Official Title:	A Safety and Efficacy Study of Ruxolitinib Cream Combined With Narrow-Band Ultraviolet B Phototherapy in Participants With Vitiligo
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Statistical Analysis Plan

INCB 18424-217

A Safety and Efficacy Study of Ruxolitinib Cream Combined With Narrow-Band Ultraviolet B Phototherapy in Participants With Vitiligo

IND Number:	**77,101**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803** **United States**
Protocol Version:	**Protocol dated 30 SEP 2021**
CRF Approval Date:	**18 FEB 2022**
SAP Version:	**Original**
SAP Author:	[redacted] [redacted] **Biostatistics**
Date of Plan:	**10 MAY 2023**

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

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LIST OF ABBREVIATIONS

Abbreviation	Term
AE	adverse event
ASR	application site reaction
BID	twice daily
BMI	body mass index
BSA	body surface area
CI	confidence interval
CRF	case report form
CTCAE	Common Terminology Criteria for Adverse Events
eCRF	electronic case report form
FAS	full analysis set
F-BSA	facial body surface area
[redacted]	[redacted]
[redacted]	[redacted]
F-VASI	Face Vitiligo Area Scoring Index
F-VASI50/75/90	≥ 50%/75%/90% improvement from baseline in Face Vitiligo Area Scoring Index score
MedDRA	Medical Dictionary for Regulatory Activities
NB-UVB	narrow-band ultraviolet B
NCI	National Cancer Institute
[redacted]	[redacted]
PD	pharmacodynamics(s)
[redacted]	[redacted]
PK	pharmacokinetic(s)
PT	preferred term
SAP	Statistical Analysis Plan
SOC	system organ class
T-BSA	total body surface area
TEAE	treatment-emergent adverse event
[redacted]	[redacted]
[redacted]	[redacted]
T-VASI	total body Vitiligo Area Scoring Index
T-VASI25/50/75/90	≥ 25%/50%/75%/90% improvement from baseline in total body Vitiligo Area Scoring Index score
VASI	Vitiligo Area Scoring Index
[redacted]	[redacted]

Abbreviation	Term
[redacted]	[redacted]
WHO	World Health Organization
[redacted]	[redacted]

1. INTRODUCTION

This is an open-label study in which participants will apply ruxolitinib 1.5% cream BID to all depigmented areas (ie, up to 10% BSA) for up to 48 weeks. Participants will continue to treat depigmented areas identified for treatment at baseline regardless of whether the area begins to improve or fully repigment.

On Day 1, all participants will apply ruxolitinib 1.5% cream BID as monotherapy. At Week 12, participants will apply ruxolitinib 1.5% cream alone or in combination with NB-UVB, the latter of which is based on improvement in T-VASI score. Participants who have < T-VASI25 will have NB-UVB phototherapy added to their ruxolitinib 1.5% cream BID regimen (Group A); this team will be given NB-UVB phototherapy 3 times per week through Week 48 (ie, 36 weeks). Participants who have ≥ T-VASI25 at Week 12 will continue on-treatment with ruxolitinib 1.5% cream BID alone (Group B).

Following the last application of ruxolitinib 1.5% cream alone or in combination with NB-UVB at Week 48, there will be a 30-day safety follow-up period.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the INCB 18424-217 Protocol. The scope of this plan will be executed by the Department of Biostatistics or designee, and the analyses of PK and PD will be executed by the Department of Clinical Pharmacokinetics or designee in this SAP.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 18424-217 Protocol dated 30 SEP 2021 and CRF approved 18 FEB 2022. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol Amendments and CRF versions.

2.2. Objectives and Endpoints

Table 1 presents the objectives and endpoints.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
To evaluate the efficacy of ruxolitinib cream in combination with NB-UVB in participants with vitiligo.	• Change from baseline in T-VASI at Week 48.
Secondary	
To evaluate the safety and tolerability of ruxolitinib cream in combination with NB-UVB.	• Occurrence of AEs and evaluation of vital signs and laboratory data.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
To further evaluate the efficacy of ruxolitinib cream in combination with NB-UVB in participants with vitiligo.	• Proportion of participants achieving F-VASI50/75/90 at each postbaseline visit. • Proportion of participants achieving T-VASI50/75/90 at each postbaseline visit. • Change and percentage change from baseline in F-VASI/T-VASI at each postbaseline visit. • Change and percentage change from baseline in F-BSA/T-BSA at each postbaseline visit.
To evaluate the ruxolitinib PK in plasma after treatment with ruxolitinib cream in combination with NB-UVB.	• Population-based (trough) plasma concentrations of ruxolitinib at Weeks 4, 12, and 16.
[redacted]	[redacted]

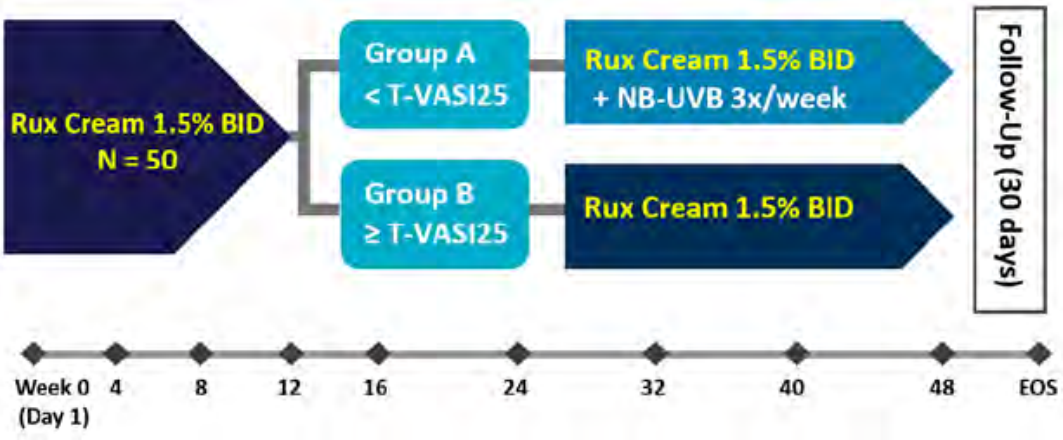
3. STUDY DESIGN

This is an open-label study in which participants will apply ruxolitinib 1.5% cream BID to all depigmented areas (up to 10% BSA) for up to 48 weeks. Participants will continue to treat depigmented areas identified for treatment at baseline regardless of whether the area begins to improve or fully repigment.

On Day 1, all participants will apply ruxolitinib 1.5% cream BID as monotherapy (see Figure 1). At Week 12, participants will apply ruxolitinib 1.5% cream BID alone or in combination with NB-UVB based on their T-VASI score. Participants who have < T-VASI25 will have NB-UVB phototherapy added to their ruxolitinib 1.5% cream BID regimen (Group A). The NB-UVB phototherapy will be given 3 times per week through Week 48 (ie, 36 weeks). Participants who have ≥ T-VASI25 at Week 12 will continue on ruxolitinib 1.5% cream BID alone (Group B).

The study schema is shown below in Figure 1. All participants will have follow-up assessments 30 (+7) days after the last application of study drug.

Figure 1: Study Design Schema



3.1. Randomization

Not applicable.

3.2. Control of Type I Error

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

3.3. Sample Size Considerations

Due to the exploratory nature of the study, the sample size is not based on calculation of statistical power. The sample size is considered to be sufficient to obtain adequate efficacy, safety, tolerability, and PK data to achieve the objectives of the study.

Approximately 50 participants will receive ruxolitinib 1.5% cream BID for 12 weeks. At Week 12, participants will be assigned to ruxolitinib cream 1.5% BID alone or in combination with NB-UVB phototherapy based on their T-VASI score.

3.4. Schedule of Assessments

Refer to the Protocol dated 30 SEP 2021 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 application of ruxolitinib cream is administered to participants in the specific period.

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 follows:

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 follows:

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 (or on) the day of first application of ruxolitinib cream.

4.1.4. Handling of Missing and Incomplete Data

In general, values for missing data will not be imputed unless methods for handling missing data are specified in this section or relevant sections. The original reported dates collected on the eCRF should be used in all relevant listings. The following rules will be used for handling partial dates for analyses requiring dates.

4.2. Variable Definitions

4.2.1. Body Mass Index

Body mass index will be calculated as follows:

BMI (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 1.5%.

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

- Before the date of first application of ruxolitinib cream 1.5% and is ongoing throughout the study or ends on/after the date of first application of study treatment.
- On/after the date of first application of ruxolitinib cream 1.5% and is ongoing or ends during the course of study treatment.

A prior medication could also be classified as "both prior and concomitant medication," if the end date is on or after the first application of ruxolitinib cream 1.5%. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, 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; v9.1 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, maximum, first quartile, third quartile, and 95% CI. 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 study composed of a 48-week treatment period, including a 12-week treatment run-in. During the 12-week run-in, all participants will apply ruxolitinib 1.5% cream BID. Following these 12 weeks, participants will receive either ruxolitinib 1.5% cream BID alone or ruxolitinib 1.5% cream BID plus NB-UVB phototherapy for 36 weeks. Participant groups were determined based on their T-VASI score at Week 12. Data will be summarized based on the treatments that the participant received.

5.3. Analysis Populations

5.3.1. All-Screened Population

The all-screened population will include all participants who signed the informed consent form.

5.3.2. Full Analysis Set

The FAS will include all participants who applied at least one dose of ruxolitinib cream.

The FAS will be used for the summary of demographics, baseline characteristics, participant disposition, and analyses of all efficacy and safety data.

5.3.3. Pharmacokinetic-Evaluable Population

The PK-evaluable population includes participants who applied at least 1 dose of ruxolitinib cream and provided at least 1 postdose blood sample. The study pharmacokineticist will review data listings of participant administration and sample records to identify participants to be excluded from the analyses.

5.3.4. Pharmacodynamic-Evaluable Population

The PD-evaluable population will include all participants who applied at least 1 dose of ruxolitinib cream and provided at least 1 PD measurement that complies with the instructions in the Protocol. The study research investigator will review data listings of PD data and sample records to identify participants to be excluded from analyses of PD data.

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Appendix A provides a list of planned tables, figures, and listings. 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 will be summarized for the FAS population: age, age group, sex, race, ethnicity, region, weight, height, and BMI.

6.1.2. Baseline Disease Characteristics and Disease History

The following baseline disease characteristics will be summarized for the FAS population and will include, but will not be limited to the following:

- Time since initial diagnosis of vitiligo
- Vitiligo diagnosed in childhood (no/yes [age]: 0-5 years, 6-11 years, 12-17 years)
- Disease status (stable/progressive)
- Skin type (Fitzpatrick scale Type I/II/III/IV/V/VI)
- Other autoimmune disorders
- Prior therapy given for vitiligo (predefined systemic treatments, phototherapy, and surgical procedures)
- History of acne vulgaris (no/yes)
- Currently have acne vulgaris on the face (no/yes)
- Itching associated with the vitiligo lesions (no/yes)
- Vitiligo in genital area (no/yes)
- Baseline F-VASI
- Baseline T-VASI
- Baseline F-BSA involvement (% of the total body)
- Baseline T-BSA involvement (% of the total body)

6.1.3. Prior Medication for Vitiligo

Prior medication information for vitiligo will be used to identify other nonpredefined medication received by participants before enrollment into the study. Prior medication for vitiligo will be summarized by treatment group.

6.1.4. Medical History

For participants in the FAS, medical history will be summarized by treatment group. This summary will include the number and percentage of participants with medical history for each body SOC/PT as documented in the eCRF.

6.2. Disposition of Participants

The number and percentage of participants who were enrolled, who were treated, and who completed the study for each period will be summarized for the ITT population.

6.3. Protocol Deviations

Protocol deviations recorded on the eCRF will be summarized and listed.

6.4. Exposure

For participants in the FAS population during the treatment period, exposure will be summarized descriptively for duration of treatment, average daily dose, and total dose.

6.5. Study Drug Compliance

For the participants in the FAS population, overall compliance (%) for the application of ruxolitinib cream during the treatment period will be calculated for all participants as follows:

> Compliance (%) of ruxolitinib cream = 100 × [total number of applied applications] / [total number of prescribed applications].

The total number of intended applications is the number of planned applications minus the number of interrupted applications.

6.6. NB-UVB Machine Compliance

Overall compliance (%) for the NB-UVB machine will be calculated by the number of sessions recorded by the NB-UVB machine.

> Compliance (%) of NB-UVB = 100 × [total number of days using NB-UVB] / [total number of days intended to use NB-UVB]

The total number of days intended to use is the number of days prescribed based on the frequency of 3 days per week. Compliance will be summarized and listed for participants in Group A.

6.7. Prior and Concomitant Medication

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary. The number and percentage of participants in the safety population for each prior and concomitant medication will be summarized by WHO drug class and WHO drug preferred term. Prior and concomitant medications will also be summarized (and listed) by treatment group.

7. EFFICACY

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

7.1. General Considerations

For all continuous variables, the actual value and change and/or percentage from baseline (if available) will be analyzed.

For continuous measurements, summary statistics will include sample size, mean, median, standard deviation, standard error of the mean, minimum, and maximum.

For categorical measurements, summary statistics will include sample size, frequency, and percentages. All by-visit analyses will include the follow-up period, if the data are available.

7.2. Efficacy Measures

7.2.1. Body Surface Area

Total % BSA (includes facial and nonfacial areas) depigmented by vitiligo will be estimated at each visit. Body surface area assessment will be performed by the Palmar Method. Body surface area should be estimated to the nearest 0.1%. The approximate size of the participant's entire palmar surface (ie, the palm plus 5 digits) should be considered as 1% BSA; the approximate size of the participant's thumb should be considered as 0.1% BSA.

7.2.2. Vitiligo Area Scoring Index

Areas affected by depigmentation due to vitiligo will be assessed using the VASI. It is based on a composite estimate of the overall area of vitiligo patches at baseline and the degree of macular repigmentation within these patches over time.

Facial VASI is measured by percentage of vitiligo involvement (% BSA) and the degree of depigmentation. The percentage of BSA (hand unit) vitiligo involvement is estimated by the investigator using the Palmar Method. The hand unit is based on participant's hand size. The investigator uses his/her hand to mimic the participant's hand size to evaluate percentage BSA vitiligo involvement. The degree of depigmentation for each vitiligo involvement site is determined and estimated to the nearest of the following percentages: 0%, 10%, 25%, 50%, 75%, 90%, or 100%. At 100% depigmentation, no pigment is present; at 90%, specks of pigment are present; at 75%, the depigmented area exceeds the pigmented area; at 50%, the depigmented and pigmented area are equal; at 25%, the pigmented area exceeds the depigmented area; and at 10%, only specks of depigmentation are present. The F-VASI is then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each site on the face, summing the values of all sites together (possible range, 0-3).

The area "Face" is defined as including the area on the forehead to the original hairline, on the cheek to the jawline vertically to the jawline and laterally from the corner of the mouth to the tragus. The area "Face" will not include surface area of the lips, scalp, ears, or neck, but will include the nose and eyelids.

Total body VASI is calculated using a formula that includes contributions from all body regions (possible range, 0-100).

The body is divided into the following 6 separate and mutually exclusive sites: 1) head/neck, 2) hands, 3) upper extremities (excluding hands), 4) trunk, 5) lower extremities (excluding feet), and 6) feet. The percentage of vitiligo involvement is estimated in hand units (% BSA) by the same investigator during the entire course of the study. Hand unit is based on participant's hand size. The investigator uses their hand to mimic the participant's hand size to evaluate % BSA vitiligo involvement. The degree of depigmentation for each body site is determined and estimated to the nearest of the following percentages: 0%, 10%, 25%, 50%, 75%, 90%, or 100%. The T-VASI is then derived by multiplying the values assessed for the vitiligo involvement by the percentage of affected skin for each body site, summing the values of all body sites together (Hamzavi et al 2004).

[redacted]

[redacted]

[redacted]

7.3. Efficacy Analysis

7.3.1. Primary Efficacy Analysis

The primary efficacy endpoint is the change from baseline in T-VASI at Week 48. For the primary endpoint, summary statistics will include sample size, mean, median, standard deviation, minimum, maximum, and the 95% CI.

7.3.2. Secondary and [redacted] Efficacy Analysis

7.3.2.1. Continuous Efficacy Endpoints

By-visit summary statistics for the following continuous measurements, including actual measurement, change from baseline, and percentage change from baseline, will be presented:

- F-VASI/T-VASI
- F-BSA/[redacted]/T-BSA
- [redacted]

Summary statistics, including sample size, mean, median, standard deviation, minimum, maximum, first quartile, third quartile, and 95% CI, will be presented by visit. In addition, line graphs and mean and standard error plots will be provided.

7.3.2.2. Categorical Efficacy Endpoints

For the following categorical parameters, summary statistics will include sample size, frequency, percentages and standard error of percentage, and the 95% CI at each visit. In addition, box plots will be provided.

- Proportion of participants achieving F-VASI50/75/90
- Proportion of participants achieving T-VASI25/50/75/90

[redacted]

8. PHARMACOKINETICSAND PHARMACODYNAMICS

8.1. Pharmacokinetic Analyses

Trough plasma ruxolitinib concentrations at applicable study visits will be summarized using descriptive statistics by treatment group.

[redacted]

8.3. Pharmacokinetic/Pharmacodynamic Analyses

Pharmacokinetic analyses will be performed using the PK-evaluable population.

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

The analyses in this section will be provided for the safety population.

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 PTs reported on relatively few participants.

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 first application of study drug and within 30 days of the last application of study drug. For participants who have NB-UVB phototherapy added, the first application date is period-specific, and the end date is 30 days after the last application date in this period, or the day before the first application date in the next period, whichever comes first. 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 drug 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. Serious AEs 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.

Application site reactions are AEs that occur at the site of drug application. A summary of ASRs will be provided.

9.2.2. Adverse Event Summaries

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

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

The following summaries will be produced by MedDRA term (if 5 or fewer participants appear in a table, a listing may be appropriate):

- Summary of TEAEs by SOC, PT, and maximum severity
- Summary of TEAEs by SOC and PT
- Summary of TEAEs by PT in decreasing order of frequency
- Summary of Grade 3 or higher AEs by SOC and PT
- Summary of Grade 3 or higher AEs by PT in decreasing order of frequency
- Summary of serious TEAEs by SOC and PT
- Summary of serious TEAEs by PT in decreasing order of frequency
- Summary of ASRs by SOC and PT
- Summary of ASRs by PT in decreasing order of frequency
- Summary of treatment-related TEAEs by 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 SOC and PT

- Summary of treatment-related serious TEAEs by SOC and PT
- Summary of TEAEs with a fatal outcome by SOC and PT
- Summary of TEAEs leading to dose interruption of study drug by SOC and PT
- Summary of TEAEs leading to discontinuation of study drug by SOC and PT

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 (when applicable). Laboratory values and change from baseline values will be summarized descriptively by visit; non-numeric test values will be tabulated when necessary.

The baseline value will be determined using the last nonmissing value collected before the first application, prioritizing scheduled assessments for baseline identification over unscheduled visits. The last record before application in the highest priority will be considered the baseline record. For baseline laboratory candidates with the same date and time in the same priority category, 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

Actual values and changes from baseline in clinical laboratory test results will be summarized using descriptive statistics. Laboratory test values outside the normal range will be assessed for severity based on the normal ranges for the clinical reference laboratory. The incidence of abnormal laboratory values will be tabulated.

Laboratory data will be classified into Grades 1 through 5 using CTCAE v5.0. The following summaries will be produced for the laboratory data:

- Number and percentage of participants with worst postbaseline CTCAE grade (regardless of baseline value). (Note: Each participant will be counted only for their worst grade observed postbaseline.)
- Shift tables from baseline to the worst postbaseline value using CTCAE grade.

In addition, box plots will be provided for hemoglobin, platelet counts, neutrophils, leukocytes, lymphocytes, erythrocytes, and reticulocytes.

9.4. Vital Signs

Descriptive statistics and mean change from baseline will be determined for vital signs (blood pressure, pulse, respiratory rate, and body temperature) at each assessment time.

Criteria for clinically notable vital sign abnormalities are defined in Table 4. The abnormal values for participants exhibiting clinically notable vital sign abnormalities will be listed along with their assigned treatment group. Alert vital signs are defined as an absolute value outside the defined range and percentage change > 25%. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 4: Criteria for Clinically Notable Vital Sign Abnormalities for ≥ 18 Years Old

Parameter	High Threshold	Low Threshold
Systolic blood pressure	> 155 mmHg	< 85 mmHg
Diastolic blood pressure	> 100 mmHg	< 40 mmHg
Pulse	> 100 bpm	< 45 bpm
Temperature	> 38ºC	< 35.5ºC
Respiratory rate	> 20 breaths/min	< 8 breaths/min

10. INTERIM ANALYSES

No formal interim analysis is planned in this study.

11. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 5.

Table 5: Statistical Analysis Plan Versions

SAP Version	Date
Original	10 MAY 2023

11.1. Changes to Protocol-Defined Analyses

Not applicable.

11.2. Changes to the Statistical Analysis Plan

Not applicable.

12. REFERENCES

[redacted]

Hamzavi I, Jain H, McLean D, Shapiro J, Zeng H, Lui H. Parametric modeling of narrowband UV-B phototherapy for vitiligo using a novel quantitative tool: the Vitiligo Area Scoring Index. Arch Dermatol 2004;140:677-683.

[redacted]

World Health Organization. Wellbeing measures in primary health care/the Depcare Project: report on a WHO meeting: Stockholm, Sweden. WHO Regional Office for Europe, Copenhagen: 12-13 February 1998.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. Shells are provided in a separate document for tables that are not in the most current Standard Safety Tables.

The list 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	Standard
1.1.1	Analysis Populations	All	X
1.1.2.1	Summary of Participant Disposition	FAS	X
1.1.3	Summary of Number of Participants Enrolled by Country and Site	FAS	X
1.1.4.1	Summary of Protocol Deviations	FAS	X
1.2.1	Summary of Demographics and Baseline Characteristics	FAS	X
1.3	Summary of Baseline Disease Characteristics	FAS	X
1.4.1	Summary of Prior Medications for Vitiligo	FAS	X
1.4.2	Summary of Prior Medications	FAS	X
1.4.3.1	Summary of Concomitant Medications	FAS	X
1.5	Summary of General Medical History	FAS	X
1.6	Summary of Participants With Assessments Not Done Due to COVID-19 Pandemic	FAS	X
Efficacy			
F-VASI/T-VASI			
2.1.1	Summary and Analysis of T-VASI During the Treatment Period	FAS	
2.1.2	Summary and Analysis of Participants Achieving T-VASI25 During the Treatment Period	FAS	
2.1.3	Summary and Analysis of Participants Achieving T-VASI50 During the Treatment Period	FAS	
2.1.4	Summary and Analysis of Participants Achieving T-VASI75 During the Treatment Period	FAS	
2.1.5	Summary and Analysis of Participants Achieving T-VASI90 During the Treatment Period	FAS	
2.2.1	Summary and Analysis of F-VASI During the Treatment Period	FAS	
2.2.2	Summary and Analysis of Participants Achieving F-VASI50 During the Treatment Period	FAS	
2.2.3	Summary and Analysis of Participants Achieving F-VASI75 During the Treatment Period	FAS	
2.2.4	Summary and Analysis of Participants Achieving F-VASI90 During the Treatment Period	FAS	
F-BSA/BSA			
2.4.1	Summary and Analysis of F-BSA During the Treatment Period	FAS	
2.4.2	[redacted]	FAS	
2.4.3	Summary and Analysis of T-BSA During the Treatment Period	FAS	

Table No.	Title	Population	Standard
[redacted]			
Exposure and Compliance			
3.1.1	Summary of Exposure in During Treatment Period	FAS	X
3.1.2	Summary of Study Drug Compliance in During Treatment Period	FAS	X
3.1.3	Summary of NB-UVB Compliance in During Treatment Period	FAS	X
Adverse Events			
3.2.1.1	Overall Summary of Treatment-Emergent Adverse Events	FAS	X
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	FAS	X
3.2.4.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X

Table No.	Title	Population	Standard
3.2.5.1.1	Summary of Application Site Reactions by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.5.1.2	Summary of Application Site Reactions by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.6.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.6.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.7.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.7.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.8.1	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.8.2	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.8.3	Summary of Treatment-Related Treatment-Emergent Adverse Events in Cohort A by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.9.1	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.10.1	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.11.1	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.12.1	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.13.1	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	FAS	X
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3.3.1	Summary of Laboratory Values - Hematology	FAS	X
3.3.3	Shift Summary of Hematology Laboratory Values in CTC Grade - to the Worst Abnormal Value	FAS	X
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3.3.6	Shift Summary of Chemistry Laboratory Values in CTC Grade - to the Worst Abnormal Value	FAS	X
3.4.1	Summary of Systolic Blood Pressure	FAS	X
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3.4.4	Summary of Respiration Rate	FAS	X
3.4.5	Summary of Body Temperature	FAS	X

Note: Cohort A includes all participants reported TEAEs related to either 1.5% BID or NB-NVB.

Figures

Figure No.	Title	Population
4.1.1	Proportion of Participants Achieving F-VASI25 During Treatment Period	FAS
4.1.2	Proportion of Participants Achieving F-VASI50 During Treatment Period	FAS
4.1.3	Proportion of Participants Achieving F-VASI75 During Treatment Period	FAS
4.1.4	Proportion of Participants Achieving F-VASI90 During Treatment Period	FAS
4.1.6	Mean and Standard Error Plot of F-VASI During Treatment Period	FAS
4.1.7	Mean and Standard Error Plot of Change From Baseline in F-VASI During Treatment Period	FAS
4.1.8	Mean and Standard Error Plot of Percent Change From Baseline in F-VASI During Treatment Period	FAS
4.2.1	Proportion of Participants Achieving T-VASI25 During Treatment Period	FAS
4.2.2	Proportion of Participants Achieving T-VASI50 During Treatment Period	FAS
4.2.3	Proportion of Participants Achieving T-VASI75 During Treatment Period	FAS
4.2.4	Proportion of Participants Achieving T-VASI90 During Treatment Period	FAS
4.2.6	Mean and Standard Error Plot of T-VASI During Treatment Period	FAS
4.2.7	Mean and Standard Error Plot of Change From Baseline in T-VASI During Treatment Period	FAS
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4.3.1	Mean and Standard Error Plot of F-BSA During Treatment Period	FAS
4.3.2	Mean and Standard Error Plot of Change From Baseline in F-BSA During Treatment Period	FAS
4.3.3	Mean and Standard Error Plot of Percent Change From Baseline in F-BSA During Treatment Period	FAS
[redacted]		
[redacted]		
4.4.1	Mean and Standard Error Plot of T-BSA During Treatment Period	FAS
4.4.2	Mean and Standard Error Plot of Change From Baseline in T-BSA During Treatment Period	FAS
4.4.3	Mean and Standard Error Plot of Percent Change From Baseline in T-BSA During Treatment Period	FAS
[redacted]		
[redacted]		

Figure No.	Title	Population
[redacted]		
5.1.1	Box Plot of Hemoglobin (g/L) by Visit	FAS
5.1.2	Box Plot of Change From Baseline in Hemoglobin (g/L) by Visit	FAS
5.1.3	Box Plot of Percentage Change From Baseline in Hemoglobin (g/L) by Visit	FAS
5.2.1	Box Plot of Platelets (10^9/L) by Visit	FAS
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5.2.3	Box Plot of Percentage Change From Baseline in Platelets (10^9/L) by Visit	FAS
5.3.1	Box Plot of Neutrophils (10^9/L) by Visit	FAS
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5.3.3	Box Plot of Percentage Change From Baseline in Neutrophils (10^9/L) by Visit	FAS
5.4.1	Box Plot of Leukocytes (10^9/L) by Visit	FAS
5.4.2	Box Plot of Change From Baseline in Leukocytes (10^9/L) by Visit	FAS
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5.6.1	Box Plot of Erythrocytes (10^{12}/L) by Visit	FAS
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2.6.3	F-BSA
[redacted]	[redacted]
2.6.5	T-BSA
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
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