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Statistical Analysis Plan

INCB 54707-301/302

Selective **T**reatment of **O**ral **P**ovorcitinib in **H**idradenitis **S**uppurativa Study **1/2** (**STOP-HS1/2**)

A Phase 3, Double-Blind, Randomized, Placebo-Controlled, Efficacy and Safety Study of Povorcitinib (INCB054707) in Participants With Moderate to Severe Hidradenitis Suppurativa

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

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	adverse event
AESI	adverse event of special interest
ALT	alanine aminotransferase
AN	abscess and inflammatory nodule
ANdT	abscess, inflammatory nodule, and draining tunnel (formerly known as draining fistula)
AST	aspartate aminotransferase
BMI	body mass index
$C_{avg,ss}$	average concentration at steady state
CI	confidence interval
$C_{max,ss}$	maximum concentration at steady state
CMH	Cochran-Mantel-Haenszel
CPK	creatine phosphokinase
CRF	Case Report Form
$C_{tau,ss}$	trough concentration at steady state
CTCAE	Common Terminology Criteria for Adverse Events
DLQI	Dermatology Life Quality Index
ECG	electrocardiogram
ECI	event of clinical interest
eCRF	electronic case report form
EMA	European Medicines Agency
EOS	end of study
EOT	end of treatment
EQ VAS	EuroQol visual analogue scale
EQ-5D-5L	EuroQol 5-dimension 5-level
EU	European Union
EXT	extension
FACIT-F	Functional Assessment of Chronic Illness Therapy - Fatigue
FDA	Food and Drug Administration
GRF	glomerular filtration rate
HDL	high-density lipoprotein
HiSCR	hidradenitis suppurativa clinical response
HiSQoL	hidradenitis suppurativa quality of life
HLT	high-level term
HS	hidradenitis suppurativa
IHS4	International Hidradenitis Suppurativa Severity Score System

Abbreviation	Definition
IL	interleukin
ITT	intent-to-treat
JAK	Janus kinase
LDL	low-density lipoprotein
MACE	major adverse cardiovascular event
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	mixed model for repeated measures
NCI	National Cancer Institute
NRS	numerical rating scale
PC	placebo-controlled
PD	pharmacodynamic(s)
PK	pharmacokinetic(s)
PP	per Protocol
PT	preferred term
PY	patient-years
QD	once daily
QoL	quality of life
QTcF	QT interval corrected using Fridericia's formula
SAP	Statistical Analysis Plan
SMQ	standardized MedDRA query
SOC	system organ class
$t_{½}$	apparent terminal-phase disposition half-life
TEAE	treatment-emergent adverse event
$t_{max,ss}$	time to maximum concentration at steady state
TNF	tumor necrosis factor
ULN	upper limit of normal
UK	United Kingdom
US	United States
VAS	visual analog scale
WHO	World Health Organization
WPAI-HS	Work Productivity and Activity Impairment in Hidradenitis Suppurativa

1. INTRODUCTION

INCB 54707-301 is a Phase 3, multicenter, randomized, parallel-group, PC, double-blind study in adult participants with moderate to severe HS (Hurley Stage II or III), HS lesions in ≥ 2 distinct anatomical areas, a total AN count ≥ 5 at screening and baseline, and a history of failure of, intolerance to, or contraindication to an adequate course of conventional systemic therapy for HS. Approximately 600 participants will be randomized 1:1:1 to povorcitinib (45 or 75 mg QD) or placebo QD for 12 weeks; participants who complete the PC period may continue to a 42-week EXT period with povorcitinib 45 or 75 mg QD. Participants will be stratified based on ANdT count (< 11 or ≥ 11) at baseline and previous treatment of HS with a biologic drug. Section 2 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 povorcitinib.

INCB 54707-302 has a study design identical to INCB 54707-301; this SAP applies to both studies. The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the INCB 54707-301 and INCB 54707-302 Protocols.

Population PK analysis will be conducted by the Incyte pharmacokineticist, and the details of the analysis methodology and results will appear in a separate report.

The details of the analysis methodology of biomarkers and PD and results will appear in a separate report.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 54707-301 Protocol Amendment 2 and INCB 54707-302 Protocol Amendment 2, both dated 01 MAY 2023, and CRFs for each study approved on 05 FEB 2024. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and eCRF versions.

2.2. Study Objectives and Endpoints

Table 1 presents the objectives and endpoints.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
To evaluate the efficacy of povorcitinib.	• Proportion of participants who achieve HiSCR at Week 12. – HiSCR is defined as at least a 50% reduction from baseline in the total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count.
Key Secondary	
To further evaluate the efficacy of povorcitinib.	• Proportion of participants who achieve HiSCR75 at Week 12. – HiSCR75 is defined as at least a 75% reduction from baseline in the total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count.
To evaluate the effect of povorcitinib in reducing the incidence of flares.	• Proportion of participants with flare by Week 12. – Participants who experience at least 1 flare over 12 weeks; flare is defined as at least a 25% increase in the total abscess and inflammatory nodule count with a minimum increase of 2 relative to baseline.
To evaluate the effect of povorcitinib in decreasing skin pain.	• Key secondary endpoint for regulatory purposes in US/FDA/aligned countries: Proportion of participants with a ≥ 3-point decrease in Skin Pain NRS score at Week 12 among participants with baseline Skin Pain NRS score ≥ 3. – Participants with a Skin Pain score of at least 3 at baseline and who experience at least a 3-point decrease in Skin Pain score at Week 12, relative to baseline. Skin Pain is an 11-point NRS, ranging from 0 (no skin pain) to 10 (worst skin pain). • Key secondary endpoint for regulatory purposes in EU/EMA/aligned countries: Proportion of participants who achieve Skin Pain NRS30 at Week 12 among participants with baseline Skin Pain NRS score ≥ 3. – Participants with a Skin Pain score of at least 3 at baseline and who achieve at Week 12 Skin Pain NRS30, defined as at least a 30% reduction and at least 1-unit reduction from baseline in the Skin Pain NRS.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
Secondary	
To further evaluate the effect of povorcitinib in decreasing skin pain.	• Secondary endpoint for regulatory purposes in US/FDA/aligned countries: Proportion of participants who achieve Skin Pain NRS30 at Week 12 among participants with baseline Skin Pain NRS score ≥ 3. − Participants with a Skin Pain score of at least 3 at baseline and who achieve at Week 12 Skin Pain NRS30, defined as at least a 30% reduction and at least 1-unit reduction from baseline in the Skin Pain NRS. • Secondary endpoint for regulatory purposes in EU/EMA/aligned countries: Proportion of participants with a ≥ 3-point decrease in Skin Pain NRS score at Week 12 among participants with baseline Skin Pain NRS score ≥ 3. − Participants with a Skin Pain score of at least 3 at baseline and who experience at least a 3-point decrease in Skin Pain score at Week 12, relative to baseline. Skin Pain is an 11-point NRS, ranging from 0 (no skin pain) to 10 (worst skin pain).
To evaluate the effect of povorcitinib in improving fatigue.	• Proportion of participants with at least a 4-point increase from baseline in FACIT-F score at Week 12. − Participants with a baseline FACIT-F score ≤ 48 and who experience at least a 4-point increase in FACIT-F score at Week 12, relative to baseline. The FACIT-F scale is a 13-item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function over the past 7 days, with scores ranging from 0 (worst fatigue) to 52 (no fatigue).
To evaluate the effect of povorcitinib on QoL during the PC and EXT periods.	Mean change from baseline in DLQI score at each visit.
To further evaluate the efficacy of povorcitinib.	• Mean change from baseline in abscess count at each visit. • Percentage change from baseline in abscess count at each visit. • Mean change from baseline in inflammatory nodule count at each visit. • Percentage change from baseline in inflammatory nodule count at each visit. • Mean change from baseline in draining tunnel count at each visit. • Percentage change from baseline in draining tunnel count at each visit.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
Secondary (continued)	
To evaluate the efficacy of povorcitinib during the EXT period.	• Proportion of participants who achieve HiSCR at Week 24. • Proportion of participants who achieve HiSCR75 at Week 24. • Proportion of participants with flare by Week 24. • Proportion of participants who achieved Skin Pain NRS30 at Week 24 among participants with baseline Skin Pain NRS score ≥ 3. • Proportion of participants who achieve HiSCR at Week 54. • Proportion of participants who achieve HiSCR75 at Week 54. • Proportion of participants with flare by Week 54. • Proportion of participants who achieved Skin Pain NRS30 at Week 54 among participants with baseline Skin Pain NRS score ≥ 3.
To evaluate the maintenance of response during the EXT period.	• Proportion of participants who achieve maintenance of HiSCR or greater response at each visit during the EXT period. − Maintenance of response defined as participants who achieve HiSCR at Week 12 and maintain it or achieve greater response at each visit during the EXT period. • Proportion of participants who achieve maintenance of HiSCR75 or greater response at each visit during the EXT period. − Maintenance of response defined as participants who achieve HiSCR75 at Week 12 and maintain it or achieve greater response at each visit during the EXT period.
Safety	
To evaluate the safety and tolerability of povorcitinib.	Frequency and severity of AEs, including changes in clinical laboratory results, vital signs, ECGs, and the results of physical examinations.
Exploratory	
To evaluate the efficacy of povorcitinib.	• Proportion of participants who achieve HiSCR at each visit. • Proportion of participants who achieve HiSCR75 at each visit. • Proportion of participants who achieve HiSCR90 at each visit. − HiSCR90 is defined as at least a 90% reduction from baseline in total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count. • Proportion of participants with a total abscess and inflammatory nodule count of 0, 1, or 2 at each visit. • Proportion of participants who achieve AN50, AN75, AN90, and AN100 (relative to baseline) at each visit. − Defined as total abscess and inflammatory nodule count change of ≥ 50%, ≥ 75%, ≥ 90%, and ≥ 100% relative to baseline, respectively. • Proportion of participants who achieve ANdT50, ANdT75, ANdT90, and ANdT100 (relative to baseline) at each visit. − Defined as abscess, inflammatory nodule, and draining tunnel count change of ≥ 50%, ≥ 75%, ≥ 90%, and ≥ 100% relative to baseline, respectively.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
Exploratory (continued)	
To evaluate the efficacy of povorcitinib (continued).	• Mean change from baseline in total abscess and inflammatory nodule count at each visit. • Percentage change from baseline in total abscess and inflammatory nodule count at each visit. • Mean change from baseline in International Hidradenitis Suppurativa Severity Score System (IHS4) score at each visit. − The IHS4 assesses the severity of HS, and the resulting score is calculated by the number of inflammatory nodules (multiplied by 1) plus the number of abscesses (multiplied by 2) plus the number of draining tunnels (multiplied by 4). • Percentage change from baseline in IHS4 score at each visit. • Proportion of participants who achieve IHS4-55 at each visit. − IHS4-55 is defined as at least a 55% reduction from baseline in total IHS4 score. • Proportion of participants in each of the IHS4 disease categories at each visit. − IHS4 disease categories are described as follows: a total score of 3 or less signifies mild, 4-10 signifies moderate, and 11 or higher signifies severe disease.
To evaluate the effect of povorcitinib in reducing the incidence of flares.	• Proportion of participants with HS flares at each visit. • Proportion of participants with at least 1 HS flare during the EXT period. • Mean number of flares during the PC period. • Mean number of flares during the EXT period. • Mean time to the first flare during the PC period. • Mean time to the first flare during the EXT period.
To evaluate the effect of povorcitinib on skin pain.	• Proportion of participants achieving Skin Pain NRS30 at each visit among participants with baseline Skin Pain NRS score ≥ 3. • Proportion of participants with a ≥ 3-point decrease from baseline in Skin Pain score at each visit. − Participants with a Skin Pain NRS score of at least 3 at baseline and who experience at least a 3-point decrease in Skin Pain score at each visit, relative to baseline. • Proportion of participants with a ≥ 4-point decrease from baseline in Skin Pain score at each visit. − Participants with a Skin Pain NRS score of at least 4 at baseline and who experience at least a 4-point decrease in Skin Pain score at each visit, relative to baseline. • Mean change from baseline in Skin Pain NRS score at each visit. • Percentage change from baseline in Skin Pain NRS score at each visit. • Proportion of participants with analgesic (nonopioid and opioid) use at each visit. • Proportion of participants with opioid use at each visit.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
Exploratory (continued)	
To evaluate the effect of povorcitinib in decreasing draining tunnel count.	• Proportion of participants with at least a 1-unit decrease from baseline in draining tunnel count at each visit. − Participants with at least 1 draining tunnel at baseline and who experience at least a 1-unit decrease in draining tunnel count at each visit, relative to baseline. • Mean change from baseline in draining tunnel count at each visit. • Percentage change from baseline in draining tunnel count at each visit.
To evaluate the effect of povorcitinib on itch.	• Proportion of participants who achieve Itch NRS30 at each visit for participants with Itch NRS score ≥ 3 at baseline. − Itch NRS30 is defined as at least a 30% reduction and at least 1-unit reduction from baseline in the Itch NRS score (range from 0 [no itch] to 10 [worst itch imaginable]). • Proportion of participants who achieve at least a 4-point reduction in Itch NRS score from baseline at each visit for participants with Itch NRS score ≥ 4 at baseline. • Mean change from baseline in Itch NRS score at each visit. • Percentage change from baseline in Itch NRS score at each visit.
To assess the need for rescue lesional treatment.	• Proportion of participants requiring rescue lesional treatment during the PC period. • Proportion of participants requiring rescue lesional treatment during the EXT period.
To assess the need for systemic antibiotic rescue therapy.	• Proportion of participants requiring systemic antibiotic rescue therapy during the PC period. • Proportion of participants requiring systemic antibiotic rescue therapy during the EXT period.
To evaluate the effect of povorcitinib on QoL.	• Mean change from baseline in HiSQoL score at each visit. • Percentage change from baseline in HiSQoL score at each visit. • Percentage change from baseline in DLQI score at each visit. • Proportion of participants with at least a 4-point decrease in DLQI score from baseline at each visit for participants with DLQI score ≥ 4 at baseline. • Mean change from baseline in FACIT-F score at each visit. • Percentage change from baseline in FACIT-F score at each visit. • Proportion of participants with at least a 4-point increase in FACIT-F score at each visit. • Mean change from baseline in WPAI-HS score at each visit. • Mean change from baseline in EQ-5D-5L score at each visit.
To explore blood biomarkers in participants treated with povorcitinib.	Expression of select biomarkers in peripheral blood at baseline, Week 3, and Week 12.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
Exploratory (continued)	
To determine the systemic exposure of povorcitinib.	Population PK parameters of povorcitinib such as apparent clearance, apparent volume of distribution, apparent oral absorption rate constant, and absorption lag time, as deemed applicable, as well as model-based post hoc predictions of steady-state PK exposures such as $C_{max,ss}$, $C_{avg,ss}$, $C_{tau,ss}$, $t_{max,ss}$, and $t_{½}$.
To determine the povorcitinib PK/PD relationship.	E-R analysis of select clinical response endpoints as deemed appropriate, such as HiSCR at Week 12, HiSCR75 at Week 12, Skin Pain at Week 12, etc.

3. STUDY DESIGN

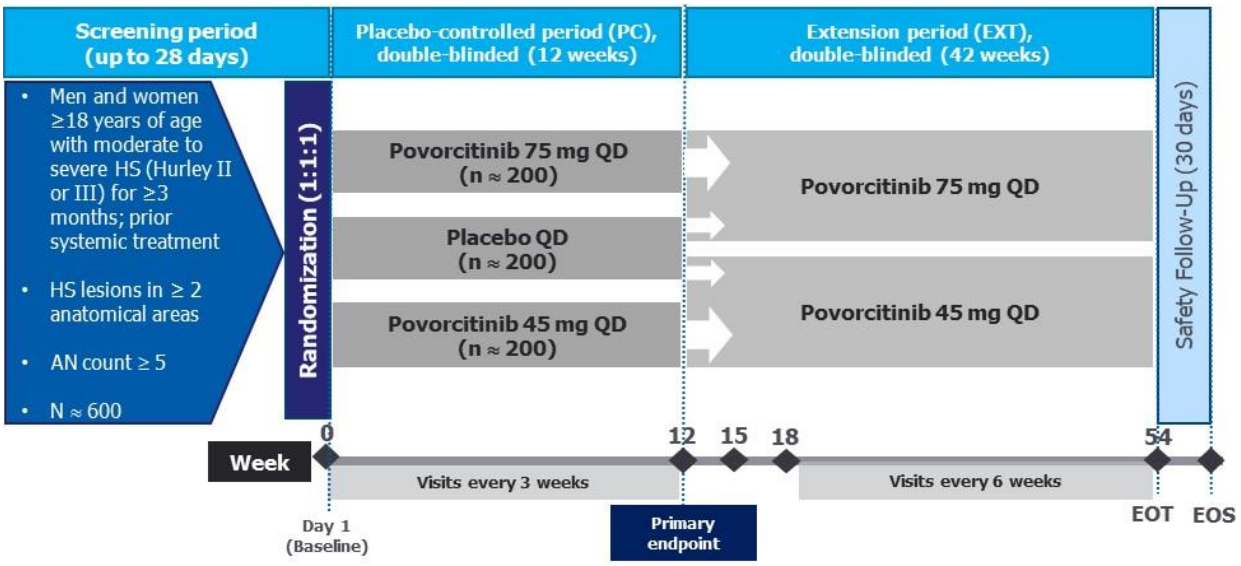
INCB 54707-301 and INCB 54707-302 are Phase 3, multicenter, randomized, parallel-group, PC, double-blind studies to evaluate the efficacy and safety of povorcitinib (45 or 75 mg QD) over a 12-week PC period followed by a 42-week EXT period. The studies will enroll participants aged 18 years or older who had a diagnosis of moderate to severe HS (Hurley Stage II or III) for at least 3 months, HS lesions in ≥ 2 distinct anatomical areas, a total AN count ≥ 5 at screening and baseline, and a history of failure of, intolerance to, or contraindication to an adequate course of conventional systemic therapy for HS.

Participants will be screened for up to 28 days before the first dose of study drug. Participants will be randomized 1:1:1 to povorcitinib (45 or 75 mg QD) or placebo QD and stratified based on ANdT count (< 11 or ≥ 11) at baseline and pervious treatment of HS with a biologic drug. Participants who complete the PC period may continue to a 42-week EXT period with povorcitinib 45 or 75 mg QD.

Participants randomized to povorcitinib at baseline will remain at their respective dose level (45 or 75 mg QD) throughout the PC and EXT periods, while participants randomized to placebo will receive povorcitinib 45 or 75 mg QD (1:1 ratio) for the EXT period after completion of the PC period. Participants who complete 54 weeks of treatment in this study may be eligible to participate in a separate EXT study to further evaluate the safety and efficacy of the investigational product. For participants who do not participate in the separate EXT study, a safety follow-up visit should be conducted approximately 30 days after the EOT visit, or last administration of study drug (in case of premature discontinuation/early termination).

The study schema is shown below in Figure 1.

Figure 1: Study Design Schema



The overall study period will include both the PC and EXT periods and is 54 weeks.

Given the design, a 12-week analysis will be performed to assess efficacy and safety during the PC, double-blind treatment period. This will occur after all participants have completed the study activities up to Week 12 and all data pertaining to the PC period are cleaned.

The final analysis will occur once the last participant completes the last visit in each study.

3.1. Randomization

In each study, approximately 600 participants will be randomized 2:2:1:1 to 1 of the following 4 treatment groups at the time of randomization (baseline):

- Povorcitinib 45 mg
- Povorcitinib 75 mg
- Placebo to povorcitinib 45 mg
- Placebo to povorcitinib 75 mg

The 2:2:1:1 randomization ratio will maintain the overall randomization ratio of 1:1:1 to povorcitinib (45 or 75 mg) or placebo for the 12-week PC period. Participant randomization will be stratified based on ANdT count (< 11 or ≥ 11) and previous treatment of HS with a biologic drug.

Participants who complete the PC period will enter the EXT period. During the EXT period, participants randomized to povorcitinib at baseline will remain at their respective dose level (45 or 75 mg), while participants randomized to placebo will receive povorcitinib 45 or 75 mg according to the treatment group assignment.

3.2. Control of Type I Error

For the primary and key secondary endpoints, the overall familywise Type I error rate will be 2-sided $\alpha = 0.05$.

The following is a list of primary and key secondary null hypotheses to be tested, denoted by $H_{ij,0}$, where i indicates the povorcitinib dose group (i = 1 for 75 mg, i = 2 for 45 mg) and j is the numerical identifier of the endpoint for the dose group (j = 1 for HiSCR at Week 12, j = 2 for HiSCR75 at Week 12, j = 3 for flare by Week 12, j = 4 for Skin Pain Response at Week 12).

Primary null hypotheses:

- $H_{11,0}$: Proportion of participants achieving HiSCR at Week 12 in the povorcitinib 75 mg group is equal to the placebo group
- $H_{21,0}$: Proportion of participants achieving HiSCR at Week 12 in the povorcitinib 45 mg group is equal to the placebo group

Key secondary null hypotheses:

- $H_{12,0}$: Proportion of participants achieving HiSCR75 at Week 12 in the povorcitinib 75 mg group is equal to the placebo group
- $H_{22,0}$: Proportion of participants achieving HiSCR75 at Week 12 in the povorcitinib 45 mg group is equal to the placebo group
- $H_{13,0}$: Proportion of participants with flare by Week 12 in the povorcitinib 75 mg group is equal to the placebo group

- $H_{23,0}$: Proportion of participants with flare by Week 12 in the povorcitinib 45 mg group is equal to the placebo group
- $H_{14,0}$: Proportion of participants achieving Skin Pain Response at Week 12 in the povorcitinib 75 mg group is equal to the placebo group
- $H_{24,0}$: Proportion of participants achieving Skin Pain Response at Week 12 in the povorcitinib 45 mg group is equal to the placebo group

where Skin Pain Response is defined as a ≥ 3-point reduction from baseline in Skin Pain NRS for regulatory purposes in US/FDA/aligned countries or Skin Pain NRS30 for regulatory purposes in EU/EMA/aligned countries.

To adjust for multiplicity and provide strong control of overall familywise error rate, the graphic approach (Bretz et al 2011) will be used in the primary and the key secondary endpoints outlined in Figure 2.

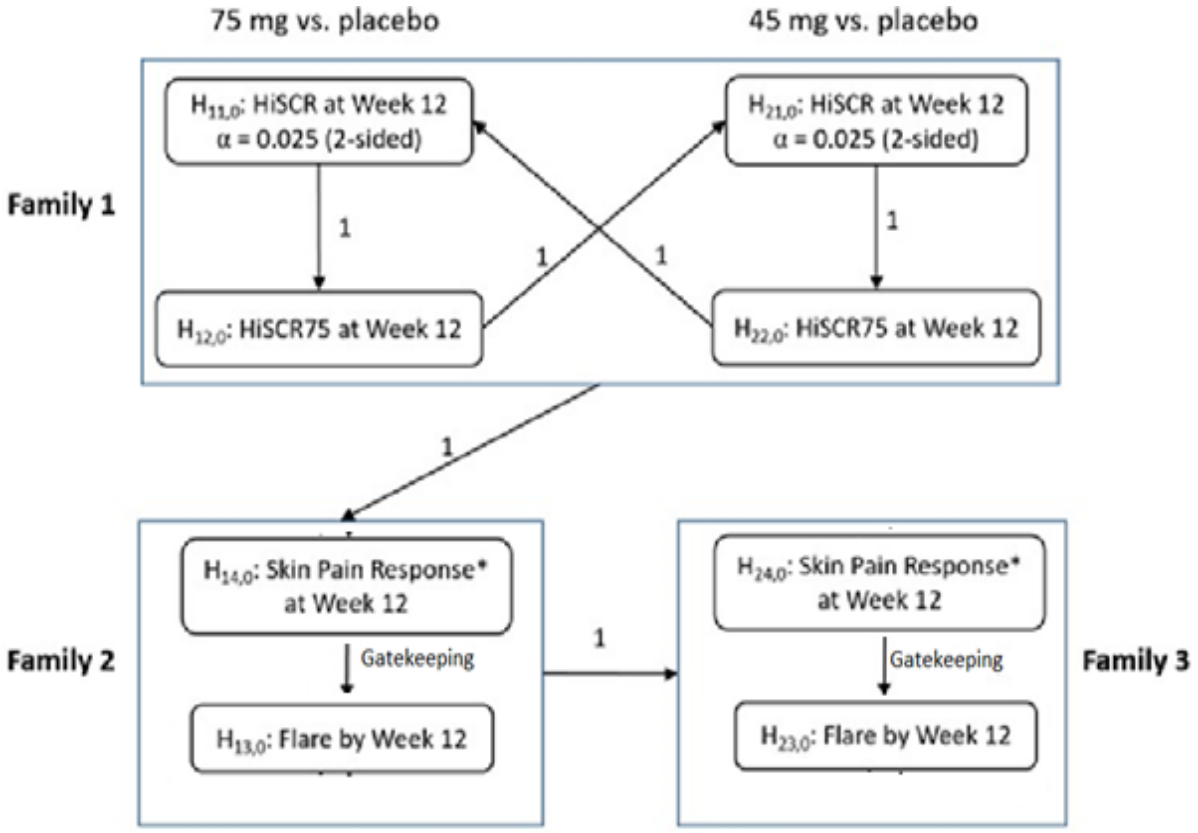
In Step 1, within Family 1, the algorithm begins by testing the null hypotheses for each of the 2 povorcitinib dose groups versus placebo on the primary endpoint ($H_{11,0}$ and $H_{21,0}$) at its assigned significance level of 2-sided $\alpha = 0.025$. If any hypothesis is rejected (ie, deemed significant), then its significance level will be transferred to the subsequent test following the arrow. The numbers along the arrows denote the weights for transferring significance levels. Specifically, a weight of 1 indicates 100% transfer of the significance level. It should be noted it is possible that a hypothesis for a particular endpoint fails to be rejected the first time it is tested but subsequently receives enough significance level from successfully rejected hypotheses and is rejected the second time it is tested. This iterative process of updating the graph and redistribution of the significance level is continued until no further hypotheses can be tested within Family 1.

In Step 2, if all 4 null hypotheses within Family 1 are rejected, the 2 null hypotheses $H_{14,0}$ and $H_{13,0}$ for povorcitinib 75 mg versus placebo within Family 2 will be tested using the gatekeeping procedure at a significance level of 2-sided $\alpha = 0.05$. The null hypothesis $H_{14,0}$ will be tested first, if it is rejected, then the null hypothesis $H_{13,0}$ will be tested.

In Step 3, if both null hypotheses $H_{13,0}$ and $H_{14,0}$ within Family 2 are rejected, the 2 null hypotheses $H_{24,0}$ and $H_{23,0}$ for povorcitinib 45 mg versus placebo within Family 3 will be tested using the gatekeeping procedure at a significance level of 2-sided $\alpha = 0.05$. The null hypothesis $H_{24,0}$ will be tested first, if it is rejected, then the null hypothesis $H_{23,0}$ will be tested.

Other secondary and exploratory endpoints will be tested using 2-sided $\alpha = 0.05$ but are not considered Type I error–controlled hypotheses.

Figure 2: Graphic Approach for Multiplicity Adjustment for Testing Primary and Key Secondary Endpoints



* Skin Pain Response is defined as a ≥ 3-point reduction from baseline in Skin Pain NRS for regulatory purposes in US/FDA/aligned countries or Skin Pain NRS30 for regulatory purposes in EU/EMA/aligned countries.

3.3. Sample Size Considerations

The primary endpoint of the studies is the proportion of participants who achieve HiSCR at Week 12. Participants will be randomized in a 1:1:1 ratio to 1 of 2 doses of povorcitinib (45 or 75 mg QD) or placebo and stratified by ANdT count (< 11 and ≥ 11; approximately ≤ 50% of participants may have an ANdT count < 11) and previous treatment of HS with a biologic drug. Based on the observed HiSCR rates at Weeks 8 and 12 reported in a Phase 2, randomized, dose-ranging study of povorcitinib (INCB 54707-204), it is assumed that the HiSCR rate at Week 12 would be 48% for the povorcitinib 75-mg group, 45% for the povorcitinib 45-mg group, and 30% for the placebo group. Using the chi-square test, without continuity correction, at a 2-sided $\alpha = 0.025$, a sample size of 200 participants per group (with a total of 600 participants) will achieve approximately 93% power to detect a statistically significant difference between the povorcitinib 75-mg group and the placebo group and approximately 80.7% power to detect a statistically significant difference between the povorcitinib 45-mg and the placebo group.

The powers for the primary and key secondary endpoints are provided in Table 2.

Table 2: Powers for Primary and Key Secondary Endpoints

Endpoints	Povorcitinib Dose Group	Response Rate for Povorcitinib Dose Group[a]	Response Rate for Placebo Group[a]	Power
Primary endpoint				
Proportion of participants who achieve HiSCR at Week 12	Povorcitinib 75 mg	48%	30%	93%
	Povorcitinib 45 mg	45%	30%	80.7%[b]
Key secondary endpoints				
Proportion of participants who achieve HiSCR75 at Week 12	Povorcitinib 75 mg	38%	20%	96.1%[b]
	Povorcitinib 45 mg	33%	20%	76.2%[b]
Proportion of participants with flare by Week 12	Povorcitinib 75 mg	20%	40%	98.5%[b]
	Povorcitinib 45 mg	25%	40%	83.5%[b]
Proportion of participants achieving ≥ 3-point reduction in Skin Pain NRS at Week 12[c], for regulatory purposes in US/FDA/aligned countries	Povorcitinib 75 mg	22.5%	7.5%	91.3%[d]
	Povorcitinib 45 mg	20%	7.5%	79.6%[d]
Proportion of participants achieving NRS30 at Week 12[e], for regulatory purposes in EU/EMA/aligned countries	Povorcitinib 75 mg	34%	18%	90.3%[b]
	Povorcitinib 45 mg	34%	18%	90.3%[b]

[a] Based on the results from a Phase 2, randomized, dose-ranging study (INCB 54707-204).
[b] Based on the chi-square test at a 2-sided $\alpha = 0.025$.
[c] It is expected that approximately 76% of participants in the ITT Population will have Skin Pain NRS score ≥ 3 at baseline based on the results from Study INCB 54707-204.
[d] Based on the Fisher exact test at a 2-sided $\alpha = 0.025$.
[e] It is expected that approximately 93% of participants in the ITT Population will have Skin Pain NRS score ≥ 1 at baseline based on the results from Study INCB 54707-204.

3.4. Schedule of Assessments

Refer to INCB 54707-301 Protocol Amendment 2 and INCB 54707-302 Protocol Amendment 2 dated 01 MAY 2023 for a full description of all study procedures and assessment schedules.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1

Day 1 is the date that the first dose of povorcitinib or placebo is administered to the participants.

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

4.1.2. Study Day

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

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

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

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

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

4.1.3. Baseline Value

Baseline for the Skin Pain NRS score is defined as the average of the 7 daily Skin Pain NRS scores before randomization. If 4 or more daily scores are missing (out of the 7), the baseline Skin Pain NRS will be set to missing.

Baseline for the Itch NRS score is defined as the average of the 7 daily Itch NRS scores before randomization. If 4 or more daily scores are missing (out of the 7), the baseline Itch NRS will be set to missing.

The baseline value of all other efficacy parameters is the last nonmissing measurement obtained before randomization, unless otherwise specified.

The baseline value of safety parameters is the last nonmissing measurement obtained before the first administration of povorcitinib or placebo in the PC period, unless otherwise specified. For randomized participants not treated with any study drug, baseline is defined as the last nonmissing assessment before or on the day of randomization for all parameters.

Note that for participants who originally received placebo in the PC period and received at least 1 dose of povorcitinib during the EXT period (hereafter referred to as crossover participants), the baseline definition in the EXT period is defined as follows:

- For efficacy evaluations in the EXT period, baseline is the last nonmissing measurement obtained before randomization in the PC period (hereafter referred to as PC baseline).
- For safety evaluations in the EXT period, baseline is the last nonmissing measurement obtained before the first administration of povorcitinib 45 or 75 mg in the EXT period (hereafter referred to as EXT baseline).

Table 3 provides an outline regarding the baseline for efficacy and safety evaluations in each period.

Table 3: Definition of Baseline

Treatment Period	Treatment Groups	Baseline For Efficacy Evaluations	Baseline For Safety Evaluations
PC period (up to Week 12)	Placebo Povorcitinib 45 mg Povorcitinib 75 mg	PC baseline	PC baseline
EXT period (Week 12 through Week 54)	Placebo to povorcitinib 45 mg Placebo to povorcitinib 75 mg	PC baseline	EXT baseline
Overall study period (up through Week 54)	Povorcitinib 45 mg Povorcitinib 75 mg	PC baseline	PC baseline

When scheduled assessments and unscheduled assessments occur on the same day and the time of the assessment or time of 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.

4.1.4. Handling of Missing and Incomplete Dates

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

When calculating the time since diagnosis of HS, a partial HS diagnosis date will be handled as follows in the calculation:

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

When the date of the last dose in a specific period is used in deriving variables such as duration of treatment or TEAE flag for the period, a missing or partial date of the last dose in the period will be handled as follows:

- If only the day is missing, then the earlier date of the last day of the month or the date that the participant discontinued treatment during the period will be used.
- Otherwise, the date that the participant discontinued treatment during the period will be used as the date of the last dose in the period.

4.2. Variable Definitions

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

4.2.1. Body Mass Index

Body mass index will be calculated as follows:

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

4.2.2. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of povorcitinib or placebo in the PC period.

Concomitant medication in the PC period is defined as any nonstudy medication that is started accordingly:

- Before the date of first administration of povorcitinib or placebo in the PC period and is ongoing throughout the PC period or ends on/after the date of first study drug administration in the PC period

  or

- On/after the date of first administration of povorcitinib or placebo in the PC period, and before the date of first administration of povorcitinib in the EXT period for participants who entered EXT period.

Concomitant medication in the EXT period is defined as any nonstudy medication that is started accordingly:

- Before the date of first administration of povorcitinib in the EXT period and is ongoing or ends on/after the date of first study drug administration in the EXT period.

  or

- On/after the date of first administration of povorcitinib in the EXT period.

Concomitant medication in the overall study period is defined as any nonstudy medication that is started accordingly:

- Before the date of first administration of povorcitinib in the PC period and is ongoing or ends on/after the date of first study drug administration in the PC period

  or

- On/after the date of first administration of povorcitinib in the PC period.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first dose of povorcitinib or placebo in the PC period. In the listing, it will be indicated whether a medication is only prior, only concomitant (by period), or both prior and concomitant.

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

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9.1 or later) will be used for the generation of all tables, graphs, and statistical analyses. Descriptive summaries for continuous variables will include but not be limited to the number of observations, mean, standard deviation, median, minimum, and maximum. Descriptive summaries for categorical variables will include the number and percentage of participants in each category.

5.2. Treatment Groups

Each study is randomized, double-blind, and PC over a 12-week PC period followed by a 42-week EXT period. Table summaries, unless otherwise indicated, will present data by treatment groups.

For the PC period, data will be summarized by the following treatment groups:

- Placebo
- Povorcitinib 45 mg
- Povorcitinib75 mg

For the EXT period, data will be summarized by the following treatment groups:

- Placebo to povorcitinib 45 mg, including participants who originally received placebo in the PC period and received at least 1 dose of povorcitinib 45 mg during the EXT period with up to 42 weeks of povorcitinib 45 mg exposure
- Placebo to povorcitinib 75 mg, including participants who originally received placebo in the PC period and received at least 1 dose of povorcitinib 75 mg during the EXT period with up to 42 weeks of povorcitinib 75 mg exposure

For the overall study period, the results will be summarized and presented by the following treatment groups:

- Povorcitinib 45 mg, including participants who received at least 1 dose of povorcitinib 45 mg during the PC period with up to 54 weeks of povorcitinib 45 mg exposure
- Povorcitinib 75 mg, including participants who received at least 1 dose of povorcitinib 75 mg during the PC period with up to 54 weeks of povorcitinib 75 mg exposure

5.3. Analysis Populations

5.3.1. All-Screened Population

The All-Screened Population will include all participants who signed the informed consent form.

5.3.2. Intent-to-Treat Population

The ITT Population will include all randomized participants. Treatment groups for this population will be defined according to the treatment assignment at the time of randomization regardless of the actual study treatment the participant might take during their participation in the PC period.

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

5.3.3. Per Protocol Population

Participants in the ITT Population who are considered to be sufficiently compliant with the Protocol will compose the PP Population.

In general, the following are considered important Protocol deviations that may significantly affect the primary analysis:

- Missing data for the primary endpoint
- Overall compliance less than 50% during the PC period
- Important Protocol deviations related to inclusion/exclusion criteria, discontinuation criteria, and use of prohibited concomitant medications.

These deviations will be reviewed by the study team. Decisions as to whether any of these deviations warrant exclusion from the PP Population by the clinical team will be made prior to database lock and randomization unblinding.

The PP Population will be used in the supportive sensitivity analysis for the primary efficacy endpoint.

5.3.4. Safety Population

The Safety Population will include all participants who received at least 1 dose of povorcitinib or placebo during the PC period. Treatment groups for this population will be determined according to the actual treatment the participant received on Day 1 regardless of assigned study treatment.

All safety analyses for the PC period as well as for the overall study period, will be conducted using the Safety Population.

5.3.5. Extension-Evaluable Population

The EXT-Evaluable Population will include all participants who received at least 1 dose of povorcitinib 45 or 75 mg during the EXT period.

The EXT-Evaluable Population will be used for the summary of demographics, baseline characteristics, and participant disposition in the EXT period.

All analyses for the participants who originally received placebo up to and including Week 12 and received at least 1 dose of povorcitinib during the EXT period will be conducted with the EXT-Evaluable Population.

6. BASELINE, EXPOSURE, AND DISPOSITION

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

6.1. Demographics, Baseline Characteristics, and Disease History

Unless otherwise stated, demographics, baseline characteristics, and disease history will be summarized by treatment group and overall.

6.1.1. Demographics and Baseline Characteristics

The following demographics and baseline characteristics will be summarized for the ITT Population and the EXT-Evaluable Population: age, age category (18 to < 65 years, ≥ 65 years), sex, race, ethnicity, weight, height, BMI, BMI category (< 25 kg/m^2, ≥ 25 to < 30 kg/m^2, ≥ 30 to < 40 kg/m^2, ≥ 40 to < 50 kg/m^2, ≥ 50 kg/m^2), and geographic region (North America, Europe [UK included] and Australia, Japan).

The following baseline characteristics will be summarized for the ITT Population only: nicotine use (never used, current user, former user), medical cannabis use (never used, current user, former user), and alcohol use (never used, current user, former user).

6.1.2. Baseline Disease Characteristics

The following baseline disease characteristics and disease history will be summarized for all participants in the ITT Population:

- Prior oral antibiotic
- Prior biologic (any, biologic anti-TNF, biologic anti–IL-17, other biologic)
- Prior other HS therapy (topical antibiotic or antiseptic, topical retinoid, topical JAK inhibitor, topical corticosteroid, topical other, intralesional corticosteroid, intravenous antibiotic, intravenous corticosteroid, oral antihyperglycemic, oral hormonal therapy, oral JAK inhibitor, oral other)
- Prior HS surgery (any, incision and drainage, deroofing, lesion ablation [electrosurgery], local excision, laser therapy, other)
- Family cardiovascular/clotting disease (history of sudden cardiac death, familial hypercholesterolemia associated with premature coronary artery disease, myocardial infarction below age 50 years, factor V Leiden, protein C and/or protein S deficiency, prothrombin gene mutation, any unprovoked deep vein thrombosis, thromboembolic disease)
- Hurley stage (Stage I, Stage II, Stage III)
- AN count
- AN count category (< 5, 5-6, 7-8, 9-10, 11-15, 16-25, > 25)
- ANdT count
- ANdT count category (< 5, 5-6, 7-8, 9-10, 11-15, 16-25, > 25; < 11 and ≥ 11)

- Abscess count
- Abscess count category (0, 1, 2, 3-5, 6-10, 11-20, > 20)
- Inflammatory nodule count
- Inflammatory nodule count category (0, 1-4, 5, 6-8, 9-11, 12-15, 16-20, > 20)
- Draining tunnel count
- Draining tunnel count category (0, 1-2, 3-5, 6-10, 11-20, > 20)
- Number of anatomical areas with HS lesions (< 2, 2, 3, 4, 5, 6, 7, 8-10, ≥ 11)
- IHS4 score
- IHS4 score category (mild [≤ 3], moderate [4-10], severe [≥ 11])
- Skin Pain NRS score
- Skin Pain NRS score category (0, 1-2, ≥ 3; mild [0 to ≤ 4], moderate [> 4 to ≤ 7], severe [> 7])
- Itch NRS score
- Itch NRS score category (0, 1-2, ≥ 3; mild [0 to ≤ 4], moderate [> 4 to ≤ 7], severe [> 7])
- Analgesic use
- Opioid use
- DLQI score
- DLQI score category (0-1, 2-5, 6-10, 11-20, 21-30)
- FACIT-F score
- HiSQoL score

6.1.3. Disease History

For participants in the ITT Population, the following HS medical history variables will be summarized by assigned treatment group:

- HS disease duration (years)
  - Calculated as: disease duration (years) = (date of randomization − date of initial HS diagnosis + 1) / 365.25
- Comorbidity/disease (HS, Crohn disease, diabetes, hypertension, metabolic syndrome, rheumatoid arthritis, polycystic ovary syndrome, psoriasis)

6.1.4. Medical History

For participants in the ITT Population, medical history will be summarized by assigned treatment group. This summary will include the number and percentage of participants with medical history for each body system/organ class as documented on the eCRF.

6.2. Disposition of Participants

The number and percentage of participants enrolled by country and/or site will be provided by treatment group and overall.

The number and percentage of participants who were randomized, who were treated, who completed treatment in the PC period, who discontinued study treatment with a primary reason for discontinuation, and who withdrew from the study with a primary reason for withdrawal will be summarized for the ITT Population in the PC period.

The number and percentage of participants who were treated, who completed treatment, who discontinued study treatment with a primary reason for discontinuation, and who withdrew from the study with a primary reason for withdrawal will be summarized for the EXT-Evaluable Population in the EXT period.

6.3. Protocol Deviations

Protocol deviations recorded will be summarized by treatment group and overall for the ITT Population in the PC period and the EXT-Evaluable Population in the EXT period. Individual Protocol deviations will also be listed.

6.4. Exposure

For the Safety Population in the PC period, the EXT-Evaluable Population in the EXT period, and the participants who took only povorcitinib 45 or 75 mg during the overall study period, study drug exposure will be summarized by treatment group descriptively as the following:

- **Duration of treatment with study drug (days):** date of last dose of study drug – date of first dose of study drug + 1.

  Note that the date of first and last dose of study drug are period-specific and defined in Table 4.

The number and percentage of participants exposed to study drug during the overall study period will be summarized for the following cumulative duration intervals: ≥ 1 month, ≥ 3 months, ≥ 6 months, and ≥ 12 months.

The average daily dose of study drug will be summarized by treatment group descriptively as the following:

- **Average daily dose of povorcitinib (mg/day):** total actual povorcitinib dose taken (mg) / duration of treatment with study drug (days).

  Total actual dose taken will be calculated based on the information entered on the Drug Accountability eCRF.

Table 4: Definition of First and Last Dose Dates

Treatment Period	Treatment Group	First Dose Date	Last Dose Date
PC period	• Placebo • Povorcitinib 45 mg • Povorcitinib 75 mg	Date of first dose of study drug in the PC period	Date of last dose of study drug in the PC period
EXT period	• Placebo to povorcitinib 45 mg • Placebo to povorcitinib 75 mg	Date of first dose of study drug in the EXT period	Date of last dose of study drug in the EXT period
Overall study period	• Povorcitinib 45 mg • Povorcitinib 75 mg	Date of first dose of study drug in the PC period	Date of last dose of study drug during the overall study period

6.5. Study Drug Compliance

For the Safety Population during the PC period, the EXT-Evaluable Population during the EXT period, and the participants who took only povorcitinib 45 or 75 mg during the overall study period, overall compliance (%) for povorcitinib/placebo will be calculated as follows:

Compliance (%) = 100 × (total dose actually taken in the specific period / total prescribed dose).

The total prescribed dose is defined as the sum of the doses prescribed by the investigator accounting for dose modifications.

The total dose actually taken will be calculated as: total number of tablets dispensed – total number of tablets returned. The total number of tablets dispensed and returned in each period will be based on information entered on the Drug Accountability eCRF. If there is dispensed drug that has not been returned, the actual dose taken starting from the dispense date of the unreturned drug will be imputed by the dose taken as reported on the Dosing eCRF.

6.6. Prior and Concomitant Medication

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary and will be summarized by treatment group and overall. The number and percentage of participants in the ITT Population for each prior medication and concomitant medication in the PC period will be summarized by WHO drug class and WHO drug PT as well as by study-specified category and type within the category (if applicable).

For the EXT-Evaluable Population, only concomitant medications in the EXT period will be summarized by WHO drug class and WHO drug PT as well as by study-specified category and type within the category (if applicable).

For participants who took only povorcitinib 45 or 75 mg, concomitant medications during the overall study period will be summarized by WHO drug class and WHO drug PT as well as by study-specified category and type within the category (if applicable).

In addition, for each study-specific prior treatment category, the main reason for discontinuation and response to treatment by type within the category (if applicable), will be summarized by treatment group and overall in the ITT Population. The reason for inadequate response to prior oral antibiotics or biologics for HS will also be summarized by treatment group and overall in the ITT Population.

7. EFFICACY

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

7.1. General Considerations

The efficacy endpoints will be analyzed by treatment group based on ITT Population. The difference between each of the povorcitinib dose groups and placebo for the primary and key secondary efficacy endpoints will be tested using a graphical approach for multiplicity adjustment to ensure a strong control of the familywise Type I error rate at 2-sided $\alpha = 0.05$ (see Figure 2). Analyses of other secondary and exploratory efficacy endpoints for the PC period will be performed at 2-sided $\alpha = 0.05$ without the multiplicity adjustment.

For crossover participants, efficacy data in EXT period will be summarized separately if needed. No statistical comparisons will be performed for EXT period.

Unless otherwise stated, the strata identified in the randomization process will be used in all efficacy analyses.

7.2. Efficacy Parameters

7.2.1. Hidradenitis Suppurativa Lesion Count

The HS lesions that will be counted in this study are outlined below:

- Abscess
- Inflammatory nodule
- Noninflammatory nodule
- Draining tunnel
- Nondraining tunnel

The distinct anatomical areas that will be considered for lesion count are outlined below:

- Face/neck
- Left axilla (armpit)/arm
- Right axilla (armpit)/arm
- Left chest/breast and inframammary area
- Right chest/breast and inframammary area
- Abdomen
- Trunk/torso (back)
- Left buttock (perianal)
- Right buttock (perianal)
- Left inguinocrural fold (groin)/thigh/leg

- Right inguinocrural fold (groin)/thigh/leg
- Genital area
- Other area(s)

7.2.1.1. Hidradenitis Suppurativa Clinical Response

The HiSCR is defined by the status of 3 types of lesions: abscess, inflammatory nodules, and draining tunnels. The definition of response requires all 3 criteria below to be met, relative to baseline:

- At least 50% reduction in AN count
- No increase in abscess count
- No increase in draining tunnel count

HiSCR75, HiSCR90, and HiSCR100 are respectively defined as at least a 75%, 90%, and 100% reduction from baseline in the total AN count, with no increase in abscess or draining tunnel count.

7.2.1.2. AN and ANdT Counts

The AN count is defined as the sum of abscess and inflammatory nodule counts. The AN count results will be used to calculate change in AN count relative to baseline as well as AN50, AN75, AN90, and AN100, defined respectively as at least a 50%, 75%, 90%, and 100% decrease in AN count relative to baseline.

The ANdT count is defined as the sum of abscess, inflammatory nodule, and draining tunnel counts. The ANdT count results will be used to calculate the change in ANdT count relative to baseline as well as ANdT50, ANdT75, ANdT90, and ANdT100, defined respectively as at least a 50%, 75%, 90%, and 100% decrease in ANdT count relative to baseline.

7.2.1.3. International Hidradenitis Suppurativa Severity Score System

The IHS4 score can be calculated as follows:

IHS4 (points) = (number of inflammatory nodules × 1) + (number of abscesses × 2) + (number of draining tunnels × 4)

The IHS4 disease categories are defined as follows:

- Mild disease: ≤ 3points
- Moderate disease: 4 to 10 points
- Severe disease: ≥ 11 points

IHS4-55, IHS4-75, IHS4-90, and IHS4-100 are respectively defined as at least a 55%, 75%, 90%, and 100% reduction from baseline in IHS4 score.

7.2.1.4. Flare Incidence

The definition of flare is outlined below:

- At least a 25% increase in the total AN count, relative to baseline

  and

- An increase of at least 2 in the total AN count, relative to baseline.

7.2.1.5. Lesion Rescue

In the event of acutely painful lesion(s) that may require intervention, the investigator or designee will perform Protocol-allowed rescue. The frequency and number of lesion rescue treatments will be assessed as endpoints. Rescued lesions will be counted as permanently present (ie, nonresponder lesions), even if they subside over the course of the study.

7.2.1.6. Hurley Stage

Each anatomical area will have the specific Hurley stage captured at scheduled visits. If more than 1 stage is present in the same area, the worst stage in that area should be documented. The participants will be assigned an overall Hurley stage classification corresponding to the stage of the worst involved anatomical area.

7.2.2. Patient-Reported Outcomes

7.2.2.1. Skin Pain NRS

Participants will answer the Skin Pain NRS question daily via eDiary from screening through Week 54 based on a 24-hour recall period.

The Skin Pain NRS scale ranges from 0 (no skin pain) to 10 (skin pain as bad as you can imagine) and evaluates the worst level of skin pain due to the participant's HS.

The Skin Pain NRS score for baseline will be determined by averaging the 7 daily NRS scores before randomization. The by-visit Skin Pain NRS score for postbaseline visits will be determined by averaging the 7 daily NRS scores before the visit day.

If 4 or more daily scores are missing (out of the 7), the Skin Pain NRS score at the visit will be set to missing.

Skin Pain NRS30 is defined as at least a 30% reduction and at least a 1-unit reduction from baseline in the Skin Pain NRS.

7.2.2.2. Analgesic Use

Analgesic (nonopioid and opioid) use is allowed during the study and will be reported as part of participant's daily diary. The first question will ask if the participant has taken any pain medication (nonopioid or opioid) for HS-related pain the past 24 hours; if yes, a second question will ask if the medication was an opioid.

The frequency of analgesic (nonopioid or opioid) use and opioid use for baseline will be determined by summing the 7 daily assessments before Day 1 (Day –7 to Day –1). The

frequency of analgesic (nonopioid or opioid) use and opioid use for postbaseline visits will be determined by summing the 7 daily assessments before the visit day.

If a participant has a frequency of > 0 analgesic (nonopioid or opioid) use/opioid use at a visit, then the participant is considered as having analgesic (nonopioid or opioid) use/opioid use at the visit.

7.2.2.3. Itch NRS

Participants will answer the Itch NRS question daily via eDiary from screening through Week 54 based on a 24-hour recall period.

The Itch NRS scale ranges from 0 (no itch) to 10 (worst itch imaginable).

The Itch NRS score for baseline will be determined by averaging the 7 daily Itch NRS scores before randomization. The by-visit Itch NRS score for postbaseline visits will be determined by averaging the 7 daily Itch NRS scores before the visit day. If 4 or more daily scores are missing (out of the 7), the Itch NRS score at the visit will be set to missing.

The most appropriate threshold for defining a clinically relevant, within-person response is a ≥ 4-point reduction relative to baseline (Kimball et al 2016).

Itch NRS30 is defined as at least a 30% reduction and at least a 1-unit reduction from baseline in the Itch NRS.

7.2.2.4. Hidradenitis Suppurativa Quality of Life

The HiSQoL is a 17-item, HS-specific, health-related, validated, QoL instrument with a 7-day recall period (Kirby et al 2020), and it will be used to assess HS symptoms and the impact of HS problems on QoL through 3 domains (symptoms, activities and adaptations, and psychosocial).

The scoring for each question is indicated in Table 5.

Table 5: Hidradenitis Suppurativa Quality of Life Scoring

Response	Score
Extremely	4
Very much	3
Moderately	2
Slightly	1
Not at all	0
Question unanswered	0
Unable to do due to my HS	4
I am not sexually active (Question 15)	0
I do not work or study (Question 17)	0

The HiSQoL total score will be calculated by summing the scores for each question. The sum will range between 0 and 68, with a higher score indicating higher HS-related impairment of QoL.

The HiSQoL can be analyzed under 3 subscales as indicated in Table 6.

Table 6: Hidradenitis Suppurativa Quality of Life Subscales

Section	Questions	Minimum Score	Maximum Score
Symptoms	8, 9, 10, 11	0	16
Psychosocial	6, 12, 13, 14, 15	0	20
Activities and adaptations	1, 2, 3, 4, 5, 7, 16, 17	0	36

Interpretation of incorrectly completed questionnaires are as follows:

- Unanswered questions are scored as 0.
- If 2 or more questions are unanswered, the questionnaire is not scored.
- If more than 1 response option is written for any item, the response option with the highest score should be recorded.
- If a response is written between 2 response options, the lower of the 2 score options should be recorded.
- When using subscales, if the answer to 1 item in a subscale is missing, that subscale should not be scored.

7.2.2.5. Dermatology Life Quality Index

The DLQI is a 10-question, validated questionnaire to measure how much the skin problem has affected the participant over the previous 7 days, across symptoms and feelings, daily activities, leisure, work and school, personal relations, and treatment (Finlay and Khan 1994).

The scoring of each question will be as follows: very much = 3; a lot = 2; a little = 1; not at all = 0; not relevant = 0.

The following imputation will be applied:

- If 1 question is left unanswered, it will be scored 0 and the scores will be summed and expressed as usual (ie, out of a maximum of 30).
- If 2 or more questions are left unanswered, the questionnaire will not be scored.
- If Question 7 is answered "yes," it will be scored 3. If Question 7 is answered "no" but then either "a lot" or "a little" is ticked, it will be scored 2 or 1, respectively. If "not relevant" is ticked, the score will be 0. If Question 7 is answered "no" but the second half is left incomplete, the score will remain 0.
- If 2 or more response options are ticked, the response option with the highest score will be recorded.
- If there is a response between 2 tick boxes, the lower of the 2 score options will be recorded.

The DLQI will be calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more QoL is impaired.

A change from baseline in DLQI score of at least a 4-point reduction is considered clinically important (Basra et al 2015).

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

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

The questionnaire will also be analyzed under 6 subscales as follows:

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

7.2.2.6. Functional Assessment of Chronic Illness Therapy – Fatigue Scale

The FACIT-F scale is a 13-item questionnaire originally designed to assess fatigue, over a 7-day recall, in patients with chronic disease. Each item uses a 5-point scale ranging from "4 = not at all" to "0 = very much." The total FACIT-F score ranges from 0 (maximum fatigue) to 52 (no fatigue), the higher the score less fatigue (better the quality of life). Lower scores are indicative of a greater impact on the participants' QoL (Cella et al 2019).

The FACIT-F Scale Questionnaire v4 will use the scoring algorithm presented by Cella et al 2002.

If greater than 50% of the 13 items (ie, ≥ 7 items) have missing responses, the total FACIT-F score will be set as missing.

A clinically important difference for the FACIT-F total score is defined as a 4-point improvement from baseline (Cella et al 2019); there is no HS-specific, clinically relevant threshold to define improvement.

7.2.2.7. Work Productivity and Activity Impairment – Hidradenitis Suppurativa

The WPAI-HS questionnaire is a validated instrument to measure impairments in both paid work and unpaid work. It measures absenteeism and presenteeism as well as impairments in unpaid activity because of HS and other health problems during the past 7 days. Absenteeism, presenteeism, and overall work impairment will be assessed only for employed participants

(Reilly et al 1993). Each item applies a standardized scoring that yields a final result expressed as a percentage, with higher percentage scores indicating greater impairment.

Questions:

- 1 = Currently employed
- 2 = Missed work hours, problem
- 3 = Missed work hours, other
- 4 = Hours actually worked
- 5 = How much problem affected productivity
- 6 = How much problem affected activities

Scores:

- Percent work time missed = 100 × [Q2 / (Q2 + Q4)]
- Percent impairment while working = 100 × (Q5 / 10)
- Percent overall work impairment = 100 × {[Q2 / (Q2 + Q4)] + ({1 – [Q2 / (Q2 + Q4)]} × (Q5 / 10))}
- Percent activity impairment = 100 × (Q6 / 10)

Missing values will not be imputed.

7.2.2.8. EQ-5D-5L Questionnaire

The EQ-5D-5L questionnaire is a standardized, validated instrument for use as a measure of health outcome (Herdman et al 2011). The EQ-5D-5L questionnaire will provide data for use in economic models and analyses, including developing health utilities or quality-adjusted life years. The EQ-5D-5L questionnaire consists of the following 2 sections: the EQ-5D descriptive system and the EQ VAS. The descriptive system comprises 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: Level 1 = no problems, Level 2 = slight problems, Level 3 = moderate problems, Level 4 = severe problems, and Level 5 = extreme problems. The EQ VAS records the participant's self-rated health on a vertical VAS (0-100), where the endpoints are labeled "the best health you can imagine" (100 score) and "the worst health you can imagine" (0 score).

7.3. Efficacy Hypotheses

The primary alternative hypothesis is that each of the povorcitinib dose groups (75 and 45 mg) is superior to placebo at Week 12 in the proportion of participants who achieve HiSCR in participants with moderate to severe HS. Assuming p_T is the proportion of participants who achieve HiSCR at Week 12 in the povorcitinib dose group (75 or 45 mg) and p_C is the proportion of participants who achieve HiSCR at Week 12 in the placebo group, the primary hypotheses of the study are as follows:

- H_0 (null hypothesis): $p_T = p_C$
- H_A (alternative hypothesis): $p_T > p_C$

7.4. Analysis of the Primary Efficacy Parameter

The primary efficacy endpoint is the proportion of participants who achieve HiSCR at Week 12.

7.4.1. Primary Estimand

The primary estimand with the 5 attributes and strategies for addressing the defined intercurrent events is provided in Table 7.

Table 7: Primary Estimand

Estimand Attribute	**Definition**
Treatment	Each of the povorcitinib dose groups (75 and 45 mg) compared with placebo
Population	Participants with moderate to severe HS (as defined by study inclusion/exclusion criteria)
Variable	Achievement of HiSCR at Week 12, defined as at least a 50% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count at Week 12
Intercurrent Events	**Strategies for Addressing Intercurrent Event**
1. Treatment discontinuation due to any reason	Participants who discontinue treatment for any reason at any time before Week 12 are considered to be nonresponders (composite strategy)
2. Initiation of systemic antibiotic rescue therapy or prohibited medication with effect on HS outcomes (eg, immunomodulatory biologics)	Participants who initiate systemic antibiotic rescue therapy or prohibited medication with effect on HS outcomes at any time before Week 12 are considered to be nonresponders (composite strategy)
3. Initiation of lesion rescue using Protocol-allowed interventions (injection with intralesional corticosteroid, or incision and drainage of the lesion)	The individual lesion(s) receiving rescue treatment will be counted as permanently present throughout the study
Population-level summary	Proportion of participants achieving HiSCR at Week 12 in each treatment group, the difference in HiSCR rate between each of the povorcitinib dose groups (75 and 45 mg) vs placebo

The primary analysis will be based on the ITT Population. The primary alternative hypothesis (superiority of each povorcitinib dose group [75 and 45 mg] compared with the placebo group) will be tested at a 2-sided $\alpha = 0.025$ level using the CMH test stratified by randomization stratification factors (baseline ANdT count [< 11 or ≥ 11] and previous treatment of HS with a biologic drug). A stratum-adjusted HiSCR rate difference between each of the povorcitinib dose groups (75 and 45 mg) versus placebo and the associated 95% Wald CI will be computed using Mantel-Haenszel stratum weights (Mantel and Haenszel 1959) and Sato's variance (Sato 1989). The stratified CMH p-value and common odds ratio with the 95% CI will be provided. The number of participants achieving HiSCR at Week 12 and the respective rates as well as the

2-sided 95% exact CIs based on the Clopper-Pearson method will also be reported by treatment group.

Based on the composite strategy for handling Intercurrent Event 1, treatment discontinuation, and Intercurrent Event 2, initiation of systemic antibiotic rescue therapy or prohibited mediation with effect on HS outcomes, participants who have any of the intercurrent events will be considered as nonresponders for all subsequent visits on or after the occurrence date of the intercurrent event. As well, participants who miss a postbaseline value at a visit (ie, true missing values due to data not collected) will be imputed as nonresponders for that visit only.

7.4.2. Sensitivity and Supportive Analyses of Primary Endpoint

A sensitivity analysis for the primary estimand will be conducted using the treatment strategy to address the intercurrent events with all data included regardless of occurrence of any intercurrent event, followed by multiple imputation of missing values. For each imputation iteration, a fully conditional specification method (van Buuren 2007) that assumes the existence of a joint distribution of all variables will be used to impute missing postbaseline values for HiSCR components, including abscess count, inflammatory nodule count, and draining tunnel count. For each of the 3 HiSCR components, a regression model including treatment group, randomization stratification factors, and baseline and scheduled postbaseline values up to Week 12 will be specified for the fully conditional specification method. After the missing HiSCR component values are imputed, the binary variables will be derived based on the definition. The stratified CMH test will be applied to each full dataset for the timepoint of interest. The imputation will be repeated 40 times with randomization seed 2024 to generate corresponding complete datasets in order to reflect the uncertainty around the true values, and the results will be combined for the inference using Rubin's rule.

Another sensitivity analysis will be conducted using a treatment strategy for intercurrent events following a tipping point analysis to examine the potential effects of missing data. The missing HiSCR at Week 12 in each treatment group will be replaced by a range of values from the most conservative scenario to the least conservative scenario. The most conservative scenario is that all the missing cases from participants in the povorcitinib dose group (75 or 45 mg) are nonresponders and all the missing cases from participants in the placebo group are responders, while the least conservative scenario is the reverse. For each scenario, comparisons between each of the povorcitinib dose groups (75 and 45 mg) versus placebo will be performed using the Fisher exact test.

In addition, the primary estimand will be performed using the same stratified CMH test in the PP Population as a supportive analysis.

7.4.3. Subgroup Analyses for Primary Endpoint

Subgroups will be formed based on the following participant characteristics and baseline variables for those participants whose data are available:

- Baseline ANdT count (< 11, ≥ 11)
- Previous treatment of HS with a biologic drug (yes, no)
- Age categories (18 to < 65 years, ≥ 65 years)

- Sex (female, male)
- Race (White, Black or African American, Asian, Other)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino)
- BMI categories (< 30 kg/m^2, 30 to < 40 kg/m^2, ≥ 40 kg/m^2)
- Geographic region (North America, Europe [UK included] and Australia, Japan)
- Baseline Hurley Stage (Stage II, Stage III)
- Baseline draining tunnel count (0, 1-2, ≥ 3)

The primary efficacy endpoint will be summarized using descriptive statistics for each subgroup defined above. For each subgroup category, the point estimate and 95% CI for treatment difference between each of the povorcitinib dose groups and placebo will be provided as well as presented in forest plots.

7.5. Analysis of the Secondary Efficacy Parameters

7.5.1. Analysis of the Key Secondary Efficacy Parameters

For the key secondary estimands, the 5 attributes and strategies for addressing the defined intercurrent events are provided in Table 8.

The key secondary analyses will be conducted based on the following populations:

- HiSCR75 at Week 12 and flare by Week 12 = ITT Population
- ≥ 3-point reduction in Skin Pain NRS at Week 12 = ITT Population with baseline Skin Pain NRS score ≥ 3

All key secondary efficacy endpoints will be analyzed using the stratified CMH method similar to that specified in the primary analysis. Similar to the primary analysis, participants who have true missing values due to data not collected will be imputed as nonresponders for that visit only.

The key secondary efficacy parameters will also be summarized for the following 2 subgroups:

- Baseline ANdT count (< 11, ≥ 11)
- Previous treatment of HS with a biologic drug (yes, no)

Table 8: Key Secondary Estimands

Estimand Attribute	**Definition**
Key secondary estimand for HiSCR75 at Week 12	
Treatment	Same as primary estimand
Population	Same as primary estimand
Variable	Achievement of HiSCR75 at Week 12, defined as at least a 75% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count
Intercurrent Events	**Strategies for Addressing Intercurrent Events**
1. Treatment discontinuation for any reason	Same as primary estimand
2. Initiation of systemic antibiotic rescue therapy or prohibited medication with effect on HS outcomes (eg, immunomodulatory biologic)	Same as primary estimand
3. Initiation of lesion rescue using Protocol-allowed interventions (injection with intralesional corticosteroid, or incision and drainage of the lesion)	Same as primary estimand
Population-level summary	Proportion of participants achieving HiSCR75 at Week 12 in each treatment group, the difference in HiSCR75 rate between each of the povorcitinib dose groups (75 and 45 mg) vs placebo
Key secondary estimand for flare by Week 12	
Treatment	Same as primary estimand
Population	Same as primary estimand
Variable	Having flare at Week 12, defined as at least a 25% increase in the total AN count with a minimum increase of 2 relative to baseline
Intercurrent Events	**Strategies for Addressing Intercurrent Events**
1. Treatment discontinuation for any reason	Participants who discontinue treatment for any reason at any time before Week 12 are considered to have a flare (composite strategy)
2. Initiation of systemic antibiotic rescue therapy or prohibited medication with effect on HS outcomes (eg, immunomodulatory biologic)	Participants who initiate systemic antibiotic rescue therapy or prohibited medication with effect on HS outcomes at any time prior to Week 12 are considered to have a flare (composite strategy)
3. Initiation of lesion rescue using Protocol-allowed interventions (injection with intralesional corticosteroid, or incision and drainage of the lesion)	Same as primary estimand

Table 8: Key Secondary Estimands (Continued)

Estimand Attribute	Definition
Population-level summary	Proportion of participants with flare by Week 12 in each treatment group, the difference between each of the povorcitinib dose groups (75 and 45 mg) vs placebo
Key secondary estimand for Skin Pain Response at Week 12	
Treatment	Same as primary estimand
Population	Same as primary estimand
Variable	Achievement of Skin Pain Response at Week 12, defined as ≥ 3-point reduction from baseline in Skin Pain NRS at Week 12
Intercurrent Events	**Strategies for Addressing Intercurrent Events**
1. Treatment discontinuation for any reason	Same as primary estimand
2. Initiation of systemic antibiotic rescue therapy or prohibited medication with effect on HS outcomes (eg, immunomodulatory biologic)	Same as primary estimand
3. Initiation of lesion rescue using Protocol-allowed interventions (injection with intralesional corticosteroid, or incision and drainage of the lesion)	Same as primary estimand
Population-level summary	Proportion of participants achieving Skin Pain Response at Week 12 in each treatment group, the difference in response rate between each of the povorcitinib dose groups (75 and 45 mg) vs placebo

7.5.2. Analysis of Other Secondary Efficacy Parameters

In the PC period, all other secondary endpoints will be analyzed by treatment group based on the ITT Population. For categorical endpoints, summary statistics will include the number of participants, frequency, and percentages. A similar stratified CMH test as specified in the primary analysis will be used at Week 12, if applicable. The same strategies will be used to handle the intercurrent events followed by the nonresponder imputation method to impute missing values. For continuous efficacy endpoints, descriptive statistics will be provided for baseline, the actual measurements will be used at each visit, and the change and percentage change from baseline will be provided at each visit, if applicable. Summary statistics will include the number of participants, mean, standard deviation, median, minimum, and maximum. An analysis of covariance model with treatment group, randomization stratification factors, and baseline measurement will be fit at Week 12, if applicable. The estimated treatment difference between each of the povorcitinib dose groups (75 and 45 mg) and the placebo group, the associated 95% CIs, and the p-value will be presented.

As a supportive analysis, the continuous efficacy endpoints for the PC period may be analyzed using the MMRM to include all available data at postbaseline visits up to Week 12. Participants

who have a baseline value and at least 1 postbaseline value in the PC period will be included in the analysis. The MMRM will include the fixed effects of treatment group, randomization stratification factors, visit, treatment by visit interaction, and covariates of baseline measurements and baseline measurements by visit interaction. The variance-covariance matrix of the within-participant errors in the MMRM will be modeled as unstructured. The Kenward-Roger method will be used to estimate the degrees of freedom. Missing values will not be otherwise imputed using the MMRM approach. The least-squares means along with 95% CIs and the p-value for the difference in mean change from baseline at each visit between each of the povorcitinib dose groups (75 and 45 mg) and the placebo group from the MMRM will be provided.

Efficacy endpoints in the EXT period and the overall study period will be summarized using descriptive statistics based on the EXT-Evaluable Population and ITT Population, respectively. For categorical measurements, summary statistics will include sample size, frequency, and percentage. For continuous measurements, summary statistics will include sample size, mean, median, standard deviation, standard error of the mean, minimum, and maximum. Summary statistics for continuous measures will be provided for baseline, the actual measurements at each visit, and the change and percentage change from baseline at each visit, if applicable.

7.6. Analysis of Exploratory Efficacy Parameters

All exploratory efficacy variables will be summarized using descriptive statistics. For the binary endpoints, summary statistics will include the number of participants, frequency, and percentages. For continuous measurements, descriptive statistics will be provided for baseline, the actual measurements will be used at each visit, and the change and percentage change from baseline will be provided at each visit, if applicable. Summary statistics will include the number of participants, mean, standard deviation, median, minimum, and maximum.

8. SAFETY AND TOLERABILITY

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

8.1. General Considerations

The analyses in this section will be provided for the Safety Population in the PC period and the overall study period, and the EXT-Evaluable Population in the EXT period, unless otherwise specified. Summary tables may be replaced with listings when appropriate. For instance, an AE frequency table may be replaced with a listing if it only contains a few unique PTs reported on relatively few participants.

8.2. Adverse Events

8.2.1. Adverse Event Definitions

A TEAE in the PC period is any AE, either reported for the first time or the worsening of a pre-existing event, occurring after the first dose of study drug in the PC period and until 30 days after the last dose of study drug for participants who do not enter the EXT period. For participants who enter the EXT period, the end date is 30 days after the last dose date in the PC period or the day before the first dose in the EXT period, whichever is first.

A TEAE in the EXT period is any AE, either reported for the first time or the worsening of a pre-existing event, occurring after the first dose of study drug in the EXT period and until 30 days after the last dose of study drug for participants who do not participate a separate EXT study. For participants who participate a separate EXT study, the end date is the last dose date in this study.

A TEAE in the overall study period is any AE, either reported for the first time or the worsening of a pre-existing event, occurring after the first dose of study drug in the PC period and until 30 days after the last dose of study drug during the overall study period for participants who do not participate a separate EXT study. For participants who participate a separate EXT study, the end date is the last dose date in this study.

Analysis of AEs (as discussed below) will be limited to TEAEs, but data listings will include all AEs regardless of their timing in relation to study drug administration. For purposes of analysis, all AEs will be considered TEAEs unless the AE can unequivocally be defined as not treatment-emergent.

Adverse events will be tabulated by MedDRA PT and SOC. Severity of AEs will be graded using the NCI CTCAE v5.0. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website.

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

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8.2.4. Adverse Events Per 100 Patient-Years

In order to adjust for differences in participants' exposure in the study and potential dropout rates between the treatment groups, TEAEs per 100 PY will be calculated for each treatment group in the Safety Population for the overall study period as follows:

TEAEs per 100 PY = 100 × (number of participants with at least 1 TEAE / total PY)

where total PY are calculated as: the sum of study drug exposure for all participants in the treatment group / 365.25.

8.2.5. Adverse Event Summaries

Adverse events will be summarized by treatment group and overall povorcitinib dose groups for the Safety Population in the PC period and overall study period and for the EXT-Evaluable Population in the EXT period.

An overall summary of AEs will include the following:

- Number (%) of participants who had any TEAEs
- Number (%) of participants who had any Grade 3 or higher TEAEs
- Number (%) of participants who had any serious TEAEs
- Number (%) of participants who had any TEAEs related to study drug
- Number (%) of participants who had any fatal TEAEs
- Number (%) of participants who temporarily interrupted study drug because of TEAEs

- Number (%) of participants who permanently discontinued study drug because of TEAEs
- Number (%) of participants who had any treatment-emergent AESIs

In addition, the exposure-adjusted TEAE rates per 100 PY will be provided for each AE category described above in an overall summary of AEs.

The following summaries will be produced (if 10 or fewer participants appear in a table, a listing may be appropriate):

- Summary of TEAEs by MedDRA SOC and PT
- Summary of TEAEs by MedDRA PT in decreasing order of frequency
- Summary of TEAEs by MedDRA SOC, PT, and maximum severity
- Summary of TEAEs by MedDRA SOC, PT, and CTCAE grade category
- Summary of Grade 3 or higher TEAEs by MedDRA SOC and PT
- Summary of Grade 3 or higher TEAEs by MedDRA PT in decreasing order of frequency
- Summary of serious TEAEs by MedDRA SOC and PT
- Summary of serious TEAEs by MedDRA PT in decreasing order of frequency
- Summary of treatment-related TEAEs by MedDRA SOC and PT
- Summary of treatment-related TEAEs by MedDRA PT in decreasing order of frequency
- Summary of Grade 3 or higher treatment-related TEAEs by MedDRA SOC and PT
- Summary of treatment-related serious TEAEs by MedDRA SOC and PT
- Summary of TEAEs with a fatal outcome by MedDRA SOC and PT
- Summary of TEAEs leading to dose interruption by MedDRA SOC and PT
- Summary of TEAEs leading to discontinuation of study drug by MedDRA SOC and PT
- Summary of treatment-emergent ECIs (PT component) by category and MedDRA PT
- Summary of treatment-emergent ECIs (laboratory component) by laboratory parameters
- Summary of treatment-emergent AESIs by category and MedDRA PT
- Summary of treatment-emergent AESIs leading to dose interruption by category and MedDRA PT
- Summary of treatment-emergent AESIs leading to discontinuation of study drug by category and MedDRA PT

In addition, TEAE rates per 100 PY will be provided in a summary of TEAEs by MedDRA SOC and PT and a summary of treatment-emergent AESIs by category and MedDRA PT. Adjudicated cardiovascular events and other embolic and thrombotic events will be listed. The laboratory component and PT component of each ECI category will also be listed as applicable.

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

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

8.3.2. Laboratory Value Summaries

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 numeric laboratory values, baseline value, postbaseline value, change from baseline and percent change from baseline will be summarized descriptively by visit. The number and percentage of participants with low, normal, and high laboratory values will be summarized by visit. The mean change from baseline will be plotted by visit. In addition, boxplots will be provided for hemoglobin, hematocrit, platelet count, hemoglobin A1c, high-sensitivity C-reactive protein, absolute lymphocyte count, absolute neutrophil count, white blood cell count, CPK, creatinine, AST, ALT, total bilirubin, cholesterol, HDL, LDL, and HDL/LDL ratio.

For test results that will be summarized with available normal ranges, the number and percentage of participants with 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. The denominator for the percentage calculation will use the number of participants in the baseline category (ie, low, high, normal, missing) as the denominator for the percentage in each of the categories during the study.

Severity grades will be assigned to laboratory test values based on the numerical component of CTCAE v5. Shift tables will also be presented showing change in CTCAE grade from baseline to the worst grade postbaseline. Separate summaries for abnormally high and abnormally low laboratory values will be provided when the laboratory parameter has both high and low grading criteria. The denominator for the percentage calculation will be the number of participants in the baseline category. The number of participants who have worsening of laboratory abnormalities will be summarized by maximum severity.

8.3.3. Potentially Clinically Important Laboratory Values

Criteria for potentially clinically important laboratory values are listed in Table 11. The number and percentage of participants with postbaseline laboratory values that meet each criterion will be summarized at each scheduled visit by treatment group. Participants with potentially clinically important laboratory values will also be listed.

Table 11: Criteria for Potentially Clinically Important Laboratory Values

Laboratory Parameter	Grade (Criteria)
Hemoglobin	Grade 1 (100 g/L to < LLN) Grade 2 (80 to < 100 g/L) Grade 3 (< 80 g/L)
Lymphocytes	Grade 1 (0.8×10^9/L to < LLN) Grade 2 (0.5 to < 0.8×10^9/L) Grade 3 (0.2 to < 0.5×10^9/L) Grade 4 (< 0.2×10^9/L)
Neutrophils	Grade 1 (1.5×10^9/L to < LLN) Grade 2 (1.0 to < 1.5×10^9/L) Grade 3 (0.5 to < 1.0×10^9/L) Grade 4 (< 0.5×10^9/L)
Platelets	Grade 1 (75×10^9/L to < LLN) Grade 2 (50 to < 75×10^9/L) Grade 3 (25 to < 50×10^9/L) Grade 4 (< 25×10^9/L)
Creatinine	Grade 1 (> ULN to 1.5 × ULN) Grade 2 (> 1.5 to 3 × ULN or > 1.5 to 3 × baseline) Grade 3 (> 3 to 6 × ULN or > 3 × baseline) Grade 4 (> 6 × ULN)
CPK	Grade 1 (> ULN to 2.5 × ULN) Grade 2 (> 2.5 to 5 × ULN) Grade 3 (> 5 to 10 × ULN) Grade 4 (> 10 × ULN)

8.3.4. Potential Hy's Law Events

The participants with elevated ALT or AST ≥ 3 × ULN range and alkaline phosphatase ≤ 2 × ULN range accompanied by total bilirubin > 2 × ULN range at the same visit will be listed and plotted by treatment group.

8.4. Vital Signs

Mean values at each scheduled visit for vital signs, including systolic blood pressure, diastolic blood pressure, pulse, respiratory rate, body temperature, weight, and BMI will be plotted.

Criteria for clinically notable vital sign abnormalities are defined in Table 12. The abnormal values for participants exhibiting clinically notable vital sign abnormalities will be listed along with their treatment group. Alert vital signs are defined as an absolute value outside the defined range and percentage change from baseline greater than 25%. Note that the definition of alert vital signs does not apply for body temperature, weight, or BMI. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 12: Criteria for Clinically Notable Vital Sign Abnormalities

Parameter	High Threshold	Low Threshold
Systolic blood pressure	≥ 155 mmHg	≤ 85 mmHg
Diastolic blood pressure	≥ 100 mmHg	≤ 40 mmHg
Pulse	≥100 bpm	≤ 45 bpm
Body temperature	≥ 38°C	≤ 35.5°C
Respiratory rate	≥ 24 breaths/min	≤ 8 breaths/min

8.5. Electrocardiograms

Twelve-lead ECGs including PR, QT, QRS, and QTcF intervals will be obtained for each participant at screening, Week 12, and Week 54. Values at each scheduled visit, change, and percentage change from baseline will be summarized for each ECG parameter. Baseline will be determined as the average of all nonmissing values before the first administration of povorcitinib or placebo.

9. INTERIM ANALYSES

No formal interim analysis is planned in this study.

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 13.

Table 13: Statistical Analysis Plan Versions

SAP Version	Date
Original	17 DEC 2024

10.1. Changes to Protocol-Defined Analyses

Analyses for HiSCR100, IHS4-75, IHS4-90, and IHS4-100, as well as subgroup analyses for the key secondary endpoints have been added.

The following has been updated based on health authority feedback:

- In Section 3.2, changed multiplicity control method from Hochberg to gatekeeping in Step 2 and Step 3 of level of significance session.
- In Section 7.4.1, removed the phrase "treatment policy strategy" regarding the strategy for addressing initiation of lesion rescue intercurrent event.
- In Section 8.2.2 and 8.2.3, ECI and AESI categories have been updated.

10.2. Changes to the Statistical Analysis Plan

Not applicable.

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APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. Shells are provided in a separate document for tables that are not in the Standard Safety Tables v2.0.

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

Note that separate TFLs will be provided for the INCB 54707-301 and INCB 54707-302 studies.

Tables

Table No.	Title	Population	Standard
Baseline and Demographic Characteristics			
1.1.1	Analysis Populations	ITT	X
1.1.1.1	Screening Failures	All Screened	X
1.1.2.1	Summary of Participant Disposition in the PC Period	ITT	X
1.1.2.2	Summary of Participant Disposition in the EXT Period	EXT-Evaluable	X
1.1.3	Summary of Number of Participants Enrolled by Country and Site	ITT	X
1.1.4.1	Summary of Protocol Deviations During the PC Period	ITT	X
1.1.4.2	Summary of Protocol Deviations During the EXT Period	EXT-Evaluable	X
1.2.1	Summary of Demographics and Baseline Characteristics in the PC Period	ITT	X
1.2.2	Summary of Demographics and Baseline Characteristics in the EXT Period	EXT-Evaluable	X
1.3	Summary of Baseline Disease Characteristics and Disease History	ITT	X
1.4.1.1	Summary of Prior Medications	ITT	X
1.4.1.2	Summary of Prior Medications by Study-Specified Category, Type, and WHO Term	ITT	
1.4.1.3.1	Summary of Prior Oral Antibiotics or Biologics for HS - Response to Treatment by Type	ITT	
1.4.1.3.2	Summary of Prior Oral Antibiotics or Biologics for HS - Main Reason for Discontinuation by Type	ITT	
1.4.1.3.3	Summary of Prior Oral Antibiotics or Biologics for HS - Reason for Inadequate Response by Type	ITT	
1.4.1.4.1	Summary of Other Prior HS Therapy (Not Antibiotic/Biologic) - Response to Treatment by Type	ITT	
1.4.1.4.2	Summary of Other Prior HS Therapy (Not Antibiotic/Biologic) - Main Reason for Discontinuation by Type	ITT	
1.4.1.5.1	Summary of Prior JAK Inhibitor Therapy (Not for HS) - Response to Treatment	ITT	
1.4.1.5.2	Summary of Prior JAK Inhibitor Therapy (Not for HS) - Main Reason for Discontinuation	ITT	
1.4.1.6.1	Summary of Prior Biologic Therapy (Not for HS) - Response to Treatment	ITT	
1.4.1.6.2	Summary of Prior Biologic Therapy (Not for HS) - Main Reason for Discontinuation	ITT	
1.4.2.1.1	Summary of Concomitant Medications During the PC Period	ITT	X

Table No.	Title	Population	Standard
1.4.2.1.2	Summary of Concomitant Medications by Study-Specified Category, Type, and WHO Term During the PC Period	ITT	
1.4.2.2.1	Summary of Concomitant Medications During the EXT Period for Crossover Participants	EXT-Evaluable	X
1.4.2.2.2	Summary of Concomitant Medications by Study-Specified Category, Type, and WHO Term During the EXT Period for Crossover Participants	EXT-Evaluable	
1.4.2.3.1	Summary of Concomitant Medications During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	X
1.4.2.3.2	Summary of Concomitant Medications by Study-Specified Category, Type, and WHO Term During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
1.5	Summary of General Medical History	ITT	X
Efficacy			
2.1.1	Summary and Analysis of Proportion of Participants Achieving HiSCR by Visit During the PC Period	ITT	
2.1.2.1	Summary and Analysis of Proportion of Participants Achieving HiSCR by Visit During the PC Period - Supportive Analysis	PP	
2.1.2.2	Summary and Analysis of Proportion of Participants Achieving HiSCR by Visit During the PC Period - Multiple Imputation Sensitivity Analysis	ITT	
2.1.2.3	Summary and Analysis of Proportion of Participants Achieving HiSCR by Visit During the PC Period - Tipping Point Sensitivity Analysis	ITT	
2.1.3.x[a]	Summary and Analysis of Proportion of Participants Achieving HiSCR by Visit During the PC Period - Subgroup Analysis	ITT	
2.1.4.1	Summary of Proportion of Participants Achieving HiSCR by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.1.4.2	Summary of Proportion of Participants Achieving HiSCR by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.1.1.1	Summary and Analysis of Proportion of Participants Achieving HiSCR75 by Visit During the PC Period	ITT	
2.2.1.1.2.x[b]	Summary and Analysis of Proportion of Participants Achieving HiSCR75 by Visit During the PC Period - Subgroup Analysis	ITT	
2.2.1.2	Summary of Proportion of Participants Achieving HiSCR75 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.1.3	Summary of Proportion of Participants Achieving HiSCR75 by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.2.1.1	Summary and Analysis of Proportion of Participants With Flare by Week 12	ITT	
2.2.2.1.2.x[b]	Summary and Analysis of Proportion of Participants With Flare by Week 12 - Subgroup Analysis	ITT	
2.2.2.2.2	Summary of Proportion of Participants With Flare by Week 24 for Participants Who Took Only Povorcitinib	ITT	
2.2.2.2.3	Summary of Proportion of Participants With Flare by Week 24 During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.2.3.2	Summary of Proportion of Participants With Flare by Week 54 for Participants Who Took Only Povorcitinib	ITT	

Table No.	Title	Population	Standard
2.2.2.3.3	Summary of Proportion of Participants With Flare by Week 54 During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.3.1.1.1	Summary and Analysis of Proportion of Participants With a >= 3-Point Decrease in Skin Pain NRS Score by Visit During the PC Period (With Baseline Skin Pain NRS Score >= 3)	ITT	
2.2.3.1.1.2.x[b]	Summary and Analysis of Proportion of Participants With a >= 3-Point Decrease in Skin Pain NRS Score by Visit During the PC Period (With Baseline Skin Pain NRS Score >= 3) - Subgroup Analysis	ITT	
2.2.3.1.2	Summary Proportion of Participants With a >= 3-Point Decrease in Skin Pain NRS Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib (With Baseline Skin Pain NRS Score >= 3)	ITT	
2.2.3.1.3	Summary of Proportion of Participants With a >= 3-Point Decrease in Skin Pain NRS Score by Visit During the EXT Period for Crossover Participants (With Baseline Skin Pain NRS Score >= 3)	EXT-Evaluable	
2.2.3.2.1.1	Summary and Analysis of Proportion of Participants Achieving Skin Pain NRS30 by Visit During the PC Period (With Baseline Skin Pain NRS Score >= 3)	ITT	
2.2.3.2.1.2.x[b]	Summary and Analysis of Proportion of Participants Achieving Skin Pain NRS30 by Visit During the PC Period (With Baseline Skin Pain NRS Score >= 3) - Subgroup Analysis	ITT	
2.2.3.2.2	Summary of Proportion of Participants Achieving Skin Pain NRS30 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib (With Baseline Skin Pain NRS Score >= 3)	ITT	
2.2.3.2.3	Summary of Proportion of Participants Achieving Skin Pain NRS30 by Visit During the EXT Period for Crossover Participants (With Baseline Skin Pain NRS Score >= 3)	EXT-Evaluable	
2.2.4.1	Summary and Analysis of Proportion of Participants With at Least a 4-Point Increase in FACIT-F Score by Visit During the PC Period	ITT	
2.2.4.2	Summary of Proportion of Participants With at Least a 4-Point Increase in FACIT-F Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.4.3	Summary of Proportion of Participants With at Least a 4-Point Increase in FACIT-F Score by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.5.1	Summary and Analysis of DLQI Score by Visit During the PC Period	ITT	
2.2.5.2	Summary of DLQI Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.5.3	Summary of DLQI Score by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.6.1	Summary of Proportion of Participants With at Least a 4-Point Decrease From Baseline in DLQI Score by Visit During the PC Period	ITT	
2.2.6.2	Summary of Proportion of Participants With at Least a 4-Point Decrease From Baseline in DLQI Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.6.3	Summary of Proportion of Participants With at Least a 4-Point Decrease From Baseline in DLQI Score by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	

Table No.	Title	Population	Standard
2.2.7.1	Summary of Abscess Count by Visit During the PC Period	ITT	
2.2.7.2	Summary of Abscess Count by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.7.3	Summary of Abscess Count by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.8.1	Summary of Inflammatory Nodule Count by Visit During the PC Period	ITT	
2.2.8.2	Summary of Inflammatory Nodule Count by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.8.3	Summary of Inflammatory Nodule Count by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.9.1	Summary of Draining Tunnel Count by Visit During the PC Period	ITT	
2.2.9.2	Summary of Draining Tunnel Count by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.9.3	Summary of Draining Tunnel Count by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.10.1	Summary of Total Abscess and Inflammatory Nodule Count by Visit During the PC Period	ITT	
2.2.10.2	Summary of Total Abscess and Inflammatory Nodule Count by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.2.10.3	Summary of Total Abscess and Inflammatory Nodule Count by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.2.11	Summary of Proportion of Participants Achieving Maintenance of HiSCR by Visit During the EXT Period for Participants Who Took Only Povorcitinib	EXT-Evaluable	
2.2.12	Summary of Proportion of Participants Achieving Maintenance of HiSCR75 by Visit During the EXT Period for Participants Who Took Only Povorcitinib	EXT-Evaluable	
2.3.1.1	Summary of Proportion of Participants Achieving HiSCR90 by Visit During the PC Period	ITT	
2.3.1.2	Summary of Proportion of Participants Achieving HiSCR90 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.1.3	Summary of Proportion of Participants Achieving HiSCR90 by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.3.2.1	Summary of Proportion of Participants Achieving HiSCR100 by Visit During the PC Period	ITT	
2.3.2.2	Summary of Proportion of Participants Achieving HiSCR100 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.2.3	Summary of Proportion of Participants Achieving HiSCR100 by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	
2.3.3.1	Summary of Proportion of Participants With Total Abscess and Inflammatory Nodule Count of 0, 1, or 2 by Visit During the PC Period	ITT	
2.3.3.2	Summary of Proportion of Participants With Total Abscess and Inflammatory Nodule Count of 0, 1, or 2 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	

Table No.	Title	Population	Standard
2.3.4.1	Summary of Proportion of Participants Achieving AN50 by Visit During the PC Period	ITT	
2.3.4.2	Summary of Proportion of Participants Achieving AN50 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.5.1	Summary of Proportion of Participants Achieving AN75 by Visit During the PC Period	ITT	
2.3.5.2	Summary of Proportion of Participants Achieving AN75 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.6.1	Summary of Proportion of Participants Achieving AN90 by Visit During the PC Period	ITT	
2.3.6.2	Summary of Proportion of Participants Achieving AN90 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.7.1	Summary of Proportion of Participants Achieving AN100 by Visit During the PC Period	ITT	
2.3.7.2	Summary of Proportion of Participants Achieving AN100 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.8.1	Summary of Proportion of Participants Achieving ANdT50 by Visit During the PC Period	ITT	
2.3.8.2	Summary of Proportion of Participants Achieving ANdT50 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.9.1	Summary of Proportion of Participants Achieving ANdT75 by Visit During the PC Period	ITT	
2.3.9.2	Summary of Proportion of Participants Achieving ANdT75 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.10.1	Summary of Proportion of Participants Achieving ANdT90 by Visit During the PC Period	ITT	
2.3.10.2	Summary of Proportion of Participants Achieving ANdT90 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.11.1	Summary of Proportion of Participants Achieving ANdT100 by Visit During the PC Period	ITT	
2.3.11.2	Summary of Proportion of Participants Achieving ANdT100 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.12.1	Summary of Proportion of Participants With at Least a 1-Unit Decrease From Baseline in Draining Tunnel Count by Visit During the PC Period	ITT	
2.3.12.2	Summary of Proportion of Participants With at Least a 1-Unit Decrease From Baseline in Draining Tunnel Count by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.13.1	Summary of ANdT Count by Visit During the PC Period	ITT	
2.3.13.2	Summary of ANdT Count by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	

Table No.	Title	Population	Standard
2.3.14.1	Summary of IHS4 Score by Visit During the PC Period	ITT	
2.3.14.2	Summary of IHS4 Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.15.1	Summary of Proportion of Participants Achieving IHS4-55 by Visit During the PC Period	ITT	
2.3.15.2	Summary of Proportion of Participants Achieving IHS4-55 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.16.1	Summary of Proportion of Participants Achieving IHS4-75 by Visit During the PC Period	ITT	
2.3.16.2	Summary of Proportion of Participants Achieving IHS4-75 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.17.1	Summary of Proportion of Participants Achieving IHS4-90 by Visit During the PC Period	ITT	
2.3.17.2	Summary of Proportion of Participants Achieving IHS4-90 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.18.1	Summary of Proportion of Participants Achieving IHS4-100 by Visit During the PC Period	ITT	
2.3.18.2	Summary of Proportion of Participants Achieving IHS4-100 by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.19.1	Summary of Proportion of Participants With IHS4 Disease Category by Visit During the PC Period	ITT	
2.3.19.2	Summary of Proportion of Participants With IHS4 Disease Category by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.20.1	Summary of Proportion of Participants With HS Flares by Visit During the PC Period	ITT	
2.3.20.2	Summary of Proportion of Participants With HS Flares by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.21	Summary of Proportion of Participants With at Least 1 HS Flare During the EXT Period for Participants Who Took Only Povorcitinib	ITT	
2.3.22.1	Summary of Flares During the PC Period	ITT	
2.3.22.2	Summary of Flares During the EXT Period for Participants Who Took Only Povorcitinib	EXT-Evaluable	
2.3.23.1	Summary of Skin Pain NRS Score by Visit During the PC Period	ITT	
2.3.23.2	Summary of Skin Pain NRS Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.24.1	Summary of Proportion of Participants With a >= 4-Point Decrease in Skin Pain NRS Score by Visit During the PC Period	ITT	
2.3.24.2	Summary of Proportion of Participants With a >= 4-Point Decrease in Skin Pain NRS Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.25.1	Summary of Proportion of Participants With Analgesic Use by Visit During the PC Period	ITT	

Table No.	Title	Population	Standard
2.3.25.2	Summary of Proportion of Participants With Analgesic Use by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.26.1	Summary of Proportion of Participants With Opioid Use by Visit During the PC Period	ITT	
2.3.26.2	Summary of Proportion of Participants With Opioid Use by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.27.1	Summary of Proportion of Participants Requiring Rescue Lesional Treatment During the PC Period	ITT	
2.3.27.2	Summary of Proportion of Participants Requiring Rescue Lesional Treatment During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.28.1	Summary of Proportion of Participants Requiring Systemic Antibiotic Rescue Therapy During the PC Period	ITT	
2.3.28.2	Summary of Proportion of Participants Requiring Systemic Antibiotic Rescue Therapy During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.29.1	Summary of Itch NRS Score by Visit During the PC Period	ITT	
2.3.29.2	Summary of Itch NRS Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.30.1	Summary of Proportion of Participants Achieving Itch NRS30 During the PC Period (With Baseline Itch NRS Score >= 3)	ITT	
2.3.30.2	Summary of Proportion of Participants Achieving Itch NRS30 During the Overall Study Period for Participants Who Took Only Povorcitinib (With Baseline Itch NRS Score >= 3)	ITT	
2.3.31.1	Summary of Proportion of Participants With a >= 4-Point Decrease in Itch NRS Score by Visit During the PC Period	ITT	
2.3.31.2	Summary of Proportion of Participants With a >= 4-Point Decrease in Itch NRS Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.32.1	Summary of HiSQoL Score by Visit During the PC Period	ITT	
2.3.32.2	Summary of HiSQoL Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.33.1	Summary of FACIT-F Score by Visit During the PC Period	ITT	
2.3.33.2	Summary of FACIT-F Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.34.1	Summary of WPAI-HS Score by Visit During the PC Period	ITT	
2.3.34.2	Summary of WPAI-HS Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.35.1	Summary of EQ-5D-5L VAS Score by Visit During the PC Period	ITT	
2.3.35.2	Summary of EQ-5D-5L VAS Score by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.36.1	Summary of EQ-5D-5L Questionnaire by Visit During the PC Period	ITT	
2.3.36.2	Summary of EQ-5D-5L Questionnaire by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	ITT	
2.3.37.1	Summary of Time to the First Flare During the PC Period	ITT	
2.3.37.2	Summary of Time to the First Flare During the EXT Period for Participants Who Took Only Povorcitinib	EXT-Evaluable	

Table No.	Title	Population	Standard
Safety			
3.1.1.1	Summary of Study Drug Exposure During the PC Period	Safety	X
3.1.1.2	Summary of Study Drug Exposure During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.1.1.3	Summary of Study Drug Exposure During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.1.2.1	Summary of Study Drug Compliance During the PC Period	Safety	X
3.1.2.2	Summary of Study Drug Compliance During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.1.2.3	Summary of Study Drug Compliance During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.1.1	Overall Summary of Treatment-Emergent Adverse Events During the PC Period	Safety	X
3.2.1.2	Overall Summary of Treatment-Emergent Adverse Events During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.1.3	Overall Summary of Treatment-Emergent Adverse Events During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the PC Period	Safety	X
3.2.3.2	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.3.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.4.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity During the PC Period	Safety	X
3.2.4.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.4.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.5.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category During the PC Period	Safety	X

Table No.	Title	Population	Standard
3.2.5.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.5.3	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and CTCAE Grade Category During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.6.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.6.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.6.3	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.7.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the PC Period	Safety	X
3.2.7.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.7.3	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.8.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.8.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.8.3	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.9.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the PC Period	Safety	X
3.2.9.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.9.3	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.10.1	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.10.2	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X

Table No.	Title	Population	Standard
3.2.10.3	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.11.1	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the PC Period	Safety	X
3.2.11.2	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.11.3	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.12.1	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.12.2	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.12.3	Summary of Grade 3 or Higher Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.13.1	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.13.2	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.13.3	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.14.1	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.14.2	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.14.3	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.15.1	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.15.2	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X

Table No.	Title	Population	Standard
3.2.15.3	Summary of Treatment-Emergent Adverse Events Leading to Dose Interruption by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.16.1	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term During the PC Period	Safety	X
3.2.16.2	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.16.3	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.17.1	Summary of Treatment-Emergent Adverse Events of Special Interest by Category and MedDRA Preferred Term During the PC Period	Safety	X
3.2.17.2	Summary of Treatment-Emergent Adverse Events of Special Interest by Category and MedDRA Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.17.3	Summary of Treatment-Emergent Adverse Events of Special Interest by Category and MedDRA Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.18.1	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Dose Interruption by Category and MedDRA Preferred Term During the PC Period	Safety	X
3.2.18.2	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Dose Interruption by Category and MedDRA Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.18.3	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Dose Interruption by Category and MedDRA Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.19.1	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Discontinuation of Study Drug by Category and MedDRA Preferred Term During the PC Period	Safety	X
3.2.19.2	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Discontinuation of Study Drug by Category and MedDRA Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.19.3	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Discontinuation of Study Drug by Category and MedDRA Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.20.1	Summary of Treatment-Emergent Events of Clinical Interest (PT Component) by Category and MedDRA Preferred Term During the PC Period	Safety	X
3.2.20.2	Summary of Treatment-Emergent Events of Clinical Interest (PT Component) by Category and MedDRA Preferred Term During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.20.3	Summary of Treatment-Emergent Events of Clinical Interest (PT Component) by Category and MedDRA Preferred Term During the EXT Period for Crossover Participants	EXT-Evaluable	X

Table No.	Title	Population	Standard
3.2.21.1	Summary of Treatment-Emergent Events of Clinical Interest (Laboratory Component) by Laboratory Parameters During the PC Period	Safety	X
3.2.21.2	Summary of Treatment-Emergent Events of Clinical Interest (Laboratory Component) by Laboratory Parameters During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.2.21.3	Summary of Treatment-Emergent Events of Clinical Interest (Laboratory Component) by Laboratory Parameters During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.2.22	Overall Summary of Exposure-Adjusted Incidence Rates of Treatment-Emergent Adverse Events During the Overall Study Period	Safety	X
3.2.23	Summary of Exposure-Adjusted Incidence Rates of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term During the Overall Study Period	Safety	X
3.2.24	Summary of Exposure-Adjusted Incidence Rates of Treatment-Emergent Adverse Events of Special Interest by Category and MedDRA Preferred Term During the Overall Study Period	Safety	X
3.3.1.1.1	Summary of Laboratory Values During the PC Period - Hematology	Safety	X
3.3.1.1.2	Summary of Laboratory Values During the Overall Study Period for Participants Who Took Only Povorcitinib - Hematology	Safety	X
3.3.1.1.3	Summary of Laboratory Values During the EXT Period for Crossover Participants - Hematology	EXT-Evaluable	X
3.3.1.2.1	Summary of Laboratory Values During the PC Period - Chemistry	Safety	X
3.3.1.2.2	Summary of Laboratory Values During the Overall Study Period for Participants Who Took Only Povorcitinib - Chemistry	Safety	X
3.3.1.2.3	Summary of Laboratory Values During the EXT Period for Crossover Participants - Chemistry	EXT-Evaluable	X
3.3.1.3.1	Summary of Laboratory Values During the PC Period - Lipid Panel	Safety	X
3.3.1.3.2	Summary of Laboratory Values During the Overall Study Period for Participants Who Took Only Povorcitinib - Lipid Panel	Safety	X
3.3.1.3.3	Summary of Laboratory Values During the EXT Period for Crossover Participants - Lipid Panel	EXT-Evaluable	X
3.3.1.4.1	Summary of Laboratory Values During the PC Period - Inflammation Markers	Safety	X
3.3.1.4.2	Summary of Laboratory Values During the Overall Study Period for Participants Who Took Only Povorcitinib - Inflammation Markers	Safety	X
3.3.1.4.3	Summary of Laboratory Values During the EXT Period for Crossover Participants - Inflammation Markers	EXT-Evaluable	X
3.3.2.1.1	Shift Summary of Hematology Laboratory Values - to the Worst Abnormal Value During the PC Period	Safety	X
3.3.2.1.2	Shift Summary of Hematology Laboratory Values - to the Worst Abnormal Value During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.2.1.3	Shift Summary of Hematology Laboratory Values - to the Worst Abnormal Value During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.2.2.1	Shift Summary of Chemistry Laboratory Values - to the Worst Abnormal Value During the PC Period	Safety	X

Table No.	Title	Population	Standard
3.3.2.2.2	Shift Summary of Chemistry Laboratory Values - to the Worst Abnormal Value During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.2.2.3	Shift Summary of Chemistry Laboratory Values - to the Worst Abnormal Value During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.2.3.1	Shift Summary of Lipid Panel Laboratory Values - to the Worst Abnormal Value During the PC Period	Safety	X
3.3.2.3.2	Shift Summary of Lipid Panel Laboratory Values - to the Worst Abnormal Value During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.2.3.3	Shift Summary of Lipid Panel Laboratory Values - to the Worst Abnormal Value During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.3.1.1	Shift Summary of Hematology Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the PC Period	Safety	X
3.3.3.1.2	Shift Summary of Hematology Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.3.1.3	Shift Summary of Hematology Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.3.2.1	Shift Summary of Chemistry Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the PC Period	Safety	X
3.3.3.2.2	Shift Summary of Chemistry Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.3.2.3	Shift Summary of Chemistry Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.3.3.1	Shift Summary of Lipid Panel Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the PC Period	Safety	X
3.3.3.3.2	Shift Summary of Lipid Panel Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.3.3.3	Shift Summary of Lipid Panel Laboratory Values in CTCAE Grade - to the Worst Grade Abnormal Value During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.4.1.1	Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology During the PC Period	Safety	X
3.3.4.1.2	Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.4.1.3	Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.4.2.1	Treatment-Emergent Worsening of Laboratory Abnormalities - Chemistry During the PC Period	Safety	X
3.3.4.2.2	Treatment-Emergent Worsening of Laboratory Abnormalities - Chemistry During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.4.2.3	Treatment-Emergent Worsening of Laboratory Abnormalities - Chemistry During the EXT Period for Crossover Participants	EXT-Evaluable	X

Table No.	Title	Population	Standard
3.3.4.3.1	Treatment-Emergent Worsening of Laboratory Abnormalities - Lipid Panel During the PC Period	Safety	X
3.3.4.3.2	Treatment-Emergent Worsening of Laboratory Abnormalities - Lipid Panel During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.4.3.3	Treatment-Emergent Worsening of Laboratory Abnormalities - Lipid Panel During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.3.5.1	Summary of Potential Clinically Important Laboratory Values by Visit During the PC Period	Safety	X
3.3.5.2	Summary of Potential Clinically Important Laboratory Values by Visit During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.3.5.3	Summary of Potential Clinically Important Laboratory Values by Visit During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.5.1.1.1	Summary of PR Interval (ms) From 12-Lead ECG During the PC Period	Safety	X
3.5.1.1.2	Summary of PR Interval (ms) From 12-Lead ECG During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.5.1.1.3	Summary of PR Interval (ms) From 12-Lead ECG During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.5.1.2.1	Summary of QRS Interval (ms) From 12-Lead ECG During the PC Period	Safety	X
3.5.1.2.2	Summary of QRS Interval (ms) From 12-Lead ECG During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.5.1.2.3	Summary of QRS Interval (ms) From 12-Lead ECG During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.5.1.3.1	Summary of QT Interval (ms) From 12-Lead ECG During the PC Period	Safety	X
3.5.1.3.2	Summary of QT Interval (ms) From 12-Lead ECG During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.5.1.3.3	Summary of QT Interval (ms) From 12-Lead ECG During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.5.1.4.1	Summary of QTcF Interval (ms) From 12-Lead ECG During the PC Period	Safety	X
3.5.1.4.2	Summary of QTcF Interval (ms) From 12-Lead ECG During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.5.1.4.3	Summary of QTcF Interval (ms) From 12-Lead ECG During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.5.1.5.1	Summary of Heart Rate (beats/min) From 12-Lead ECG During the PC Period	Safety	X
3.5.1.5.2	Summary of Heart Rate (beats/min) From 12-Lead ECG During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X
3.5.1.5.3	Summary of Heart Rate (beats/min) From 12-Lead ECG During the EXT Period for Crossover Participants	EXT-Evaluable	X
3.5.1.6.1	Summary of Clinically Significant ECG Abnormalities During the PC Period	Safety	X
3.5.1.6.2	Summary of Clinically Significant ECG Abnormalities During the Overall Study Period for Participants Who Took Only Povorcitinib	Safety	X

Table No.	Title	Population	Standard
3.5.1.6.3	Summary of Clinically Significant ECG Abnormalities During the EXT Period for Crossover Participants	EXT-Evaluable	X

[a] x = 1 to 10 for each subgroup described in Section 7.4.3.
[b] x = 1 to 2 for each subgroup described in Section 7.5.1.

Figures

Figure No.	Title
4.1.1	Proportion of Participants Achieving HiSCR by Visit and Treatment Group During the PC Period Using Nonresponder Imputation
4.1.2	Forest Plot of Participants Achieving HiSCR at Week 12 by Subgroup
4.1.3	Proportion of Participants Achieving HiSCR by Visit and Treatment Group During the Overall Study Period
4.2.1.1	Proportion of Participants Achieving HiSCR75 by Visit and Treatment Group During the PC Period Using Nonresponder Imputation
4.2.1.2	Proportion of Participants Achieving HiSCR75 by Visit and Treatment Group During the Overall Study Period
4.2.2.1	Mean (+/- SE) Percent Change From Baseline in AN Count by Visit and Treatment Group During the PC Period
4.2.2.2	Mean (+/- SE) Percent Change From Baseline in AN Count by Visit and Treatment Group During the Overall Study Period
4.2.3.1	Proportion of Participants With >= 3-Point Decrease in Skin Pain NRS Score by Visit During the PC Period (With Baseline Skin Pain NRS Score >= 3)
4.2.3.2	Proportion of Participants With >= 3-Point Decrease in Skin Pain NRS Score by Visit During the Overall Study Period (With Baseline Skin Pain NRS Score >= 3)
4.2.4.1	Summary and Analysis of Proportion of Participants Achieving Skin Pain NRS30 by Visit During the PC Period (With Baseline Skin Pain NRS Score >= 3)
4.2.4.2	Summary of Proportion of Participants Achieving Skin Pain NRS30 by Visit During the Overall Study Period (With Baseline Skin Pain NRS Score >= 3)
4.2.5.1	Mean (+/- SE) Percent Change From Baseline in Skin Pain NRS Score by Visit and Treatment Group During the PC Period
4.2.5.2	Mean (+/- SE) Percent Change From Baseline in Skin Pain NRS Score by Visit and Treatment Group During the Overall Study Period
4.2.6.1	Proportion of Participants With at Least a 4-Point Increase in FACIT-F Score by Visit During PC Period
4.2.6.2	Proportion of Participants With at Least a 4-Point Increase in FACIT-F Score by Visit During the Overall Study Period
4.2.7.1	Mean (+/- SE) Change From Baseline in FACIT-F Scale Score by Visit and Treatment Group During the PC Period
4.2.7.2	Mean (+/- SE) Change From Baseline in FACIT-F Scale Score by Visit and Treatment Group During the Overall Study Period
4.2.8.1	Mean (+/- SE) Change From Baseline in DLQI Total Score by Visit and Treatment Group During the PC Period
4.2.8.2	Mean (+/- SE) Change From Baseline in DLQI Total Score by Visit and Treatment Group During the Overall Study Period
4.2.9.1	Proportion of Participants Achieving HiSCR90 by Visit and Treatment Group During the PC Period Using Nonresponder Imputation
4.2.9.2	Proportion of Participants Achieving HiSCR90 by Visit and Treatment Group During the Overall Study Period

Figure No.	Title
4.2.10.1	Proportion of Participants Achieving HiSCR100 by Visit and Treatment Group During the PC Period Using Nonresponder Imputation
4.2.10.2	Proportion of Participants Achieving HiSCR100 by Visit and Treatment Group During the Overall Study Period
4.6.1.1.1	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the PC Period - Hematology
4.6.1.1.2	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Hematology
4.6.1.1.3	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the EXT Period for Crossover Participants - Hematology
4.6.1.2.1	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the PC Period - Chemistry
4.6.1.2.2	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Chemistry
4.6.1.2.3	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the EXT Period for Crossover Participants - Chemistry
4.6.1.3.1	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the PC Period - Lipid Panel
4.6.1.3.2	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Lipid Panel
4.6.1.3.3	Mean Laboratory Data Change From Baseline by Visit and Treatment Group During the EXT Period for Crossover Participants - Lipid Panel
4.6.2.1.1	Box-and-Whisker Plot of Select Laboratory Values by Visit and Treatment Group During the PC Period
4.6.2.1.2	Box-and-Whisker Plot of Select Laboratory Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib
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4.6.2.2.1	Box-and-Whisker Plot of Change From Baseline in Select Laboratory Values by Visit and Treatment Group During the PC Period
4.6.2.2.2	Box-and-Whisker Plot of Change From Baseline in Select Laboratory Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib
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4.6.2.3.3	Box-and-Whisker Plot of Percent Change From Baseline in Select Laboratory Values by Visit and Treatment Group During the EXT Period for Crossover Participants
4.6.2.4.1	Box-and-Whisker Plot of Lipid Panel Values by Visit and Treatment Group During the PC Period
4.6.2.4.2	Box-and-Whisker Plot of Lipid Panel Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib
4.6.2.4.3	Box-and-Whisker Plot of Lipid Panel Values by Visit and Treatment Group During the EXT Period for Crossover Participants
4.6.2.5.1	Box-and-Whisker Plot of Change From Baseline in Lipid Panel Values by Visit and Treatment Group During the PC Period
4.6.2.5.2	Box-and-Whisker Plot of Change From Baseline in Lipid Panel Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib

Figure No.	Title
4.6.2.5.3	Box-and-Whisker Plot of Change From Baseline in Lipid Panel Values by Visit and Treatment Group During the EXT Period for Crossover Participants
4.6.2.6.1	Box-and-Whisker Plot of Percent Change From Baseline in Lipid Panel Values by Visit and Treatment Group During the PC Period
4.6.2.6.2	Box-and-Whisker Plot of Percent Change From Baseline in Lipid Panel Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib
4.6.2.6.3	Box-and-Whisker Plot of Percent Change From Baseline in Lipid Panel Values by Visit and Treatment Group During the EXT Period for Crossover Participants
4.6.3	Plot of Potential Hy's Law Events
4.7.1.1	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the PC Period - Systolic Blood Pressure
4.7.1.2	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Systolic Blood Pressure
4.7.1.3	Mean and 95% Confidence Interval Vital Sign Values by Visit During the EXT Period for Crossover Participants - Systolic Blood Pressure
4.7.2.1	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the PC Period - Diastolic Blood Pressure
4.7.2.2	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Diastolic Blood Pressure
4.7.2.3	Mean and 95% Confidence Interval Vital Sign Values by Visit During the EXT Period for Crossover Participants - Diastolic Blood Pressure
4.7.3.1	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the PC Period - Pulse
4.7.3.2	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Pulse
4.7.3.3	Mean and 95% Confidence Interval Vital Sign Values by Visit During the EXT Period for Crossover Participants - Pulse
4.7.4.1	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the PC Period - Respiratory Rate
4.7.4.2	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Respiratory Rate
4.7.4.3	Mean and 95% Confidence Interval Vital Sign Values by Visit During the EXT Period for Crossover Participants - Respiratory Rate
4.7.5.1	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the PC Period - Body Temperature
4.7.5.2	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Body Temperature
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4.7.6.2	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - Body Weight
4.7.6.3	Mean and 95% Confidence Interval Vital Sign Values by Visit During the EXT Period for Crossover Participants - Body Weight
4.7.7.1	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the PC Period - BMI
4.7.7.2	Mean and 95% Confidence Interval Vital Sign Values by Visit and Treatment Group During the Overall Study Period for Participants Who Took Only Povorcitinib - BMI

Figure No.	Title
4.7.7.3	Mean and 95% Confidence Interval Vital Sign Values by Visit During the EXT Period for Crossover Participants - BMI

Listings

Listing No.	Title
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2.1.1.2	Participant Enrollment and Disposition Status for the EXT Period
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2.2.2	Protocol Deviations
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2.4.3	Prior Therapy for Hidradenitis Suppurativa
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2.5.2	Study Drug Administration
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2.6.2	AN Count, ANdT Count, HiSCR, HiSCR75, HiSCR90, HiSCR100, and Flare
2.6.3	IHS4 Score
2.6.4	Analgesic Use
2.6.5	Rescue Lesional Treatment
2.6.6	HiSQoL Total and Subscale Scores
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2.6.8	Skin Pain NRS Score
2.6.9	Itch NRS Score
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2.6.11	WPAI-HS Score
2.6.12	EQ-5D-5L Score and EQ VAS
2.6.13	Hurley Stage
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2.7.8	Adverse Events of Special Interest
2.7.9.1.1	Events of Clinical Interest (Laboratory Component) - Increased Serum Creatinine and Renal Disfunction
2.7.9.1.2	Events of Clinical Interest (Preferred Term Component) - Increased Serum Creatinine and Renal Disfunction
2.7.9.2.1	Events of Clinical Interest (Laboratory Component) - Hepatic Events and Increased Hepatic Transaminases

Listing No.	Title
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2.7.9.3.1	Events of Clinical Interest (Laboratory Component) - Increased Creatine Phosphokinase
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2.9.3	Alert Vital Sign Values
2.10.1	12-Lead ECG Values

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