Official Title:	**Safety, Pharmacokinetics, and Pharmacodynamics of Escalating Oral Doses of the Arginase Inhibitor INCB001158 (Formerly Known as CB1158) as a Single Agent and in Combination With Immune Checkpoint Therapy in Patients With Advanced/Metastatic Solid Tumors**
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Statistical Analysis Plan

INCB 01158-101

Safety, Pharmacokinetics, and Pharmacodynamics of Escalating Oral Doses of the Arginase Inhibitor INCB001158 (Formerly Known as CB-1158) as a Single Agent and in Combination With Immune Checkpoint Therapy in Patients With Advanced/Metastatic Solid Tumors

IND Number:	**128,080**
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Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803** **United States**
Protocol Version:	**Protocol Amendment 2-US 3 dated 10 NOV 2020**
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SAP Version:	**Original**
SAP Author:	[redacted]
Date of Plan:	**22 FEB 2021**

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
AUC_{0-12}	area under the steady-state plasma or serum concentration-time curve over 1 dose interval
AUC_t	area under the plasma or serum concentration-time curve from time = 0 to the last measurable concentration at time = t
BID	twice daily
BOR	best overall response
CI	confidence interval
CL/F	apparent oral dose clearance
C_{max}	maximum observed plasma or serum concentration
CR	complete response
CRC	colorectal cancer
CrCL	creatinine clearance
CRF	case report form
CTCAE	Common Terminology Criteria for Adverse Events
DLT	dose-limiting toxicity
dMMR	mismatch repair deficient
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
FAS	full analysis set
FDA	Food and Drug Administration
iRECIST	modified form of RECIST v1.1 for immune-based therapeutics
IV	intravenous(ly)
MedDRA	Medical Dictionary for Regulatory Activities
MSI-H	microsatellite instability-high
NCI	National Cancer Institute
NE	not evaluable
NSCLC	non–small cell lung cancer
ORR	objective response rate
PD	progressive disease
PD-1	programmed cell death protein-1
PD-L1	programmed death ligand 1
PFS	progression-free survival

Abbreviation	Term
PK	pharmacokinetic(s)
PO	per os (orally)
PR	partial response
PT	preferred term
QTcF	QT interval corrected using Fridericia's formula
RCC	renal cell carcinoma
RECIST	Response Evaluation Criteria in Solid Tumors
RP2D	recommended Phase 2 dose
SAP	Statistical Analysis Plan
SCCHN	squamous cell carcinoma of the head and neck
SD	stable disease
SOC	system organ class
TEAE	treatment-emergent adverse event
t_{max}	time to maximum observed concentration
UC	urothelial carcinoma
WHO	World Health Organization

1. INTRODUCTION

This is a Phase 1 open-label, nonrandomized study to evaluate the safety, tolerability, PK, pharmacodynamics, and antitumor activity of the arginase inhibitor INCB001158 (formerly known as CB-1158), both as monotherapy and in combination with the immune checkpoint inhibitor pembrolizumab, an anti–PD-1 agent, in participants with advanced/metastatic solid tumors. The background and rationale for the study can be found in the study protocol.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the INCB 01158-101 Protocol.

Detailed methodology of PK, [redacted] pharmacodynamic analyses will be presented separately.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 01158-101 Protocol Amendment 2-US 3 dated 10 NOV 2020 and CRFs approved 08 APR 2019. 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

Primary Objectives	**Primary Endpoints**
Parts 1a and 2	
To evaluate the safety and tolerability of INCB001158 for participants with advanced/metastatic and/or treatment refractory solid tumors	AEs and changes in laboratory values, vital signs, and physical examinations
Parts 1b, 1c, and 3	
To evaluate the safety and tolerability of INCB001158 in combination with pembrolizumab in participants with advanced/metastatic and/or treatment-refractory solid tumors	AEs and changes in laboratory values, vital signs, and physical examinations
Secondary Objectives	**Secondary Endpoints**
Parts 1a and 2	
To select the RP2D of INCB001158 for participants with advanced/metastatic solid tumors	Based on an evaluation of AEs, PK, pharmacodynamics, and evidence of clinical activity
Parts 1b and 3	
To select the RP2D of INCB001158 in combination with pembrolizumab for participants with advanced/metastatic solid tumors	Based on an evaluation of AEs, PK, pharmacodynamics, and evidence of clinical activity
Parts 1a, 1b, 1c, 2, and 3	
To evaluate the antitumor effect of INCB001158 as monotherapy and in combination with pembrolizumab for participants with advanced/metastatic solid tumors	Assessed by standard RECIST v1.1 criteria, except for pleural mesothelioma, which will be evaluated using modified RECIST criteria (ORR, BOR, DOR, and PFS)
Determine PK of INCB001158 alone and in combination with pembrolizumab	C_{max}, t_{max}, AUC_t, AUC_{0-12}, and CL/F in participants with CrCL 30-49 mL/min (Part 1c only) or CrCL ≥ 50 mL/min (Parts 1a, 1b, 2, and 3)

Table 1: Objectives and Endpoints (Continued)

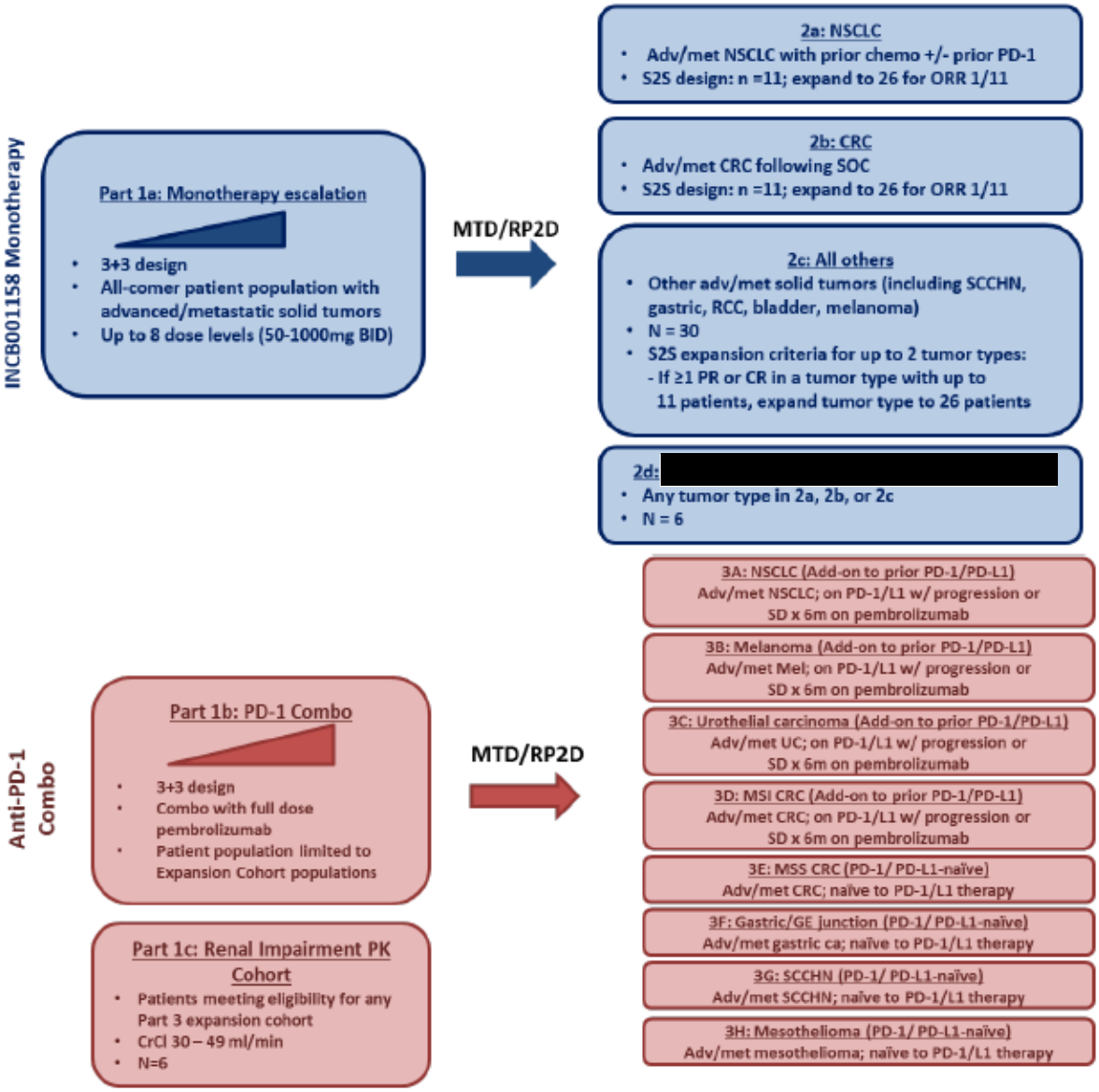
3. STUDY DESIGN

Part 1 will consist of dose-escalation using a 3 + 3 design and will determine the RP2D of INCB001158 as monotherapy (Part 1a) and in combination with pembrolizumab (Part 1b and Part 1c); efficacy will also be explored.

Part 2 and Part 3 will consist of tumor expansion cohorts and use a Simon 2-stage design (Simon 1989) to determine whether INCB001158 as monotherapy (Part 2) or in combination with pembrolizumab (Part 3) has sufficient antitumor activity to warrant further testing in subsequent clinical studies. Part 2 and Part 3, respectively, will further evaluate the safety and tolerability of the RP2D of INCB001158 as monotherapy and in combination with pembrolizumab.

The study design is illustrated in Figure 1. The details can be found in the study protocol.

Figure 1: Overall Study Design



3.1. Randomization

Not applicable.

3.2. Control of Type I Error

All statistical analyses are exploratory in nature. Unless otherwise specified, all CIs provided will be at the 95% confidence level.

3.3. Sample Size Considerations

Refer to Protocol Amendment 2-US 3 dated 10 NOV 2020 for the sample size considerations.

3.4. Schedule of Assessments

Refer to Protocol Amendment 2-US 3 dated 10 NOV 2020 for a full description of all study procedures and assessment schedules for this study.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1

Day 1 is the date that the first dose of study drug (INCB001158 or pembrolizumab) 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 INCB001158 or pembrolizumab, unless otherwise defined.

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 imputed 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 disease/cancer, a partial disease/cancer diagnosis date will be handled as follows in the calculation:

- If only the day 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 is used in deriving variables such as duration of treatment or TEAE flag, a missing or partial date of the last dose 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 will be used.
- If both the month and day are missing, then the earlier date of 31 DEC of the year or the date that the participant discontinued treatment will be used.
- Otherwise, the date that the participant discontinued treatment will be used as the date of the last dose.

For relevant efficacy endpoints, a partial date of the death date will be handled as follows in the calculation:

- If mmyyyy for the last known alive date = mmyyyy for the death date, then the death date will be set to the day after the last known alive date.
- If mmyyyy for the last known alive date < mmyyyy for the death date, then the death date will be set to the first day of the death month.
- Otherwise, the partial death date will not be imputed.

4.1.5. Cycle Length and Duration

Cycle 1 Day 1 is the day that the first dose of INCB001158 or pembrolizumab is administered. The scheduled cycle length is 28 days for participants in Parts 1a and 2. The scheduled cycle length is 21 days for participants in Parts 1b, 1c, and 3.

INCB001158 dosing will not be adjusted for body weight or surface area. Participants will continue to receive INCB001158 until disease progression (confirmed per iRECIST), intolerable toxicity, consent withdrawal, or the investigator determines that it is not in the participant's best interest to remain on-study.

- **INCB001158:** In Part 1, INCB001158 will be administrated PO BID with the dose corresponding to cohort assignment. In Parts 2 and 3, INCB001158 will be administrated PO BID at the RP2D determined in Part 1 as long as the participant is deriving benefit and has not met any of the protocol-defined conditions for treatment withdrawal.
- **Pembrolizumab:** 200 mg IV on Day 1 of each 21-day cycle. The maximum duration of pembrolizumab treatment on-study will be up to 35 doses (approximately 2 years).

4.2. Variable Definitions

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

4.2.1. Age

Participant age will be calculated as the integer part of the number of years from date of birth to the date of signing the ICF, using the following formula:

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

4.2.2. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of INCB001158 or pembrolizumab.

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

- Before the date of first administration of INCB001158 or pembrolizumab and is ongoing throughout the study or ends on/after the date of first study drug administration.
- On/after the date of first administration of INCB001158 or pembrolizumab and is ongoing or ends during the course of study.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first dose of INCB001158 or pembrolizumab. In the listing, it will be indicated whether a medication is only prior, only concomitant, 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 or later) will be used for the generation of all tables, graphs, and statistical analyses.

Since this is an open-label clinical trial, descriptive statistics will be employed to analyze the data. 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, and time-to-event variables will be summarized by Kaplan-Meier plots, medians, and ranges.

Safety data may be presented by treatment group (INCB001158 monotherapy in Parts 1a and 2, INCB001158 + pembrolizumab in Parts 1b and 3, INCB001158 + pembrolizumab in participants with impaired renal functions in Part 1c) and by INCB001158 dose level.

Efficacy data may be presented by treatment group and dose level in the dose-escalation parts (Parts 1a and 1b) and by treatment group and tumor type for participants in the expansion cohorts (Parts 2 and 3) with data from the renal impairment cohort (Part 1c) included with Part 3.

Data listings will be created to support each table and to present all data collected.

5.2. Treatment Groups

In Part 1a, participants with advanced or metastatic solid tumors will be enrolled in INCB001158 monotherapy treatment groups for dose escalation. In Part 2, participants with specific tumor types will be enrolled to receive INCB001158 monotherapy at the RP2D.

In Parts 1b and 1c, participants with advanced or metastatic solid tumors specified in the expansion cohorts will be enrolled in INCB001158 + pembrolizumab combination treatment groups for dose escalation (Part 1b) and safety assessments for participants with renal impairment (Part 1c). In Part 3, participants with specific tumor types will be enrolled to receive INCB001158 at the RP2D + pembrolizumab. Treatment groups and INCB001158 and pembrolizumab dose levels are outlined in Table 2.

Table 2: Treatment Groups for Participants Enrolled

Part	Treatment Group	Drug	Dose
Part 1a	INCB001158 monotherapy	INCB001158	50-150 mg PO BID
Part 1b	INCB001158 + pembrolizumab	INCB001158	50-100 mg PO BID
		Pembrolizumab	200 mg IV on Day 1 of each 21-day cycle
Part 1c	INCB001158 + pembrolizumab[a]	INCB001158	50 mg PO BID
		Pembrolizumab	200 mg IV on Day 1 of each 21-day cycle
Part 2	INCB001158 monotherapy	INCB001158	RP2D from Part 1a
Part 3	INCB001158 + pembrolizumab	INCB001158	RP2D from Part 1b
		Pembrolizumab	200 mg IV on Day 1 of each 21-day cycle

[a] Participants with impaired renal function.

5.3. Analysis Populations

5.3.1. Full Analysis Set

The FAS will include all participants who received at least 1 dose of INCB001158 or pembrolizumab. Participants will be analyzed according to the treatment to which they have been initially assigned.

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

5.3.2. Safety Population

The safety population will include all participants who received at least 1 dose of INCB001158 or pembrolizumab. Treatment groups for this population will be determined according to the actual treatment the participant received regardless of assigned study treatment.

All safety analyses will be conducted using the safety population.

5.3.3. DLT-Evaluable Population in Dose Escalation

The DLT-evaluable population in the dose-escalation part will include participants treated with the assigned dose level of INCB001158 who have had a DLT or those who have received at least 75% of the planned doses (ie, ≥ 32 of the maximum 42 doses to be given in a 21-day cycle or ≥ 42 of the maximum 56 doses to be given in a 28-day cycle). For participants in Part 1b, participants must receive the planned doses of pembrolizumab in Cycle 1 in order to be evaluable for DLTs. This population will be considered evaluable for determining the tolerability of the given dose.

5.3.4. Efficacy-Evaluable Population

See Protocol Section 15.3.3. The efficacy-evaluable population will be used for the analysis of efficacy data except PFS.

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

6.1.1. Demographics and Baseline Characteristics

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

6.1.2. Baseline Disease Characteristics and Disease History

The following baseline disease characteristics may be summarized for all or applicable participants in the FAS: primary diagnosis, time since diagnosis, time since metastatic disease or diagnosis of locally advanced inoperable cancer, stage at initial diagnosis, disease histology, histological grade, P16/HPV (for participants with SCCHN)/PD-L1 status, MSI-h/dMMR status, mutation status (listing), and ECOG performance status.

6.1.3. Prior Therapy

The number of participants receiving any prior therapy and the number of prior systemic cancer therapy regimens will be summarized for all participants in the FAS. The regimen name, component drugs, start and stop dates, purpose of the regimen, best response, reason for discontinuation, and date of relapse/progression will be listed.

For participants who received prior radiation, the body site, start and stop dates, and total dose will be listed.

For participants who had prior surgery or surgical procedure for the malignancies under study, the date and description of the surgery/procedure will be listed.

6.1.4. Medical History

For participants in the FAS who experienced past and/or concomitant medical conditions, the medical history condition/event, start and end dates, and whether the condition was ongoing or intermittent will be listed.

6.2. Disposition of Participant

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

6.3. Protocol Deviations

Protocol deviations recorded may be summarized and listed.

6.4. Exposure

For participants in the safety population, exposure to INCB001158 and pembrolizumab will be summarized descriptively as follows:

- Exposure to INCB001158
  - **Total actual dose (mg):** total actual dose taken of INCB001158.
  - **Duration of treatment with INCB001158 (days)**: date of last dose of INCB001158 – date of first dose of INCB001158 + 1.
  - **Average daily dose of INCB001158 (mg/day)**: total actual INCB001158 dose taken (mg) / duration of treatment with INCB001158 with nonzero dosing (days).
- Exposure to pembrolizumab
  - **Number of cycles**: number of cycles with a nonzero dose of pembrolizumab.
  - **Total number of infusions:** total number of infusions per participant with a nonzero dose of pembrolizumab.
  - **Total dose administered (mg):** sum of the cumulative dose of pembrolizumab that has been administered to the participant.

    For an infusion i, let C_i be the concentration (mg/mL) of pembrolizumab and V_i be the total volume administered (in mL) reported on the pembrolizumab dosing eCRF; let N be the total number of infusions:

    $$\text{total dose administered (mg)} = \sum_{i=1}^{N} C_i \times V_i.$$

  - **Average dose (mg):** total dose administered (mg) / the total number of infusions.

6.5. Study Drug Compliance

For participants in the safety population, overall compliance (%) for INCB001158 will be calculated as follows:

compliance (%) = 100 × [total dose actually taken] / [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 actual dose taken will be calculated based on information entered on the Drug Accountability eCRF. If there are dispensed drugs that have not been returned yet, the actual dose taken starting from the dispense date of the unreturned drugs 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. The number and percentage of participants in the FAS for each prior and concomitant medication will be summarized by WHO drug class and WHO drug PT.

7. EFFICACY

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

7.1. General Considerations

This study had no primary efficacy endpoint. The secondary efficacy endpoints include ORR, BOR, DOR, and PFS by investigator assessment based on RECIST v1.1.

7.2. Efficacy Hypotheses

Each Simon 2-stage design (Simon 1989) will test the null hypothesis that the true ORR is less than or equal to the clinically insignificant response rate p_0% against the alternative hypothesis that the true ORR is equal to or greater than the target rate of p_1%. For each Simon 2-stage design, the value for p_0 is determined by a historical response rate (refer to Protocol Section 15.2).

7.3. Analysis of the Efficacy Parameters

7.3.1. Response Criteria

Overall disease status will be categorized using RECIST v1.1 (Eisenhauer et al 2009) based on investigator assessment. Participants will have their overall response evaluated as CR, PR, SD, non-CR/non-PD (only for participants with nonmeasureable disease alone at baseline), PD, or NE at each postbaseline radiologic assessment based on changes in target lesions, nontarget lesions, and appearance of new lesions.

7.3.2. Unconfirmed and Confirmed Best Overall Response

In general, under RECIST v1.1, the unconfirmed best overall response is the best response recorded postbaseline prior to and including the first PD, in the order of CR, PR, SD (non-CR/non-PD), PD, and NE. The best overall response will be determined from response assessments prior to or on the same day as new anticancer therapy. If any alternative cancer therapy is taken while on study, any subsequent assessments will be excluded from the best overall response determination.

In the case of SD (non-CR/non-PD), measurements must meet the SD (non-CR/non-PD) criteria at least once after the date of first dose at a minimum interval of 8 weeks. Participants that fail to meet this criterion will have best overall response of PD if the next available assessment indicates PD or NE if there is no additional assessment available.

The participant's confirmed best overall response assessment will depend on the achievement of both measurement and confirmation criteria in Table 3.

Table 3: Confirmed Response Based on Subsequent Assessments

First Timepoint Response	Second Timepoint Response	Confirmed Response
CR	CR	CR or SD or NE[a]
CR	PR[b]	SD or NE[c]
CR	PR[a]	SD or NE[a]
CR	Non-CR/Non-PD[d]	Non-CR/Non-PD[a] or NE
CR	PD	SD or NE[a] or Non-CR/Non-PD[a]
CR	NE	SD or NE[a] or Non-CR/Non-PD[a]
CR	No further evaluation	SD or NE[a] or Non-CR/Non-PD[a]
PR	CR	PR or SD or NE[e]
PR	PR	PR or SD or NE[a]
PR	SD	SD or NE[a]
PR	NE	SD or NE[a]
PR	PD	SD or NE[a]
PR	No further evaluation	SD or NE[a]
SD	CR	SD or NE[a]
SD	PR	SD or NE[a]
SD	SD	SD or NE[a]
SD	PD	SD or NE[a]
SD	NE	SD or NE[a]
SD	No further evaluation	SD or NE[a]
Non-CR/Non-PD[a]	CR	Non-CR/Non-PD[a] or NE
Non-CR/Non-PD[a]	Non-CR/Non-PD[a]	Non-CR/Non-PD[a] or NE
Non-CR/Non-PD[a]	PD	Non-CR/Non-PD[a] or NE
Non-CR/Non-PD[a]	NE	Non-CR/Non-PD[a] or NE
Non-CR/Non-PD[a]	No further evaluation	Non-CR/Non-PD[a] or NE
PD	No further evaluation	PD
NE	CR	NE
NE	PR	NE
NE	SD	NE
NE	Non-CR/Non-PD[a]	NE
NE	PD	NE
NE	NE	NE
NE	No further evaluation	NE

Note: A confirmed response of SD can only be made after the participant is on-study for a minimum of 8 weeks according to study protocol or SAP. If the participant is on-study less than 8 weeks, any tumor assessment indicating stable disease before this time period will have a confirmed response of NE. NE is not required to be confirmed according to the table.

Note: Subsequent documentation of CR may provide confirmation of a previously identified CR for participants where the second integrated response was NE. Subsequent documentation of PR may provide confirmation of a previously identified PR for participants where the second integrated response was NE or SD. If the third tumor assessment confirms the CR (or PR) then the confirmed response will be CR (or PR). Only 1 intervening NE is allowed between CRs/PRs. For example: CR NE CR = CR; PR NE PR/CR = PR. Additionally, 1 SD (≥ 25% reduction in target lesions comparing with baseline) is allowed between PRs (eg, PR SD PR/CR = PR). Note: in the following scenario, PR SD NE PR, the second PR is not a confirmed PR.

[a] Confirmed response is CR if gap (4 weeks) is met. Otherwise, confirmed response is SD if at least 8 weeks on study, or NE if within 8 weeks on study.
[a] Special case programming: assign PR or SD following CR as PD in confirmed response.
[a] Confirmed response will be SD if the first tumor assessment is at least 8 weeks on-study. Otherwise, the confirmed response will be NE.
[a] Non-CR/Non-PD applies to participants with nonmeasurable disease at baseline. A confirmed response of Non-CR/Non-PD can only be made after the participant is on-study for a minimum of 8 weeks according to study protocol or SAP. If the participant is on-study less than 8 weeks, any tumor assessment indicating stable disease before this time period will have a confirmed response of NE.
[a] Confirmed response is PR if gap (4 weeks) is met. Otherwise, confirmed response is SD if at least 8 weeks/days on study, or NE if within 8 weeks on study.

7.3.3. Objective Response Rate

A participant is considered an objective responder if they have a best overall response of CR or PR before first PD and start of any subsequent anticancer therapy.

The ORR based on both unconfirmed and confirmed best overall responses will be estimated with 95% CIs. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.4. Duration of Response

For objective responders, the DOR is the time from the first overall response contributing to an objective response to the earlier of the participant's death or first overall response of PD as assessed by RECIST v1.1 occurring after the first overall response contributing to the objective response. Partial death dates will be handled using the rules described in Section 4.1.4. Censoring of DOR will follow the same algorithm as the censoring of PFS (see Section 7.3.6).

Kaplan-Meier curves for DOR based on both unconfirmed and confirmed responses will be presented by treatment group. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI. The 95% CI will be calculated using the generalization of Brookmeyer and Crowley's method (1982) with log-log transformation (Klein and Moeschberger 1997).

Duration of response analyses will only include responders, and any Kaplan-Meier analyses will only be provided if appropriate. For example, if there are a very small number of responders, Kaplan-Meier analysis will not be provided.

7.3.5. Largest Percentage Reduction in Sum of Diameters of Target Lesions

For each participant in the FAS with target lesions at baseline, target lesion sizes will be measured by the sum of the diameters. The best percent change from baseline, defined as the largest decrease in target lesion size for each participant, will be summarized descriptively, and a waterfall plot of the best percent change will be generated. Note that for participants who only have increases in target lesion sizes from baseline, the smallest increase will be considered as the best change from baseline.

Per RECIST v1.1 criteria, target lesions considered "too small to measure" will be assigned a default value of 5 mm for purposes of this analysis. Likewise, target lesions identified as "not present" at postbaseline assessments will be assigned 0 mm for this analysis. In the event a target lesion is unaccounted for in a particular postbaseline timepoint (ie, assessment missing or NE), then the overall sum of diameters for target lesions will not be evaluable for that postbaseline timepoint.

7.3.6. Progression-Free Survival

Progression-free survival is defined as the length of time between the date of first dose and the earlier of death or PD as assessed by RECIST v1.1 per investigator assessment. Partial death dates will be handled using the rules described in Section 4.1.4. Censoring for PFS will follow the algorithm outlined in Table 4, which is based on FDA guidance (FDA 2015, FDA 2018).

Table 4: Evaluation and Censoring of Progression-Free Survival

Situation	Outcome	Date of Progression or Censoring
No baseline tumor assessments	Censored	Day 1
No valid postbaseline response assessments	Censored	Day 1
Progression documented between scheduled response assessments	Progressed	Date of first overall response of PD
No progression	Censored	Date of last valid radiologic assessment (not NE and not missing)
Study discontinuation for undocumented progression	Censored	Date of last valid radiologic assessment (not NE and not missing)
Study discontinuation for toxicity or other reason	Censored	Date of last valid radiologic assessment (not NE and not missing)
New anticancer treatment started	Censored	Date of last valid radiologic assessment (not NE and not missing) on/before starting a new anticancer treatment
Death before first progressive response assessment	Progressed	Date of death
Death between adequate response assessments	Progressed	Date of death
Death or progression after 2 or more missed assessments	Censored	Date of last valid radiologic assessment (not NE and not missing)

Kaplan-Meier curves for PFS will be presented by treatment groups. The Kaplan-Meier estimate of median PFS will be presented with its 95% CI. The 95% CI will be calculated using the generalization of Brookmeyer and Crowley's method (1982) with log-log transformation (Klein and Moeschberger 1997).

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

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 TEAEs.

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 the first dose 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. 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 (v19.0) PT and SOC. Severity of AEs will be graded using the NCI CTCAE v4.03. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website.

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

8.2.2. Dose-Limiting Toxicities

The participants with DLTs and the type of DLT will be listed by dose level.

8.2.3. Adverse Event Summaries

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

- Number (%) of participants who had any TEAEs
- Number (%) of participants who had any serious TEAEs
- Number (%) of participants who had any Grade 3 or higher TEAEs
- Number (%) of participants who had any TEAEs related to INCB001158
- Number (%) of participants who had any TEAEs related to pembrolizumab
- Number (%) of participants who had any TEAE leading to temporary interruption of INCB001158
- Number (%) of participants who had any TEAE leading to temporary interruption of pembrolizumab

- Number (%) of participants who had any TEAE leading to permanent discontinuation of INCB001158
- Number (%) of participants who had any TEAE leading to permanent discontinuation of pembrolizumab
- Number (%) of participants who had any TEAE leading to INCB001158 dose reductions
- Number (%) of participants who had any fatal TEAEs
- Number (%) of participants who had an irAE

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

- Number (%) of participants who had an irAE
- Number (%) of participants who had any Grade 3 or higher irAEs
- Number (%) of participants who had any irAEs related to INCB001158
- Number (%) of participants who had any irAEs related to pembrolizumab
- Number (%) of participants who had any irAEs leading to discontinuation of INCB001158
- Number (%) of participants who had any irAEs leading to discontinuation of pembrolizumab
- Number (%) of participants who had any irAEs leading to discontinuation of INCB001158 and pembrolizumab
- Number (%) of participants who had any irAEs leading to discontinuation of INCB001158 or pembrolizumab
- Number (%) of participants who had irAEs leading to INCB001158 dose interruption and/or reductions
- Number (%) of participants who had irAEs leading to pembrolizumab dose interruption
- Number (%) of participants who had any fatal irAEs

The following summaries will be produced by MedDRA term (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 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 PT in decreasing order of frequency

- Summary of pembrolizumab treatment-related TEAEs by PT in decreasing order of frequency
- Summary of INCB001158 treatment-related TEAEs by MedDRA PT in decreasing order of frequency
- Summary of TEAEs with a fatal outcome by MedDRA SOC and PT
- Summary of TEAEs leading to INCB001158 dose reduction by MedDRA SOC and PT
- Summary of TEAEs leading to discontinuation of INCB001158 by MedDRA SOC and PT
- Summary of TEAEs leading to discontinuation of pembrolizumab by MedDRA SOC and PT
- Summary of immune-related TEAEs by SOC and PT

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

Laboratory values and change from baseline values will be summarized descriptively by visit. The baseline value will be determined using the nonmissing values collected before the first dose using the priority defined in Table 5. The last record before administration in the highest priority will be considered the baseline record. For baseline laboratory candidates with the same date and time in the same priority category, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

Table 5: Identification of Baseline Record

Priority	Laboratory Visit	Central or Local Laboratory
1	Scheduled	Central
2	Scheduled	Local
3	Unscheduled	Central
4	Unscheduled	Local

Laboratory test values will be assessed for severity based on the numerical component of CTCAE v4.03.

8.3.2. Laboratory Value Summaries

All test results and associated normal ranges from central laboratories will be reported in SI units. Any laboratory test results and associated normal ranges from local laboratories will be converted to SI units.

When there are multiple nonmissing laboratory values for a participant's particular test within a visit window, the convention described in Table 6 will be used to determine the record used for by-visit tabulations and summaries. If a tie still exists, the laboratory value with the smallest laboratory sequence number will be used.

Table 6: Identification of Records for Postbaseline By-Visit Summaries

Priority	Laboratory Visit	Central or Local Laboratory	Proximity to Visit Window	Tiebreaker
1	Scheduled	Central	In-window	Use smallest laboratory sequence number
2	Scheduled	Local	In-window	
3	Unscheduled	Central	In-window	
4	Unscheduled	Local	In-window	
5	Scheduled	Central	Out-of-window	
6	Scheduled	Local	Out-of-window	

For coagulation and urinalysis laboratory values, listings will be provided.

Numeric chemistry and hematology laboratory values will be summarized descriptively in SI units, and non-numeric test values will be tabulated when necessary.

Severity grades will be assigned to laboratory test values based on the numerical component of CTCAE v4.03. The number of participants who experienced worsening of laboratory abnormalities will be summarized by maximum severity.

In cases where differentials of hematology parameters are obtained without corresponding absolute count data, efforts will be made to investigate if the conversion to an absolute value will lead to additional abnormalities. This will be discussed with the clinical team regarding appropriate documentation and action.

8.4. Vital Signs

Values at each scheduled visit, change, and percentage change from baseline for vital signs, including systolic blood pressure and diastolic blood pressure will be summarized descriptively. Listings will be provided for all vital-sign parameters.

Normal ranges for vital sign values are defined in Table 7. For participants exhibiting vital sign abnormalities, the abnormal values will be listed along with their assigned treatment group.

Table 7: Normal Ranges for Vital Sign Values

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

8.5. Electrocardiograms

Twelve-lead ECGs including PR, RR, QT, QRS, and QTcF intervals will be obtained for each participant during the study. Baseline will be determined as the average of all nonmissing values before the first administration of INCB001158 or pembrolizumab. Listings will be provided for all ECG parameters.

Normal ranges for ECG values are defined in Table 8. Electrocardiogram values will also be considered abnormal if the absolute percentage change from baseline is more than 25% (30% for QRS interval). Participants exhibiting ECG abnormalities will be listed with study visit and assigned treatment group. Outliers of QT and QTcF values, defined as absolute values > 450 milliseconds, > 500 milliseconds, or change from baseline > 30 milliseconds, will be summarized.

Table 8: Normal Ranges for Electrocardiogram Intervals

Parameter	High Threshold	Low Threshold
PR	≤ 220 ms	≥ 75 ms
RR	≤ 1330 ms	≥ 600 ms
QT	≤ 500 ms	≥ 300 ms
QRS	≤ 120 ms	≥ 50 ms
QTcF	≤ 450 ms	≥ 295 ms

9. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 9.

Table 9: Statistical Analysis Plan Versions

SAP Version	Date
Original	22 FEB 2021

9.1. Changes to Protocol-Defined Analyses

Not applicable.

9.2. Changes to the Statistical Analysis Plan

Not applicable.

10. REFERENCES

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Klein JP, Moeschberger ML. Survival analysis: techniques for censored and truncated data. New York: Springer-Verlag. 1997.

Simon R. Optimal two-stage designs for Phase II clinical trials. Control Clin Trials 1989;10:1-10.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report.

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

Tables

Table No.	Title	Population	Standard
Baseline and Demographic Characteristics			
1.1 Disposition			
1.1.1.1	Analysis Populations	Part 1a, Part 2 FAS	X
1.1.1.2	Analysis Populations	Part 1b, Part 3 FAS	X
1.1.1.3	Analysis Populations	Part 1c FAS	X
1.1.2.1	Summary of Participant Disposition	Part 1a, Part 2 FAS	X
1.1.2.2	Summary of Participant Disposition	Part 1b, Part 3 FAS	X
1.1.2.3	Summary of Participant Disposition	Part 1c FAS	X
1.1.3.1	Summary of Number of Participants Enrolled by Country and Site	FAS	X
1.1.4.1	Summary of Protocol Deviations	FAS	X
1.2 Demography and Baseline Characteristics			
1.2.1.1	Summary of Demographics and Baseline Characteristics	Part 1a, Part 2 FAS	X
1.2.1.2	Summary of Demographics and Baseline Characteristics	Part 1b, Part 3 FAS	X
1.2.1.3	Summary of Demographics and Baseline Characteristics	Part 1c FAS	X
1.3 Baseline Disease Characteristics			
1.3.1.1	Summary of Baseline Disease Characteristics	Part 1a, Part 2 FAS	X
1.3.1.2	Summary of Baseline Disease Characteristics	Part 1b, Part 3 FAS	X
1.3.1.3	Summary of Baseline Disease Characteristics	Part 1c FAS	X
1.3.2.1	Summary of Prior Systemic Cancer Therapy	Part 1a, Part 2 FAS	
1.3.2.2	Summary of Prior Systemic Cancer Therapy	Part 1b, Part 3 FAS	
1.3.2.3	Summary of Prior Systemic Cancer Therapy	Part 1c FAS	
1.4 Prior Medication and Concomitant Medication			
1.4.1.1	Summary of Prior Medications	Part 1a, Part 2 FAS	X
1.4.1.2	Summary of Prior Medications	Part 1b, Part 3 FAS	X
1.4.1.3	Summary of Prior Medications	Part 1c FAS	X
1.4.2.1	Summary of Concomitant Medications	Part 1a, Part 2 FAS	X
1.4.2.2	Summary of Concomitant Medications	Part 1b, Part 3 FAS	X
1.4.2.3	Summary of Concomitant Medications	Part 1c FAS	X
Efficacy			
2.1 Efficacy			
2.1.1.1.1	Summary of Confirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 1a Efficacy Evaluable Population	
2.1.1.1.2	Summary of Confirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 1b Efficacy Evaluable Population	
2.1.1.1.3	Summary of Confirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 2 Efficacy Evaluable Population	

Table No.	Title	Population	Standard
2.1.1.1.4	Summary of Confirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 1c, Part 3 Efficacy Evaluable Population	
2.1.1.2.1	Summary of Confirmed Duration of Response Under RECIST v1.1	Part 1a Efficacy Evaluable Population	
2.1.1.2.2	Summary of Confirmed Duration of Response Under RECIST v1.1	Part 1b Efficacy Evaluable Population	
2.1.1.2.3	Summary of Confirmed Duration of Response Under RECIST v1.1	Part 2 Efficacy Evaluable Population	
2.1.1.2.4	Summary of Confirmed Duration of Response Under RECIST v1.1	Part 1c, Part 3 Efficacy Evaluable Population	
2.1.1.3.1	Summary of Unconfirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 1a Efficacy Evaluable Population	
2.1.1.3.2	Summary of Unconfirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 1b Efficacy Evaluable Population	
2.1.1.3.3	Summary of Unconfirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 2 Efficacy Evaluable Population	
2.1.1.3.4	Summary of Unconfirmed Best Overall Response and Objective Response Rate Under RECIST v1.1	Part 1c, Part 3 Efficacy Evaluable Population	
2.1.1.4.1	Summary of Unconfirmed Duration of Response Under RECIST v1.1	Part 1a Efficacy Evaluable Population	
2.1.1.4.2	Summary of Unconfirmed Duration of Response Under RECIST v1.1	Part 1b Efficacy Evaluable Population	
2.1.1.4.3	Summary of Unconfirmed Duration of Response Under RECIST v1.1	Part 2 Efficacy Evaluable Population	
2.1.1.4.4	Summary of Unconfirmed Duration of Response Under RECIST v1.1	Part 1c, Part 3 Efficacy Evaluable Population	
2.1.2.1	Summary of Progression-Free Survival Under RECIST v1.1	Part 1a FAS	
2.1.2.2	Summary of Progression-Free Survival Under RECIST v1.1	Part 1b FAS	
2.1.2.3	Summary of Progression-Free Survival Under RECIST v1.1	Part 2 FAS	
2.1.2.4	Summary of Progression-Free Survival Under RECIST v1.1	Part 1c, Part 3 FAS	
Safety			
3.1 Dose Exposure			
3.1.1.1	Summary of Total Dose, Duration of Exposure, and Average Daily Dose of INCB001158	Part 1a, Part 2 Safety	X
3.1.1.2	Summary of Total Dose, Duration of Exposure, and Average Daily Dose of INCB001158	Part 1b, Part 3 Safety	X
3.1.1.3	Summary of Total Dose, Duration of Exposure, and Average Daily Dose of INCB001158	Part 1c Safety	X
3.1.2.2	Summary of Pembrolizumab Exposure	Part 1b, Part 3 Safety	X
3.1.2.3	Summary of Pembrolizumab Exposure	Part 1c Safety	X
3.2 Adverse Events			
3.2.1.1	Overall Summary of Treatment-Emergent Adverse Events	Part 1a, Part 2 Safety	X
3.2.1.2	Overall Summary of Treatment-Emergent Adverse Events	Part 1b, Part 3 Safety	X
3.2.1.4	Overall Summary of Immune-Related Adverse Event	Part 1a, Part 2 Safety	
3.2.1.5	Overall Summary of Immune-Related Adverse Event	Part 1b, Part 3 Safety	
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1a, Part 2 Safety	X

Table No.	Title	Population	Standard
3.2.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1b, Part 3 Safety	X
3.2.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1a, Part 2 Safety	X
3.2.3.2	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1b, Part 3 Safety	X
3.2.5.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1a, Part 2 Safety	X
3.2.5.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1b, Part 3 Safety	X
3.2.6.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1a, Part 2 Safety	X
3.2.6.2	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1b, Part 3 Safety	X
3.2.8.1	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1a, Part 2 Safety	X
3.2.8.2	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1b, Part 3 Safety	X
3.2.10.1.1	Summary of INCB001158 Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1a, Part 2 Safety	X
3.2.10.1.2	Summary of INCB001158 Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1b, Part 3 Safety	X
3.2.10.2.2	Summary of Pembrolizumab Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Part 1b, Part 3 Safety	X
3.2.13.1	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Part 1a, Part 2 Safety	X
3.2.13.2	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Part 1b, Part 3 Safety	X
3.2.14.1	Summary of Treatment-Emergent Adverse Events Leading to INCB001158 Dose Reduction by MedDRA System Organ Class and Preferred Term	Part 1a, Part 2 Safety	X
3.2.14.2	Summary of Treatment-Emergent Adverse Events Leading to INCB001158 Dose Reduction by MedDRA System Organ Class and Preferred Term	Part 1b, Part 3 Safety	X
3.2.15.1.1	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCB001158 by MedDRA System Organ Class and Preferred Term	Part 1a, Part 2 Safety	X
3.2.15.1.2	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCB001158 by MedDRA System Organ Class and Preferred Term	Part 1b, Part 3 Safety	X
3.2.15.2.2	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Pembrolizumab by MedDRA System Organ Class and Preferred Term	Part 1b, Part 3 Safety	X

Table No.	Title	Population	Standard
3.2.16.1	Summary of Immune-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1a, Part 2 Safety	X
3.2.16.2	Summary of Immune-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Part 1b, Part 3 Safety	X
3.3 Laboratory			
3.3.1.1.1	Summary of Laboratory Values - Hematology	Part 1a, Part 2 Safety	X
3.3.1.1.2	Summary of Laboratory Values - Hematology	Part 1b, Part 3 Safety	X
3.3.1.2.1	Summary of Laboratory Values - Chemistry	Part 1a, Part 2 Safety	X
3.3.1.2.2	Summary of Laboratory Values - Chemistry	Part 1b, Part 3 Safety	X
3.3.2.1.1	Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology	Part 1a, Part 2 Safety	X
3.3.2.1.2	Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology	Part 1b, Part 3 Safety	X
3.3.2.2.1	Treatment-Emergent Worsening of Laboratory Abnormalities - Chemistry	Part 1a, Part 2 Safety	X
3.3.2.2.2	Treatment-Emergent Worsening of Laboratory Abnormalities - Chemistry	Part 1b, Part 3 Safety	X
3.4 Vital Signs			
3.4.1.1	Summary of Systolic Blood Pressure	Part 1a, Part 2 Safety	X
3.4.1.2	Summary of Systolic Blood Pressure	Part 1b, Part 3 Safety	X
3.4.2.1	Summary of Diastolic Blood Pressure	Part 1a, Part 2 Safety	X
3.4.2.2	Summary of Diastolic Blood Pressure	Part 1b, Part 3 Safety	X
3.5 ECG			
3.5.1.1	Summary of Outliers of QT and QTcF Interval Values (ms) From 12-Lead ECG	Part 1a, Part 2 Safety	X
3.5.1.2	Summary of Outliers of QT and QTcF Interval Values (ms) From 12-Lead ECG	Part 1b, Part 3 Safety	X

Figures

Figure No.	Title
4.1 Efficacy	
4.1.1	Kaplan-Meier Estimates of Progression-Free Survival
4.1.2	Kaplan-Meier Estimates of Duration of Response
4.1.3	Waterfall Plot of Best Percentage Change From Baseline in Sum of Target Lesions
4.1.4	Spider Plot of Sum of Target Lesions

Listings

Listing No.	Title
2.1.1	Participant Enrollment and Disposition Status
2.1.2	Participant Inclusion and Exclusion Criteria Violations
2.2	Protocol Deviations
2.3	Analysis Population
2.4.1	Demographic and Baseline Characteristics
2.4.2	Disease History
2.4.3	Prior Radiation Treatment
2.4.4	Prior Systemic Therapy
2.4.5	Prior Surgery or Surgical Procedure
2.4.6	Medical History
2.4.7	Prior and Concomitant Medication
2.4.8	Concomitant Procedures
2.5.1	Study Drug Compliance
2.5.2	Study Drug Administration
2.6.2	Best Overall Response, Duration of Response, and Progression-Free Survival
2.6.3	Response Assessment (Investigator Assessments)
2.6.4	Summary (Target Lesions)
2.6.5	Summary (Non-Target Lesions)
2.6.6	Summary (New Lesions)
2.6.7	ECOG Status
2.7.1	Adverse Events
2.7.2	Dose-Limiting Toxicities
2.7.3	Serious Adverse Events
2.7.4	Grade 3 and Higher Adverse Events
2.7.5	Adverse Events Leading to Interruption, Reduction, or Discontinuation of INCB001158 or Pembrolizumab
2.8.1	Clinical Laboratory Values – Hematology
2.8.2	Clinical Laboratory Values – Chemistry
2.8.3	Clinical Laboratory Values – Coagulation
2.8.4	Clinical Laboratory Values – Urinalysis
2.8..5	Clinical Laboratory Values – Orotic Acid, BUN/UREA, and Ammonia for Potential Urea Cycle Inhibition
2.8.6	Abnormal Clinical Laboratory Values
2.9.1	Vital Signs
2.9.2	Abnormal Vital Sign Values
2.10.1	12-Lead ECG Values
2.10.2	Abnormal 12-Lead ECG Values