance (%) = 100 × (total number of nonmissing applications) / (total number of intended applications),

where the total number of nonmissing applications is the total number of applications that the participant actually applied during the study and the total number of intended applications is the number of days in treatment – the number of days with an approved interruption.

6.6. Prior and Concomitant Medication

For participants in the FAS population during the CT period, prior and concomitant medications will be coded using the WHO Drug Dictionary and summarized as number and percentage of participants with prior and concomitant medications by WHO drug class and WHO drug term. Additionally, separate prior AD therapy will also be summarized for the FAS population.

For participants in the LTS period, only concomitant medications will be summarized.

7. EFFICACY

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

7.1. General Considerations

All by-visit analyses will include the follow-up period if the data are available.

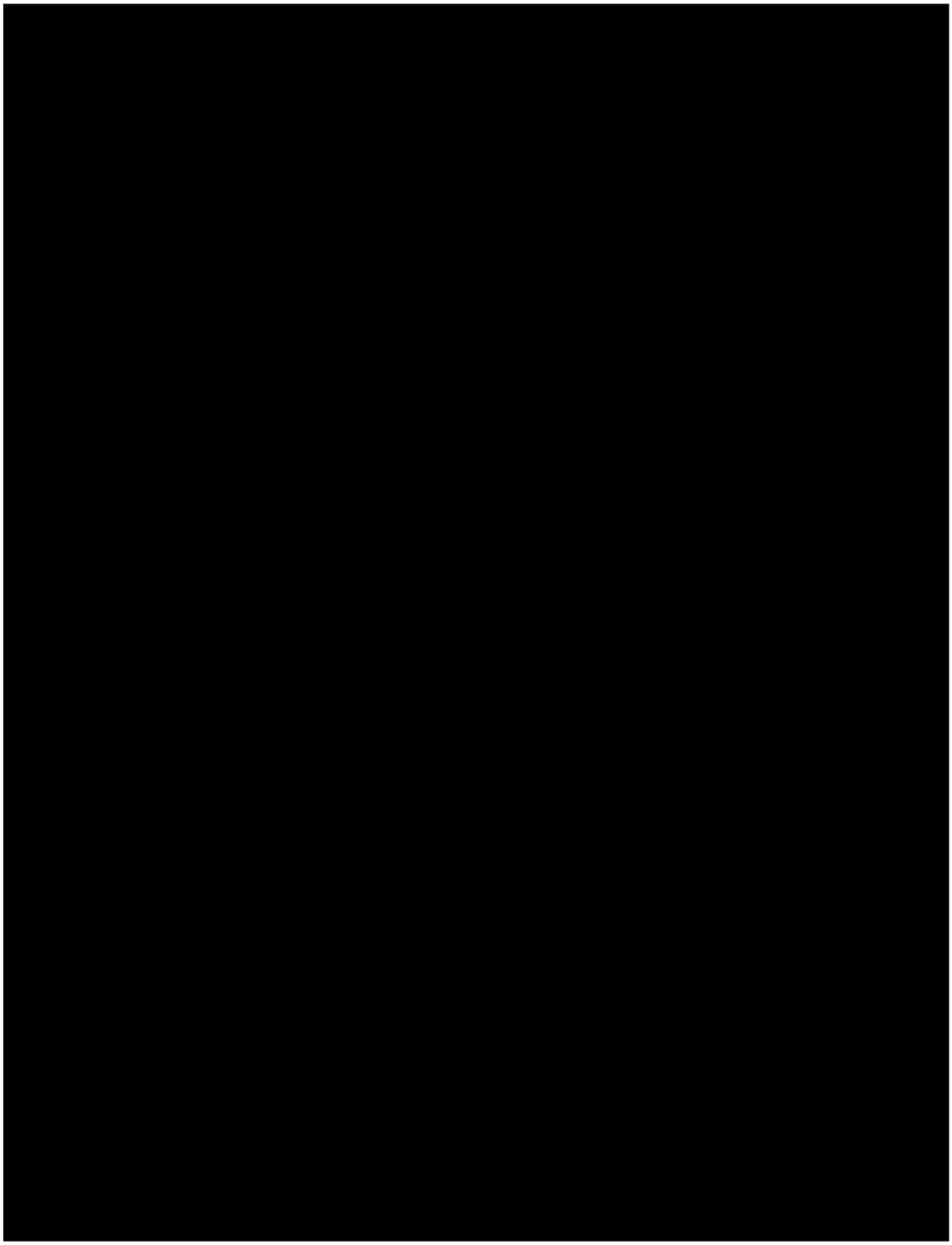
7.2. Efficacy Hypotheses

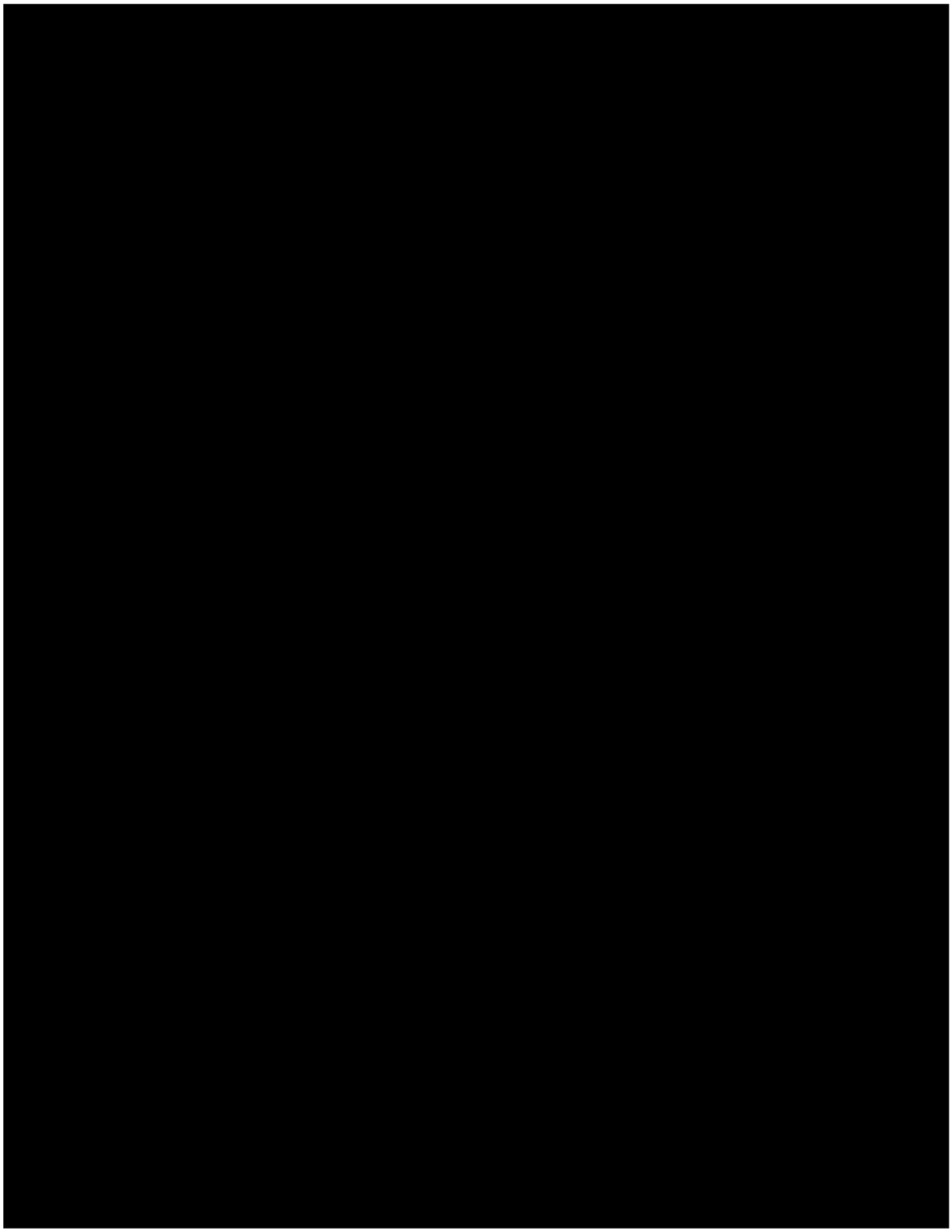
Not applicable.

7.3. Analysis of Exploratory Efficacy Parameters

All efficacy analyses are exploratory. Hence, no p-values will be provided, and multiple adjustments will not be made.

7.3.1. Exploratory Efficacy Measures





8. PHARMACOKINETICS AND PHARMACODYNAMICS

8.1. Pharmacokinetic Analyses

Trough plasma concentrations of ruxolitinib at 2 visits during the CT period will be summarized using descriptive statistics by visit. Mean trough plasma concentrations of ruxolitinib will be calculated for each individual and then summarized using descriptive statistics.

Trough saliva concentrations of ruxolitinib at 3 visits during the CT period and at 6 visits during the LTS period will be summarized using descriptive statistics by visit. Mean trough saliva concentrations of ruxolitinib will be calculated for each individual by period and then summarized using descriptive statistics.

9. SAFETY AND TOLERABILITY

Appendix A provides a list of data displays. Sample data displays are included in a separate document.

9.1. General Considerations

Summary tables may be replaced with listings when appropriate. For instance, an AE frequency table may be replaced with a listing if it only contains a few unique preferred terms reported on relatively few participants.

Unless otherwise stated, table summaries will be limited to AEs occurring within 30 days after the last application of ruxolitinib cream.

9.2. Adverse Events

9.2.1. Adverse Event Definitions

A TEAE is any AE either reported for the first time or worsening of a pre-existing event after the first application of study drug until 30 days after the last application of study drug. Analysis of AEs (as discussed below) will be limited to TEAEs, but data listings will include all AEs regardless of their timing in relation to study application.

Adverse events will be tabulated by MedDRA PT and SOC. Severity of AEs will be graded using the NCI CTCAE v5. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website.

The subset of AEs considered by the investigator to be related to study drug will be considered to be treatment-related AEs. If the investigator does not specify the relationship of the AE to study drug, the AE will be considered to be treatment-related. The incidence of AEs and treatment-related AEs will be tabulated. In addition, serious TEAEs will also be tabulated.

Any missing onset date, causality, or severity must be queried for resolution. Unresolved missing causality and severity will be handled according to the following rules:

- An unresolved missing causality will be considered treatment-related.
- An unresolved missing severity will be identified as an unknown severity.

For purposes of analysis, all AEs will be considered TEAEs unless the AE can unequivocally be defined as not treatment-emergent.

An application site reaction is an AE that occurs solely at one or more sites of ruxolitinib cream application and could be related to application of ruxolitinib cream. A summary of ASRs will be provided.

9.2.2. Adverse Event Summaries

An overall summary of AEs by treatment period will include the following:

- Number (%) of participants who had any TEAEs
- Number (%) of participants who had any ASRs
- Number (%) of participants who had any serious TEAEs
- Number (%) of participants who had any Grade 3 or higher TEAEs
- Number (%) of participants who had any treatment-related TEAEs
- Number (%) of participants who temporarily interrupted ruxolitinib cream because of TEAEs
- Number (%) of participants who permanently discontinued ruxolitinib cream because of TEAEs
- Number (%) of participants who had a fatal TEAE

Subgroup analysis (sex, race, ethnicity) for overall TEAEs will also be provided.

The following summaries will be produced by MedDRA term (if 2 or fewer participants appear in a table, a listing may be appropriate):

- Summary of TEAEs by MedDRA SOC and PT
- Summary of TEAEs by MedDRA PT in decreasing order of frequency
- Summary of ASRs by MedDRA PT in decreasing order of frequency
- Summary of Grade 3 or higher TEAEs by MedDRA SOC and PT
- Summary of Grade 3 or higher TEAEs by MedDRA PT in decreasing order of frequency
- Summary of serious TEAEs by MedDRA SOC and PT
- Summary of serious TEAEs by MedDRA PT in decreasing order of frequency
- Summary of treatment-related TEAEs by MedDRA SOC and PT
- Summary of treatment-related TEAEs by PT in decreasing order of frequency
- Summary of Grade 3 or higher treatment-related TEAEs by MedDRA SOC and PT
- Summary of treatment-related serious TEAEs by MedDRA SOC and PT
- Summary of TEAEs with a fatal outcome by MedDRA SOC and PT

- Summary of TEAEs leading to ruxolitinib cream dose interruption by MedDRA SOC and PT
- Summary of TEAEs leading to discontinuation of ruxolitinib cream by MedDRA SOC and PT

Subgroup analysis (sex, race, ethnicity) for TEAEs by MedDRA PT will also be provided.

Adverse events of interest will be summarized in the following categories:

- Cytopenias
  - Anemia
  - Thrombocytopenia
  - Neutropenia
- Herpes zoster
- Nonmelanoma skin neoplasms
- Liver function test elevations
- Malignancies
- Major Adverse Cardiovascular Events
- Venous and arterial thromboembolic events
- Thrombocytosis and elevated mean platelet volume

9.3. Clinical Laboratory Tests

9.3.1. Laboratory Value Definitions

All laboratory assessments will be performed using a central laboratory except for urine pregnancy tests (as applicable). Laboratory values and change from baseline values will be summarized descriptively by visit, and non-numeric test values will be tabulated when necessary.

Baseline will be determined according to Section 4.1.3. If there are multiple values that meet the criteria for baseline, the value from the central laboratory has priority over the value from the local laboratory. Thereafter, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

9.3.2. Laboratory Value Summaries

Clinical laboratory tests, including hematology and serum chemistry, will be performed at the Protocol-specified visits. If specific safety issues arise, additional unscheduled laboratory tests/analyses may be performed at the discretion of the investigator.

All test results and associated normal ranges from central laboratories will be reported in SI units. All tests with numeric values will have a unique unit per test. Any laboratory test results and associated normal ranges from local laboratories will be converted to SI units.

When there are multiple laboratory nonmissing values for a participant's particular test within a visit window, the laboratory value with the smallest laboratory sequence number will be used in by-visit summaries.

For test results that will be summarized with available normal ranges, the number and percentage of participants with laboratory values being low, normal, high, and both low and high will be calculated for each test. This shift summary will be produced for each test for the FAS population in the CT period, as well as the LTS period for the LTS-EV population. Shift tables will be presented showing the change in CTCAE grade from baseline to worst grade postbaseline as well. The denominator for the percentage calculation will use the number of participants in the baseline category.

9.4. Vital Signs

Values at each scheduled visit, change, and percentage change from baseline for vital signs, including systolic blood pressure, diastolic blood pressure, pulse, temperature, and respiratory rate will be summarized descriptively. Height and weight values at each scheduled visit, change, and percentage change from baseline for height and weight will be summarized descriptively.

Criteria for clinically notable vital sign abnormalities are defined in Table 4 and Table 5. The abnormal values for participants exhibiting clinically notable vital sign abnormalities will be listed by age group. Alert vital signs are defined as an absolute value outside the defined normal range and percentage change greater than 25%. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 4: Criteria for Clinically Notable Vital Sign Abnormalities for Age ≥ 12 to < 16 Years

Parameter	High Threshold	Low Threshold
Systolic blood pressure	> 131 mmHg	< 110 mmHg
Diastolic blood pressure	> 83 mmHg	< 64 mmHg
Pulse	> 100 bpm	< 60 bpm
Temperature	> 38.0°C	< 35.5°C
Respiratory rate	> 20 breaths/min	< 8 breaths/min

Table 5: Criteria for Clinically Notable Vital Sign Abnormalities for Age ≥ 16 to < 18 Years

Parameter	High Threshold	Low Threshold
Systolic blood pressure	> 120 mmHg	< 90 mmHg
Diastolic blood pressure	> 85 mmHg	< 50 mmHg
Pulse	> 100 bpm	< 45 bpm
Temperature	> 38.0°C	< 35.5°C
Respiratory rate	> 20 breaths/min	< 8 breaths/min

10. INTERIM ANALYSES

No formal interim analysis is planned for this study.

11. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 6.

Table 6: Statistical Analysis Plan Versions

SAP Version	Date
Original	10 MAY 2024

11.1. Changes to Protocol-Defined Analyses

Not applicable.

11.2. Changes to the Statistical Analysis Plan

Not applicable.

12. REFERENCES

Food and Drug Administration. Draft Guidance on Pimecrolimus. March 2012.

Hanifin JM, Thurston M, Omoto M, Cherill R, Tofte SJ, Graeber M. The eczema area and severity index (EASI): assessment of reliability in atopic dermatitis EASI Evaluator Group. Exp Dermatol 2001;10:11-18.

Leshem YA, Hajar T, Hanifin JM, Simpson EL. What the Eczema Area and Severity Index score tells us about the severity of atopic dermatitis: an interpretability study. Br J Dermatol 2015;172:1353-1357.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. Standard tables will follow the conventions in the Standard Safety Tables v1.6.

The lists of tables, figures, and listings are to be used as guidelines. Modifications of the lists that do not otherwise affect the nature of the analysis will not warrant an amendment to the SAP.

Tables

Table No.	Title	Population
Baseline and Demographics Characteristics		
1.1 Disposition		
1.1.1	Analysis Populations	FAS
1.1.2.1	Summary of Participant Disposition in the CT Period	FAS
1.1.2.2	Summary of Participant Disposition in the LTS Period	LTS-EV
1.1.3	Summary of Number of Participants Enrolled by Country and Site	FAS
1.1.4.1	Summary of Protocol Deviations for the CT Period	FAS
1.1.4.2	Summary of Protocol Deviations for the LTS Period	LTS-EV
1.2 Demography and Baseline Characteristics		
1.2	Summary of Demographics and Baseline Characteristics	FAS
1.3 Baseline Disease Characteristics		
1.3	Summary of Baseline Disease Characteristics	FAS
1.4 Prior Medication and Concomitant Medication		
1.4.1	Summary of Prior Medications	FAS
1.4.2	Summary of Prior Medications for Atopic Dermatitis	FAS
1.4.3.1	Summary of Concomitant Medications in the CT Period	FAS
1.4.3.2	Summary of Concomitant Medications in the LTS Period	LTS-EV
1.5+ Others		
1.5	Summary of General Medical History	FAS
Efficacy		
2.1 IGA		
2.1.1.1	Summary of Participants Achieving IGA-TS by Visit	FAS
2.1.1.2	Summary of Participants in Each Category of IGA Score by Visit	FAS
2.1.1.3	Summary of Participants Achieving an IGA score of 0 or 1 by Visit	FAS
2.1.1.4	Summary of Participants Achieving a Facial IGA score of 0 or 1 by Visit	FAS
2.2 EASI		
2.2.1	Summary of Participants Achieving EASI75 by Visit During the Treatment Period	FAS
2.2.2	Summary of EASI Score by Visit During the Treatment Period	FAS
2.3 Itch NRS Score		
2.3.1	Summary of Participants Achieving ≥ 4-Point Improvement in Itch NRS Score by Visit During the Treatment Period	FAS with baseline Itch NRS score ≥ 4
2.3.2	Summary of By-Visit Itch NRS Score	FAS
2.3.3	Summary of Participant Achieving ≥ 4-Point Improvement in Daily Itch NRS Score	FAS with baseline Itch NRS score ≥ 4
2.3.4	Summary of Daily Itch NRS Score	FAS

Table No.	Title	Population
2.4 BSA		
2.4.1	Summary and Analysis of Total %BSA Affected by AD	FAS
Safety		
3.1 Exposure		
3.1.1.1	Summary of Exposure in the CT Period	FAS
3.1.1.2	Summary of Exposure in the LTS Period	LTS-EV
3.1.1.3	Summary of Exposure from Baseline to Week 52	FAS
3.1.2	Summary of Study Drug Compliance in the CT Period	FAS
3.1.3	Summary of Study Drug Compliance in the LTS Period	LTS-EV
3.2 Adverse Events		
3.2.1.1.1	Overall Summary of Treatment-Emergent Adverse Events in the CT Period	FAS
3.2.1.1.2	Overall Summary of Treatment-Emergent Adverse Events in the CT Period by Sex	FAS
3.2.1.1.3	Overall Summary of Treatment-Emergent Adverse Events in the CT Period by Race	FAS
3.2.1.1.4	Overall Summary of Treatment-Emergent Adverse Events in the CT Period by Ethnicity	FAS
3.2.1.2.1	Overall Summary of Treatment-Emergent Adverse Events in the LTS Period	LTS-EV
3.2.1.2.2	Overall Summary of Treatment-Emergent Adverse Events in the LTS Period by Sex	LTS-EV
3.2.1.2.3	Overall Summary of Treatment-Emergent Adverse Events in the LTS Period by Race	LTS-EV
3.2.1.2.4	Overall Summary of Treatment-Emergent Adverse Events in the LTS Period by Ethnicity	LTS-EV
3.2.1.3.1	Overall Summary of Treatment-Emergent Adverse Events From Baseline to Week 52	FAS
3.2.1.3.2	Overall Summary of Treatment-Emergent Adverse Events From Baseline to Week 52 by Sex	FAS
3.2.1.3.3	Overall Summary of Treatment-Emergent Adverse Events From Baseline to Week 52 by Race	FAS
3.2.1.3.4	Overall Summary of Treatment-Emergent Adverse Events From Baseline to Week 52 by Ethnicity	FAS
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.3.1.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period	FAS
3.2.3.1.2	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period by Sex	FAS
3.2.3.1.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period by Race	FAS

Table No.	Title	Population
3.2.3.1.4	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period by Ethnicity	FAS
3.2.3.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period	LTS-EV
3.2.3.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period by Sex	LTS-EV
3.2.3.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period by Race	LTS-EV
3.2.3.2.4	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period by Ethnicity	LTS-EV
3.2.3.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52	FAS
3.2.3.3.2	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52 by Sex	FAS
3.2.3.3.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52 by Race	FAS
3.2.3.3.4	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52 by Ethnicity	FAS
3.2.3.4.1	Summary of Application Site Reactions by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period	FAS
3.2.3.4.2	Summary of Application Site Reactions by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period	LTS-EV
3.2.3.4.3	Summary of Application Site Reactions by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52	FAS
3.2.4.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.4.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.4.3	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term from Baseline to Week 52	FAS
3.2.5.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period	FAS
3.2.5.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period	LTS-EV
3.2.5.3	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52	FAS

Table No.	Title	Population
3.2.6.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.6.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.6.3	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.7.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period	FAS
3.2.7.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period	LTS-EV
3.2.7.3	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52	FAS
3.2.8.1	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.8.2	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.8.3	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.9.1	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period	FAS
3.2.9.2	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period	LTS-EV
3.2.9.3	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52	FAS
3.2.10.1	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.10.2	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.10.3	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.11.1	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.11.2	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV

Table No.	Title	Population
3.2.11.3	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.12.1	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.12.2	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.12.3	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.13.1	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.13.2	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.13.3	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.14.1	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Ruxolitinib Cream by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.14.2	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Ruxolitinib Cream by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.14.3	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Ruxolitinib Cream by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.15.1	Summary of Treatment-Emergent Adverse Events of Interest by MedDRA System Organ Class and Preferred Term in the CT Period	FAS
3.2.15.2	Summary of Treatment-Emergent Adverse Events of Interest by MedDRA System Organ Class and Preferred Term in the LTS Period	LTS-EV
3.2.15.3	Summary of Treatment-Emergent Adverse Events of Interest by MedDRA System Organ Class and Preferred Term From Baseline to Week 52	FAS
3.2.16.1	Summary of Treatment-Emergent Adverse Events of Interest by MedDRA Preferred Term in Decreasing Order of Frequency in the CT Period	FAS
3.2.16.2	Summary of Treatment-Emergent Adverse Events of Interest by MedDRA Preferred Term in Decreasing Order of Frequency in the LTS Period	LTS-EV
3.2.16.3	Summary of Treatment-Emergent Adverse Events of Interest by MedDRA Preferred Term in Decreasing Order of Frequency From Baseline to Week 52	FAS
3.3 Laboratory		
3.3.1	Summary of Laboratory Values - Hematology in the Treatment Period	FAS
3.3.2	Summary of Laboratory Values - Chemistry in the Treatment Period	FAS
3.3.3.1	Shift Summary of Hematology Laboratory Values in CTCAE Grade - to the Worst Abnormal Value in the CT Period	FAS

Table No.	Title	Population
3.3.3.2	Shift Summary of Hematology Laboratory Values in CTCAE Grade - to the Worst Abnormal Value in the LTS Period	LTS-EV
3.3.4.1	Shift Summary of Chemistry Laboratory Values in CTCAE Grade - to the Worst Abnormal Value in the CT Period	FAS
3.3.4.2	Shift Summary of Chemistry Laboratory Values in CTCAE Grade - to the Worst Abnormal Value in the LTS Period	LTS-EV
3.3.5.1	Shift Summary of Hematology Values - to the Worst Abnormal Value in the CT Period	FAS
3.3.5.2	Shift Summary of Hematology Values - to the Worst Abnormal Value in the LTS Period	LTS-EV
3.3.6.1	Shift Summary of Chemistry Values - to the Worst Abnormal Value in the CT Period	FAS
3.3.6.2	Shift Summary of Chemistry Values - to the Worst Abnormal Value in the LTS Period	LTS-EV
3.4 Vital Signs		
3.4.1	Summary of Systolic Blood Pressure in the Treatment Period	FAS
3.4.2	Summary of Diastolic Blood Pressure in the Treatment Period	FAS
3.4.3	Summary of Pulse in the Treatment Period	FAS
3.4.4	Summary of Respiratory Rate in the Treatment Period	FAS
3.4.5	Summary of Body Temperature in the Treatment Period	FAS
3.4.6	Summary of Height in the Treatment Period	FAS
3.4.7	Summary of Weight in the Treatment Period	FAS

Figures

Figure No.	Title	Population
4.1 IGA		
4.1.1	Proportion of Participants Achieving an IGA Score of 0 or 1 by Visit	FAS
4.1.2	Proportion of Participants Achieving a facial IGA Score of 0 or 1 by Visit	FAS
4.2 EASI		
4.2.1	Proportion of Participants Achieving EASI75 by Visit	FAS
4.2.4.1	Mean and Standard Error Plot of EASI Score by Visit	FAS
4.2.4.2	Mean and Standard Error Plot of Change From Baseline in EASI Score by Visit	FAS
4.2.4.3	Mean and Standard Error Plot of Percent Change From Baseline in EASI Score by Visit	FAS
4.3 Itch NRS		
4.3.1	Proportion of Participants Achieving ≥ 4-Point Improvement in Itch NRS Score by Visit	FAS with baseline Itch NRS score ≥ 4
4.3.2.1	Mean and Standard Error Plot of Itch NRS Score by Visit	FAS
4.3.2.2	Mean and Standard Error Plot of Change From Baseline in Itch NRS Score by Visit	FAS
4.3.2.3	Mean and Standard Error Plot of Percent Change From Baseline in Itch NRS Score by Visit	FAS
4.3.3	Proportion of Participants Achieving ≥ 4-Point Improvement in Daily Itch NRS Score	FAS with baseline Itch NRS score ≥ 4

Figure No.	Title	Population
4.3.4.1	Mean and Standard Error Plot of Daily Itch NRS Score	FAS
4.3.4.2	Mean and Standard Error Plot of Change From Baseline in Daily Itch NRS Score	FAS
4.3.4.3	Mean and Standard Error Plot of Percent Change From Baseline in Daily Itch NRS Score	FAS
4.4 BSA		
4.4.1	Mean and Standard Error Plot of AD-Affected %BSA by Visit	FAS
4.4.2	Mean and Standard Error Plot of Change From Baseline in AD-Affected %BSA by Visit	FAS
4.4.3	Mean and Standard Error Plot of Percent Change From Baseline in AD-Affected %BSA by Visit	FAS
4.5 Laboratory Data		
4.5.1	Mean and Standard Error Plot of Selected Laboratory Hematology Values by Visit	FAS
4.5.2	Mean and Standard Error Plot of Change From Baseline in Selected Laboratory Hematology Values by Visit	FAS
4.5.3	Mean and Standard Error Plot of Percentage Change From Baseline in Selected Laboratory Hematology Values by Visit	FAS
4.6.1	Mean and Standard Error Plot of Selected Laboratory Chemistry Values by Visit	FAS
4.6.2	Mean and Standard Error Plot of Change From Baseline in Selected Laboratory Chemistry Values by Visit	FAS
4.6.3	Mean and Standard Error Plot of Percentage Change From Baseline in Selected Laboratory Chemistry Values by Visit	FAS

Listings

Listing No.	Title
2.1 Participant Disposition	
2.1.1	Participant Enrollment and Disposition Status
2.1.2	Participant Inclusion and Exclusion Criteria Violations
2.2 Protocol Deviations	
2.2	Protocol Deviations
2.3 Data Excluded From PK, Efficacy, and/or Safety Analyses	
2.3	Analysis Populations
2.4 Demographic and Baseline Characteristics (Including Prior and Concomitant Medications)	
2.4.1	Demographic Characteristics
2.4.2	Baseline Disease Characteristics
2.4.3	Prior and Concomitant Medications
2.4.4	Prior Medications for Atopic Dermatitis
2.4.5	Medical History
2.5 Drug Compliance	
2.5	Study Drug Exposure and Compliance
2.6 Efficacy	
2.6.1	IGA Score
2.6.2	Facial IGA Score
2.6.3	EASI Score

Listing No.	Title
2.6.4	Itch NRS Score
2.6.5	AD-Affected %BSA
2.7 Adverse Events	
2.7.1	Adverse Events
2.7.2	Adverse Events Leading to Drug Discontinuation
2.7.3	Serious Adverse Events
2.7.4	Treatment-Related Adverse Events
2.7.5	Adverse Events with a Fatal Outcome
2.7.6	Adverse Events Leading to Interruption of Study Drug
2.7.7	Adverse Events with Grade 3 or Higher
2.7.8	Application Site Reactions
2.7.9	Adverse Events of Interest
2.8 Laboratory Data	
2.8.1	Clinical Laboratory Values – Hematology
2.8.2	Clinical Laboratory Values – Serum Chemistry
2.8.3	Abnormal Clinical Laboratory Values – Hematology
2.8.4	Abnormal Clinical Laboratory Values – Serum Chemistry
2.9 Vital Signs	
2.9.1	Vital Signs
2.9.2	Clinically Notable Vital Sign Values
2.9.3	Alert Vital Sign Values