STATISTICAL ANALYSIS PLAN

INCB 50465-207

An Open-Label Phase 2 Study of INCB050465 in Participants With Primary Sjögren's Syndrome

IND Number:	[redacted]
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803**
Protocol Version:	**Original Protocol dated 12 JUN 2018**
CRF Approval Date:	**11 OCT 2018**
SAP Version:	**Original**
SAP Author:	[redacted]
Date of Plan:	**25 FEB 2019**

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

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LIST OF ABBREVIATIONS

Abbreviation	Term
AE	adverse event
ANC	absolute neutrophil count
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
BMI	body mass index
[redacted]	[redacted]
CRF	case report form
CTC	Common Terminology Criteria
CTCAE	Common Terminology Criteria for Adverse Events
CXCL13	CXC motif chemokine ligand 13
ECG	electrocardiogram
eCRF	electronic case report form
EQ-5D	European Quality Of Life 5 Dimensions questionnaire
ESSDAI	EULAR Sjögren's Syndrome Disease Activity Index
ESSPRI	EULAR Sjögren's Syndrome Patient Reported Index
EULAR	European League Against Rheumatism
FAS	full analysis set
FSFI	Female Sexual Function Index
[redacted]	[redacted]
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
PD	pharmacodynamic
PGIC	Patient Global Impression of Change questionnaire
PI3Kδ	phosphatidylinositide 3-kinase delta isoform
[redacted]	[redacted]
PROMIS	Patient-Reported-Outcomes Measurement Information System
PT	preferred term
QD	once daily
QTcF	QT interval corrected for heart rate using Fridericia's formula
SAE	serious adverse event
SAP	Statistical Analysis Plan
SGUS	salivary gland ultrasound
SOC	system organ class
SS	Sjögren's syndrome
[redacted]	[redacted]
TEAE	treatment-emergent adverse event
WHO	World Health Organization

1. INTRODUCTION

This is a single-group, open-label study of the impact of PI3Kδ inhibitor INCB050465 on signs and symptoms of SS. Twelve participants meeting the inclusion criteria and none of the exclusion criteria will be enrolled. Participants will receive treatment with INCB050465 [redacted] for 12 weeks and undergo ultrasound measurement of salivary glands, measurements of salivary flow, collection of symptom questionnaires, and PD [redacted] blood sampling to allow studies of cytokine levels, gene expression levels, and other PD markers.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the Study INCB 50465-207 Protocol.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 50465-207 Protocol dated 12 JUN 2018 and CRFs approved 11 OCT 2018. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and CRF versions.

2.2. Objectives and Endpoints

Table 1 presents the objectives and endpoints.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
• To determine the impact of INCB050465 on salivary gland echostructure.	• Proportion of participants with a 1 point or greater improvement on the SGUS score for parotid and submandibular glands at Week 4 and Week 12.
Secondary	
• To assess the impact of INCB050465 on salivary CXCL13.	• Change and percent change from baseline in salivary CXCL13 levels at Week 4 and Week 12.
• To assess the efficacy of INCB050465.	• Change and percent change in stimulated and unstimulated whole salivary flow from baseline at Weeks 4, 8, and 12. • Change and percent change in ESSDAI at Week 12. • Change and percent change in ESSPRI at Weeks 4, 8, and 12. • Change and percent change in symptom scores for dryness of eyes, mouth, and vagina at Weeks 4, 8, and 12. • Proportions of participants in each PGIC category at Weeks 4, 8, and 12. • Change and percent change in PROMIS Fatigue short form at Weeks 4, 8, and 12. • Change and percent change in FSFI at Weeks 4, 8, and 12 (female participants only). • Change and percent change in EQ-5D at Weeks 4, 8, and 12.
• To evaluate the safety and tolerability of INCB050465.	• Frequency, duration, and severity of AEs, clinical laboratory test results, vital sign results, ECGs, and physical examination findings.
[redacted]	

3. STUDY DESIGN

This is a single-group, open-label study of the impact of PI3Kδ inhibitor INCB050465 on signs and symptoms of SS. Twelve participants meeting the inclusion criteria and none of the exclusion criteria will be enrolled. Participants will receive treatment with INCB050465 [redacted] for 12 weeks and undergo ultrasound measurement of salivary glands, measurements of salivary flow, collection of symptom questionnaires, and PD [redacted] blood sampling to allow studies of cytokine levels, gene expression levels, and other PD markers.

3.1. Randomization

Not applicable.

3.2. Control of Type I Error

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

3.3. Sample Size Considerations

The sample size is based on the demonstration of preliminary findings of efficacy, which also depends on the occurrence of safety findings. Approximately 12 participants will be enrolled, which will provide > 90% chance of detecting at least 1 AE of interest (eg, platelets, hemoglobin, ANC, liver functions, and infections) if the underlying AE rate is 20%.

3.4. Schedule of Assessments

Refer to the Protocol dated 12 JUN 2018 for a full description of all study procedures and assessment schedules for this study.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations

4.1.1. Day 1

Day 1 is the date that the first dose of study drug INCB050465 is administered to the participants.

4.1.2. Study Day

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

Day # = (Visit/Reporting Date – Day 1 date + 1).

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

Day # = (Visit/Reporting Date – Day 1 date).

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

4.1.3. Baseline Value

Baseline is the last nonmissing measurement obtained before the first administration of INCB050465.

When scheduled assessments and unscheduled assessments occur on the same day and 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. Last Available Value

The last available value is the last nonmissing measurement obtained after starting INCB050465 and within 30 days after the last dose of INCB050465.

4.1.5. Handling of Missing and Incomplete Data

In general, values for missing data will not be imputed unless methods for handling missing data are specified in relevant sections.

4.2. Variable Definitions

4.2.1. Age

Participant age will be directly copied from the Demography Form of the eCRF.

4.2.2. Body Mass Index

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

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

4.2.3. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of INCB050465.

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

- Before the date of first administration of INCB050465 and is ongoing throughout the study or ends on/after the date of first administration of INCB050465.
- On/after the date of first administration of INCB050465 and is ongoing or ends during the course of study treatment.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first administration of INCB050465. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, or both prior and concomitant.

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

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; Version 9.1 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

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

5.3. Analysis Populations

5.3.1. Full Analysis Set

The FAS includes all participants enrolled in the study who received at least 1 dose of study drug.

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

5.3.2. [redacted]

[redacted]

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

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

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

6.1.1. Demographics

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

6.1.2. Baseline Disease Characteristics

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

- Years since first onset of SS
- Severity of disease (Mild/Moderate/Severe)
- Current state of disease (Progressive/Stable)
- Prior or current treatment for SS (No/Yes)
- Prior surgery (No/Yes)
- Type of disease (Glandular/Extraglandular [categories of symptoms])
- Other autoimmune disease (No/Yes)
- Oral dryness (No/Yes [years since oral dryness started])
- Ocular dryness (No/Yes [years since ocular dryness started])

6.1.3. Prior Therapy

Prior medication information for SS will be used to identify medication received by participants before enrollment into the study. Prior medications for SS will be summarized.

6.1.4. General Medical History

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

6.2. Disposition of Participants

The number and percentage of participants who were treated, completed study treatment, completed the study, discontinued study treatment with a primary reason for discontinuation, and discontinued from the study with a primary reason for withdrawal will be summarized for the FAS. The number of participants enrolled by site will also be provided.

6.3. Protocol Deviations

Protocol deviations recorded on the CRF will be presented in the participant data listings. A summary table of major protocol deviations will also be provided.

6.4. Exposure

For participants in the FAS, descriptive statistics will be provided for duration of treatment, average daily dose, and total dose. Duration of treatment with INCB050465 is defined as the number of days from Day 1 to the date of last record of INCB050465 administration.

6.5. Study Drug Compliance

For participants in the FAS, overall compliance (%) for INCB050465 will be calculated for all participants as

> Compliance (%) = 100 × [total number of tablets dispensed – total number of tablets returned] / [total intended number of tablets].

The total intended number of tablets will be based on the earliest study day of permanent discontinuation of the study drug. The total intended number of tablets is defined as the sum of the tablets prescribed by the investigator accounting both for planned dose modifications as well as those modifications mandated by the investigator.

6.6. Prior and Concomitant Medication

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

7. EFFICACY

Appendix A provides a list of planned tables and listings. Sample data displays are included in a separate document. All efficacy analyses are exploratory. Hence, no p-values will be provided, and multiple adjustment will not be made.

7.1. Efficacy Parameters

7.1.1. Ultrasound of Salivary Glands

The echostructure of each gland on B-mode images will be graded on a 5-point scales (0 to 4) as described by Gazeau et al (2018). Grade 0 indicates a normal homogeneous gland, Grade 1 small hypoechoic areas with hyperechoic bands, Grade 2 multiple hypoechoic areas < 2 mm, Grade 3 multiple hypoechoic areas 2 to 6 mm, and Grade 4 multiple hypoechoic areas > 6 mm. For each participant at each timepoint, 4 grades will be obtained, one for each parotid and submandibular gland. The SGUS score is the numeric sum of the 4 individual grades. [redacted]

7.1.2. EULAR Sjögren's Syndrome Disease Activity Index

The ESSDAI assesses 12 domains: constitutional, lymphadenopathy/lymphoma, glandular, articular, cutaneous, pulmonary, renal, muscular, peripheral neuropathy, central nervous system, hematologic, and biologic.

7.1.3. Salivary Flow

Stimulated and unstimulated salivary flow will be measured at visits.

7.1.4. Patient-Reported Outcomes

Patient-reported outcome instruments will be given to participants for completion at study visits.

7.1.4.1. Dryness Questionnaire

The dryness questionnaire will ask participants to rate the dryness of eyes, mouth, or vagina (female participants only) with 24-hour recall using an 11-point numerical rating system ranging from 0 (no dryness) to 10 (worst imaginable).

7.1.4.2. EULAR Sjögren's Syndrome Patient Reported Index

The ESSPRI consists of 3 items, each with a 0 (no symptom) to 10 (maximum imaginable symptom) scale. The 3 items are dryness, fatigue, and pain. The recall period is 2 weeks.

7.1.4.3. Patient Global Impression of Change Questionnaire

The PGIC asks a single question regarding how the patient is feeling since beginning new therapy. The questionnaire uses a 7-point scale ranging from "very much worse" to "very much improved," with the midpoint as no change.

7.1.4.4. Female Sexual Function Index

The FSFI is a brief, self-report measure of female sexual function (female participants only). The questionnaire contains 19 items covering 6 domains of sexual function. The recall period is 4 weeks.

7.1.4.5. PROMIS Fatigue Short Form

The PROMIS fatigue short form includes 7 items with a rating sale of 1 to 5. The recall period is 7 days.

7.1.4.6. European Quality of Life 5 Dimensions Questionnaire

The EQ-5D is a standardized measure of health status. It consists of 5 questions, each with a 5-item rating scale plus a visual analog scale rating from 1 to 100 for overall health status. The questionnaire probes the participants' responses for the current day.

7.2. Analysis of Efficacy Endpoints

The efficacy endpoints include the following:

- Proportion of participants with a 1 point or greater improvement on the SGUS score for parotid and submandibular glands at Week 4 and Week 12.
- Change and percentage change in SGUS score from baseline at Week 4 and Week 12.
- Change and percentage change in stimulated and unstimulated whole salivary flow from baseline at Weeks 4, 8, and 12.
- Change and percentage change in ESSDAI at Week 12.
- Change and percentage change in ESSPRI at Weeks 4, 8, and 12.
- Change and percentage change in symptom scores for dryness of eyes, mouth, and vagina and in total symptom scores in female at Weeks 4, 8, and 12.
- Proportions of participants in each PGIC category at Weeks 4, 8, and 12.
- Change and percentage change in PROMIS Fatigue short form at Weeks 4, 8, and 12.
- Change and percentage change in FSFI at Weeks 4, 8, and 12 (female participants only).
- Change and percentage change in EQ-5D at Weeks 4, 8, and 12.

Category variables will be summarized using descriptive statistics including sample size, frequency, and percentages. Continuous variables will be summarized using descriptive statistics including sample size, mean, median, standard deviation, minimum, and maximum. For endpoints with clinically meaningful subscores, these subscores will also be summarized.

[redacted]

[redacted]

8. SAFETY AND TOLERABILITY

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

8.1. General Considerations

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

Unless otherwise stated, table summaries will be limited to AEs occurring within 30 days of the last administration of study drug.

8.2. Adverse Events

8.2.1. Adverse Event Definitions

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

Adverse events will be tabulated by MedDRA PT and SOC. Severity of AEs will be graded using the NCI CTCAE. The CTCAE v4.03 (2010) is used for this study. 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. The incidence of AEs and treatment-related AEs will be tabulated. Serious AEs (SAEs) will also be tabulated.

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

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

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

8.2.2. Adverse Event Summaries

An overall summary of AEs will include the following:

- Number (%) of participants reporting any TEAEs
- Number (%) of participants reporting any SAEs
- Number (%) of participants reporting any Grade 3 or 4 TEAEs
- Number (%) of participants reporting any treatment-related TEAEs
- Number (%) of participants who temporarily interrupted study treatment because of TEAEs
- Number (%) of participants who permanently discontinued study treatment because of TEAEs
- Number (%) of participants who had a TEAE leading to death

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

- Summary of TEAEs by SOC and PT
- Summary of TEAEs by PT in decreasing order of frequency
- Summary of TEAEs by SOC, PT, and maximum severity
- Summary of treatment-related AEs by SOC and PT
- Summary of treatment-related AEs by PT in decreasing order of frequency
- Summary of treatment-related AEs by SOC, PT, and maximum severity
- Summary of Grade 3 or 4 AEs by SOC and PT
- Summary of Grade 3 or 4 treatment-related AEs by SOC and PT
- Summary of TEAEs leading to death by SOC and PT
- Summary of treatment-emergent SAEs by SOC and PT
- Summary of treatment-emergent SAEs by PT in descending order of frequency
- Summary of treatment-related SAEs by SOC and PT
- Summary of TEAEs leading to dose interruption by SOC and PT
- Summary of TEAEs leading to discontinuation of treatment by SOC and PT
- Summary of nonserious TEAEs by SOC and PT

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

Laboratory values, change from baseline values, and percentage change from baseline values will be summarized descriptively by visit. Baseline values will be determined using the nonmissing values collected before the first administration, prioritizing scheduled assessments over unscheduled visits. For baseline laboratory candidates with the same date and time in the same priority category, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

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

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.

When there are multiple laboratory nonmissing values for a participant's particular test at a scheduled postbaseline visit, use the smallest laboratory sequence number to identify the record.

Laboratory hematology and serum chemistry parameters identified in Protocol Table 10 will be summarized. Numeric laboratory values will be summarized descriptively in SI units, and non-numeric test values will be tabulated when necessary. In addition, box-and-whisker plots may be provided for some tests if applicable.

For test results that will be summarized with available normal ranges, the number and percentage of participants with the laboratory values being low, normal, high, and missing will be tabulated for each test and each visit.

Shift tables will be presented showing change in CTCAE grade from baseline to worst grade postbaseline. The denominator for the percentage calculation will be the number of participants in the baseline category.

8.4. Vital Signs

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

Criteria for clinically notable vital sign abnormalities are defined in Table 2. The abnormal values for participants exhibiting clinically notable vital sign abnormalities will be listed. Alert vital signs are defined as an absolute value outside the defined range and percentage change from baseline outside (-25%, 25%). The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 2: 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
Respiratory rate	> 24 breaths/min	< 8 breaths/min
Temperature	> 38°C	< 35.5°C

8.5. Electrocardiograms

Twelve-lead ECGs including PR, QRS, QT, QTcB, QTcF, and RR intervals will be obtained for each participant during the study. Change and percentage change from baseline will be calculated at each postbaseline assessment time. Descriptive statistics will be determined for each ECG parameter.

Incidences of clinically notable ECG abnormalities are defined in Table 3. Participants exhibiting clinically notable ECG abnormalities will be listed with study visit. Abnormal values for participants with alert ECG values, defined as an absolute value outside the defined normal ranges and the percentage change from baseline outside (-25%,25%), will be identified and listed.

When triple ECGs are measured, the average of the 3 ECGs will be used in the summary table, but all 3 of these ECGs will be listed.

Table 3: Criteria for Clinically Notable Electrocardiogram Abnormalities

Parameter	High Threshold	Low Threshold
QTcF	> 460 msec	< 295 msec
QTcB	> 460 msec	< 295 msec
PR	> 220 msec	< 75 msec
QRS	> 120 msec	< 50 msec
QT	> 500 msec	< 300 msec
RR	> 1330 msec	< 600 msec

QTcF = Fridericia correction.

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 4.

Table 4: Statistical Analysis Plan Versions

SAP Version	Date
Original	25 FEB 2019

10.1. Changes to Protocol-Defined Analyses

Not applicable.

10.2. Changes to the Statistical Analysis Plan

Not applicable.

11. REFERENCES

Gazeau P, Cornec D, Jousse-Joulin S, Guellec D, Saraux A, Devauchelle-Pensec V. Time-course of ultrasound abnormalities of major salivary glands in suspected Sjögren's syndrome. Joint Bone Spine 2018;85:227-232.

National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03. 2010. https://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf. Accessed March 20, 2018.

APPENDIX A. PLANNED TABLES AND LISTINGS

This appendix provides a list of the planned tables and listings for the Clinical Study Report. Standard tables will follow the conventions in the Standard Safety Tables initial version. Shells are provided for nonstandard tables in a separate document. In-text tables are identical in structure and content as appendix tables but follow a Rich Text Format.

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

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Adverse Events and Exposure	
2.7.1	Study Drug Administration
2.7.2	Adverse Events
2.7.3	Serious Adverse Events
2.7.4	Grade 3 and Higher Adverse Events
2.7.5	Adverse Events Leading to Death
2.7.6	Treatment-Related Adverse Events
2.7.8	Adverse Events Leading to Dose Interruption
2.7.9	Adverse Events Leading to Discontinuation

Listing No.	Title
Laboratory Data	
2.8.1	Clinical Laboratory Values – Hematology
2.8.2	Clinical Laboratory Values – Serum Chemistry
2.8.3	Abnormal Clinical Laboratory Values – Hematology
2.8.4	Abnormal Clinical Laboratory Values – Serum Chemistry
Vital Signs	
2.9.1	Vital Signs
2.9.2	Abnormal Vital Sign Values
2.9.3	Alert Vital Sign Values
ECG	
2.10.1	12-Lead ECG Values
2.10.2	Abnormal 12-Lead ECG Values
2.10.3	Alert 12-Lead ECG Values