STATISTICAL ANALYSIS PLAN

INCB018424 CREAM

INCB 18424-204

An Open-Label (Part A) and a Double-Blind, Randomized, Placebo-Controlled (Part B) Study, With an Open-Label Extension, of INCB018424 Phosphate Cream Applied Topically to Subjects With Alopecia Areata

IND Number: 77101

Date of Plan: 27 OCT 2015

Based on: Protocol dated 14 JUL 2015

CRF version approved 08 SEP 2015

SPONSOR:

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This study is being conducted in compliance with good clinical practice, including the archiving of essential documents.

STATISTICAL ANALYSIS PLAN APPROVAL

SAP:	INCB 18424-204 SAP
SAP Version:	Final
Submitter:	[redacted], Biostatistics
Date Submitted:	27 OCT 2015
Protocol Version:	14 JUL 2015
CRF Approval Date:	08 SEP 2015

NOTE:

1. An amendment made before the release of unblinded data (eg, treatment assignment received by each subject) for a blinded study or database release for an open-label study must be included in an updated SAP.

2. An amendment made to the statistical analyses defined in the SAP that occurs after unblinding or database release must be documented in the final Clinical Study Report.

3. The approvers must ensure that all relevant functions are in agreement with the final SAP.

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LIST OF ABBREVIATIONS

Abbreviation	Term
AA	alopecia areata
AE	adverse event
ALT	alanine aminotransferase
AST	aspartate aminotransferase
BMI	body mass index
BID	twice daily
CRF	case report form
CSR	clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
ECG	electrocardiogram
EOS	end of study
EOT	end of treatment
ITT	intent-to-treat population
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	mixed model repeated measures
NRI	nonresponder imputation
PD	pharmacodynamics
PI	percent improvement
[redacted]	[redacted]
PP	per protocol population
rAAIG	revised Alopecia Areata Investigational Guidelines
SALT	Severity of Alopecia Tool
SAE	serious adverse event
SAP	Statistical Analysis Plan
TEAE	treatment-emergent adverse event
WHO	World Health Organization

1. INTRODUCTION

This is a 2-part study in subjects with alopecia areata (AA), with Part A being open-label and Part B being double-blind, randomized, and placebo-controlled and both followed by an open-label extension. Section 1 of the Protocol provides a detailed description of the investigational product, target patient population, rationale for doses to be examined, and potential risks and benefits of treatment with INCB018424 cream. The purpose of this Statistical Analysis Plan (SAP) is to define the methodology for analyzing and summarizing the data collected during the conduct of Study INCB 18424-204.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on Protocol INCB 18424-204 Amendment 1 dated 14 JUL 2015 and case report forms (CRFs) approved 08 SEP 2015. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and CRF versions.

2.2. Study Objectives

2.2.1. Primary Objective

The primary objective of the study is to evaluate preliminary efficacy of INCB018424 cream when applied twice daily (BID) to subjects with AA.

2.2.2. Secondary Objective

The secondary objective of the study is to evaluate the safety and tolerability of INCB018424 cream when applied BID to subjects with AA.

2.3. Study Endpoints

2.3.1. Primary Endpoints

Part A: Percentage of subjects achieving a ≥ 50% improvement in Severity of Alopecia Tool (SALT50) response in terminal hair (pigmented and nonpigmented) at any visit up to Week 24 (inclusive).

Part B: Percentage of subjects achieving a SALT50 response in terminal hair (pigmented and nonpigmented) at Week 24.

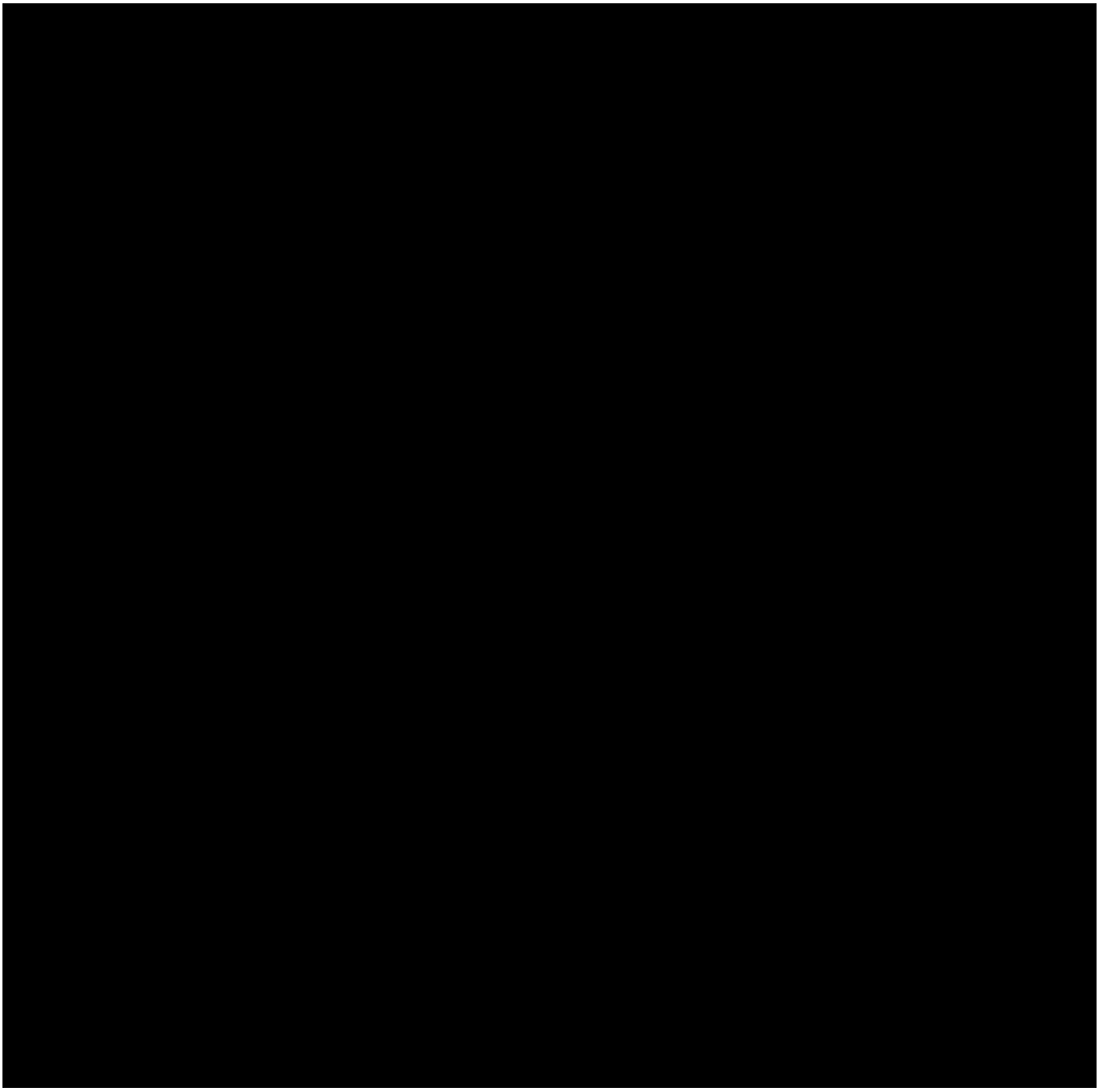
2.3.2. Secondary Endpoints

Part A:

- Percentage of subjects with 50% to 100% scalp involvement at baseline achieving a SALT50 response in terminal hair at any visit through Week 24.
- Percentage of subjects achieving a SALT90 response in terminal hair at Weeks 4, 8, 12, 18, and 24.
- Safety and tolerability assessed by monitoring the frequency, duration, and severity of adverse events (AEs); performing physical examinations; collecting vital signs; and collecting laboratory data for hematology, serum chemistry, and urinalysis.

Part B:

- Percentage of subjects with 50% to 100% scalp involvement at baseline achieving a SALT50 response in terminal hair (pigmented and nonpigmented) at Week 24.
- Percentage of subjects achieving a SALT50 in terminal hair (pigmented and nonpigmented) at Weeks 4, 8, 12, and 18.
- Percentage of subjects achieving a SALT90 in terminal hair (pigmented and nonpigmented) at Weeks 4, 8, 12, 18, and 24.
- Mean change from baseline in SALT score at Weeks 4, 8, 12, 18, and 24.
- Safety and tolerability assessed by monitoring the frequency, duration, and severity of AEs; performing physical examinations; collecting vital signs; and collecting laboratory data for hematology, serum chemistry, and urinalysis.



3. STUDY DESIGN

This is a 2-part study in subjects with AA, with Part A being open-label and Part B being double-blind, randomized, and placebo-controlled.

In Part A, 10 subjects will be treated with open-label topical INCB018424 1.5% cream BID for 24 weeks to examine efficacy, safety, and tolerability. After completion of the Week 24 efficacy assessments, eligible subjects in Part A will be offered an additional 24 weeks of open-label treatment.

Part B is double-blind, randomized, and placebo-controlled, with an open-label extension in up to 68 subjects. Initially, 34 subjects will be randomized to INCB018424 1.5% cream or placebo cream, stratified by baseline percentage of scalp involvement with AA (25% to < 50% or 50% to 100%) using the revised Alopecia Areata Investigational Guidelines (rAAIG). Up to 2 interim analyses, with conduct of the second interim analysis being contingent on the results of the first interim analysis, will be performed in Part B. Overall, Part B will complete randomization of up to 68 subjects if sufficient evidence of terminal hair growth is demonstrated either in Part A or at 1 of the 2 interim analyses in Part B. In Part B, subjects will be treated for 24 weeks to examine efficacy, safety, and tolerability. After the completion of the efficacy assessments for the primary endpoint (Week 24) in the double-blind portion of the study, treatment assignment in Part B will not be unblinded; however, all eligible subjects will be dispensed INCB018424 cream for an additional 24 weeks of open-label treatment.

For subjects in Part A treatment and Part B treatment periods, drug prescription will be based upon the baseline SALT score measured at either enrollment or randomization, and the prescribed dose will not be changed during the treatment periods. In Part A extension and Part B extension periods, subjects may have their dose of study medication adjusted based on the SALT measured at each visit during the extension periods.

3.1. Randomization

In Part B of the study, subjects will be randomized 1:1 between the 2 treatment groups. Subjects will be stratified at randomization into 2 strata: 25% to < 50% scalp involvement (rAAIG Group S2) and 50% to 100% (rAAIG Groups S3, S4, and S5). Subjects with 25% to < 50% scalp involvement will be limited to no more than 70% of the randomized population , and subjects with alopecia totalis will be limited to no more than 10% of the randomized population in Part B.

3.2. Control of Type I Error

For the primary endpoint, the overall 2-sided Type I error is 0.05.

No adjustment for alpha-spending is considered, as there are no plans to stop the study early for overwhelming efficacy. An internal committee in Incyte will be charged with evaluating the unblinded interim results based on the efficacy results in interim analysis, as well as considering interim safety results.

3.3. Sample Size Considerations

In Part A, the sample size is based on the demonstration of preliminary findings of hair regrowth. It is anticipated that a sample of 10 subjects will permit sufficient data to decide to enroll more than the 34 subjects required for the first interim analysis in Part B.

In Part B, for subjects with 25% to < 50% (Stratum A) and 50% to 100% scalp involvement (Stratum B), the response rate is assumed to be 61% for active versus 25% for placebo, and 35% for active versus 5% for placebo, respectively. Using a 2-sided alpha of 0.05 with a continuity correction, 34 per group will have an 80% power to detect a difference between treatment groups.

3.4. Schedule of Assessments

Table 1, Table 2, and Table 3 provide the schedules for study visit assessments and laboratory sampling for the safety and efficacy variables defined for this study.

Parameters for clinical laboratory assessments are provided in Table 7.

Table 1: Schedule of Assessments for the First 24 Weeks of Treatment in Parts A and B

	Screening	Treatment Periods A and B						Follow-Up	
Evaluation	**Day -28 to -1**	**Day 1**	**Week 4 Day 29 ± 3 days**	**Week 8 Day 56 ± 3 days**	**Week 12 Day 84 ± 3 days**	**Week 18 Day 126 ± 7 days**	**Week 24 EOT Day 168 ± 7 days**	**Month 1 ± 7 days**	**Month 3 EOS ± 7 days**
Clinic visit	X	X	X	X	X	X	X	X	X
Informed consent	X								
Contact IRT	X	X	X	X	X	X	X	X	X
Inclusion/exclusion criteria	X	X							
Medical history	X								
Prior/concomitant medications	X	X	X	X	X	X	X	X	X
Height and body weight	X								
Comprehensive physical exam	X						X		
Targeted physical exam		X	X	X	X	X		X	X
Vital signs	X	X	X	X	X	X	X	X	X
Laboratory assessments	X	X	X	X	X	X	X		X
Hepatitis screening tests	X								
Urinalysis	X						X		
FSH[a]	X								
Pregnancy test[b]	X	X	X	X	X	X	X	X	X
12-lead ECG	X						X		
Efficacy assessments	X	X	X	X	X	X	X	X	X
Apply study drug		X	X	X	X	X			
Study drug and diary card dispensed		X	X	X	X	X			
Collect study drug tubes; collect and review diary cards			X	X	X	X	X		
Assess compliance			X	X	X	X	X		
[redacted]									
Photography of scalp		X	X[d]		X		X		X
Assess AEs	X	X	X	X	X	X	X	X	X

ECG = electrocardiogram; EOS = end of study; FSH = follicle-stimulating hormone.

[a] Serum FSH to be performed for all postmenopausal women only, defined by last menstrual period > 12 months before screening.

[b] All women will have a serum pregnancy test conducted at the screening visit and urine pregnancy tests conducted at all other visits (including baseline)

[redacted]

For Part A only: photography of scalp at Week 4.

Table 2: Schedule of Assessments for the Open-Label Extension of Part A

Evaluation	Open-Label Extension Part A					Follow-Up	
	Week 24 Day 168 ± 7 days[a]	**Week 30 Day 210 ± 7 days**	**Week 36 Day 252 ± 7 days**	**Week 42 Day 294 ± 7 days**	**Week 48 EOT Day 336 ± 7 days**	**Month 1 ± 7 days**	**Month 3 EOS ± 7 days**
Clinic visit		X	X	X	X	X	X
Contact IRT	X[a]	X	X	X	X	X	X
Prior/concomitant medications		X	X	X	X	X	X
Comprehensive physical exam					X		
Targeted physical exam		X	X	X		X	X
Vital signs		X	X	X	X	X	X
Laboratory assessments		X	X	X	X		X
Urinalysis					X		
Pregnancy test[b]		X	X	X	X	X	X
12-lead ECG					X		
Efficacy assessments		X	X	X	X	X	X
Apply study drug	X[a]	X	X	X			
Study drug and diary card dispensed	X[a]	X	X	X			
Collect study drug tubes; collect and review diary cards		X	X	X	X		
Assess compliance		X	X	X	X		
Photography of scalp			X		X		X
Assess AEs		X	X	X	X	X	X

EOT = end of treatment.

[a] All assessments for the Week 24 visit as well as these additional activities must be performed before the subjects who meet eligibility criteria (refer to Protocol Section 5.2) may enter the open-label extension.

[b] Urine pregnancy tests during the open-label extension will be performed on all women.

Table 3: Schedule of Assessments for the Open-Label Extension of Part B

	Open-Label Extension Part B						Follow-Up	
Evaluation	**Week 24 Day 168 ± 7 days**[a]	**Week 28 Day 196 ± 7 days**	**Week 32 Day 224 ± 7 days**	**Week 36 Day 252 ± 7 days**	**Week 42 Day 294 ± 7 days**	**Week 48 EOT Day 336 ± 7 days**	**Month 1 ± 7 days**	**Month 3 EOS ± 7 days**
Clinic visit		X	X	X	X	X	X	X
Contact IRT	X[a]	X	X	X	X	X	X	X
Prior/concomitant medications		X	X	X	X	X	X	X
Comprehensive physical exam						X		
Targeted physical exam		X	X	X	X		X	X
Vital signs		X	X	X	X	X	X	X
Laboratory assessments		X	X	X	X	X		X
Urinalysis						X		
Pregnancy test[b]		X	X	X	X	X	X	X
12-lead ECG						X		
Clinical assessment		X	X	X	X	X	X	X
Apply study drug	X[a]	X	X	X	X			
Study drug and diary card dispensed	X[a]	X	X	X	X			
Collect study drug tubes; collect and review diary cards		X	X	X	X	X		
Assess compliance		X	X	X	X	X		
Photography of scalp				X		X		X
Assess AEs		X	X	X	X	X	X	X

[a] All assessments for the Week 24 visit noted in Table 1 as well as these additional activities must be performed before subjects who meet eligibility criteria may enter the open-label extension.
[b] All nonscreening visit urine pregnancy tests to be performed on all women.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1, Baseline, and Last Available Value

Day 1, baseline, and last available value are defined in Table 4.

Table 4: Definition of Day 1, Baseline, and Last Available Value

	Treatment Group	Day 1	Baseline	Last Available Value
Part A				
Treatment period	INCB018424 cream	Date of first dose of INCB018424 cream in treatment period	The last nonmissing measurement obtained on or before the day of the first administration of INCB018424 cream	The last nonmissing measurement obtained after starting INCB018424 cream, and within 30 days after the last dose of INCB018424 cream in treatment period or before the first dose of INCB018424 cream in extension period, whichever is earlier.
Extension period	INCB018424 cream	Date of first dose of INCB018424 cream in treatment period	The last nonmissing measurement obtained on or before the day of the first administration of INCB018424 cream	The last nonmissing measurement obtained after starting INCB018424 cream and within 30 days after the last dose of INCB018424 cream.
Part B				
Treatment period	INCB018424 cream	Date of first dose of INCB018424 cream or date of randomization for subjects randomized but not treated in treatment period	The last nonmissing measurement obtained on or before the day of the first administration of INCB018424 cream	The last nonmissing measurement obtained after starting INCB018424 cream, and within 30 days after the last dose of INCB018424 cream or before the first dose of INCB018424 cream in extension period, whichever is earlier.
	Placebo	Date of first dose of placebo or date of randomization for subjects randomized but not treated in treatment period	The last nonmissing measurement obtained on or before the day of the first administration of placebo	The last nonmissing measurement obtained after starting placebo, and within 30 days after the last dose of placebo or before the first dose of INCB018424 cream in extension period, whichever is earlier.

Table 4: Definition of Day 1, Baseline, and Last Available Value (Continued)

	Treatment Group	Day 1	Baseline	Last Available Value
Part B				
Extension period	INCB018424 cream in treatment period	Date of first dose of INCB018424 cream in treatment period	The last nonmissing measurement obtained on or before the day of the first administration of INCB018424 cream in treatment period	The last nonmissing measurement obtained after starting INCB018424 cream and within 30 days after the last dose of INCB018424 cream.
	Placebo in treatment period	Date of first dose of INCB018424 cream in extension period	The last nonmissing measurement obtained on or before the day of the first administration of INCB018424 cream in extension period	The last nonmissing measurement obtained after starting INCB018424 cream and within 30 days after the last dose of INCB018424 cream.

For the baseline value, when scheduled assessments and unscheduled assessments occur on the same day and time of the assessment or first dose 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 dose and the time is missing, use the scheduled assessment as baseline.
- If all scheduled assessments are missing on the day of the first dose and an unscheduled assessment is available, use the unscheduled assessment as baseline.

4.1.2. Study Day

Study Day 1 is used to calculate the study day for mapping scheduled visits. Study Day 1 is the date of first dose of INCB018424 cream or placebo in the study.

The study day at a visit/reporting date will be calculated by the visit/reporting date minus the study Day 1 date plus 1 (visit date – study Day 1 date + 1). This study day will be subtracted by 1 if it is less than or equal to zero, so that a study day of zero will never occur. A study day of -1 indicates 1 day before study Day 1.

4.1.3. Scheduled Visits

Study evaluations in weeks/days from study Day 1 are presented in Table 1.

4.2. Variable Definitions

4.2.1. Age

Subject age will be calculated as the integer part of the number of years from date of birth to the date of signing the informed consent form (ICF), using the following formula:

Age = integer part of (date of informed consent – date of birth + 1)/365.25

4.2.2. Body Mass Index

Body mass index (BMI) will be calculated as follows:

BMI (kg/m^2) = [weight (kg)] / [height (m)]^2

4.2.3. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before Day 1 defined in Table 4. Concomitant medication is defined as any nonstudy medication that is:

- Started before Day 1 and is ongoing throughout the study or ends on/after Day 1.
- Started on/after Day 1 and is ongoing or ends during the course of study medication.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after Day 1. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, or both prior and concomitant medication.

The start/stop dates recorded in the CRF by the investigator and his/her research staff will be used to identify when a concomitant medication was taken during the study. Any missing start date must be queried for resolution. Unresolved missing start dates will be handled as follows:

- If the date is completely missing, the medication will be considered both prior and concomitant.
- If only the day is missing, and the last day of the month is before the first dose date on Day 1, then the concomitant medication will be considered as starting before Day 1, and the incomplete date will be imputed as the last day of the month.
- If only the day is missing, and the first day of the month is after the first dose date on Day 1, then the concomitant medication will be considered as starting after Day 1, and the incomplete date will be imputed as the first day of the month.
- If only the day is missing, and the month is equal to the month of the first dose date on Day 1, then the incomplete date will be imputed as the first day of the month.
- If both the month and day are missing, and the last day of the year is before the first dose date on Day 1, then the concomitant medication will be considered as starting before Day 1, and the incomplete date will be imputed as if it is the last day of the year. Otherwise, the incomplete date will be imputed as if it is the first day of the year.

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; Version 9 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 subjects in each category.

In the Part B treatment period, the safety population will be used for all safety analyses, and the intent-to-treat (ITT) population will be used for all efficacy analyses. [redacted]

Interim analyses are planned for this Protocol as defined in Section 9.

5.2. Treatment Groups

This is a 2-part study in subjects with AA, with Part A being open label in single-treatment and extension and Part B being double-blind, randomized, and placebo-controlled followed by an open-label extension.

In Part A, subjects will be summarized overall by total only. In Part B, subjects will be summarized overall and based on the dose regimen initially assigned or subjects received in the Part B treatment period.

Part A (treatment period and extension period):

- INCB018424 cream

Part B (treatment period):

- INCB018424 cream
- Placebo

Part B (extension period):

- INCB018424 cream
- Placebo to INCB018424 cream

Table summaries, unless otherwise indicated, will be provided by treatment group. Note that separate summaries will be provided for the different portions of the study: Part A treatment, Part B treatment, Part A extension, and Part B extension.

5.3. Analysis Populations

5.3.1. Part A

All analyses for Part A will be conducted with the Part A evaluable population in treatment period or extension period, which includes all subjects exposed to at least 1 dose of study drug in that period.

5.3.2. Part B

5.3.2.1. Intent-to-Treat Population

All subjects who are randomized constitute the ITT population in the Part B treatment period. Treatment groups for this population will be defined according to the treatment assignment at the time of randomization regardless of the actual study drug that the subject might take during his/her participation in the study. This population will be used for analyses of all efficacy data in the Part B treatment period.

5.3.2.2. Per Protocol Population

Subjects in the ITT population who are considered to be sufficiently compliant with the Protocol compose the per protocol (PP) population, which is defined for supportive sensitivity analyses for efficacy endpoints in the Part B treatment period.

5.3.2.3. Safety Population

The safety population in the Part B treatment period includes all enrolled subjects who received at least 1 dose of INCB018424 cream or placebo. Treatment groups for this population will be determined according to the actual treatment that the subject received regardless of assigned study drug treatment. All safety analyses will be conducted using the safety population.

5.3.2.4. Part B Evaluable Population in Extension Period

All analyses for the Part B extension period will be conducted with the Part B evaluable population in the extension period, which includes all subjects exposed to at least 1 dose of study drug in that period.

[redacted]

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Sample data displays are provided in Appendix A.

6.1. Baseline and Demographics, Physical Characteristics, and Disease History

The following demographic variables will be summarized for the Part A evaluable population, Part B ITT population, and Part B evaluable population in the extension period: age, sex, race, ethnicity, weight, height, BMI.

The following baseline disease characteristics will be summarized for the ITT population:

- History of AA:
  - SALT scores: continuous and categorical (25%-< 50%/50%-100%)
  - Predominant hair color (black/brown/red/blonde/gray/white)
  - Number of days since first onset of AA
  - Number of prior episodes of AA
  - Estimated maximum extent of hair loss due to AA
  - History of alopecia totalis at any time (yes/no)
  - History of alopecia totalis > or ≤ 2 years duration
  - History of alopecia universalis at any time (yes/no)
  - Duration of alopecia universalis: > or ≤ to 2 years duration
  - History of male/female pattern baldness (yes/no)
  - Pattern baldness (anterior scalp/mid scalp/temporal scalp/vertex of scalp/other)
  - Prior therapy for AA (yes/no)
- Current AA:
  - Number of days since onset of current AA
  - Duration of current episode (< 6 months/6-12 months/12-24 months/> 2-5 years/ > 5 years)
  - Type of hair remaining (terminal hair/vellus/indeterminant)
  - Pattern of scalp hair loss (patchy/totalis/ophiasis)
  - Body hair loss (no body hair loss/some body hair loss/100% body [excluding scalp] hair loss)

– Nail involvement (no nail involvement/some nail involvement/twenty nail dystrophy/trachyonychia)

6.2. Disposition of Subjects

The number and percentage of subjects who were treated, randomized (Part B treatment period only), complete the study through Week 24, complete the study through Week 48, discontinued from the study during the treatment period, and discontinued from the study during the extension period with a primary reason for withdrawal will be summarized for the Part A evaluable population, Part B ITT population, and Part B evaluable population in the extension period.

6.3. Protocol Deviations

Protocol deviations will be presented in the subject data listings.

6.4. Exposure

For subjects in the Part A evaluable population in the treatment period and extension period, Part B safety population, and Part B evaluable population in extension period, descriptive statistics will be provided by treatment group for duration of treatment, average daily dose, and total dose of INCB018424 cream/placebo.

- Duration of treatment with INCB018424 cream or placebo: the number of study days between Day 1 and the last record (defined in Table 5) of INCB018424 cream or placebo taken by the subject.

Table 5: Duration of Treatment

	Treatment Group	Day 1	Last Record
Part A			
Treatment period	INCB018424 cream	Date of first dose of INCB018424 cream in treatment period	Date of last record of INCB018424 cream in treatment period
Extension period	INCB018424 cream	Date of first dose of INCB018424 cream in treatment period	Date of last record of INCB018424 cream in extension period
Part B			
Treatment period	INCB018424 cream	Date of first dose of INCB018424 cream in treatment period	Date of last record of INCB018424 cream in treatment period
	Placebo	Date of first dose of placebo in treatment period	Date of last record of placebo in treatment period
Extension period	INCB018424 cream in treatment period	Date of first dose of INCB018424 cream in treatment period	Date of last record of INCB018424 cream in extension period
	Placebo in treatment period	Date of first dose of INCB018424 cream in extension period	Date of last record of INCB018424 cream in extension period

6.5. Study Drug Compliance

For subjects in the Part A evaluable population in the treatment period and Part B safety population in the treatment period, overall compliance (%) for INCB018424 cream or placebo will be calculated for all subjects as follows:

Overall compliance (%) = 100 × [Total dose dispensed – Total dose returned] / [Intended dose].

- Total dose dispensed is the sum of the weights of tubes dispensed prior to the current visit.
- Total dose returned is the sum of the tubes retuned prior to and on the current visit.
- The intended dose will be based on the earliest study day of permanent discontinuation of the study drug (ie, AE discontinuation is the first AE with action taken = "drug withdrawn") or last study medication record in the database.

A subject will be considered significantly noncompliant if he or she misses more than 20% of the intended doses during the study (ie, compliance < 80%). Similarly, a subject will be considered significantly noncompliant if he or she is judged by the investigator to have intentionally or repeatedly taken more than the intended amount of medication (ie, compliance > 120%). Persistent noncompliance may result in the subject being discontinued from the study.

6.6. Medical History

For subjects in the Part A evaluable population in the treatment period and Part B ITT population in the treatment period, medical history will be summarized by assigned treatment group. This summary will include the number and percentage of subjects.

Subjects with significant medical history for each body system/organ class as documented on the CRF page.

6.7. Prior and Concomitant Medication

For subjects in the Part A evaluable population, Part B safety population, and Part B evaluable population in the extension period, prior medications and concomitant medications will be coded using the WHO Drug Dictionary and summarized by WHO drug class and WHO drug term. In the data listing, each medication will be recorded as prior, concomitant, or both prior and concomitant. Results will be summarized as number and percentage of subjects with prior and concomitant medications by preferred term and WHO drug class.

Prior medication information for AA will also be used to identify medication received by subjects before enrollment into the study in the treatment periods of Part A and Part B. Data of prior medication for AA will be summarized and presented by treatment group as well as by listings.

7. EFFICACY

Sample data displays are provided in Appendix A.

7.1. General Considerations

Missing observations will be handled for specific endpoints as detailed in the sections addressing each analysis.

Generally, for response endpoints on SALT50 and SALT90, all nonresponders in the Part B treatment period, as well as all subjects who discontinue study treatment at any time prior to the timepoint of interest or who discontinue from the study for any reason, will be defined as nonresponders for the nonresponder imputation (NRI) analysis. Randomized subjects without at least 1 postbaseline observation will also be defined as nonresponders for the NRI analysis.

For continuous endpoints, mixed model repeated measures (MMRM) implicitly adjusts for missing data through a variance-covariance structure.

7.2. Analysis of the Primary Efficacy Parameter

7.2.1. Primary Efficacy Analysis

Alopecia areata will be assessed using the SALT scoring system recommended by the National Alopecia Areata Foundation group published in the Journal of the American Academy of Dermatology (Olsen et al 2004).

The scalp will be divided into 4 areas:

- Top of scalp is 40% (0.4) of scalp surface area.
- Right side of scalp is 18% (0.18) of scalp surface area.
- Left side of scalp is 18% (0.18) of scalp surface area.
- Back side of scalp is 24% (0.24) of scalp surface area.

Percentage of hair loss in any of these areas is percentage hair loss multiplied by the percentage of surface area of the scalp in that area. Severity of Alopecia Tool score is the sum of the percentage of hair loss in all of the above mentioned areas.

For example, if the percentages of hair loss in the top, right side, left side, and back are 20%, 30%, 40%, and 50%, respectively, then the SALT score = (20 × 0.4) = (30 × 0.18) + (40 × 0.18) + (50 × 0.24) = 8 + 5.4 + 7.2 + 12 = 32.6.

The percent improvement (PI) in SALT scores from baseline will be computed as follows:

$$PI = 100 \times (\text{Baseline SALT score} - \text{Observed SALT score})/\text{Baseline SALT score}.$$

For improved outcome, this measure is positive, and for worsening outcome, this measure is negative.

The categorical variable SALT50 is defined to be equal to 1 for PI from baseline in SALT scores of 50 or greater and 0 for less than 50. This definition is introduced for the purpose of identifying subjects who respond to the treatment (1 – responder, 0 – nonresponder). SALT90 is defined in a similar fashion.

The primary efficacy endpoint in the Part A treatment period will be the best SALT50 throughout the treatment period; that said, if a subject has positive SALT50 at any one visit, he/she will be counted as responder throughout the Part A treatment period. The primary endpoint will be summarized using descriptive statistics in the Part A evaluable population in the treatment period.

In the Part B treatment period, subjects will be stratified at randomization into 2 strata: 25% to < 50% and 50% to 100% scalp involvement. The response rate assessed based on SALT50 between active- and placebo-treated subjects will be compared in the ITT population in the treatment period, using a logistic regression with covariates of baseline SALT score and stratification factor of rAAIG group. Exact logistic regression (Mehta and Patel 1995) will be used if any expected numbers are less than 5. Treatment comparison at 24 weeks will be used to assess the primary objective. The 2-sided 95% confidence interval for the odds ratio of the SALT50 (INCB018424 cream over placebo), along with p-value for the treatment comparison at Week 24 will be displayed.

7.2.2. Subgroup Analyses for Primary Endpoint

Subgroups will be formed based on the following baseline variables for those subjects whose data are available:

- 25% to < 50% and 50% to 100% scalp involvement
- Duration of current episode (< 6 months/ 6-12 months/12-24 months/> 2-5 years/ > 5 years)
- Pattern of scalp hair loss (patchy/totalis/ophiasis)

7.2.3. Sensitivity and Supportive Analyses for Primary Endpoint

The primary endpoint will be analyzed using the PP population as a sensitivity analysis to the ITT population in treatment period.

7.3. Analysis of the Secondary Efficacy Parameter

Secondary efficacy analyses will be conducted for the Part A evaluable population and ITT population in Part B. The following endpoints will be summarized using similar methods as specified in the primary analysis.

- Part A:
  - SALT50 responses for subjects with 50% to 100% scalp involvement at baseline in terminal hair at any visit through Week 24.
  - SALT90 response in terminal hair at Weeks 4, 8, 12, 18, and 24.
- Part B:
  - SALT50 response in terminal hair (pigmented and nonpigmented) at Week 24, for subjects with 50%-100% scalp involvement at baseline.
  - SALT50 response in terminal hair (pigmented and nonpigmented) at Weeks 4, 8, 12, and 18.
  - SALT90 response in terminal hair (pigmented and nonpigmented) at Weeks 4, 8, 12, 18, and 24.

All efficacy endpoints regarding the actual measurement, change from baseline, and percentage change from baseline in SALT will be summarized using descriptive statistics in the Part A evaluable population.

In the Part B treatment period, the actual measurement, change from baseline, and percentage change from baseline in SALT score to Weeks 4, 8, 12, 18, and 24 will be analyzed by the MMRM model with repeated measures. This model will include the fixed effects of treatment (INCB018424 cream vs placebo), stratification factor (25% to < 50% and 50% to 100% scalp involvement), visit, treatment by visit interaction, and baseline SALT scores as the fixed effects and subjects as the random effect. In the MMRM model, the within-patient errors are modeled as an unstructured variance-covariance matrix.

8. SAFETY AND TOLERABILITY

Sample data displays are provided in Appendix A.

8.1. General Considerations

The analyses for this section will be provided using Part A evaluable population in the treatment period and extension period, Part B safety evaluable population, and Part B evaluable population in the extension period. 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 subjects. Unless otherwise stated, table summaries will be limited to AEs occurring within 30 days of the last administration of study medication or the first dose of the next phase (extension period, if available) of the study, whichever is earlier.

8.2. Adverse Events

8.2.1. Adverse Event Definitions

A treatment-emergent adverse event (TEAE) is any AE either reported for the first time or worsening of a pre-existing event after first dose of study medication. Adverse events will be considered treatment emergent if they first occurred or worsened in severity after *the first dose*,

and on or prior to the date of *the last visit* of the period. *Maximum severity* from previous period(s) will be considered as the baseline severity for TEAEs.

Treatment-emergent AEs will be assigned to the study period according to the rules specified in Table 6.

Table 6: Definition of Treatment-Emergent Adverse Event

	Treatment Group	First Dose Date	Last Visit	Identification of Maximum Severity
Part A				
Treatment period	INCB018424 cream	Date of first dose of INCB018424 cream	Date of last visit in treatment period	Maximum severity from baseline
Extension period	INCB018424 cream	Date of first dose of INCB018424 cream	Date of last visit in extension period	Maximum severity from baseline
Part B				
Treatment period	INCB018424 cream	Date of first dose of INCB018424 cream	Date of last visit in treatment period	Maximum severity from baseline
	Placebo	Date of first dose of placebo	Date of last visit in treatment period	Maximum severity from baseline
Extension period	INCB018424 cream in treatment period	Date of first dose of INCB018424 cream in treatment period	Date of last visit in extension period	Maximum severity from baseline
	Placebo in treatment period	Date of first dose of INCB018424 cream in extension period	Date of last visit in extension period	Maximum severity from baseline and treatment period

Analysis of AEs (as discussed below) will be limited to TEAEs, but data listings will include all AEs regardless of their timing to study drug administration.

Adverse events will be tabulated by MedDRA preferred term and system organ class. Severity of AEs will be described and graded using the NCI CTCAE. The CTCAE version 4.03 is used for this Protocol. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program (CTEP) website.

A grading (severity) scale is provided for each AE term. If the toxicity is not included in the CTCAE v4 criteria, it will be rated on a 1 to 4 scale as follows: (1) mild, (2) moderate, (3) severe, (4) life-threatening. All toxicities will be graded based on the worst level reached, not the level that they may have reached if they had not been treated. When the intensity of an AE changes over time for a reporting period (eg, between visits), each change in intensity will be reported as an AE until the event resolves.

The subset of AEs considered by the investigator to be related to INCB018424 cream/placebo will be considered to be treatment-related AEs. If the investigator does not specify the relationship of the AE to study medication, the AE will be considered to be treatment-related.

The incidence of AEs and treatment-related AEs will be tabulated. In addition, serious adverse events (SAEs) will also be tabulated.

Any missing onset date, causality, or severity must be queried for resolution. Unresolved missing values 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. Therefore, a missing onset date will be considered treatment emergent, with the following examples illustrating exceptions:

- If the stop/resolution date is prior to the first dose date, then the AE will be considered as not being treatment emergent.
- If both the month and day are missing, and the last day of the year is prior to the first dose date, then the AE will not be considered treatment emergent.
- If only the day is missing, and the last day of the month is before the first dose date, then the AE will not be considered treatment emergent.
- If only the day is missing, and the first day of the month is after the first dose date, then the AE will be considered treatment emergent.

8.2.2. Adverse Event Summaries

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

- Number (%) of subjects reporting any TEAEs
- Number (%) of subjects reporting any treatment-related TEAEs
- Number (%) of subjects reporting any SAEs
- Number (%) of subjects reporting any Grade 3 or 4 TEAEs
- Number (%) of subjects who temporarily interrupted study drug because of TEAEs
- Number (%) of subjects who permanently discontinued study drug because of TEAEs
- Number (%) of subjects who had a fatal TEAE

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

- Number (%) of subjects reporting TEAEs by system organ class and preferred term
- Number (%) of subjects reporting TEAEs by preferred term in decreasing order of frequency
- Number (%) of subjects reporting TEAEs by system organ class, preferred term, and maximum severity
- Number (%) of subjects reporting TEAEs by system organ class, preferred term, and CTCAE grade group
- Number (%) of subjects reporting treatment-related AEs by system organ class and preferred term
- Number (%) of subjects reporting treatment-related AEs by preferred term in decreasing order of frequency
- Number (%) of subjects reporting treatment-related AEs by system organ class, preferred term, and maximum severity
- Number (%) of subjects reporting treatment-related AEs by system organ class, preferred term, and CTCAE grade group
- Number (%) of subjects reporting TEAEs leading to death by system organ class and preferred term
- Number (%) of subjects reporting treatment-emergent SAEs by system organ class and preferred term
- Number (%) of subjects reporting treatment-related SAEs by system organ class and preferred term
- Number (%) of subjects reporting TEAEs leading to interruption of drug by system organ class and preferred term
- Number (%) of subjects reporting TEAEs leading to discontinuation of study drug by system organ class and preferred term
- Number (%) of subjects reporting treatment-emergent non-SAEs by system organ class and preferred term.
- Number (%) of subjects reporting TEAEs requiring concomitant medications by system organ class and preferred term

8.3. Clinical Laboratory Tests

8.3.1. 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. The baseline value will be determined using the nonmissing values collected before the first dose defined in Section 4.1.1. The last scheduled record before administration has higher priority, which will be considered the baseline record, compared with the unscheduled 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.

Laboratory test values outside the normal range will be assessed for severity based on CTCAE grade or similar criteria where clinical intervention is required for CTCAE grading for laboratory grading criteria. The incidence of abnormal laboratory values and shift tables relative to baseline will be tabulated.

8.3.2. Laboratory Value Summaries

Clinical laboratory tests, including hematology and serum chemistry (see Table 7), will be performed for each subject during the study in accordance with Table 1. 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. For the limited number of cases where the associated normal ranges from a local laboratory cannot be obtained despite due diligence, associated central laboratory normal ranges will be applied. In the event that central laboratory normal ranges are not available, a set of standard normal ranges based upon documented reference ranges will be applied to facilitate reporting the test results.

When there are multiple laboratory nonmissing values for a subject's particular test within a visit window, use the smallest laboratory sequence number to identify the record for postbaseline visits.

Laboratory parameters identified in Table 7 will be summarized. Shift tables based on the worst postbaseline value recorded will use all postbaseline values occurring within 30 days of stopping study treatment or the first dose of the next phase (extension period, if available) of the study, whichever is earlier. Other laboratory parameters collected will only be listed in an appendix to the clinical study report (CSR) in their original units without SI conversions.

Table 7: Laboratory Parameters to be Summarized

Panel	Summary	
Serum chemistry	Albumin	Creatinine
	Alkaline phosphatase	Glucose
	ALT	Lactate dehydrogenase
	AST	Sodium
	Bicarbonate	Total bilirubin
	Blood urea nitrogen	Total protein
	Calcium	Potassium
	Chloride	Phosphorus
Hematology	Hematocrit	White blood cell differential (5 part):
	Hemoglobin	• Basophils
	Mean corpuscular volume	• Eosinophils
	Platelet count	• Lymphocytes
	Red blood cell count	• Monocytes
	Reticulocyte count	• Neutrophils
	White blood cell count	

ALT = alanine aminotransferase; AST = aspartate aminotransferase.

Numeric laboratory values will be summarized descriptively, and non-numeric test values will be tabulated when necessary.

For test results that will be summarized with available normal ranges, the number and percentage of subjects 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. This shift summary will be produced for each test for the Part A evaluable population and Part B safety population in the treatment period. The denominator for the percentage calculation will use the number of subjects in the baseline category (ie, low, high, normal, missing) as the denominator for the percentage in each of the categories.

For all gradable laboratory parameters identified in Table 7, the values will be classified into grade levels corresponding to CTCAE v4.03 criteria. For specific laboratory parameters requiring clinical intervention to grade, the classification according to the quantitative component will be provided for laboratory grading criteria. A listing of abnormal laboratory values, including the laboratory grade, will be provided.

For safety population in the treatment period in Part A and Part B, the results of the lab tests of Free T4 and TSH obtained during the screening period will be summarized.

8.4. Vital Signs

Vital signs, including systolic blood pressure, diastolic blood pressure, pulse, respiratory rate, and body temperature will be taken in the seated position for each subject during the study in

accordance with Table 1. Change and percentage change from baseline will be calculated using the last nonmissing value before first dose of study medication (Day 1) as the baseline value defined in Table 4.

Incidences of clinically notable vital sign abnormalities are defined in Table 8. The abnormal values for subjects 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 greater than 25%.

Table 8: Criteria for Clinically Notable Vital Sign Abnormalities

Vital Sign	Raw Value	Percentage Change
Systolic blood pressure	90-150 mmHg	± 25%
Diastolic blood pressure	50-90 mmHg	± 25%
Heart rate	45-100 beats/min	± 25%
Respiratory rate	8-20 breaths/min	± 25%
Temperature	35.5°C-38.0°C	± 25%

8.5. Electrocardiograms

Twelve-lead ECGs including PR, QRS, QT, QTcF, QTcB, and RR intervals will be obtained for each subject during the study in accordance with Table 1. Descriptive statistics and mean change from baseline will be determined for each ECG parameter at each assessment time. Change and percentage change from baseline (defined in Table 9) will be calculated.

Incidences of clinically notable ECG abnormalities are defined in Table 9. Subjects exhibiting clinically notable ECG abnormalities will be listed with study visit and assigned treatment group. Abnormal values for subjects with alert ECG values, defined as both the absolute value and the percentage change from baseline being outside normal ranges, will be identified and listed.

Table 9: Criteria for Clinically Notable Electrocardiogram Abnormalities

Parameter	High Threshold	Low Threshold	Percentage Change
QTcF	> 460 msec	< 295 msec	± 25%
QTcB	> 460 msec	< 295 msec	± 25%
PR	> 220 msec	< 75 msec	± 25%
QRS	> 120 msec	< 50 msec	± 30%
QT	> 500 msec	< 300 msec	± 25%
RR	> 1330 msec	< 600 msec	± 25%

QTcF = Fridericia correction.

Twelve-lead ECGs will be obtained for each subject during the study in accordance with Table 1. Electrocardiogram abnormalities, both at baseline and postbaseline visits, will be tabulated by treatment group. Incidences of abnormalities will be listed with study visit, assigned treatment group, and a description of the abnormality.

9. INTERIM ANALYSES

9.1. Overview of Interim Analyses

Two formal interim analyses and a third, potential interim analysis are planned for this study. The 2 formal analyses in Part A and Part B are futility analyses to determine whether to enroll the last 34 randomized subjects in Part B. If there is insufficient evidence of terminal hair growth demonstrated in the first 2 interim analyses and any Part B stratum contains ≤ 10 subjects at the second interim analysis, enrollment in said stratum will be reopened, and a third interim analysis in Part B will be conducted. Overall, Part B will complete randomization if sufficient evidence of terminal hair growth is demonstrated either at the interim analysis in Part A or at 1 of the 2 interim analyses in Part B.

9.1.1. Part A

In Part A, the decision to enroll more than 34 subjects in Part B will be mainly driven by the number of SALT50 responders observed or by the number of subjects with evidence on other endpoints for hair regrowth throughout the treatment period.

For subjects with 25% to < 50% and 50% to 100% scalp involvement, the response rate is assumed to be 61% for active versus 25% for placebo and 35% for active versus 5% for placebo, respectively. Because of the different response rates between the 2 strata, the overall response rates will be different depending on the proportion of subjects enrolled in the 2 strata; therefore, the number of responders who are considered to have sufficient efficacy to complete enrollment of Part B will also be different. A likelihood-based approach applying a binomial distribution and assuming the null hypothesis rates of response in the 2 strata are used to test for futility in Part A. Assuming the number of responders among the 10 subjects in Part A follows binomial distribution with the overall response rates, the futility rule is that the cumulative probability of observing the exact number of responders (x) must be greater than 20%; that said, the probability of observing more than x responders among the 10 subjects in Part A must be less than 80%.

Table 10 presents the number of responders required to complete enrollment of Part B, given the overall responses in different combinations of the subjects in the 2 stratums.

Table 10: Part A Interim Analysis

Number of Subjects in 25%-< 50% Stratum	Number of Subjects in 50%-100% Stratum	Overall Response Rate for Active Agent (%)	Number of Responders Required to Complete Part B (%)	Probability to Go to Complete Part B for Active Agent (%)	Overall Response Rate for Inactive Agent (%)	Probability to Go to Complete Part B for Inactive Agent (%)
10	0	61	5	65.9	25	2
9	1	58.4	5	59.2	23	1.4
8	2	55.8	4	75.5	21	4
7	3	53.2	4	69.8	19	2.7
6	4	50.6	4	63.7	17	1.7
5	5	48	3	79.5	15	5
4	6	45.4	3	74.3	13	3.2
3	7	42.8	3	68.6	11	1.8
2	8	40.2	3	62.3	9	1
1	9	37.6	2	79.1	7	2.9
0	10	35	2	73.9	5	1.1

For example, if all subjects are enrolled in the > 25% to 50% stratum, the probability of observing ≥ 5 responses in the 10 subjects is 66%, then 5 responders will be sufficient to complete enrollment of Part B. If all subjects are in > 50% to 100% stratum, the probability of observing 2 or more responses is 74%, then 2 responders will be sufficient to complete enrollment of Part B.

Other evidence on hair regrowth will be also considered in Part A, in addition to the numbers of SALT50 responders, for any decision to enroll more than 34 subjects in Part B.

9.1.2. Part B

An interim analysis will be performed when 34 subjects, randomized in Part B, have Week 12 data available and a test for futility will be performed based upon conditional power. The conditional power is the probability to reach significance at the end of the study given the data at the interim. The conditional power will be approximated using the empirical estimates of the treatment effect under the observed trend for a 2-sided alpha of 0.05.

If the conditional power is ≤ 30% and there are more than 10 subjects in each defined stratum, then the study will be stopped for futility. If conditional power is ≤ 30% but there is a stratum with ≤ 10 subjects, then enrollment of Part B will be continued for that stratum until a total of 20 subjects in that stratum have been randomized in Part B. The additional futility analysis in Part B will be conducted using the observed difference in SALT50 response rates between the 2 treatment groups in the expanded stratum. If the difference between the 2 observed percentages for the expanded stratum is ≥ 20 percentage points, then randomization will be reopened to that expanded stratum until 68 subjects are randomized in Part B.

Sites will remain blinded to study drug, but some personnel at Incyte without direct contact with sites will be unblinded. An internal committee at Incyte will be charged with evaluating the unblinded interim results based on the futility rule above, as well as considering interim safety results. If the study is stopped for futility, investigators and subjects will be unblinded, and the decision to continue study drug will be left to the discretion of the investigator, based on an individual assessment of clinical benefit. As there are no plans for stopping early for efficacy, no adjustments of alpha or final p-values for repeated testing are necessary.

9.2. Data Cut-Off for Interim Analysis

In Part A, data will be monitored on a regular and ongoing basis during the study.

In Part B, for analysis of the primary endpoint, a cutoff for clinical data used in the second interim analysis will be based on the earliest date that the first 34 subjects in Part B of the study completed the Week 12 visit or discontinued the study. Data will include all visits occurring on or before this date for these 34 subjects. This cutoff will ensure that the statistical properties of the conditional power calculations are as intended. The cutoff for the third interim analysis (if needed) will be defined in a similar fashion.

9.3. Derivations and Calculations for Interim Analyses

The conditional power is the conditional probability of a statistically significant benefit at the end of the study, given the interim data.

The test statistic, Z_1, given the data at the interim analysis could be calculated as follows:

$$Z_1 = \frac{p_{1c} - p_{1t}}{\sqrt{\frac{p_{1c}q_{1c}}{n_{1c}} + \frac{p_{1t}q_{1t}}{n_{1t}}}},$$

where p_{1c} and p_{1t} are the observed response rates at the interim analysis.

$$p_{1c} = \frac{Y_{1c}}{n_{1c}} \quad \text{and} \quad p_{1t} = \frac{Y_{1t}}{n_{1t}}$$

Y_{1c} and Y_{1t} are numbers of SALT50 responders at the interim for placebo group and active treatment group, and $n_{1c} = n_{1t} = 17$ subjects per treatment arm at the interim.

Using the conditional power formula provided by Lan and Wittes (1988), the conditional power under the observed trend for a 2-sided test is

$$CP(\Theta; t) = \Phi\left(\frac{\Phi^{-1}(\alpha/2) + Z_1\sqrt{t} + \Theta(1-t)}{\sqrt{1-t}}\right),$$

where Φ^{-1} and Φ are inverse cumulative and cumulative distribution functions for a standard normal distribution, $t = 0.5$, and $\Theta = Z_1 / \sqrt{t}$.

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

Dates for the SAP, including any amendments, are included in Table 11.

Table 11: Dates for the SAP

SAP Version	Date
Original	27 OCT 2015

10.1. Changes to Protocol Defined Analyses

Not applicable.

10.2. Changes to the SAP

Not applicable.

11. REFERENCES

Olsen EA, Hordinsky MK, Price VH, et al. Alopecia areata investigational assessment guidelines--Part II. National Alopecia Areata Foundation. J Am Acad Dermatol 2004;51:440-447.

Mehta CR, Patel NR. Exact logistic regression: theory and examples. Stat Med 1995;14:2143-2160.

Lan KK, Wittes J. The B-value: a tool for monitoring data. Biometrics 1988;44:579-585.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the CSR. Standard tables will follow the conventions in the Standard Safety Tables initial version. Sample shells are provided for nonstandard, in-text CSR tables. Modifications of the list or shells that do not otherwise affect the nature of the analysis will not warrant an amendment to the SAP.

Tables

Table No.	Title	Population
Baseline Demographic and Characteristics		
1.1.1.1	Analysis Populations	
1.1.1.2	Analysis Populations	
1.1.2.1	Summary of Subject Disposition	Part A Evaluable Treatment
1.1.2.2	Summary of Subject Disposition	Part B Intent-to-Treat
1.1.2.4	Summary of Subject Disposition	Part B Evaluable Extension
1.1.3.1	Summary of Number of Subjects Enrolled by Site	Part A Evaluable Treatment
1.1.3.2	Summary of Number of Subjects Enrolled by Site	Part B Intent-to-Treat
1.2.1.1	Summary of Demographics	Part A Evaluable Treatment
1.2.1.2	Summary of Demographics	Part B Intent-to-Treat
1.3.1.1	Summary of Baseline Characteristics	Part A Evaluable Treatment
1.3.1.2	Summary of Baseline Characteristics	Part B Intent-to-Treat
1.3.2.1	Summary of Medical History	Part A Evaluable Treatment
1.3.2.2	Summary of Medical History	Part B Intent-to-Treat
1.4.1.1	Summary of Prior Medications	Part A Evaluable Treatment
1.4.1.2	Summary of Prior Medications	Part B Intent-to-Treat
1.4.2.1	Summary of Concomitant Medications	Part A Evaluable Treatment
1.4.2.2	Summary of Concomitant Medications	Part B Intent-to-Treat
1.4.2.3	Summary of Concomitant Medications	Part A Evaluable Extension
1.4.2.4	Summary of Concomitant Medications	Part B Evaluable Extension
1.4.3.1	Summary of Prior Medications for Alopecia Areata	Part A Evaluable Treatment
1.4.3.2	Summary of Prior Medications for Alopecia Areata	Part B Intent-to-Treat
1.5.1.1	Summary of Study Drug Compliance	Part A Evaluable Treatment
1.5.1.2	Summary of Study Drug Compliance	Part B Intent-to-Treat
1.5.1.3	Summary of Study Drug Compliance	Part A Evaluable Extension
1.5.1.4	Summary of Study Drug Compliance	Part B Evaluable Extension
Efficacy		
2.1.1.1	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24	Part A Evaluable Treatment
2.1.1.2	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24	Part B Intent-to-Treat
2.1.1.3	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score by Visit	Part A Evaluable Extension
2.1.1.4	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score by Visit	Part B Evaluable Extension

Table No.	Title	Population
2.1.1.5	Summary of Subjects Achieving >= 50% Reduction From Baseline in SALT Score at Week 24	Part B Intent-to-Treat
2.1.2	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24	Part B Per-Protocol
2.1.3.1	Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Baseline Scalp Involvement	Part A Evaluable Treatment
2.1.3.2	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24 by Baseline Scalp Involvement	Part B Intent-to-Treat
2.1.3.3	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score by Visit by Baseline Scalp Involvement	Part A Evaluable Extension
2.1.3.4	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score by Visit by Baseline Scalp Involvement	Part B Evaluable Extension
2.1.4	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24 by Baseline Scalp Involvement	Part B Per-Protocol
2.1.5.1	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24 by Duration of Current Episode	Part A Evaluable Treatment
2.1.5.2	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24 by Duration of Current Episode	Part B Intent-to-Treat
2.1.6.1	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24 by Pattern of Hair Loss	Part A Evaluable Treatment
2.1.6.2	Summary of Subjects Achieving >= 50% and >= 90% Reduction From Baseline in SALT Score to Week 24 by Pattern of Hair Loss	Part B Intent-to-Treat
2.2.1.1	Summary and Analysis of SALT Score From Baseline to Week 24	Part A Evaluable Treatment
2.2.1.2	Summary and Analysis of SALT Score From Baseline to Week 24	Part B Intent-to-Treat
2.2.1.3	Summary of Analysis of SALT Score From Baseline to Week 24	Part A Evaluable Extension
2.2.1.4	Summary of Analysis of SALT Score From Baseline to Week 24	Part B Evaluable Extension
2.2.2.1	Summary and Analysis of SALT Score From Baseline to Week 24 by Baseline Scalp Involvement	Part A Evaluable Treatment
2.2.2.2	Summary and Analysis of SALT Score From Baseline to Week 24 by Baseline Scalp Involvement	Part B Intent-to-Treat
2.2.2.3	Summary and Analysis of SALT Score by Visit and Baseline Scalp Involvement	Part A Evaluable Extension
2.2.2.4	Summary and Analysis of SALT Score by Visit and Baseline Scalp Involvement	Part B Evaluable Extension
2.2.3	Summary and Analysis of SALT Score From Baseline to Week 24	Part B Per-Protocol
2.2.4	Summary and Analysis of SALT Score From Baseline to Week 24 by Baseline Scalp Involvement	Part B Per-Protocol
2.3.1.1	Summary of Subjects Achieving Complete Clinical Response in SALT Score From Baseline to Week 24	Part A Evaluable Treatment
2.3.1.2	Summary of Subjects Achieving Complete Clinical Response in SALT Score From Baseline to Week 24	Part B Intent-to-Treat

Table No.	Title	Population
2.3.3.1	Summary of Subjects Achieving Complete Clinical Response in SALT Score From Baseline to Week 24 by Baseline Scalp Involvement	Part A Evaluable Treatment
2.3.3.2	Summary of Subjects Achieving Complete Clinical Response in SALT Score From Baseline to Week 24 by Baseline Scalp Involvement	Part B Intent-to-Treat
Exposure		
3.1.1	Summary of Exposure and Duration of Exposure	Part A Evaluable Treatment
3.1.2	Summary of Exposure and Duration of Exposure	Part B Safety Treatment
3.1.3	Summary of Exposure and Duration of Exposure	Part A Evaluable Extension
3.1.4	Summary of Exposure and Duration of Exposure	Part B Evaluable Extension
Adverse Events		
3.2.1.1	Overall Summary of Treatment-Emergent Adverse Events	Part A Evaluable Treatment
3.2.1.2	Overall Summary of Treatment-Emergent Adverse Events	Part B Safety
3.2.1.3	Overall Summary of Treatment-Emergent Adverse Events	Part A Evaluable Extension
3.2.1.4	Overall Summary of Treatment-Emergent Adverse Events	Part B Evaluable Extension
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.2.4	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
3.2.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part A Evaluable Treatment
3.2.3.2	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part B Safety
3.2.3.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part A Evaluable Extension
3.2.3.4	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part B Evaluable Extension
3.2.4.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part A Evaluable Treatment
3.2.4.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part B Safety
3.2.4.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part A Evaluable Extension
3.2.4.4	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part B Evaluable Extension
3.2.5.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part A Evaluable Treatment
3.2.5.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part B Safety
3.2.5.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part A Evaluable Extension
3.2.5.4	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part B Evaluable Extension

Table No.	Title	Population
3.2.6.1	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.6.2	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.6.3	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.6.4	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
3.2.7.1	Summary of Treatment-Related Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part A Evaluable Treatment
3.2.7.2	Summary of Treatment-Related Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part B Safety
3.2.7.3	Summary of Treatment-Related Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part A Evaluable Extension
3.2.7.4	Summary of Treatment-Related Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part B Evaluable Extension
3.2.8.1	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part A Evaluable Treatment
3.2.8.2	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part B Safety
3.2.8.3	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part A Evaluable Extension
3.2.8.4	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Part B Evaluable Extension
3.2.9.1	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part A Evaluable Treatment
3.2.9.2	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part B Safety
3.2.9.3	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part A Evaluable Extension
3.2.9.4	Summary of Treatment-Related Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group	Part B Evaluable Extension
3.2.10.1	Summary of Treatment-Emergent Adverse Events Leading to Death by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.10.2	Summary of Treatment-Emergent Adverse Events Leading to Death by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.10.3	Summary of Treatment-Emergent Adverse Events Leading to Death by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.10.4	Summary of Treatment-Emergent Adverse Events Leading to Death by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
3.2.11.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.11.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.11.3	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.11.4	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension

Table No.	Title	Population
3.2.12.1	Summary of Non-Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.12.2	Summary of Non-Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.12.3	Summary of Non-Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.12.4	Summary of Non-Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
3.2.13.1	Summary of Treatment-Related Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.13.2	Summary of Treatment-Related Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.13.3	Summary of Treatment-Related Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.13.4	Summary of Treatment-Related Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
3.2.14.1	Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.14.2	Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.14.3	Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.14.4	Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
3.2.15.1	Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.15.2	Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.15.3	Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension
3.2.15.4	Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
3.2.16.1	Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications by MedDRA System Organ Class and Preferred Term	Part A Evaluable Treatment
3.2.16.2	Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications by MedDRA System Organ Class and Preferred Term	Part B Safety
3.2.16.3	Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications by MedDRA System Organ Class and Preferred Term	Part A Evaluable Extension

Table No.	Title	Population
3.2.16.4	Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications by MedDRA System Organ Class and Preferred Term	Part B Evaluable Extension
Laboratory		
3.3.1.1	Summary of Laboratory Values - Hematology	Part A Evaluable Treatment
3.3.1.2	Summary of Laboratory Values - Hematology	Part B Safety
3.3.1.3	Summary of Laboratory Values - Hematology	Part A Evaluable Extension
3.3.1.4	Summary of Laboratory Values - Hematology	Part B Evaluable Extension
3.3.1.5	Summary of Laboratory Values - Free T4 and TSH	Part A Evaluable Treatment
3.3.1.6	Summary of Laboratory Values - Free T4 and TSH	Part B Safety
3.3.2.1	Shift Summary of Hematology Laboratory Values - to the Worst Abnormal Value	Part A Evaluable Treatment
3.3.2.2	Shift Summary of Hematology Values - to the Worst Abnormal Value	Part B Safety
3.3.2.3	Shift Summary of Hematology Values - to the Worst Abnormal Value	Part A Evaluable Extension
3.3.2.4	Shift Summary of Hematology Values - to the Worst Abnormal Value	Part B Evaluable Extension
3.3.3.1	Summary of Laboratory Values - Chemistry	Part A Evaluable Treatment
3.3.3.2	Summary of Laboratory Values - Chemistry	Part B Safety
3.3.3.3	Summary of Laboratory Values - Chemistry	Part A Evaluable Extension
3.3.3.4	Summary of Laboratory Values - Chemistry	Part B Evaluable Extension
3.3.4.1	Shift Summary of Chemistry Values - to the Worst Abnormal Value	Part A Evaluable Treatment
3.3.4.2	Shift Summary of Chemistry Values - to the Worst Abnormal Value	Part B Safety
3.3.4.3	Shift Summary of Chemistry Values - to the Worst Abnormal Value	Part A Evaluable Extension
3.3.4.4	Shift Summary of Chemistry Values - to the Worst Abnormal Value	Part B Evaluable Extension
3.3.5.1	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part A Evaluable Treatment
3.3.5.2	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part B Safety
3.3.5.3	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part A Evaluable Extension
3.3.5.4	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part B Evaluable Extension
3.3.6.1	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part A Evaluable Treatment
3.3.6.2	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part B Safety
3.3.6.3	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part A Evaluable Extension
3.3.6.4	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (One Directional CTC Grade)	Part B Evaluable Extension
3.3.7.1	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part A Evaluable Treatment

Table No.	Title	Population
3.3.7.2	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part B Safety
3.3.7.3	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part A Evaluable Extension
3.3.7.4	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part B Evaluable Extension
3.3.8.1	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part A Evaluable Treatment
3.3.8.2	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part B Safety
3.3.8.3	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part A Evaluable Extension
3.3.8.4	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value (Two Directional CTC Grade)	Part B Evaluable Extension
3.3.9.1	Summary of Laboratory Values - Urinalysis	Part A Evaluable Treatment
3.3.9.2	Summary of Laboratory Values - Urinalysis	Part B Safety
3.3.9.3	Summary of Laboratory Values - Urinalysis	Part A Evaluable Extension
3.3.9.4	Summary of Laboratory Values - Urinalysis	Part B Evaluable Extension
Vital Signs		
3.4.1.1	Summary of Systolic Blood Pressure	Part A Evaluable Treatment
3.4.1.2	Summary of Systolic Blood Pressure	Part B Safety
3.4.1.3	Summary of Systolic Blood Pressure	Part A Evaluable Extension
3.4.1.4	Summary of Systolic Blood Pressure	Part B Evaluable Extension
3.4.2.1	Summary of Diastolic Blood Pressure	Part A Evaluable Treatment
3.4.2.2	Summary of Diastolic Blood Pressure	Part B Safety
3.4.2.3	Summary of Diastolic Blood Pressure	Part A Evaluable Extension
3.4.2.4	Summary of Diastolic Blood Pressure	Part B Evaluable Extension
3.4.3.1	Summary of Pulse	Part A Evaluable Treatment
3.4.3.2	Summary of Pulse	Part B Safety
3.4.3.3	Summary of Pulse	Part A Evaluable Extension
3.4.3.4	Summary of Pulse	Part B Evaluable Extension
3.4.4.1	Summary of Body Temperature	Part A Evaluable Treatment
3.4.4.2	Summary of Body Temperature	Part B Safety
3.4.4.3	Summary of Body Temperature	Part A Evaluable Extension
3.4.4.4	Summary of Body Temperature	Part B Evaluable Extension
3.4.5.1	Summary of Respiration Rate	Part A Evaluable Treatment
3.4.5.2	Summary of Respiration Rate	Part B Safety
3.4.5.3	Summary of Respiration Rate	Part A Evaluable Extension
3.4.5.4	Summary of Respiration Rate	Part B Evaluable Extension
ECG		
3.5.1.1	Summary of 12-Lead ECG: PR Interval Values	Part A Evaluable Treatment
3.5.1.2	Summary of 12-Lead ECG: PR Interval Values	Part B Safety
3.5.1.3	Summary of 12-Lead ECG: PR Interval Values	Part A Evaluable Extension
3.5.1.4	Summary of 12-Lead ECG: PR Interval Values	Part B Evaluable Extension
3.5.2.1	Summary of 12-Lead ECG: QRS Interval Values	Part A Evaluable Treatment

Table No.	Title	Population
3.5.2.2	Summary of 12-Lead ECG: QRS Interval Values	Part B Safety
3.5.2.3	Summary of 12-Lead ECG: QRS Interval Values	Part A Evaluable Extension
3.5.2.4	Summary of 12-Lead ECG: QRS Interval Values	Part B Evaluable Extension
3.5.3.1	Summary of 12-Lead ECG: QT Interval Values	Part A Evaluable Treatment
3.5.3.2	Summary of 12-Lead ECG: QT Interval Values	Part B Safety
3.5.3.3	Summary of 12-Lead ECG: QT Interval Values	Part A Evaluable Extension
3.5.3.4	Summary of 12-Lead ECG: QT Interval Values	Part B Evaluable Extension
3.5.4.1	Summary of 12-Lead ECG: QTcB Interval Values	Part A Evaluable Treatment
3.5.4.2	Summary of 12-Lead ECG: QTcB Interval Values	Part B Safety
3.5.4.3	Summary of 12-Lead ECG: QTcB Interval Values	Part A Evaluable Extension
3.5.4.4	Summary of 12-Lead ECG: QTcB Interval Values	Part B Evaluable Extension
3.5.5.1	Summary of 12-Lead ECG: QTcF Interval Values	Part A Evaluable Treatment
3.5.5.2	Summary of 12-Lead ECG: QTcF Interval Values	Part B Safety
3.5.5.3	Summary of 12-Lead ECG: QTcF Interval Values	Part A Evaluable Extension
3.5.5.4	Summary of 12-Lead ECG: QTcF Interval Values	Part B Evaluable Extension
3.5.6.1	Summary of 12-Lead ECG: RR Interval Values	Part A Evaluable Treatment
3.5.6.2	Summary of 12-Lead ECG: RR Interval Values	Part B Safety
3.5.6.3	Summary of 12-Lead ECG: RR Interval Values	Part A Evaluable Extension
3.5.6.4	Summary of 12-Lead ECG: RR Interval Values	Part B Evaluable Extension
3.5.7.1	Summary of Treatment Emergent, Clinically Significant ECG Abnormality From Baseline	Part A Evaluable Treatment
3.5.7.2	Summary of Treatment Emergent, Clinically Significant ECG Abnormality From Baseline	Part B Safety
3.5.7.3	Summary of Treatment Emergent, Clinically Significant ECG Abnormality From Baseline	Part A Evaluable Extension
3.5.7.4	Summary of Treatment Emergent, Clinically Significant ECG Abnormality From Baseline	Part B Evaluable Extension

Listings

Listing No.	Title
2.1 Discontinued Subjects (Subject Disposition)	
2.1.1	Subject Enrollment and Disposition Status
2.1.3	Subject Inclusion and Exclusion Criteria
2.1.5.1	Medical History
2.2	Protocol Deviations
2.4.1	Demographic and Baseline Characteristics
2.4.2	Prior and Concomitant Drug Treatments
2.4.3	Prior and Concomitant Drug Treatments for Alopecia Areata
2.1.4	Primary Reason of Study Discontinuation
2.5 Drug Compliance	
2.5	Study Drug Compliance
2.6 Efficacy [redacted]	
2.6.1	SALT Scores
2.6.2	Subjects With Complete Clinical Response
[redacted]	[redacted]

Listing No.	Title
2.7 Adverse Events (and Exposure)	
2.7.1	Study Drug Administration
2.7.2	Adverse Events
2.7.4	Adverse Events Leading to Discontinuation of Study Drug
2.7.5	Serious Adverse Events
2.7.6	Fatal Adverse Events
2.8 Laboratory Data	
2.8.1.1	Clinical Laboratory Values – Hematology
2.8.1.2	Clinical Laboratory Values – Serum Chemistry
2.8.1.3	Clinical Laboratory Values – Urinalysis
2.8.2	Abnormal Clinical Laboratory Values
[redacted]	[redacted]
[redacted]	[redacted]
2.8.6	Central Laboratory Collection Times
2.9 Vital Signs	
2.9.1	Vital Signs
2.9.2	Abnormal Vital Sign Values
2.9.3	Alert Vital Sign Values
2.10 ECG	
2.10.1	12-Lead ECG Values
2.10.2	Abnormal 12-Lead ECG Values
2.10.3	Alert 12-Lead ECG Values

Figures

Figure No.[a]	Title	Part B Population	Part A Evaluable Population	Part A/B Evaluable Population in Extension Period
4.1.1.x	Proportion of Subjects with a >=50% Reduction in SALT Score by Visit and Treatment Group	ITT	X	X
4.1.2	Proportion of Subjects with a >=50% Reduction in SALT Score by Visit and Treatment Group (Per-Protocol Population)	Per-Protocol		
4.1.2.1.x	Proportion of Subjects with a >=90% Reduction in SALT Score by Visit and Treatment Group	ITT	X	X
4.1.2.2	Proportion of Subjects with a >=90% Reduction in SALT Score by Visit and Treatment Group (Per-Protocol Population)	Per-Protocol		
4.1.3.1.x[b]	Mean and LS Mean Plot with Standard Errors for Percent Change in SALT Score by Visit and Treatment Group	ITT	X	X
4.1.3.2	Mean and LS Mean Plot with Standard Errors for Percent Change in SALT Score by Visit and Treatment Group (Per-Protocol Population)	Per-Protocol		

Figure No.[a]	Title	Part B Population	Part A Evaluable Population	Part A/B Evaluable Population in Extension Period
4.1.4	Kaplan –Meier Plot for Time to First Worsening of Disease during Extension Period (Subjects with dose suspended due to clinical responses at the end of treatment periods who continue to extension period)			X
4.1.5	Kaplan –Meier Plot for Time to First Worsening of Disease (Subjects with clinical responses at any time of the study)	X	X	X
4.4.1.x	Line Graph of Selected Laboratory Values by Visit for Subjects Discontinued the Study Drug or Drug Interruption	Safety	X	X
4.4.2.x	Box-and-Whisker Plot of Selected Laboratory Values by Study Visit	Safety	X	X

[a] Figure No of #.#.#..x where x = 1 for Part A treatment period, x = 2 for Part B treatment period, x = 3 for Part A Extension Period, and x = 4 for Part B extension period.
[b] Mean and LS Mean plots will be set in different pages; LS Mean will only be available for Part B treatment period.

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Table 1.1.1.1

Analysis Populations Part A

Variable	INCB018424 All Subjects
Number (%) of Subjects Enrolled in Part A	## (###.#)
Number (%) of Subjects in Part A Open Label Treatment Period	## (###.#)
Number (%) of Subjects in Part A Open Label Extension Period	## (###.#)

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Table 1.1.1.2
Analysis Populations Part B

Variable	Treatment Group		
	INCB018424	Placebo	Total
Number (%) of Subjects Enrolled in Part B Treatment Period	## (###.#)	## (###.#)	## (###.#)
Number (%) of Intent-to-Treat Subjects in Part B Treatment Period	## (###.#)	## (###.#)	## (###.#)
Number (%) of Safety Subjects in Part B Treatment Period	## (###.#)	## (###.#)	## (###.#)
Number (%) of Per-Protocol Subjects in Part B Treatment Period	## (###.#)	## (###.#)	## (###.#)
Number (%) of [redacted] Subjects	## (###.#)	## (###.#)	## (###.#)
Number (%) of Evaluable Subjects in Part B Extension Period	## (###.#)	## (###.#)	## (###.#)

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Table 1.1.2.1
Summary of Subject Disposition

(Population: Part A Evaluable Subjects)

Variable	INCB018424 Total (N=##)
Number (%) of Subjects Treated in Part A: Treatment Period	## (###.#)
Number (%) of Subjects Treated in Part A: Extension Period	## (###.#)
Number (%) of Subjects who Completed Study through Week 24	## (###.#)
Number (%) of Subjects who Completed Study through Week 48	## (###.#)
Number (%) of Subjects who entered Follow-up Phase	## (###.#)
Number (%) of Subjects Discontinued from Study: Part A Treatment Period	## (###.#)
Adverse Event	## (##.#)
Lost to Follow-up	## (##.#)
Physician Decision	## (##.#)
Consent Withdrawn	## (##.#)
Xxxxxxxx	## (##.#)
Number (%) of Subjects Discontinued from Study: Part A Extension Period	## (###.#)
Adverse Event	## (##.#)
Lost to Follow-up	## (##.#)
Physician Decision	## (##.#)
Consent Withdrawn	## (##.#)
Xxxxxxxx	## (##.#)

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Table 1.1.2.2
Summary of Subject Disposition

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Number (%) of Subjects Randomized	## (###.#)	## (###.#)	## (###.#)
Number (%) of Subjects Treated	## (###.#)	## (###.#)	## (###.#)
Number (%) of Subjects who Completed Study through Week 24	## (###.#)	## (###.#)	## (###.#)
Number (%) of Subjects who entered Follow-up Phase	## (###.#)	## (###.#)	## (###.#)
Number (%) of Subjects Discontinued from Study:	## (###.#)	## (###.#)	## (###.#)
Adverse Event	## (##.#)	## (##.#)	## (##.#)
Lost to Follow-up	## (##.#)	## (##.#)	## (##.#)
Physician Decision	## (##.#)	## (##.#)	## (##.#)
Consent Withdrawn	## (##.#)	## (##.#)	## (##.#)
Xxxxxxxx	## (##.#)	## (##.#)	## (##.#)
.	## (##.#)	## (##.#)	## (##.#)
.	## (##.#)	## (##.#)	## (##.#)
.	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DISPBITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.1.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.1.2.4

Summary of Subject Disposition
(Population: Part B Evaluable Subjects: Extension Period)

	Treatment Group		
Variable	INCB018424 (N=##)	Placebo to INCB018424 (N=##)	Total (N=##)
Number (%) of Subjects Treated	## (###.#)	## (###.#)	## (###.#)
Number (%) of Subjects who Completed Study through Week 48	## (###.#)	## (###.#)	## (###.#)
Number (%) of Subjects who entered Follow-up Phase	## (###.#)	## (###.#)	## (###.#)
Number (%) of Subjects Discontinued from Study:	## (###.#)	## (###.#)	## (###.#)
Adverse Event	## (##.#)	## (##.#)	## (##.#)
Lost to Follow-up	## (##.#)	## (##.#)	## (##.#)
Physician Decision	## (##.#)	## (##.#)	## (##.#)
Consent Withdrawn	## (##.#)	## (##.#)	## (##.#)
Xxxxxxxx	## (##.#)	## (##.#)	## (##.#)
.	## (##.#)	## (##.#)	## (##.#)
.	## (##.#)	## (##.#)	## (##.#)
.	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DISPBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.1.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.1.3.1
Summary of Number of Subjects Enrolled By Site

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=##)
Site 1	## (###.#)
Site 2	## (###.#)
Site 3	## (###.#)
...	## (###.#)
...	## (###.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ENRLA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.1.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.1.3.2
Summary of Number of Subjects Enrolled By Site

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

	Treatment Group		
Variable	INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Site 1	## (###.#)	## (###.#)	## (###.#)
Site 2	## (###.#)	## (###.#)	## (###.#)
Site 3	## (###.#)	## (###.#)	## (###.#)
...	## (###.#)	## (###.#)	## (###.#)
...	## (###.#)	## (###.#)	## (###.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ENRLBITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.1.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.2.1.1
Summary of Demographics

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=##)
Age (years)	
N	##
Mean	##.#
STD	##.##
Min	##
Median	##.#
Max	##
Sex n(%)	
Male	## (##.#)
Female	## (##.#)
Ethnicity n(%)	
Hispanic or Latino	## (##.#)
Not Hispanic or Latino	## (##.#)
Other	## (##.#)
Race n(%)	
White	## (##.#)
Black or African American	## (##.#)
Asian	## (##.#)
Native Hawaiian or Other Pacific Islander	## (##.#)
American Indian or Alaska Native	## (##.#)
Other	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMOA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.2.1.1
Summary of Demographics

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=##)
Height (cm)	
N	##
Mean	##.##
STD	##.###
Min	##.#
Median	##.##
Max	##.#
Weight (kg)	
N	##
Mean	##.##
STD	##.###
Min	##.#
Median	##.##
Max	##.#
Body Mass Index (kg/m|2)	
N	##
Mean	##.###
STD	##.####
Min	##.##
Median	##.###
Max	##.##

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMOA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.2.1.2
Summary of Demographics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Age (years)			
N	##	##	##
Mean	##.#	##.#	##.#
STD	##.##	##.##	##.##
Min	##	##	##
Median	##.#	##.#	##.#
Max	##	##	##
Sex n(%)			
Male	## (##.#)	## (##.#)	## (##.#)
Female	## (##.#)	## (##.#)	## (##.#)
Ethnicity n(%)			
Hispanic or Latino	## (##.#)	## (##.#)	## (##.#)
Not Hispanic or Latino	## (##.#)	## (##.#)	## (##.#)
Other	## (##.#)	## (##.#)	## (##.#)
Race n(%)			
White	## (##.#)	## (##.#)	## (##.#)
Black or African American	## (##.#)	## (##.#)	## (##.#)
Asian	## (##.#)	## (##.#)	## (##.#)
Native Hawaiian or Other Pacific Islander	## (##.#)	## (##.#)	## (##.#)
American Indian or Alaska Native	## (##.#)	## (##.#)	## (##.#)
Other	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMOBITT.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.2.1.2
Summary of Demographics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Height (cm)			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Weight (kg)			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Body Mass Index (kg/m|2)			
N	##	##	##
Mean	##.###	##.###	##.###
STD	##.####	##.####	##.####
Min	##.##	##.##	##.##
Median	##.###	##.###	##.###
Max	##.##	##.##	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMOBITT.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.1.1
Summary of Baseline Characteristics

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 1.3.1.2 with appropriate treatment group

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PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2A.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.1.2
Summary of Baseline Characteristics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Numeric Baseline SALT Score			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Categorical Baseline SALT Score n(%)			
25 - <50%	## (##.#)	## (##.#)	## (##.#)
50 - 100%	## (##.#)	## (##.#)	## (##.#)
Predominant Hair Color n(%)			
Black	## (##.#)	## (##.#)	## (##.#)
Brown	## (##.#)	## (##.#)	## (##.#)
Red	## (##.#)	## (##.#)	## (##.#)
Blonde	## (##.#)	## (##.#)	## (##.#)
Gray	## (##.#)	## (##.#)	## (##.#)
White	## (##.#)	## (##.#)	## (##.#)
Other	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2BITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft

TLF VERSION: Draft TASK: Draft

Table 1.3.1.2
Summary of Baseline Characteristics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group		
	INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Days since first onset of Alopecia Areata			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Number of Prior episodes of Alopecia Areata			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Estimated maximum extent of hair loss for current episode (%)			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2BITT.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.1.2
Summary of Baseline Characteristics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
History of Alopecia Totalis at any time n(%)			
Yes	## (##.#)	## (##.#)	## (##.#)
<= 2 years	## (##.#)	## (##.#)	## (##.#)
> 2 years	## (##.#)	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)	## (##.#)
History of Alopecia Universalis at any time n(%)			
Yes	## (##.#)	## (##.#)	## (##.#)
<= 2 years	## (##.#)	## (##.#)	## (##.#)
> 2 years	## (##.#)	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)	## (##.#)
History of Male/Female Pattern Baldness n(%)			
No	## (##.#)	## (##.#)	## (##.#)
Yes	## (##.#)	## (##.#)	## (##.#)
Anterior Scalp	## (##.#)	## (##.#)	## (##.#)
Mid Scalp	## (##.#)	## (##.#)	## (##.#)
Temporal Scalp	## (##.#)	## (##.#)	## (##.#)
Vertex of Scalp	## (##.#)	## (##.#)	## (##.#)
Other	## (##.#)	## (##.#)	## (##.#)
Prior Therapy for Alopecia Areata n(%)			
Yes	## (##.#)	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2BITT.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.1.2
Summary of Baseline Characteristics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Days since first onset of Current Alopecia Areata			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Duration of Current Episode n(%)			
<6 months	## (##.#)	## (##.#)	## (##.#)
6-<12 months	## (##.#)	## (##.#)	## (##.#)
12-<24 months	## (##.#)	## (##.#)	## (##.#)
2-5 years	## (##.#)	## (##.#)	## (##.#)
>5 years	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2BITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.1.2
Summary of Baseline Characteristics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Type of Hair remaining			
Terminal n(%)	## (##.#)	## (##.#)	## (##.#)
Percent Pigmented Hair			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Percent Non-pigmented Hair			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2BITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.1.2
Summary of Baseline Characteristics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Type of Hair remaining			
Vellus/Indeterminant n(%)	## (##.#)	## (##.#)	## (##.#)
Percent Vellus/Indeterminant			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2BITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.1.2
Summary of Baseline Characteristics

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Pattern of scalp hair loss n(%)			
Patchy	## (##.#)	## (##.#)	## (##.#)
Totalis	## (##.#)	## (##.#)	## (##.#)
Ophiasis	## (##.#)	## (##.#)	## (##.#)
Body Hair Loss (Excluding scalp) n(%)			
No body hair loss	## (##.#)	## (##.#)	## (##.#)
Some body hair loss	## (##.#)	## (##.#)	## (##.#)
100% body hair loss	## (##.#)	## (##.#)	## (##.#)
Nail Involvement n(%)			
No nail involvement	## (##.#)	## (##.#)	## (##.#)
Some nail involvement	## (##.#)	## (##.#)	## (##.#)
Twenty nail dystrophy/Trachyonychia	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DEMO2BITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.2.1
Summary of Medical History

(Population: Part A Evaluable Subjects: Treatment Period)

MedDRA System Organ Class/ MedDRA Preferred Term	INCB018424 All Subjects (N=##)
Number (%) of Subjects with Medical History	## (##.#)
System Organ Class 1	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
System Organ Class 2	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
System Organ Class ...	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_MEDHA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.1.5.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.3.2.2
Summary of Medical History

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

MedDRA System Organ Class/ MedDRA Preferred Term	Treatment Group		
	INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Number (%) of Subjects with Medical History	## (##.#)	## (##.#)	## (##.#)
System Organ Class 1			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
System Organ Class 2			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
System Organ Class ...			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_MEDHBITT.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.1.5.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.1.1
Summary of Prior Medications

(Population: Part A Evaluable Subjects: Treatment Period)

ATC Class/ WHO Preferred Term	INCB018424 All Subjects (N=##)
Number (%) of Subjects with Prior Medications	## (##.#)
Drug Class 1	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
Drug Class 2	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
Drug Class ...	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PRMEDA.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.4.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.1.2
Summary of Prior Medications

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

ATC Class/ WHO Preferred Term	Treatment Group		
	INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Number (%) of Subjects with Medical History	## (##.#)	## (##.#)	## (##.#)
System Organ Class 1			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
System Organ Class 2			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
System Organ Class ...			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PRMEDBITT.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.4.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.2.1
Summary of Concomitant Medications

(Population: Part A Evaluable Subjects: Treatment Period)

ATC Class/ WHO Preferred Term	INCB018424 All Subjects (N=##)
Number (%) of Subjects with Concomitant Medications	## (##.#)
Drug Class 1	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
Drug Class 2	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
Drug Class ...	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CONMEDA.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.4.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.2.2
Summary of Concomitant Medications

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

This table follows same shell as that for Table 1.4.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CONMEDBITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.2.3
Summary of Concomitant Medications

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 1.4.2.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CONMEDAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.2.4
Summary of Concomitant Medications

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 1.4.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CONMEDBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.3.1
Summary of Prior Medications for Alopecia Areata

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 1.4.1.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PRMEDAAA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.3

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.4.3.2
Summary of Prior Medications for Alopecia Areata

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

This table follows same shell as that for Table 1.4.1.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PRMEDAABITT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.3

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.5.1.1
Summary of Drug Compliance

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=##)
Duration of Treatment (days)	
N	##
Mean	##.##
STD	##.###
Min	##.#
Median	##.##
Max	##.#
Dose Compliance (%)	
N	##
Mean	##.##
STD	##.###
Min	##.#
Median	##.##
Max	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DCMPLNCA.LST DATE(TIME): 18AUG15(13:51)
Note: Dose Compliance (100%) = 100 × [total dose taken]/[intended dose].

Reference: Listing 2.5.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.5.1.2
Summary of Drug Compliance

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 1.5.1.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ DCMPLNCBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.3

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.5.1.3
Summary of Drug Compliance

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 1.5.1.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ DCMPLNCAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.3

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 1.5.1.4
Summary of Drug Compliance

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 1.5.1.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ DCMPLNCBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.4.3

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.1.1
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=xx)
Number (%) of Evaluable Subjects [1]	## (###.#)
Week 4	
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Week XX	
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTA.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Number of subjects who have ever achieved SALT50 or SALT90 at any visit in the Part A Treatment Period.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.1.2
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group	
	INCB018424 N=##	Placebo (N=##)
Number (%) of Evaluable Subjects [1]	## (###.#)	## (###.#)
Week 4		
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Reason for Subjects not achieving >=50% OR >= 90% Reduction N (%)		
Less than 50% Reduction at the visit	## (##.#)	## (##.#)
Less than 90% Reduction at the visit	## (##.#)	## (##.#)
Missing Values at the Visit	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBITT.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study before the assessed visit for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score.
[3] Logistic Regression model including treatment, stratification factor(baseline scalp, 25%-<50% vs 50% to 100%), and baseline SALT score.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.1.2
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 N=##	Treatment Group: Placebo (N=##)
Week xx		
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Reason for Subjects not achieving >=50% OR >= 90% Reduction N (%)		
Less than 50% Reduction at the visit	## (##.#)	## (##.#)
Less than 90% Reduction at the visit	## (##.#)	## (##.#)
Missing Values at the Visit	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBITT.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study before the assessed visit for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score.
[3] Logistic Regression model including treatment, stratification factor(baseline scalp, 25%-<50% vs 50% to 100%), and baseline SALT score.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.1.3
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score by Visit

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 2.1.3.1 with appropriate treatment groups without sub-groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSAEXT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.1.4
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score by Visit

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 2.1.3.1 with appropriate treatment groups without sub-groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBEXT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.1.5
Summary of Subjects Achieving >= 50% Reduction from Baseline in SALT Score at Week 24

(Population: Part B Intent to Treat Subjects: Treatment Period)

Variable	Treatment Group	
	INCB018424	Placebo
Number (%) of Evaluable Subjects [1]	## (###.#)	## (###.#)
Week 24 (Primary Endpoint)		
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Reason for Subjects not achieving >=50% Reduction N (%)		
Less than 50% Reduction at the visit	## (##.#)	## (##.#)
Discontinued prior to the visit	## (##.#)	## (##.#)
Missing Values at the Visit	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBPP.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study for any reason are considered as not having achieved the >= 50% reduction in SALT score.
[3] Logistic Regression model including treatment, stratification factor(baseline scalp, 25%-<50% vs 50% to 100%), and baseline SALT score.
Reference: Listing 2.6.1
Programming Note: For interim analysis when some subjects are still ongoing and week 24 data is not available, use the footnote below in place of foot note 1.
[1] A subject was not evaluable if the subject had a missing score at baseline or is ongoing without reaching Week 24. In this case a, patients with missing week 24 SALT and missing discontinuation status will be excluded from evaluable subjects.

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.2
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24

(Population: Part B Per-Protocol Subjects)

Variable	Treatment Group	
	INCB018424 N=##	Placebo (N=##)
Number (%) of Evaluable Subjects [1]	## (###.#)	## (###.#)
Week 4		
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Reason for Subjects not achieving >=50% OR >= 90% Reduction N (%)		
Less than 50% Reduction at the visit	## (##.#)	## (##.#)
Less than 90% Reduction at the visit	## (##.#)	## (##.#)
Missing Values at the Visit	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBPP.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study before the assessed visit for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score .
[3] Logistic Regression model including treatment, stratification factor(baseline scalp, 25%-<50% vs 50% to 100%), and baseline SALT score.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.2
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24

(Population: Part B Per-Protocol Subjects)

Variable	Treatment Group	
	INCB018424	Placebo
Week XX		
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]		
Yes	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #.##)	
P-value	0.##	
Reason for Subjects not achieving >=50% OR >= 90% Reduction N (%)		
Less than 50% Reduction at the visit	## (##.#)	## (##.#)
Less than 90% Reduction at the visit	## (##.#)	## (##.#)
Missing Values at the Visit	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBPP.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score.
[3] Logistic Regression model including treatment, stratification factor(baseline scalp, 25%-<50% vs 50% to 100%), and baseline SALT score.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.3.1

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Baseline Scalp Involvement

(Population: Part A Evaluable Subjects: Treatment Period)

---------- Baseline Scalp Involvement 25% to <50% ----------

Variable	INCB018424 All Subjects
Number (%) of Evaluable Subjects [1]	## (###.#)
Week 4	
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Week XX	
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLPA.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Number of subjects who have ever achieved SALT50 or SALT90 at any visit in the Part A Treatment Period.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.3.1

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Baseline Scalp Involvement

(Population: Part A Evaluable Subjects: Treatment Period)

---------- Baseline Scalp Involvement 50% to 100% ----------

Variable	INCB018424 All Subjects
Number (%) of Evaluable Subjects [1]	## (###.#)
Week 4	
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Week XX	
Subjects Achieving >= 50% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Subjects Achieving >= 90% Reduction from Baseline N (%)[2]	
Yes	## (##.#)
No	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLPA.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Number of subjects who have ever achieved SALT50 or SALT90 at any visit in the Part A Treatment Period.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.3.2

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Baseline Scalp Involvement

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

This table follows same shell as that for Table 2.1.2 with appropriate treatment groups for each baseline scalp involvement sub-group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLPBITT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score .
[3] Logistic Regression model including treatment and baseline SALT score.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.3.3

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score by Visit by Baseline Scalp Involvement

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 2.1.3.1 with appropriate treatment groups for each baseline scalp involvement sub-group for all visits

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLPAEXT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.3.4

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score by Visit by Baseline Scalp Involvement

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 2.1.3.1 with appropriate treatment groups for each baseline scalp involvement sub-group for all visits

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLPBEXT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.4

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Baseline Scalp Involvement

(Population: Part B Per-Protocol Subjects)

This table follows same shell as that for Table 2.1.2 with appropriate treatment groups for each baseline scalp involvement sub-group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLPBPP.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score .
[3] Logistic Regression model including treatment and baseline SALT score.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.1.1
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=xxx)
Measured SALT Score at Baseline	
N[1]	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)
Measured SALT Score at week XX	
N	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)
Change in SALT Score from Baseline at week XX	
N	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSA.LST DATE(TIME): 18AUG15(13:51)
[1] A subject was not evaluable if the subject had a missing score at baseline.
Abbreviations: Q1 =; Q2 =; STD = Standard deviation; SE = Standard error; Max = Maximum; Min = Minimum.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.1.1
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=xxx)
Percentage change in SALT Score from Baseline at week XX	
N	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSA.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
Abbreviations: Q1 =; Q2 =; STD = Standard deviation; SE = Standard error; Max = Maximum; Min = Minimum.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.1.2
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part B Intent-to-Treat Evaluable Subjects: Treatment Period)

Variable	Treatment Group	
	INCB018424 (N=xx)	Placebo (N=xx)
Measured SALT Score at Baseline		
N	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
(Q1,Q3)	(xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBITT.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum; MMRM = Mixed-Model with Repeated Measures

[1] MMRM model for post-baseline measures: [Response Variable = Baseline + Treatment + Stratification factor (baseline scalp involvement, 25-<50% vs 50-100%) + Visit + Treatment*Visit].

Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.

Reference: Listing 2.6.1

TLF VERSION: Draft TASK: Draft

Table 2.2.1.2
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group	
	INCB018424 (N=xx)	Placebo (N=xx)
Measured SALT Score at week XX		
N	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
(Q1,Q3)	(xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	xx.x, xx.x)	(xx.x, xx.x)
Results from MMRM [1]		
LS Mean(SE)	x.xx(x.xxx)	x.xx(x.xxx)
95% CI of the LS Mean	(x.xxx, x.xx)	(x.xxx, x.xx)
Within-group P-value	0.xxx	0.xxx
INCB018424 - Placebo		
LS Mean Difference(SE)	x.xx(x.xxx)	
95% CI of the LS Mean Difference	(x.xxx, x.xx)	
Between-group P-value	0.xxx	

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBITT.LST DATE(TIME): 18AUG15(13:51)
Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum; MMRM = Mixed-Model with Repeated Measures
[1] MMRM model for post-baseline measures: [Response Variable = Baseline + Treatment + Stratification factor (baseline scalp involvement, 25-<50% vs 50-100%) + Visit + Treatment*Visit].
Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.1.2
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group	
	INCB018424	Placebo
Change in SALT Score from Baseline at week XX		
N	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
(Q1,Q3)	(xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)
Results from MMRM [1]		
LS Mean(SE)	x.xx(x.xxx)	x.xx(x.xxx)
95% CI of the LS Mean	(x.xxx, x.xx)	(x.xxx, x.xx)
Within-group P-value	0.xxx	0.xxx
INCB018424 - Placebo		
LS Mean Difference(SE)	x.xx(x.xxx)	
95% CI of the LS Mean Difference	(x.xxx, x.xx)	
Between-group P-value	0.xxx	

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBITT.LST DATE(TIME): 18AUG15(13:51)
Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum; MMRM = Mixed-Model with Repeated Measures
[1] MMRM model for post-baseline measures: [Response Variable = Baseline + Treatment + Stratification factor (baseline scalp involvement, 25-<50% vs 50-100%) + Visit + Treatment*Visit].
Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
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Table 2.2.1.2
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

Variable	Treatment Group	
	INCB018424	Placebo
Percentage change in SALT Score from Baseline at week XX		
N	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x
(Q1,Q3)	xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	xx.x, xx.x)	(xx.x, xx.x)
Results from MMRM [1]		
LS Mean(SE)	x.xx(x.xxx)	x.xx(x.xxx)
95% CI of the LS Mean	(x.xxx, x.xx)	(x.xxx, x.xx)
Within-group P-value	0.xxx	0.xxx
INCB018424 - Placebo		
LS Mean Difference(SE)	x.xx(x.xxx)	
95% CI of the LS Mean Difference	(x.xxx, x.xx)	
Between-group P-value	0.xxx	

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBITT.LST DATE(TIME): 18AUG15(13:51)
Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum; MMRM = Mixed-Model with Repeated Measures
[1] MMRM model for post-baseline measures: [Response Variable = Baseline + Treatment + Stratification factor (baseline scalp involvement, 25-<50% vs 50-100%) + Visit + Treatment*Visit].
Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
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Table 2.2.1.3
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part A Evaluable Subjects: Extension Period)

Variable	Treatment Group: INCB018424 (N=xx)
Measured SALT Score at Baseline	
N	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSAEXT.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum;

Reference: Listing 2.6.1

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TLF VERSION: Draft TASK: Draft

Table 2.2.1.3
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part A Evaluable Subjects: Extension Period)

Variable	Treatment Group: INCB018424 (N=xx)
Measured SALT Score at Week xx	
N	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)
Change in SALT Score from Baseline at week XX	
N	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)
Percentage change in SALT Score from Baseline at week XX	
N	#
Mean(STD)	xx.x(xx.xx)
Median	xx.x
(Q1,Q3)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSAEXT.LST DATE(TIME): 18AUG15(13:51)
Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
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TLF VERSION: Draft TASK: Draft

Table 2.2.1.4
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part B Evaluable Subjects: Extension Period)

Variable	Treatment Group: INCB018424 (N=##)	Treatment Group: Placebo to INCB018424 (N=##)	Total (N=##)
Measured SALT Score at Baseline			
N	#	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
(Q1,Q3)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBEXT.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error;
Max = maximum; Min = minimum;

Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.1.4
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part B Evaluable Subjects: Extension Period)

Variable	Treatment Group: INCB018424 (N=##)	Treatment Group: Placebo to INCB018424 (N=##)	Total (N=##)
Measured SALT Score at Week xx			
N	#	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
(Q1,Q3)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Change in SALT Score from Baseline at week XX			
N	#	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
(Q1,Q3)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
Percentage change in SALT Score from Baseline at week XX			
N	#	#	#
Mean(STD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median	xx.x	xx.x	xx.x
(Q1,Q3)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)
(Min,Max)	(xx.x, xx.x)	(xx.x, xx.x)	(xx.x, xx.x)

...
PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBEXT.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error;
Max = maximum; Min = minimum;
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.2.1
Summary and Analysis of SALT Score from Baseline to Week 24 by Baseline Scalp Involvement

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 2.2.1.1 with appropriate treatment groups for each baseline scalp involvement sub-group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLP2A.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
Abbreviations: Q1 =; Q2 =; STD = Standard deviation; SE = Standard error; Max = Maximum; Min = Minimum.
Reference: Listing 2.6.1

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DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.2.2
Summary and Analysis of SALT Score from Baseline to Week 24 by Baseline Scalp Involvement

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

This table follows same shell as that for Table 2.2.1.2 with appropriate treatment groups for each baseline scalp involvement sub-group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLP2BITT.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error;
Max = maximum; Min = minimum; MMRM = Mixed-Model with Repeated Measures
[1] MMRM model for post-baseline measures: [Response Variable = Baseline + Treatment + Visit + Treatment*Visit].
Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.2.3
Summary and Analysis of SALT Score by Visit and Baseline Scalp Involvement

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 2.2.1.1 with appropriate treatment groups for each baseline scalp involvement group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLP2AEXT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
Abbreviations: Q1 =; Q2 =; STD = Standard deviation; SE = Standard error; Max = Maximum; Min = Minimum.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.2.4
Summary and Analysis of SALT Score by Visit and Baseline Scalp Involvement

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 2.2.1.1 with appropriate treatment groups for each baseline scalp involvement group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLP2BEXT.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum.
Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.3
Summary and Analysis of SALT Score from Baseline to Week 24

(Population: Part B Per-Protocol Subjects)

This table follows same shell as that for Table 2.2.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTVSBPP.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error;
Max = maximum; Min = minimum; MMRM = Mixed-Model with Repeated Measures
[1] MMRM model for post-baseline measures: [Response Variable = Baseline + Treatment + Stratification facto
(baseline scalp involvement, 25-<50% vs 50-100%) + Visit + Treatment*Visit].
Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.2.4
Summary and Analysis of SALT Score from Baseline to Week 24 by Baseline Scalp Involvement

(Population: Part B Per-Protocol Subjects)

This table follows same shell as that for Table 2.2.1.2 with appropriate treatment groups for each baseline scalp involvement sub-group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTBSCLP2BPP.LST DATE(TIME): 18AUG15(13:51)

Abbreviations: CI = confidence interval; LSMean = least squares mean; STD = standard deviation; SE = standard error; Max = maximum; Min = minimum; MMRM = Mixed-Model with Repeated Measures
[1] MMRM model for post-baseline measures: [Response Variable = Baseline + Treatment + Visit + Treatment*Visit].
Note: Only Subjects with non-missing baseline value and at least one non-missing post-baseline value of the response variable were included in summary and analysis.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
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TLF VERSION: Draft TASK: Draft

Table 2.3.1.1
Summary of Subjects Achieving Complete Clinical Response in SALT Score from Baseline to Week 24

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects
Number (%) of Evaluable Subjects [1]	## (###.#)
Week 8	
Subjects Achieving Complete Clinical Response N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Week XX	
Subjects Achieving Complete Clinical Response N (%)[2]	
Yes	## (##.#)
No	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CCRESPA.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Complete Clinical Response is defined as 100% terminal hair regrowth and no evidence of active hair loss at 2 consecutive visits

Reference: Listing 2.6.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.3.1.2
Summary of Subjects Achieving Complete Clinical Response in SALT Score from Baseline to Week 24

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

	Treatment Group		
Variable	INCB018424	Placebo	Total
Number (%) of Evaluable Subjects [1]	## (###.#)	## (###.#)	## (###.#)
Week 8			
Subjects Achieving Complete Clinical Response N (%)[2]			
Yes	## (##.#)	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #. #.#)		
P-value	0.##		
Week XX			
Subjects Achieving Complete Clinical Response N (%)[2]			
Yes	## (##.#)	## (##.#)	## (##.#)
No	## (##.#)	## (##.#)	## (##.#)
INCB018424/Placebo Odds Ratio (95% CI) [3]	#.#(#.##, #. #.#)		
P-value	0.##		

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CCRESPBITT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Complete Clinical Response is defined as 100% terminal hair regrowth and no evidence of active hair loss at 2 consecutive visits
[3] Logistic regression model including treatment, stratification factor (baseline scalp involvement, 25-<50% vs 50-100%), and baseline SALT score.
Reference: Listing 2.6.2

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TLF VERSION: Draft TASK: Draft

Table 2.3.2.1

Summary of Subjects Achieving Complete Clinical Response in SALT Score from Baseline to Week 24 by Baseline Scalp Involvement

(Population: Part A Evaluable Subjects: Extension Period)

---------- Baseline Scalp Involvement 25% to <50% ----------

Variable	INCB018424 All Subjects
Number (%) of Evaluable Subjects [1]	## (###.#)
Week 4	
Subjects Achieving Complete Clinical Response N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Week XX	
Subjects Achieving Complete Clinical Response N (%)[2]	
Yes	## (##.#)
No	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CCRESPBSA.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Complete Clinical Response is defined as 100% terminal hair regrowth and no evidence of active hair loss at 2 consecutive visits

Reference: Listing 2.6.2

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TLF VERSION: Draft TASK: Draft

Table 2.3.2.1

Summary of Subjects Achieving Complete Clinical Response in SALT Score from Baseline to Week 24 by Baseline Scalp Involvement

(Population: Part A Evaluable Subjects: Extension Period)

---------- Baseline Scalp Involvement 50% to 100% ----------

Variable	INCB018424 All Subjects
Number (%) of Evaluable Subjects [1]	## (###.#)
Week 4	
Subjects Achieving Complete Clinical Response N (%)[2]	
Yes	## (##.#)
No	## (##.#)
Week XX	
Subjects Achieving Complete Clinical Response N (%)[2]	
Yes	## (##.#)
No	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CCRESPBSA.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Complete Clinical Response is defined as 100% terminal hair regrowth and no evidence of active hair loss at 2 consecutive visits
Reference: Listing 2.6.2

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TLF VERSION: Draft TASK: Draft

Table 2.3.2.2
Summary of Subjects Achieving Complete Clinical Response in SALT Score from Baseline to Week 24 by Baseline Scalp Involvement

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

This table follows same shell as that for Table 2.3.3.1/2.1.1.2(without reasons) with appropriate treatment groups for each baseline scalp Involvement group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_CCRESPBSBITT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Complete Clinical Response is defined as 100% terminal hair regrowth and no evidence of active hair loss at 2 consecutive visits
[3] Logistic regression model including treatment, stratification factor (baseline scalp involvement, 25-<50% vs 50-100%), and baseline SALT score.
Reference: Listing 2.6.2

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TLF VERSION: Draft TASK: Draft

Table 2.1.5.1

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Duration of Current Episode

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 2.1.1.1 for each Duration of Current Episode Group

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PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTDURA.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Number of subjects who have ever achieved SALT50 or SALT90 at any visit in the Part A Treatment Period.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.5.2

Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Duration of Current Episode

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

This table follows same shell as that for Table 2.1.1.2 for each Duration of Current Episode Group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTDURBITT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study before the assessed visit for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score.
[3] Logistic regression model including treatment, stratification factor (baseline scalp involvement, 25-<50% vs 50-100%), and baseline SALT score.
Reference: Listing 2.6.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.6.1
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Pattern of Hair Loss

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 2.1.1.1 for each Pattern of Scalp Hair Loss

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTHRLSA.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Number of subjects who have ever achieved SALT50 or SALT90 at any visit in the Part A Treatment Period.
Reference: Listing 2.6.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 2.1.6.2
Summary of Subjects Achieving >= 50% and >= 90% Reduction from Baseline in SALT Score to Week 24 by Pattern of Hair Loss

(Population: Part B Intent-to-Treat Subjects: Treatment Period)

This table follows same shell as that for Table 2.1.1.2 for each Pattern of Scalp Hair Loss

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SALTHRLSBITT.LST DATE(TIME): 18AUG15(13:51)

[1] A subject was not evaluable if the subject had a missing score at baseline.
[2] Subjects who discontinued from the study before the assessed visit for any reason are considered as not having achieved the >= 50% or >= 90% reduction in SALT score.
[3] Logistic regression model including treatment, stratification factor (baseline scalp involvement, 25-<50% vs 50-100%), and baseline SALT score.

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.1.1
Summary of Exposure and Duration of Exposure

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects (N=##)
Duration of Treatment (days)	
N	##
Mean	##.##
STD	##.###
Min	##.#
Median	##.##
Max	##.#
Average Daily Dose (g/day)	
N	##
Mean	##.##
STD	##.###
Min	##.#
Median	##.##
Max	##.#
Total Dose of INCB018424	
N	##
Mean	##.##
STD	##.###
Min	##.#
Median	##.##
Max	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EXPA.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.1.2
Summary of Exposure and Duration of Exposure

(Population: Part B Safety Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Duration of Treatment (days)			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Average Daily Dose (g/day)			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#
Total Dose			
N	##	##	##
Mean	##.##	##.##	##.##
STD	##.###	##.###	##.###
Min	##.#	##.#	##.#
Median	##.##	##.##	##.##
Max	##.#	##.#	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EXPBSAF.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.1.3
Summary of Exposure and Duration of Exposure

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.1.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EXPAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.1.4
Summary of Exposure and Duration of Exposure

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for 3.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EXPBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.1.1
Overall Summary of Treatment-Emergent Adverse Events

(Population: Part A Evaluable Subjects: Treatment Period)

Variable	INCB018424 All Subjects
Treatment-Emergent Adverse Events Reported	####
Subjects Who Had any Treatment-Emergent Adverse Event	## (##.#)
Subjects Who Had any Treatment-Related TEAEs	## (##.#)
Subjects Who Had any Serious Adverse Event	## (##.#)
Subjects Who Had Adverse Events of Grade 3 or 4 TEAE	## (##.#)
Subjects Who Had any Severe TEAEs	## (##.#)
Subjects Who Had a Fatal Adverse Event	## (##.#)
Subjects Who Had TEAEs Leading to Discontinuation of Study Drug	## (##.#)
Additional Customized Category 1	## (##.#)
Additional Customized Category 2	## (##.#)
.....	## (##.#)
.....	## (##.#)

Abbreviation: TEAE = Treatment-Emergent Adverse Event.

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESUMA.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.1.2
Overall Summary of Treatment-Emergent Adverse Events

(Population: Part B Safety Subjects: Treatment Period)

Variable	Treatment Group: INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Treatment-Emergent Adverse Events Reported	####	####	####
Subjects Who Had any Treatment-Emergent Adverse Event	## (##.#)	## (##.#)	## (##.#)
Subjects Who Had any Treatment-Related TEAEs	## (##.#)	## (##.#)	## (##.#)
Subjects Who Had any Serious Adverse Event	## (##.#)	## (##.#)	## (##.#)
Subjects Who Had Adverse Events of Grade 3 or 4 TEAE	## (##.#)	## (##.#)	## (##.#)
Subjects Who Had any Severe TEAEs	## (##.#)	## (##.#)	## (##.#)
Subjects Who Had a Fatal Adverse Event	## (##.#)	## (##.#)	## (##.#)
Subjects Who Had TEAEs Leading to Discontinuation of Study Drug	## (##.#)	## (##.#)	## (##.#)
Additional Customized Category 1			
Additional Customized Category 2	## (##.#)	## (##.#)	## (##.#)
.....	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESUMBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.1.3
Overall Summary of Treatment-Emergent Adverse Events

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.1.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESUMAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.1.4
Overall Summary of Treatment-Emergent Adverse Events

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESUMBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.2.1
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

MedDRA System Organ Class/ MedDRA Preferred Term	INCB018424 All Subjects
Number (%) of Subjects With Any Adverse Events	## (##.#)
System Organ Class 1	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
System Organ Class 2	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)
System Organ Class ...	
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESOCPTA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.2.2
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

MedDRA System Organ Class/ MedDRA Preferred Term	Treatment Group		
	INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)	## (##.#)
System Organ Class 1			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
System Organ Class 2			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
System Organ Class ...			
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESOCPTBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.2.3
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.2.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESOCPTAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.2.4
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.2.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESOCPTBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.3.1
Summary of Treatment-Emergent Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part A Evaluable Subjects: Treatment Period)

MedDRA Preferred Term	INCB018424 All Subjects
Number (%) of Subjects With Any Adverse Events	## (##.#)
Preferred Term 1	## (##.#)
Preferred Term 2	## (##.#)
Preferred Term 3	## (##.#)
...	## (##.#)
...	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEPTDA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.3.2
Summary of Treatment-Emergent Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part B Safety Subjects: Treatment Period)

MedDRA Preferred Term	Treatment Group		
	INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)	## (##.#)
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEPTDBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.3.3
Summary of Treatment-Emergent Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table Table 3.2.3.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEPTDAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.3.4
Summary of Treatment-Emergent Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.3.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEPTDBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.4.1
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part A Evaluable Subjects: Treatment Period)

MedDRA System Organ Class/ MedDRA Preferred Term	INCB018424 (N=##)				
	Grade 1	Grade 2	Grade 3	Grade 4	Any
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 1					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 2					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class ...					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)

Note: Maximum Severity was determined from the first dose of INCB018424 cream.

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEMXSVA.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.4.2
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part B Safety Subjects: Treatment Period)

---------- Treatment Group=INCB018424 ----------

MedDRA System Organ Class/ MedDRA Preferred Term	Toxicity Grade				
	Grade 1	Grade 2	Grade 3	Grade 4	Any
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 1					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 2					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class ...					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)

Note: Maximum Severity was determined from the first dose of INCB018424 cream or Placebo in Treatment Period.

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEMXSVBSAF.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.4.2
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part B Safety Subjects: Treatment Period)

---------- Treatment Group=Placebo ----------

MedDRA System Organ Class/ MedDRA Preferred Term	Toxicity Grade				
	Grade 1	Grade 2	Grade 3	Grade 4	Any
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 1					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 2					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class ...					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)

Note: Maximum Severity was determined from the first dose of INCB018424 cream or Placebo in Treatment Period.

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEMXSVBSAF.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.4.2
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part B Safety Subjects: Treatment Period)

---------- Treatment Group=Total ----------

MedDRA System Organ Class/ MedDRA Preferred Term	Toxicity Grade				
	Grade 1	Grade 2	Grade 3	Grade 4	Any
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 1					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class 2					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
System Organ Class ...					
Preferred Term 1	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)	## (##.#)	## (##.#)	## (##.#)

Note: Maximum Severity was determined from the first dose of INCB018424 cream or Placebo in Treatment Period.

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEMXSVBSAF.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.4.3
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

Note: Maximum Severity was determined from the first dose of INCB018424 cream in Treatment Period.

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEMXSVAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.4.4
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

Note: Maximum Severity was determined from the first dose of INCB018424 cream in Treatment Period, or in Extension Period for subjects who cross over to INCB018424.

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEMXSVBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.5.1
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part A Evaluable Subjects: Treatment Period)

MedDRA System Organ Class/ MedDRA Preferred Term	INCB018424 (N=##)	
	Grades 1-2	Grade 3-4
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)
System Organ Class 1		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class 2		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class ...		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGPA.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.5.2
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part B Safety Subjects: Treatment Period)

---------- Treatment Group=INCB018424 ----------

MedDRA System Organ Class/ MedDRA Preferred Term	Toxicity Grade	
	Grades 1-2	Grades 3-4
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)
System Organ Class 1		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class 2		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class ...		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGPBSAF.LST DATE(TIME): 18AUG15(13:51)
Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.5.2
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part B Safety Subjects: Treatment Period)

---------- Treatment Group=Placebo ----------

MedDRA System Organ Class/ MedDRA Preferred Term	Toxicity Grade	
	Grades 1-2	Grades 3-4
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)
System Organ Class 1		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class 2		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class ...		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGPBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.5.2
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part B Safety Subjects: Treatment Period)

---------- Treatment Group=Total ----------

MedDRA System Organ Class/ MedDRA Preferred Term	Toxicity Grade	
	Grades 1-2	Grades 3-4
Number (%) of Subjects With Any Adverse Events	## (##.#)	## (##.#)
System Organ Class 1		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class 2		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)
System Organ Class ...		
Preferred Term 1	## (##.#)	## (##.#)
Preferred Term 2	## (##.#)	## (##.#)
Preferred Term 3	## (##.#)	## (##.#)
...	## (##.#)	## (##.#)

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGPBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.5.3
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.5.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGPAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.5.4
Summary of Treatment-Emergent Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.5.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGPBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.6.1
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.2.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.6.2
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.2.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.6.3
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.2.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.6.4
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.2.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.7.1

Summary of Treatment-Related Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.3.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLPTDA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.7.2
Summary of Treatment-Related Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.3.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLPTDBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.7.3
Summary of Treatment-Related Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.3.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLPTDAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.7.4
Summary of Treatment-Related Adverse Events By MedDRA Preferred Term in Decreasing Order of Frequency

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.3.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLPTDBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.8.1
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLMXSVA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.8.2
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLMXSVBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.8.3
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLMXSVAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.8.4
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and Maximum Severity

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERLMXSVBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.9.1
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.5.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGDA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.9.2
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.5.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGDBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.9.3
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.5.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGDAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.9.4
Summary of Treatment-Related Adverse Events By MedDRA System Organ Class, Preferred Term, and CTCAE Grade Group

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.5.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECTCGDBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.10.1
Summary of Treatment-Emergent Adverse Events Leading to Death By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEFATALA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.6

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.10.2
Summary of Treatment-Emergent Adverse Events Leading to Death By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEFATALBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.6

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.10.3
Summary of Treatment-Emergent Adverse Events Leading to Death By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEFATALAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.6

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.10.4
Summary of Treatment-Emergent Adverse Events Leading to Death By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEFATALBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.6

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.11.1
Summary of Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESERA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.11.2
Summary of Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESERBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.11.3
Summary of Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESERAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.11.4
Summary of Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AESERBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.12.1

Summary of Non-Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AENSERA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.12.2
Summary of Non-Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AENSERBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.12.3
Summary of Non-Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AENSERAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.12.4

Summary of Non-Serious Treatment-Emergent Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AENSERBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.13.1
Summary of Treatment-Related Serious Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERSERA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.13.2
Summary of Treatment-Related Serious Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERSERBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.13.3
Summary of Treatment-Related Serious Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERSERAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.13.4
Summary of Treatment-Related Serious Adverse Events By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AERSERBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.5

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.14.1

Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEWDRWLA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.4

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.14.2

Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEWDRWLBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.4

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.14.3

Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEWDRWLAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.4

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.14.4

Summary of Treatment-Emergent Adverse Events Leading to Permanent Discontinuation of Study Drug By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEWDRWLBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.4

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.15.1

Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEDSINTA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.15.2

Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEDSINTBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.15.3

Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEDSINTAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.15.4

Summary of Treatment-Emergent Adverse Events Leading to Interruption of Drug By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AEDSINTBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.16.1

Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECNMEDA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.16.2

Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications By MedDRA System Organ Class and Preferred Term

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECNMEDBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.16.3

Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications By MedDRA System Organ Class and Preferred Term

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.1 with appropriate treatment group

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECNMEDAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.2.16.4

Summary of Treatment-Emergent Adverse Events Requiring Concomitant Medications By MedDRA System Organ Class and Preferred Term

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.2.4.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_AECNMEDBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.7.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.1.1
Summary of Laboratory Values - Hematology

(Population: Part A Evaluable Subjects: Treatment Period)

Laboratory Test (unit) : Test Name (unit)

Treatment Group	Study Visit		Descriptive Summary						N (%) of Subjects		
			N	Mean	STD	Min	Median	Max	Low	Normal	High
INCB018424	Baseline	Baseline	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
	Week 4 Day...	Measured	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
		Change	##	##.#	#.##	##	##.#	##			
		% Change	##	##.#	#.##	##	##.#	##			
	Week... Day...	Measured	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
		Change	##	##.#	#.##	##	##.#	##			
		% Change	##	##.#	#.##	##	##.#	##			

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.1.2
Summary of Laboratory Values - Hematology

(Population: Part B Safety Subjects: Treatment Period)

Laboratory Test (unit) : Test Name (unit)

Treatment Group	Study Visit		Descriptive Summary						N (%) of Subjects		
			N	Mean	STD	Min	Median	Max	Low	Normal	High
INCB018424	Baseline	Baseline	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
	Week 4 Day...	Measured	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
		Change	##	##.#	#.##	##	##.#	##			
		% Change	##	##.#	#.##	##	##.#	##			
	Week... Day...	Measured	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
		Change	##	##.#	#.##	##	##.#	##			
		% Change	##	##.#	#.##	##	##.#	##			
Placebo	Baseline	Baseline	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
	Week 4 Day...	Measured	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
		Change	##	##.#	#.##	##	##.#	##			
		% Change	##	##.#	#.##	##	##.#	##			
	Week... Day...	Measured	##	##.#	#.##	##	##.#	##	## (##.#)	## (##.#)	## (##.#)
		Change	##	##.#	#.##	##	##.#	##			
		% Change	##	##.#	#.##	##	##.#	##			

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.1.3
Summary of Laboratory Values - Hematology

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.1.4
Summary of Laboratory Values - Hematology

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.1.5
Summary of Laboratory Values – Free T4 and TSH

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.1.6
Summary of Laboratory Values – Free T4 and TSH

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.2.1
Shift Summary of Hematology Values - To the Worst Abnormal Value

(Population: Part A Evaluable Subjects: Treatment Period)

Laboratory Test (unit): test name (unit)

	Baseline [1]		During the Treatment Period [2]				
Treatment	Value	n (%)	Low	Normal	High	Low & High	Missing
INCB018424 cream (N=#)	Low	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Normal	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	High	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Missing	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)
	Total	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)	# (##.#)

[1] The baseline total was used as the denominator
[2] For each row, the number of subjects with given abnormality category at baseline was used as the denominator;
- Low = subjects with >=1 low value but not any high values
- High = subjects with >=1 high value but not any low values
- Normal = subjects without any low or high values
- Low & High = subjects with both low and high values

PROGRAM\OUTPUT: T_LBSHIFT.SAS\T_LAB8.LST DATE(TIME): 15SEP15(14:29)

Notes 1: Baseline = Last non-missing value before first dose
2: This table does not include data from unscheduled visits after first dose.
3: When there are multiple values per test*subject*visit combination, the last value was selected.

Reference: Listing 2.8.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.2.2
Shift Summary of Hematology Values - To the Worst Abnormal Value

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHSHFTBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.2.3
Shift Summary of Hematology Values - To the Worst Abnormal Value

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHSHFTAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.2.4
Shift Summary of Hematology Values - To the Worst Abnormal Value

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBHSHFTBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.3.1
Summary of Laboratory Values - Chemistry

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.3.2
Summary of Laboratory Values - Chemistry

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.3.3
Summary of Laboratory Values - Chemistry

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.3.4
Summary of Laboratory Values - Chemistry

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.9.1
Summary of Laboratory Values - Urinalysis

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.9.2
Summary of Laboratory Values - Urinalysis

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.3.3
Summary of Laboratory Values - Urinalysis

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.9.4
Summary of Laboratory Values - Urinalysis

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.1.2 with appropriate treatment groups

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.4.1
Shift Summary of Chemistry Values - To the Worst Abnormal Value

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCSHFTA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.4.2
Shift Summary of Chemistry Values - To the Worst Abnormal Value

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCSHFTBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.4.3
Shift Summary of Chemistry Values - To the Worst Abnormal Value

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCSHFTAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.4.4
Shift Summary of Chemistry Values - To the Worst Abnormal Value

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_LBCSHFTBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.5.1
Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part A Evaluable Subjects: Treatment Period)

Treatment Group	Baseline[1]		Extreme Post-Baseline Value[2]					
	Grade	N (%)	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Missing
INCB018424	Grade 0	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%
	Grade 1	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%
	Grade 2	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%
	Grade 3	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%
	Grade 4	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%
	Missing	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%
	Total	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%	## ##.#%

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTH1DA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.5.2

Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTH1DBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.5.3
Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTH1DAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.5.4
Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTH1DBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.6.1
Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC1DA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.6.2
Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC1DBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.6.3
Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC1DAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.6.4
Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (One Directional CTC Grade)

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC1DBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.7.1
Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTH2DLA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.7.2
Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTH2DLBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.7.3
Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTH2DLAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.7.4
Shift Summary of Hematology Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFT2DLBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.8.1

Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC2DHA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.8.2
Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC2DHBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.8.3
Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC2DHAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.3.8.4
Shift Summary of Chemistry Values in CTC Grade - To the Worst Abnormal Value (Two Directional CTC Grade)

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.3.2.1 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\LBSHFTC2DHBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.8.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.1.1
Summary of Systolic Blood Pressure

(Population: Part A Evaluable Subjects: Treatment Period)

Treatment: INCB018424

		Descriptive Summary						Low		Normal		High		Alert	
Visit (Time Point)	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week 4 Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week... Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SBPA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.1.2
Summary of Systolic Blood Pressure

(Population: Part B Safety Subjects: Treatment Period)

Treatment: INCB018424 cream

		Descriptive Summary						Low		Normal		High		Alert	
Visit (Time Point)	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week 4 Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week... Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SBPBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.1.3
Summary of Systolic Blood Pressure

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SBPAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.1.4
Summary of Systolic Blood Pressure

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_SBPBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.2.1
Summary of Diastolic Blood Pressure

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DBPA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.2.2
Summary of Diastolic Blood Pressure

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DBPBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.2.3
Summary of Diastolic Blood Pressure

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DBPAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.2.4
Summary of Diastolic Blood Pressure

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_DBPBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.3.1
Summary of Pulse

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PULSA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.3.2
Summary of Pulse

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PULSBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.3.3
Summary of Pulse

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PULSAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.3.4
Summary of Pulse

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_PULSBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.4.1
Summary of Body Temperature

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_TEMPA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.4.2
Summary of Body Temperature

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_TEMPBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.4.3
Summary of Body Temperature

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_TEMPAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.4.4
Summary of Body Temperature

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_TEMPBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.5.1
Summary of Respiration Rate

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_RESPA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.5.2
Summary of Respiration Rate

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_RESPBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.5.3
Summary of Respiration Rate

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_RESPAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.4.5.4
Summary of Respiration Rate

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.4.1.2 with appropriate treatment groups

---

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_RESPBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.9.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.1.1
Summary of 12-Lead ECG: PR Interval Values
(Population: Part A Evaluable Subjects: Treatment Period)

Treatment: INCB018424

		Descriptive Summary						Low		Normal		High		Alert	
Visit (Time Point)	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week 4 Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week ... Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGPRA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.1.2
Summary of 12-Lead ECG: PR Interval Values
(Population: Part B Safety Subjects: Treatment Period)

Treatment: INCB018424/Placebo

		Descriptive Summary						Low		Normal		High		Alert	
Visit (Time Point)	Variable	N	Mean	STD	Min	Median	Max	N	%	N	%	N	%	N	%
Baseline	Baseline	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week 4 Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
Week ... Day ...	Measured	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#
	% Change	##	##.#	#.##	##	##.#	##	##	##.#	##	##.#	##	##.#	##	##.#

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGPRBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.1.3
Summary of 12-Lead ECG: PR Interval Values

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGPRAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.1.4
Summary of 12-Lead ECG: PR Interval Values

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGPRBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.2.1
Summary of 12-Lead ECG: QRS Interval Values

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQRSA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.2.2
Summary of 12-Lead ECG: QRS Interval Values

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQRSBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.2.3
Summary of 12-Lead ECG: QRS Interval Values

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQRSAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.2.4
Summary of 12-Lead ECG: QRS Interval Values

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQRSBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.3.1
Summary of 12-Lead ECG: QT Interval Values

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.3.2
Summary of 12-Lead ECG: QT Interval Values

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.3.3
Summary of 12-Lead ECG: QT Interval Values

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.3.4
Summary of 12-Lead ECG: QT Interval Values

(Population: Part B Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.4.1
Summary of 12-Lead ECG: QTcB Interval Values

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCBA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.4.2
Summary of 12-Lead ECG: QTcB Interval Values

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCBBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.4.3
Summary of 12-Lead ECG: QTcB Interval Values

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCBAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.4.4
Summary of 12-Lead ECG: QTcB Interval Values

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCBBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.5.1
Summary of 12-Lead ECG: QTcF Interval Values

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCFA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.5.2
Summary of 12-Lead ECG: QTcF Interval Values

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCFBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.5.3
Summary of 12-Lead ECG: QTcF Interval Values

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCFAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.5.4
Summary of 12-Lead ECG: QTcF Interval Values

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGQTCFBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.6.1
Summary of 12-Lead ECG: RR Interval Values

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGRRA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.6.2
Summary of 12-Lead ECG: RR Interval Values

(Population: Part B Safety Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGRRBSAF.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.6.3
Summary of 12-Lead ECG: RR Interval Values

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.1

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGRRAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.6.4
Summary of 12-Lead ECG: RR Interval Values

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.1.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_EGRRBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.1

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.7.1
Summary of Treatment Emergent, Clinically Significant ECG Abnormality from Baseline

(Population: Part A Evaluable Subjects: Treatment Period)

This table follows same shell as that for Table 3.5.7.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ECGCSA.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.2

PROTOCOL: INCB018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.7.2
Summary of Treatment Emergent, Clinically Significant ECG Abnormality

(Population: Part B Safety Subjects: Treatment Period)

MedDRA Preferred Term	Treatment Group		
	INCB018424 (N=##)	Placebo (N=##)	Total (N=##)
Number (%) of Subjects With a Post-Baseline ECG Evaluation	# (##.#)	# (##.#)	# (##.#)
Number (%) of Subjects With a Clin Sig Post-Baseline Abnormality	# (##.#)	# (##.#)	# (##.#)

PROGRAM\OUTPUT: T_ECGEVAL.SAS\T_ECG8.LST DATE(TIME): 27AUG15(22:45)

Abbreviation: Clin Sig = Clinically Significant.

Reference: Listing 2.10.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.7.3
Summary of Treatment Emergent, Clinically Significant ECG Abnormality from Baseline

(Population: Part A Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.7.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ECGCSAEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.2

PROTOCOL: INCB 018424-204 (Page n of N)
DRUG/INDICATION: INCB018424 cream/Alopecia Areata DATABASE VERSION: Draft
TLF VERSION: Draft TASK: Draft

Table 3.5.7.4
Summary of Treatment Emergent, Clinically Significant ECG Abnormality from Baseline

(Population: Part B Evaluable Subjects: Extension Period)

This table follows same shell as that for Table 3.5.7.2

PROGRAM\OUTPUT: _MAKESHELLS.SAS\T_ECGCSBEXT.LST DATE(TIME): 18AUG15(13:51)

Reference: Listing 2.10.2

Signature Manifest

Document Number: IC-STS-SAP-0058 **Revision:** 0
Title: INCB 18424-204 SAP

All dates and times are in Eastern Standard Time.

INCB18424-204 SAP Review

Approval

Name/Signature	Title	Date	Meaning/Reason
[redacted]	[redacted]	27 Oct 2015, 01:39:14 PM	Approved
[redacted]	[redacted]	27 Oct 2015, 03:21:35 PM	Approved
[redacted]	[redacted]	28 Oct 2015, 10:00:56 AM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
[redacted]	[redacted]	28 Oct 2015, 10:43:23 AM	Approved