Official Title: A Double-Blind, Vehicle-Controlled, Randomized Withdrawal and Treatment Extension Study to Assess the Long-Term Efficacy and Safety of Ruxolitinib Cream in Participants With Vitiligo (TRuE-V LTE)

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Statistical Analysis Plan

INCB 18424-308

A Double-Blind, Vehicle-Controlled, Randomized Withdrawal and Treatment Extension Study Assess the Long-Term Efficacy and Safety of Ruxolitinib Cream in Participants With Vitiligo
(TRuE-V LTE)

IND Number:	[redacted]
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Phase of Study:	**3**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803** **United States**
Protocol Version:	**Protocol Amendment 2 dated 10 NOV 2020**
CRF Approval Date:	**01 DEC 2020**
SAP Version:	**Original**
SAP Author:	[redacted], **Biostatistics**
Date of Plan:	**06 OCT 2022**

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
AE	adverse event
ASR	application site reaction
BID	twice daily
BMI	body mass index
BSA	body surface area
CDLQI	Children's Dermatology Life Quality Index
CI	confidence interval
$C_{min,ss}$	minimum concentration during a dosing interval at steady state
CRF	case report form
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DLQI	Dermatology Life Quality Index
EOT	end of treatment
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
IFN	interferon
IL	interleukin
ITT-Ext	intent-to-treat in long-term extension
MedDRA	Medical Dictionary for Regulatory Activities
[redacted]	[redacted]
[redacted]	[redacted]
PK	pharmacokinetic
PT	preferred term
RES	relapse evaluable set
SAP	Statistical Analysis Plan
SOC	system organ class
T-BSA	total body surface area
TEAE	treatment-emergent adverse event
[redacted]	

Abbreviation	Term
T-VASI	total body Vitiligo Area Scoring Index
T-VASI50/75/90	≥ 50%/75%/90% improvement in total body Vitiligo Area Scoring Index
VASI	Vitiligo Area Scoring Index
[redacted]	[redacted]
VNS	Vitiligo Noticeability Scale
WHO	World Health Organization
[redacted]	[redacted]

1. INTRODUCTION

This is a Phase 3, double-blind, vehicle-controlled, randomized withdrawal and treatment extension study that will enroll eligible participants who have completed either Study INCB 18424-306 or Study INCB 18424-307 (parent studies) in which the participants will have been using ruxolitinib cream 1.5% BID for the previous 28 to 52 weeks (depending on their initial randomization in the parent study). Participants who successfully completed either of the parent studies and tolerated ruxolitinib cream treatment without a safety concern and with good compliance for continuation may be eligible to participate in this treatment extension study.

Eligible participants in this treatment extension study will be assigned to 1 of 2 cohorts, Cohort A or Cohort B, based on their F-VASI responses at the time of enrollment in this extension study (ie, at Week 52). Participants who achieved complete or almost complete facial repigmentation (ie, achieved ≥ F-VASI90) at Week 52 in the parent study will be assigned to Cohort A, stratified by the original treatment received on study Day 1 of the parent study, and randomized 1:1 to treatment with vehicle cream BID or ruxolitinib cream 1.5% BID for an additional 52 weeks (ie, until EOT or at Week 104). However, any participant in Cohort A who experiences relapse (defined as < F-VASI75) will receive ruxolitinib cream 1.5% BID as an open-label rescue treatment until they complete treatment (Week 104 or EOT). Participants who did not achieve ≥ F-VASI90 at Week 52 of the parent studies will be assigned to Cohort B and will continue ruxolitinib cream 1.5% BID for up to 52 weeks (ie, EOT or Week 104).

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

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 18424-308 Protocol (Amendment 2 dated 10 NOV 2020) and INCB 18424-308 CRF approved 01 DEC 2020. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and CRF versions.

2.2. Study Objectives and Endpoints

Table 1 presents the endpoints and objectives.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
To evaluate the duration of clinical response of ruxolitinib cream in participants with vitiligo.	For participants who are randomized in Cohort A: • Time to relapse (defined as < F-VASI75).
Key Secondary	
To evaluate the duration of clinical response of ruxolitinib cream in participants with vitiligo.	For participants who are randomized in Cohort A: • Time to maintain ≥ F-VASI90 response.
Secondary	
To further evaluate the efficacy of ruxolitinib cream.	• Proportion of participants who achieve F-VASI50/75/90 during the extension treatment period. • Actual measurements, change, and percentage change from baseline in F-VASI. • Proportion of participants who achieve T-VASI50/75/90 during the extension treatment period. • Actual measurements, change, and percentage change from baseline in T-VASI. • Actual measurements, change, and percentage change from baseline in F-BSA. • Actual measurements, change, and percentage change from baseline in T-BSA. • Proportion of participants achieving a VNS of "4 – A lot less noticeable" or "5 – No longer noticeable" during the extension treatment period.
To determine the participants' quality of life.	• Change from Week 52 in DLQI (or CDLQI) during the extension treatment period.
To evaluate the safety and tolerability of ruxolitinib cream.	• The frequency and severity of AEs; includes performing physical examinations and collecting vital signs and laboratory data for hematology and serum chemistry.
To evaluate the ruxolitinib PK in plasma after treatment with ruxolitinib cream.	• Trough plasma concentrations of ruxolitinib at Week 80 and Week 104.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
[redacted]	

3. STUDY DESIGN

This is a Phase 3, double-blind, vehicle-controlled, randomized withdrawal and treatment extension study that will enroll eligible participants who have completed either Study INCB 18424-306 or Study INCB 18424-307 (parent studies) in which the participants will have been using ruxolitinib cream 1.5% BID for the previous 28 to 52 weeks (depending on their initial randomization in the parent study; see Figure 1).

The parent studies are randomized, vehicle-controlled studies in adolescent and adult participants (age ≥ 12 years) with nonsegmental vitiligo who have depigmented areas including ≥ 0.5% BSA on the face, ≥ 0.5 F-VASI, ≥ 3% BSA on nonfacial areas, and ≥ 3 T-VASI. Total body involved vitiligo area (facial and nonfacial) was not to exceed 10% BSA. In each parent study, approximately 300 participants were to be randomized 2:1 to receive an initial, double-blind study treatment of ruxolitinib cream 1.5% BID or vehicle cream BID (applied to depigmented vitiligo areas on the face and body up to 10% total BSA) for 24 weeks. After completion of the Week 24 assessments, participants in these studies were offered the opportunity to receive an additional 28 weeks of open-label treatment extension with ruxolitinib cream 1.5% BID under the parent study protocol.

Participants who successfully completed the 52-week treatment in either of the parent studies (ie, 52 weeks of ruxolitinib cream or 24 weeks of vehicle cream plus 28 weeks of ruxolitinib cream) and tolerated ruxolitinib cream treatment without safety concern and with good compliance for continuation may be eligible to participate in this treatment extension study.

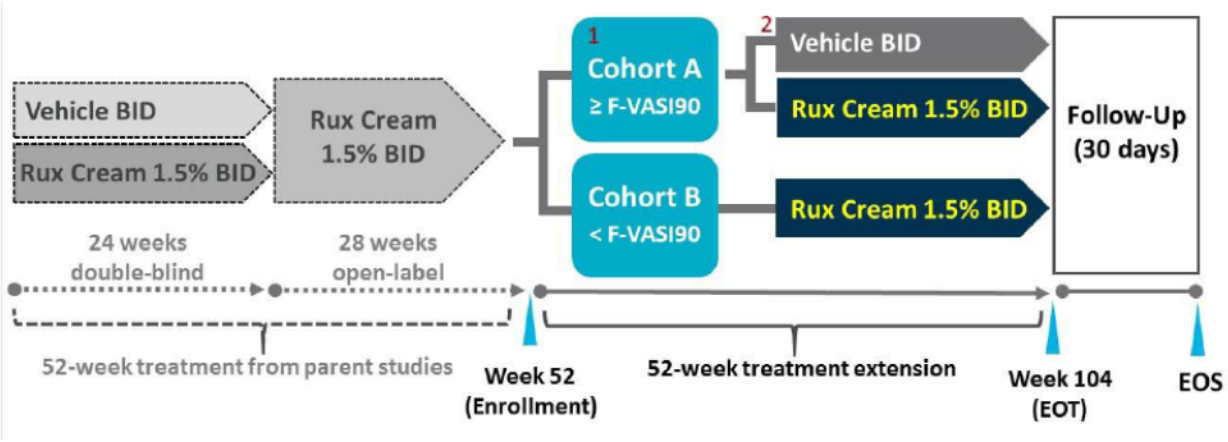
Visits in this treatment extension study are named to reflect continuation from the parent studies, with the first visit of this treatment extension study occurring at Week 52. The eligibility assessment for this extension study occurs at Week 52. The treatment extension period of this study comprises the period from the Week 52 visit to the Week 104 visit (inclusive). Following the last application of study treatment at Week 104, there will be a 30-day safety follow-up period to evaluate safety and duration of response.

Eligible participants in this study will be assigned to 1 of 2 cohorts, Cohort A or Cohort B, based on their F-VASI responses at the time of enrollment in this study (ie, at Week 52).

Treatment in Cohort A is a randomized withdrawal design and will provide data on the duration of response following withdrawal of ruxolitinib cream and maintenance of response with its continued use. Participants who achieve complete or almost complete facial repigmentation (ie, achieve ≥ F-VASI90) at Week 52 in the parent study will be assigned to Cohort A and will be stratified by the original treatment received on study Day 1 of the parent study and randomized 1:1 to treatment with vehicle cream BID or ruxolitinib cream 1.5% BID for an additional 52 weeks (ie, until EOT at Week 104). However, any participants in Cohort A who experience relapse (defined as < F-VASI75) will receive ruxolitinib cream 1.5% BID as an open-label rescue treatment until they complete treatment (Week 104 or EOT).

Treatment in Cohort B will provide long-term efficacy and safety data for ruxolitinib cream in participants with vitiligo. Participants who did not achieve ≥ F-VASI90 at Week 52 of the parent studies will be assigned to Cohort B and will continue ruxolitinib cream 1.5% BID for 52 weeks (ie, until EOT Week 104).

Figure 1: Study Design Schema



[1] All participants in Cohort A will use their randomly assigned treatment (either vehicle or ruxolitinib cream) on both the face and total body.
[2] Rescue treatment: If, at any time, a participant in Cohort A loses a clinically meaningful response on the face (< F-VASI75), the participant will receive open-label 1.5% BID ruxolitinib cream until Week 104 or EOT.

3.1. Randomization

All participants will be centrally assigned to study treatment using an IRT system. For Cohort A, the system will assign in a 1:1 ratio (ruxolitinib cream 1.5% BID/vehicle). For Cohort B, the system will assign all participants to ruxolitinib cream 1.5% BID.

3.2. Control of Type I Error

All statistical analyses 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

Any eligible participants will be enrolled from the 2 parent Phase 3 studies, INCB 18424-306 and INCB 18424-307. The sample size is not based on any statistical power calculations.

3.4. Schedule of Assessments

Refer to Protocol Amendment 2 dated 10 NOV 2020 for a full description of all study procedures and assessment schedules (Protocol Table 3) 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 or vehicle cream is administered to the participants in the extension treatment period (ie, Study INCB 18424-308).

For randomized participants not treated with any study drug, Day 1 is defined as the day of randomization.

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

For randomized participants not treated with any study drug, baseline is defined as the last nonmissing assessment before or on the day of randomization for all parameters.

For participants who continue in the extension treatment period, baseline is defined as follows:

- For efficacy evaluation, baseline is the last nonmissing measurement obtained before the first application of study drug in the parent study.
- For Cohort B safety evaluation, baseline is the last nonmissing measurement obtained before or on the day of first application of ruxolitinib cream in the parent study.
- For Cohort A safety evaluation,
  - For participants who are initially randomized to receive ruxolitinib cream in the extension treatment period (ie, Study INCB 18424-308), baseline is the last nonmissing measurement obtained before the first application of ruxolitinib cream in the parent study.
  - For participants who are initially randomized to receive vehicle cream in the extension treatment period (ie, Study INCB 18424-308), baseline is the last nonmissing measurement obtained before the first application of vehicle cream in the extension period.

When scheduled assessments and unscheduled assessments occur on the same day and 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 Data

For the primary and key secondary endpoints, which are durations of responses, the algorithm in Table 2 will be applied to determine censoring or event.

Table 2: Algorithm for Censoring

Situation	Date of Relapse/Lost Response or Censoring	Outcome
Relapse/lost response documented on or between scheduled visits	Date of relapse/lost response	Relapsed/lost response
No relapse/maintain response	Date of last assessment	Censored
Treatment discontinuation	Date of last assessment	Censored
Applying rescue treatment (1.5% BID) in extension treatment period without relapse/lost response status	Date of rescue treatment	Censored

For all other endpoints, no imputation will be performed for missing values unless otherwise specified.

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. Concomitant Medication

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

- Before the date of first application of study drug in Study INCB 18424-308 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 study drug in Study INCB 18424-308 and is ongoing or ends during the course of study treatment.

A concomitant medication could also be classified as "both prior and concomitant medication" if the end date is on or after the first application of study drug. 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 a double-blind, vehicle-controlled, randomized withdrawal and treatment extension study that will enroll eligible participants who have completed either Study INCB 18424-306 or Study INCB 18424-307 (parent studies). Data will be summarized based on the treatment regimen that was assigned at Week 52 (ITT-Ext) or that the participant actually applied (FAS).

For Cohort A, treatment groups are ruxolitinib cream 1.5% BID and vehicle cream for participants before open-label rescue treatment. For participants who cross over from vehicle cream to open-label ruxolitinib cream, the treatment group will be Vehicle-1.5% BID. For Cohort B, the treatment group will be based on the treatment assignment at Day 1 of the parent study (vehicle to 1.5% BID and 1.5% BID to 1.5% BID).

5.3. Analysis Populations

The data from participants at Site 710 were removed from all efficacy analyses performed on the ITT-Ext population and FAS owing to noncompliance with the Protocol in the parent study resulting in serious concerns with the data quality.

5.3.1. Full Analysis Set

All participants enrolled in the study who applied study drug (ruxolitinib cream or vehicle) at least once at or after Week 52 for each cohort (FAS Cohort A and FAS Cohort B) will constitute the FAS.

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

5.3.2. Intent-to-Treat in Long-term Extension

All participants who achieved ≥ F-VASI90 at Week 52 will be randomized into Cohort A and will constitute the ITT-Ext population. Treatment groups for this population will be defined according to the treatment assignment at the time of randomization regardless of the actual study medication the participant might take during the study.

5.3.3. Relapse Evaluable Set

All participants who are in the ITT-Ext population, experience relapse (defined as < F-VASI75), and receive open-label rescue treatment will constitute the RES.

5.3.4. Pharmacokinetic [redacted] Evaluable Population

The PK[redacted] evaluable population will include all participants who applied ruxolitinib cream at least once and provided at least 1 blood sample (1 PK[redacted] measurement) that complies with the instructions in the Protocol. The study pharmacokineticist will review data listings of study drug application and sample records to identify participants to be excluded from PK data analyses. The study research investigator will review data listings of [redacted] data and sample records to identify participants to be excluded from analyses of [redacted] data.

6. BASELINE, EXPOSURE, AND DISPOSITION

Appendix A provides a list of planned tables, figures, and listings. Sample data displays are included in a separate document.

6.1. Baseline, Demographics, and Disease History

6.1.1. Demographics

The following demographics will be summarized for the FAS population for each cohort by treatment group: age, age group (< 18 years, 18 to < 65 years, ≥ 65 years; < 18 years, ≥ 18 years), sex, race, ethnicity, region, weight, height, and BMI.

6.1.2. Baseline Disease Characteristics

Baseline disease characteristics summarized for the FAS population include but are not 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 (Type I/II/III/IV/V/VI)
- Other autoimmune disorders
- Prior therapy for vitiligo (predefined systemic treatments, phototherapy, and surgical procedures)
- History of acne vulgaris (No/Yes)
- Currently have acne vulgaris on the face (No/Yes)
- Vitiligo in genital area (No/Yes)
- Baseline F-VASI score
- Baseline T-VASI score

- Baseline F-BSA involvement (% of the total body)
- Baseline T-BSA involvement (% of the total body)

6.2. Disposition of Participants

The number and percentage of participants who were randomized, treated, and completed the extension treatment period will be summarized by treatment groups for each cohort. Moreover, participants who discontinued the treatment or withdrew from the study during the extension treatment period with a primary reason for discontinuation will also be summarized.

6.3. Protocol Deviations

Protocol deviations will be summarized by treatment groups for each cohort.

6.4. Exposure

A summary for overall exposure within this study will be provided for the FAS for each cohort. For Cohort A, a summary will be provided based on the actual treatment received as defined in Section 5.2.

6.5. Study Drug Compliance

Overall compliance (%) for the application of ruxolitinib cream or vehicle cream will be calculated for all participants based on the actual treatment received in the FAS population as follows:

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

6.6. Concomitant Medications

For participants in the FAS population, concomitant medications will be coded using the WHO Drug Dictionary and summarized as number and percentage of participants with concomitant medications by WHO drug class and WHO drug term.

Concomitant medications will be summarized by treatment groups for each cohort. Also, listings will be provided for both Cohorts A and B.

7. EFFICACY

Appendix A provides a list of planned tables, figures, and listings. Sample data displays are included in a separate document.

7.1. General Considerations

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

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

Facial and 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, and 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. Hand unit is based on the participant's hand size. The investigator uses their hand to mimic the participant's hand size to evaluate percentage of 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; 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 and 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 the 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).

$$VASI = \sum_{all\ body\ sites} [hand\ units]\ x\ [Residual\ Depigmentation]$$

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 the 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 and summing the values of all body sites together (Hamzavi et al 2004).

The categorical variable F-VASI50 will be equal to 1 for percentage improvement from baseline in F-VASI of ≥ 50% and will be equal to 0 for percentage improvement of < 50%. The F-VASI75/90 and T-VASI75/90 will be defined with the same pattern.

[redacted]

7.2.5. Patient-Reported Outcomes

Patient-reported outcomes and quality of life will be assessed using the following tools:

- VNS (see Section 7.2.5.1)

[redacted]

- DLQI or CDLQI (see Section 7.2.5.5)

[redacted]

7.2.5.1. Vitiligo Noticeability Scale

The VNS is a patient-reported measure of vitiligo treatment success, which has a 5-point scale (Batchelor et al 2016). The baseline facial photograph from the parent study (INCB 18424-306 or INCB 18424-307) will be shown to the participants for reference and a mirror will be provided for the participants to assess the vitiligo on their face. The participant will be asked to respond to the following query:

> Compared with before treatment, how noticeable is the vitiligo now? Responses: (1) More noticeable, (2) As noticeable, (3) Slightly less noticeable, (4) A lot less noticeable, and (5) No longer noticeable

VNS scores of 4 or 5 can be interpreted as representing treatment success.

[redacted]

7.2.5.5. Dermatology Life Quality Index

The DLQI is a simple, 10-question validated questionnaire to measure how much the skin problem has affected the participant over the previous 7 days (Finlay and Khan 1994). Participants aged ≥ 16 years will answer the questionnaire with (1) very much, (2) a lot, (3) a little, or (4) not at all.

The questionnaire is analyzed under 6 headings as follows:

- Symptoms and feelings (Questions 1 and 2)
- Daily activities (Questions 3 and 4)
- Leisure (Questions 5 and 6)
- Work and school (Question 7)

- Personal relations (Questions 8 and 9)
- Treatment (Question 10)

The scoring of each question is as follows: Very much = 3; A lot = 2; A little = 1; Not at all = 0; Not relevant = 0; Question 7, "Prevented work or studying" = 3.

The following imputations will be applied for incorrectly completed questionnaires:

- If 1 question is left unanswered, this is scored 0 and the scores are summed and expressed as usual out of a maximum of 30.
- If 2 or more questions are left unanswered, the questionnaire is not scored.
- If Question 7 is answered "yes," this is scored 3. If Question 7 is answered "no," but then either "a lot" or "a little" is ticked, this is then scored 2 or 1. If "Not relevant" is ticked, the score for Question 7 is 0. If it is answered "no," but the second half is left incomplete, the score will remain 0.
- If 2 or more response options are ticked, the response option with the highest score should be recorded.
- If there is a response between 2 tick boxes, the lower of the 2 score options should be recorded.
- For the 6 DLQI subscales, if the answer to 1 question in a subscale is missing, that subscale should not be scored.

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.

The meaning of total DLQI scores can be categorized as follows:

- 0 to 1 = No effect
- 2 to 5 = Small effect
- 6 to 10 = Moderate effect
- 11 to 20 = Very large effect
- 21 to 30 = Extremely large effect

A change from baseline in DLQI and CDLQI score of at least 4 points is considered clinically important (Basra et al 2015, Waters et al 2010).

The questionnaire is also analyzed under 6 subscales as follows:

- Symptoms and feelings (Questions 1 and 2)
- Daily activities (Questions 3 and 4)
- Leisure (Questions 5 and 6)
- Work and school (Question 7)
- Personal relations (Questions 8 and 9)
- Treatment (Question 10)

The CDLQI is the youth/children's version of the DLQI. For participants who are aged < 16 years at baseline (Day 1) of the parent study (INCB 18424-306 or INCB 18424-307), the CDLQI will be completed instead of the DLQI throughout their participation in this extension study.

The scoring of each question is as follows: Very much = 3; Quite a lot = 2; Only a little = 1; Not at all = 0; Question unanswered = 0; Question 7: "Prevented school" = 3.

The CDLQI 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.

The questionnaire is also analyzed under 6 subscales as follows:

- Symptoms and feelings (Questions 1 and 2)
- Leisure (Questions 4, 5, and 6)
- School or holidays (Question 7)
- Personal relationships (Questions 3 and 8)
- Sleep (Question 9)
- Treatment (Question 10)

The severity banding for CDLQI scores is as follows:

- 0 to 1 = No effect on child's life
- 2 to 6 = Small effect
- 7 to 12 = Moderate effect
- 13 to 18 = Very large effect
- 19 to 30 = Extremely large effect

The following imputations will be applied for incorrectly completed questionnaires:

- If 1 question is left unanswered, this is scored 0, and the scores are summed and expressed as usual out of a maximum of 30.
- If 2 or more questions are left unanswered, the questionnaire is not scored.
- If both parts of Question 7 are completed, the higher of the 2 scores should be counted.

7.3. Analysis of the Primary Efficacy Parameter

The primary endpoint is time to relapse (defined as < F-VASI75) for participants who are randomized in Cohort A.

7.3.1. Primary Efficacy Analysis

The primary analysis will be based on the ITT-Ext population (defined as achieving ≥ F-VASI90 at Week 52). Relapse, a binary variable event, is defined as a loss of F-VASI75 response assessed as percentage improvement from baseline (Day 1 of the parent study) to F-VASI < 75%. The time to relapse is defined as the number of days from the Week 52 randomization date to the first evaluation date at which the participant meets the definition of relapse. For participants who discontinue early, complete the study without meeting criteria for the event, or received open-label rescue treatment (1.5% BID) without meeting the criteria for the event, the time to event will be censored at the last assessment date or the date of rescue treatment. Details of the censoring and missing data handling are provided in Table 2. The time-to-event data will be assessed using the Kaplan-Meier product limit method. Treatment comparisons between ruxolitinib 1.5% cream BID and vehicle cream BID will be performed using the log-rank test. Hazard ratios and the corresponding 95% CIs will be estimated using the Cox proportional hazards model. This model will include the treatment group (1.5% BID and vehicle) and stratification factors (skin type and region).

The incidence of relapse will be summarized by ruxolitinib cream 1.5% BID and vehicle at each timepoint. Swimmer plots will be provided for the time to relapse and subgroup swimmer plots by baseline characteristics, such as age group and duration of disease, will be provided.

7.4. Analysis of the Key Secondary Efficacy Parameters

The key secondary endpoint will be analyzed using the ITT-Ext population.

The key secondary endpoint will be the time to maintain ≥ F-VASI90 response. For F-VASI90 response, a categorical variable event is defined to be equal to 1 (Yes) when the improvement from baseline in F-VASI is ≥ 90% and 0 (No) if < 90%. The time to maintain ≥ F-VASI90 response is defined as the number of days from the Week 52 randomization to the first evaluation date at which the participant has percentage change from baseline in F-VASI < 90%.

The statistical comparisons and censoring and missing data handling for the key secondary endpoint will be analyzed using a similar method as specified in the primary analysis.

7.5. Analysis of Other Secondary Efficacy Parameters

7.5.1. Other Secondary Efficacy Analysis

All other secondary efficacy analyses will be conducted based on the FAS for Cohorts A and B separately. For Cohort A, only assessments on or before the first dose date of open-label rescue treatment will be summarized and all assessments will be listed.

7.5.1.1. 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 for the following:

- F-VASI/T-VASI
- F-BSA/T-BSA
- DLQI (or CDLQI) total score and subscores

Summary statistics, including sample size, mean, median, standard deviation, minimum, maximum, first quartile, third quartile, and 95% CI, will be presented by visits for both Cohorts A and B.

7.5.1.2. Categorical Efficacy Endpoints

For the following categorical parameters, summary statistics, including sample size, frequency, and percentages, will be presented by visit for both cohorts.

- Proportion of participants achieving F-VASI50/75/90
- Proportion of participants achieving T-VASI50/75/90
- Proportion of participants achieving a VNS of "4 – A lot less noticeable" or "5 – No longer noticeable"

[redacted]

7.7. Pharmacokinetic Analyses

Plasma concentrations of ruxolitinib at all study visits will be summarized using descriptive statistics by cohort, treatment group, and/or visit.

Plasma ruxolitinib steady-state exposures ($C_{min,ss}$) will be derived as the average of all preapplication concentrations of ruxolitinib for each participant, and then descriptive summaries of $C_{min,ss}$ will be generated by cohort and treatment group.

[redacted]

[redacted]

8. SAFETY AND TOLERABILITY

Appendix A provides a list of planned tables, figures, and listings. Sample data displays are included in a separate document.

8.1. General Considerations

The analyses in this section will be provided for the FAS population for each cohort. Safety data for each cohort will be summarized in separate tables.

For AEs, summary tables will be provided based on the actual treatment received as defined in Section 5.2.

For laboratory tests and vital signs, summary tables will be provided based on the actual treatment received at Week 52. For Cohort A, only assessments on or before the first dose date of open-label rescue treatment will be summarized.

Also, for safety evaluations, baseline will be defined as stated in Section 4.1.3.

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.

8.2. Adverse Events

8.2.1. 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 in Study INCB 18424-308 and within 30 days of the last dose of study drug. For participants who cross over treatments, the first application date is treatment-specific, and the end date is 30 days after the last application date of this treatment, or the first application date in the next treatment, 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 National Cancer Institute CTCAE v5.0. 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.

8.2.2. Adverse Events of Interest

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

- Cytopenias
  - Anemia
  - Thrombocytopenia
  - Neutropenia
- Herpes zoster
- Viral skin infections
- Skin neoplasms
- Venous and arterial thromboembolic events
- Thrombocytosis and elevated mean platelet volume
- Liver function test elevations

8.2.3. Adverse Event Summaries

An overall summary of AEs by treatment groups (as defined in Section 4.2) will be summarized separately for each cohort and will include the following:

- Number (%) of participants reporting any TEAEs
- Number (%) of participants reporting any ASRs
- 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 2 or fewer participants appear in a table, a listing may be appropriate):

- Summary of TEAEs by SOC and PT
- Summary of TEAEs by PT in decreasing order of frequency
- Summary of exposure-adjusted incidence rates of TEAEs by PT in decreasing order of frequency (Cohort A only)
- 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 exposure-adjusted incidence rates of ASRs by PT in decreasing order of frequency (Cohort A only)
- 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
- Summary of AEs of interest by PT in decreasing order of frequency

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

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

8.3.2. Laboratory Value Summaries

Clinical laboratory tests, including hematology and serum chemistry, will be performed at the Protocol-specified visits.

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.

For test results that will be summarized with available normal ranges, the number and percentage of participants with the laboratory values being low (but never high), normal, high (but never low), and both low and high will be calculated for each test.

These shift summaries will be produced for each test for the FAS population according to the treatment groups defined for the 2 cohorts in Section 5.2. Shift tables will also be presented showing change in CTCAE grade from baseline to worst grade postbaseline. The denominator for the percentage calculation will use the number of participants in the baseline category.

8.4. Vital Signs

Values at each scheduled visit, change, and percentage change from baseline for vital signs, including systolic blood pressure, diastolic blood pressure, pulse, respiratory rate, and body temperature, will be summarized descriptively by treatment group.

Criteria for clinically notable vital sign abnormalities are defined in Table 5, Table 6, and Table 7. The abnormal values for participants exhibiting clinically notable vital sign abnormalities will be listed along with their assigned cohort and 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 5: Criteria for Clinically Notable Vital Sign Abnormalities for Participants 12 to 15 Years Old

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 6: Criteria for Clinically Notable Vital Sign Abnormalities for Participants 16 to 17 Years Old

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

Table 7: Criteria for Clinically Notable Vital Sign Abnormalities for Participants ≥ 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	> 38°C	< 35.5°C
Respiratory rate	> 20 breaths/min	< 8 breaths/min

9. PLANNED ANALYSES

The primary analysis will occur after the primary database lock, when all participants have completed the vehicle-controlled, double-blind treatment period.

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 8.

Table 8: Statistical Analysis Plan Versions

SAP Version	Date
Original	06 OCT 2022

10.1. Changes to Protocol-Defined Analyses

The data from participants at Site 710 were removed from all efficacy analyses performed on the ITT-Ext population and FAS for the final CSR owing to noncompliance with the Protocol in the parent study resulting in serious concerns with the data quality. Data from participants at Site 710 were included in all other analyses because all participants at Site 710 applied study drug at least once.

10.2. Changes to the Statistical Analysis Plan

Not applicable.

11. REFERENCES

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Batchelor JM, Tan W, Tour S, Yong A, Montgomery AA, Thomas KS. Validation of the Vitiligo Noticeability Scale: a patient-reported outcome measure of vitiligo treatment success. Br J Dermatol 2016;174:386-394.

Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI) — a simple practical measure for routine clinical use. Clin Exp Dermatol 1994;19:210-216.

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.

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Waters A, Sandhu D, Beattie P, Ezughah F, Lewis-Jones S. Severity stratification of Children's Dermatology Life Quality Index (CDLQI) scores. Br J Dermatol 2010;163(suppl 1):121 [abstr PA-8].

World Health Organization. WHO Model Prescribing Information: Drugs Used in Skin Diseases. 1997. https://apps.who.int/medicinedocs/en/d/Jh2918e/

APPENDIX A. PLANNED TABLES AND FIGURES

This appendix provides a list of the planned tables, figures, and listings for the CSR. Shells are provided in a separate document for tables that are not in the Standard Safety Tables v1.12.

The lists of tables, figures, 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.

For tables and figures using the FAS population, separate tables and figures will be provided for Cohort A and Cohort B.

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	Summary of Protocol Deviations	FAS	X
1.2	Summary of Demographics and Baseline Characteristics	FAS	X
1.3	Summary of Baseline Disease Characteristics	FAS	X
1.4.1	Summary of Prior Therapy for Vitiligo	FAS	X
1.4.2	Summary of Prior Medications	FAS	X
1.4.3	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	
2.1.1.1	Summary and Analysis of Time to Relapse	ITT-Ext	X
2.1.1.2	Summary of Relapse by Visit	ITT-Ext	X
2.2.1.1	Summary and Analysis of Time to Maintain ≥ F-VASI90	ITT-Ext	
2.2.1.2	Summary of Time to Loss of F-VASI90 Response	ITT-Ext	
2.3.1.1	Summary and Analysis of Participants Achieving F-VASI50	FAS	X
2.3.1.2	Summary and Analysis of Participants Achieving F-VASI75	FAS	X
2.3.1.3	Summary and Analysis of Participants Achieving F-VASI90	FAS	X
2.3.1.4	Summary and Analysis of F-VASI	FAS	X
2.3.1.5	Shift Summary of F-VASI	FAS[a]	
2.3.2.1	Summary and Analysis of Participants Achieving T-VASI50	FAS	X
2.3.2.2	Summary and Analysis of Participants Achieving T-VASI75	FAS	X
2.3.2.3	Summary and Analysis of Participants Achieving T-VASI90	FAS	X
2.3.2.4	Summary and Analysis of T-VASI	FAS	X
2.3.2.5	Shift Summary of T-VASI	FAS[a]	
2.4.1	Summary and Analysis of F-BSA	FAS	X
2.4.2	Summary and Analysis of T-BSA	FAS	X
2.4.1	Summary and Analysis of Participants Achieving VNS Scores of 4 or 5	FAS	X
2.4.2	Summary of Participants in Each Category of VNS Scores	FAS	X
2.4.3	Shift Summary of VNS Scores	FAS[a]	
[redacted]			

Table No.	Title	Population	Standard
[redacted]			
2.9.2	Summary of DLQI	FAS	X
2.9.3	Summary of CDLQI	FAS	X
[redacted]			
3.1.1	Summary of Exposure	FAS	X
3.1.2	Summary of Study Drug Compliance	FAS	X
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 Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.3.2	Summary of Exposure-Adjusted Incidence Rates of TEAEs by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.4.1	Summary of Grade 3 or Higher Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.5.1	Summary of Grade 3 or Higher Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.6.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.7.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.8.1	Summary of Application Site Reactions by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.9.1	Summary of Application Site Reactions by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.9.2	Summary of Exposure-Adjusted Incidence Rates of ASRs by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.10.1	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.11.1	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X

Table No.	Title	Population	Standard
3.2.12.1	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.13.1	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.14.1	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.15.1	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption of Study Drug by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.16.1	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.17.1	Summary of Adverse Events of Interest by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.3.1	Summary of Laboratory Values – Hematology	FAS	X
3.3.2	Shift Summary of Hematology Laboratory Values in CTCAE Grade – To the Worst Abnormal Value	FAS	X
3.3.3	Summary of Laboratory Values – Chemistry	FAS	X
3.3.4	Shift Summary of Chemistry Laboratory Values in CTCAE Grade – To the Worst Abnormal Value	FAS	X
3.4.1.1	Summary of Systolic Blood Pressure	FAS	X
3.4.2.1	Summary of Diastolic Blood Pressure	FAS	X
3.4.3.1	Summary of Pulse	FAS	X
3.4.4.1	Summary of Respiratory Rate	FAS	X
3.4.5.1	Summary of Body Temperature	FAS	X

[a] FAS Cohort B only.

Figures

Figure No.	Title	Population
4.1.1	Kaplan-Meier Curve of the Time to Relapse	ITT-Ext
4.1.1.1	Swimmer Plot of the Time to Relapse	ITT-Ext
4.1.1.2	Swimmer Plot of the Time to Relapse by Subgroups	ITT-Ext
4.1.2	Kaplan-Meier Curve for Maintenance of F-VASI90 Response	ITT-Ext
4.1.3	Proportion of Participants Achieving F-VASI50	FAS
4.1.4	Proportion of Participants Achieving F-VASI75	FAS
4.1.5	Proportion of Participants Achieving F-VASI90	FAS
4.1.6	Mean and Standard Error Plot of F-VASI	FAS
4.1.7	Mean and Standard Error Plot of Change From Baseline in F-VASI	FAS
4.1.8	Mean and Standard Error Plot of Percentage Change From Baseline in F-VASI	FAS
4.2.1	Proportion of Participants Achieving T-VASI50	FAS
4.2.2	Proportion of Participants Achieving T-VASI75	FAS
4.2.3	Proportion of Participants Achieving T-VASI90	FAS
4.2.4	Mean and Standard Error Plot of T-VASI	FAS
4.2.5	Mean and Standard Error Plot of Change From Baseline in T-VASI	FAS
4.2.6	Mean and Standard Error Plot of Percentage Change From Baseline in T-VASI	FAS

Figure No.	Title	Population
4.3.1	Mean and Standard Error Plot of F-BSA	FAS
4.3.2	Mean and Standard Error Plot of Change From Baseline in F-BSA	FAS
4.3.3	Mean and Standard Error Plot of Percentage Change From Baseline in F-BSA	FAS
4.4.1	Mean and Standard Error Plot of T-BSA	FAS
4.4.2	Mean and Standard Error Plot of Change From Baseline in T-BSA	FAS
4.4.3	Mean and Standard Error Plot of Percentage Change From Baseline in T-BSA	FAS
4.5	Proportion of Participants Achieving VNS Scores of 4 or 5	FAS
[redacted]		
4.1	Kaplan-Meier Curve of the Time to Regain F-VASI75	RES
4.11	Kaplan-Meier Curve of the Time to Regain F-VASI90	RES
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
5.2.2	Box Plot of Change From Baseline in Platelets (10^9/L) by Visit	FAS
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
5.3.2	Box Plot of Change From Baseline in Neutrophils (10^9/L) by Visit	FAS
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
5.4.3	Box Plot of Percentage Change From Baseline in Leukocytes (10^9/L) by Visit	FAS
5.5.1	Box Plot of Lymphocytes (10^9/L) by Visit	FAS
5.5.2	Box Plot of Change From Baseline in Lymphocytes (10^9/L) by Visit	FAS
5.5.3	Box Plot of Percentage Change From Baseline in Lymphocytes (10^9/L) by Visit	FAS
5.6.1	Box Plot of Erythrocytes (10^12/L) by Visit	FAS
5.6.2	Box Plot of Change From Baseline in Erythrocytes (10^12/L) by Visit	FAS
5.6.3	Box Plot of Percentage Change From Baseline in Erythrocytes (10^12/L) by Visit	FAS
5.7.1	Box Plot of Reticulocytes (10^9/L) by Visit	FAS
5.7.2	Box Plot of Change From Baseline in Reticulocytes (10^9/L) by Visit	FAS
5.7.3	Box Plot of Percentage Change From Baseline in Reticulocytes (10^9/L) by Visit	FAS

Listings

Listing No.	Title
2.1.1	Participant Enrollment and Disposition Status
2.1.2	Participants Who Discontinued Treatment or Discontinued From Study Due to COVID-19
2.1.3	Participants With Assessments Not Done Due to COVID-19 Pandemic
2.2.1	Participant Inclusion and Exclusion Criteria Violations
2.2.2	Protocol Deviations
2.3	Analysis Populations
2.4.1	Demographic Characteristics
2.4.2	Baseline Disease Characteristics
2.4.3	Medical History
2.4.4	Prior and Concomitant Medications
2.4.5	Prior Therapy for Vitiligo
2.5.1	Study Drug Exposure and Compliance
2.6.1	Time to Relapse
2.6.2	Time to Loss of Adequate Response
[redacted]	
2.6.5	F-VASI Score
2.6.6	T-VASI Score
2.6.7	F-BSA
2.6.8	T-BSA
2.6.9	VNS Score
[redacted]	
2.6.15	DLQI Score
2.6.16	CDLQI Score
[redacted]	
2.6.19	Participants With F-VASI Assessments Not Done Due to COVID-19 Pandemic
2.7.1	Adverse Events
2.7.2	Adverse Events Leading to Study 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
2.7.8	Grade 3 or Higher Adverse Events
2.7.9	Application Site Reactions
2.7.10	Adverse Events of Interest
2.7.11	Prior Adverse Events
2.8.1.1	Clinical Laboratory Values – Hematology
2.8.1.2	Clinical Laboratory Values – Chemistry

2.8.1.3	Abnormal Clinical Laboratory Values – Hematology
2.8.1.4	Abnormal Clinical Laboratory Values – Chemistry
2.8.2.1	Vital Signs
2.8.2.2	Abnormal Vital Sign Values
2.8.2.3	Alert Vital Sign Values