Official Title: **A Phase 2 Study of INCMGA00012 (PD-1 Inhibitor) in Participants With Selected Solid Tumors (POD1UM-203)**

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STATISTICAL ANALYSIS PLAN

INCMGA 0012-203

A Phase 2 Study of INCMGA00012 (PD-1 Inhibitor) in Participants With Selected Solid Tumors (POD1UM-203)

IND Number	**130952**
EudraCT Number:	**2018-002941-12**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803**
Protocol Version:	**Protocol Amendment 3 dated 10 DEC 2019**
CRF Approval Date:	**10 JAN 2019**
SAP Version:	**Amendment 1**
SAP Author:	[redacted] [redacted]**Biostatistician**
Date of Plan:	**23 JUN 2020**

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
[redacted]	[redacted]
AE	adverse event
AESI	adverse event of special interest
ALP	alkaline phosphatase
ALT	alanine aminotransferase
AST	aspartate aminotransferase
AUC_t	area under the plasma or serum concentration-time curve from time = 0 to the last measurable concentration at time = t
BMI	body mass index
BOR	best overall response
CI	confidence interval
C_{max}	maximum observed plasma or serum concentration
C_{min}	minimum observed plasma or serum concentration over the dose interval
CR	complete response according to RECIST v1.1
CRF	case report form
CTCAE	Common Terminology Criteria for Adverse Events
DCR	disease control rate
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
EGFR	epidermal growth factor receptor
ELISA	enzyme-linked immunosorbent assay
FAS	full analysis set
HIV	human immunodeficiency virus
HR	heart rate
ICF	informed consent form
irAE	immune-related adverse event
iRECIST	immune Response Evaluation Criteria in Solid Tumors

IV	intravenously
MedDRA	Medical Dictionary for Regulatory Activities

Abbreviation	**Definition**
NCI	National Cancer Institute
NSCLC	non–small cell lung cancer
ORR	overall response rate
OS	overall survival
PD	progressive disease
PD-1	programmed cell death protein 1
PD-L1	programmed cell death ligand protein 1
PFS	progression-free survival
PK	pharmacokinetics
PR	partial response according to RECIST v1.1
PT	preferred term
Q4W	once every 4 weeks
RCC	renal cell carcinoma
RECIST	Response Evaluation Criteria in Solid Tumors
ROS1	Proto-Oncogene 1, Receptor Tyrosine Kinase
SAP	Statistical Analysis Plan
SD	stable disease
SOC	system organ class
TEAE	treatment-emergent adverse event
T_{max}	time to maximum concentration
UC	urothelial carcinoma
ULN	upper limit of normal
WHO	World Health Organization

1. INTRODUCTION

This study is a Phase 2, open-label, multicenter study designed to assess the clinical activity and safety of INCMGA00012 in participants with advanced solid tumors where the efficacy of PD-1 inhibitors has previously been established.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the Protocol. The scope of this plan includes the interim and final analyses that are planned and will be executed by the Department of Biostatistics or designee. The analyses of PK and pharmacodynamics that will be executed by the Department of Clinical Pharmacokinetics and [redacted] respectively, are not described in detail in this SAP.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCMGA 0012-203 Protocol Amendment 3 dated 10 DEC 2019 and CRFs approved 10 JAN 2019. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and CRF versions.

2.2. Study Objectives and Endpoints

The study objective and endpoints are presented in Table 1.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
To assess the efficacy of INCMGA00012 in terms of the ORR in tumor types of interest.	ORR, defined as the percentage of participants having a CR or PR, according to RECIST v1.1 as determined by the investigator.
Secondary	
To determine the DOR to INCMGA00012.	DOR, defined as the time from an initial objective response (CR or PR) according to RECIST v1.1 until first observation of documented disease progression as determined by investigator or death due to any cause.
To determine the DCR.	DCR, defined as the proportion of participants with either an objective response (CR and PR) or SD, according to RECIST v1.1.
To determine the PFS of INCMGA00012.	PFS, defined as the time from the start of therapy until disease progression, as determined by investigator or death due to any cause.
To determine the OS of INCMGA00012.	OS, defined as the time from the start of therapy until death due to any cause.

To evaluate the safety of INCMGA00012.	Safety, determined by the number of participants, frequency, duration, and severity of AEs, laboratory tests, vital signs, and ECGs.
To determine the PK of INCMAG00012 when administered as a 30-minute infusion.	The PK of INCMAG00012, including C_{max}, T_{max}, C_{min}, and AUC_t, will be summarized.
[redacted]	

3. STUDY DESIGN

3.1. Overall Study Design

This study is a Phase 2, open-label, multicenter study designed to assess the clinical activity and safety of INCMGA00012 in participants with advanced solid tumors where the efficacy of PD-1 inhibitors has previously been established. Participants with the following tumor types will be enrolled into disease-specific cohorts:

- Treatment-naïve metastatic NSCLC with high PD-L1 expression (TPS ≥ 50%) and no EGFR, ALK, or ROS activating genomic tumor aberrations.
- Locally-advanced or metastatic urothelial cancer in cisplatin ineligible participants (determined by the investigator) whose tumors express PD-L1 (CPS ≥ 10 of PD-L1).
- Unresectable or metastatic melanoma.
- Locally advanced or metastatic clear–cell RCC without prior systemic treatment. The primary endpoint is ORR according to RECIST v1.1 as determined by the investigator. The study consists of 3 periods: screening, study drug treatment, and follow-up.

3.2. Overall Study Duration

The study begins when the first participant signs the ICF. The end of the study is defined as the date of the last visit of the last participant in the study. Participants completing treatment or prematurely discontinuing the study drug will be followed for survival until death, withdrawal of consent, or the end of the study, whichever occurs first.

3.3. Randomization

Not applicable.

3.4. Control of Type I Error

There is no formal hypothesis testing in this study and no control of Type I error rate. Response rate as well as the associated 95% CI will be provided. For analysis of efficacy endpoints such as ORR and DCR, 2-sided 95% confidence level will be reported.

3.5. Sample Size Considerations

This study is planned as a signal-finding study for efficacy in tumor types of interest for future development. Approximately 30 participants are planned to be enrolled in each disease-specific cohort to provide a preliminary assessment of efficacy, safety, and PK. The response rate and 95% CIs based on numbers of responses among 30 participants are provided in Table 2.

Table 2: Response Rate and 95% Confidence Interval

Sample Size	Number of Responses	Response Rate (%)	95% CI (%)
30	3	10.0	2.1, 26.5
30	5	16.7	5.6, 34.7
30	7	23.3	9.9, 42.3
30	9	30.0	14.7, 49.4
30	11	36.7	19.9, 56.1
30	12	40.0	22.7, 59.4

3.6. Schedule of Assessments

Refer to Protocol Amendment 3 dated 10 DEC 2019 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. Study Drug and Dose Level

INCMGA00012 is the only study drug in this study. The dose level of INCMGA00012 is 500 mg Q4W in this study, administered as a 30-minute infusion.

4.1.2. Day 1

Day 1 is the date when the first dose of INCMGA00012 is administered.

4.1.3. 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.

4.1.4. Baseline Value

Baseline is the last nonmissing assessment obtained before the first administration of INCMGA00012.

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.

4.1.5. 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 this section or relevant sections.

Partial disease/cancer diagnosis date will be handled as follows:

- If only the day is missing, then the imputed day will be the first of the month.
- If both the month and day are missing, then the imputed day and month will be 01 JAN.

For relevant efficacy endpoints, partial death date will be imputed as follows:

- If mmyyyy for the last contact date = mmyyyy for the death date, then the death date will be set to the day after the last contact date.
- If mmyyyy for the last contact 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.
- No imputation will be done if the date is completely missing.

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

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

- If only the day is missing, and the first day of the month is on or after the first dose date on Day 1, then the concomitant medication will be considered as starting on or after Day 1, and the incomplete date will be imputed as the first day of the month.
- If only the day is missing, and the month is equal to the month of the first dose date on Day 1, then the incomplete date will be imputed as the first day of the month.
- If both the month and day are missing, and the last day of the year is before the first dose date on Day 1, then the concomitant medication will be considered as starting before Day 1, and the incomplete date will be imputed as if it is the last day of the year. Otherwise, if the last day of the year is on or after the first dose date Day 1, the incomplete date will be imputed as if it is the first day of the year.
- If the imputed start date through the above procedure is after stop date recorded in the eCRF, then the imputed start date will be set equal to stop date.

4.1.6. Cycle Length and Duration

One cycle is 28 days (4 weeks) for all participants in this study. Cycle 1 Day 1 is the day the first infusion of INCMGA00012, with the exception for records of clinical laboratory tests, vital signs, and ECGs, where visit Cycle 1 Day 1 could be within 7 days before the day of first infusion of INCMGA00012. Day 1 of subsequent cycles will correspond to the infusion date of INCMGA00012 within the cycle. Tumor assessments follow Protocol-defined schedule, that is, Q8W with ± 7-day window within 1 year and Q12W with ± 14-day window after 1 year. Analysis of tumor response assessments follow the same time window.

4.1.7. On-Treatment Assessment/Event

Safety summaries and selected summaries of deaths will summarize only on-treatment assessments/events. On-treatment assessment/event is defined as any assessment/event obtained in the time interval:

- Date of first infusion of INCMGA00012 through date of last infusion of INCMGA00012 + 90 days;

Adverse events that begin or worsen after informed consent obtained should be recorded in the Adverse Events CRF.

If the last date of study drug administration is missing, on-treatment assessments/events include any assessment/event recorded in the database and those that occur after the start date of study drug unless there are other datasets indicating treatment is ended.

Data listings will include all assessments/events, flagging those that are not on-treatment assessments/events.

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. Creatinine Clearance

Creatinine clearance by Cockcroft-Gault equation (Cockcroft and Gault 1976) is estimated from serum creatinine (mg/dL) determination using the following formula:

Creatinine clearance (mL/min) = [140 − age (years)] × weight (kg) × {0.85* for female participants} / [72 × serum creatinine (mg/dL)]. *Note: For male participants use 1.0.

4.2.3. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of INCMGA00012.

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

- Before the date of first administration of INCMGA00012 and is ongoing throughout the study or ends on/after the date and time of first study drug administration.
- On/after the date of first administration of INCMGA00012 and is ongoing or ends during the course of study drug administration.

A medication could also be classified as "both prior and concomitant medication" if the end date is on or after the date of first administration of INCMGA00012. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, or both prior and concomitant medication.

For the purposes of analysis, all medications will be considered concomitant medications unless the medications can unequivocally be defined as not concomitant (ie, if start date and end date are all missing, then the medication is considered as concomitant medication). See Section 4.1.5 for handling if missing/incomplete data.

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9.4 or later) will be used for the generation of all tables, figures, 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

Analysis will be presented by disease-specific cohorts: melanoma, NSCLC, urothelial cancer (bladder cancer), and RCC. Safety data will also be presented for all cohorts combined.

5.3. Analysis Populations

5.3.1. Full Analysis Set

The FAS includes all participants who received at least 1 dose of study drug. The FAS will be used for demographics, disposition, baseline characteristics, and all efficacy analyses.

5.3.2. Safety Evaluable Population

The safety evaluable population includes all participants who received at least 1 dose of study drug. All safety and exposure analyses will be conducted using the safety evaluable population. In this study, the FAS and safety evaluable population are identical.

5.3.3. Pharmacokinetic Evaluable Population

The PK evaluable population will include all participants who received at least 1 dose of study drug and have provided a baseline and at least 1 postdose PK sample.

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Appendix A provides a list of planned tables, figures, and listings.

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

Baseline disease characteristics and demographics will be summarized by disease-specific cohort. Overall summaries combining 4 tumor-specific cohorts will be presented.

6.1.1. Demographics

Demographics will be listed in detail. The following demographics will be summarized for the FAS by disease-specific cohort and overall FAS: age, sex, race, ethnicity, body weight, height, BMI, and creatinine clearance. Qualitative data will be summarized by contingency table while quantitative data will be summarized by descriptive summary statistics.

6.1.2. Baseline Disease Characteristics and Cancer History

According to data collected in the eCRF, the following information determined at initial diagnosis and baseline will be summarized for in the FAS by disease-specific cohort:

- Melanoma: time since initial diagnosis, time since unresectable/metastatic diagnosis, stage at baseline, classification M at baseline, histology at baseline, sites of disease at baseline, BRAF status, PD-L1 status, and ECOG performance status at baseline.
- NSCLC: time since initial diagnosis, time since metastatic diagnosis, histopathology at initial diagnosis, stage at baseline, T staging at baseline, N staging at baseline, M staging at baseline, sites of disease at baseline, PD-L1 status, EGFR mutation, ALK re-arrangement status, ROS1 re-arrangement status, and ECOG performance status at baseline.
- Urothelial cancer (bladder cancer): time since initial diagnosis, time since advanced/metastatic diagnosis, cancer type at initial diagnosis, histology at initial diagnosis, reason for cisplatin ineligibility at initial diagnosis, TNM classification T at baseline, TNM classification N at baseline, TNM classification M at baseline, grade at baseline, histology at baseline, sites of disease at baseline, stage at baseline, PD-L1 status, and ECOG performance status at baseline.
- RCC: time since initial diagnosis, time since advanced/metastatic diagnosis, histology at initial diagnosis, MSKCC criteria at initial diagnosis, stage of disease at baseline, TNM classification T at baseline, TNM classification N at baseline, TNM classification M at baseline, sites of disease at baseline, PD-L1 status, and ECOG performance status at baseline.

Additional baseline disease characteristics and cancer history for individual cancer types listed in eCRF may be summarized or listed for all participants by tumor type specific cohort.
Time since initial diagnosis (advanced/ unresectable /metastatic diagnosis) will be calculated as follows:

Time since initial diagnosis (months) = (Day 1 date – date of diagnosis + 1) / 30.4375.

6.1.3. Prior Therapy

The number and percentage of participants recording any prior systemic cancer therapy, prior radiotherapy, or prior surgery will be summarized. The component drugs of prior systemic therapy regimens will be coded using the WHO Drug Dictionary. Lines of prior systemic cancer therapy will be summarized by disease-specific cohort. Best response from prior therapy, purpose, reason for discontinuation, as well as time to progression on prior therapy will be summarized and listed wherever the data are available.

Number of participants who received prior radiotherapy will be listed for the FAS. Anatomical location of the administration, start and stop date, reason for regimen, best response, number of fractions received and total dose will be listed.

Number of participants who had prior surgery or surgical procedure for cancer treatment will be listed for the FAS. Date and description of the surgery/surgical procedure will be listed. Detailed information on prior systemic cancer therapy, prior radiation, and prior surgery will be listed in 3 separate listings.

6.1.4. Medical History

For all participants in the FAS, medical history will be summarized by disease-specific cohort. This summary will be presented by MedDRA primary SOC and PT.

6.2. Disposition of Participants

The number and percentage of participants who complete treatment, who are on treatment, who discontinue study drug with primary reason for discontinuation, who are on study, and who withdraw from the study with a primary reason for study withdrawal will be summarized for all participants in FAS by tumor type specific cohort. All participants with deviations to inclusion and/or exclusion criteria will be listed.

6.3. Protocol Deviations

Protocol deviations recorded in the eCRF will be presented in the participant data listings. Protocol deviations will be summarized descriptively.

6.4. Exposure

For participants in the safety evaluable population, exposure to INCMGA00012 will be summarized descriptively by disease-specific cohort separately as follows:

- **Total number of infusions:** Total number of infusions by participant with a nonzero dose of INCMGA00012.
- **Total dose administered (mg):** Sum of the cumulative actual dose that has been administered. Actual dose at each infusion is calculated as estimated volume delivered / prepared volume × 500 mg at each infusion.
- **Average dose (mg):** Total dose administered (mg) / total number of infusions.

- **Duration of treatment (days):** Date of last dose of INCMGA00012 – date of first dose of INCMGA00012 + 1.
- **Dose modifications:** Number of participants who had dose delay or infusion interruption of INCMGA00012 and reason for infusion interruption will be summarized by disease-specific cohort.

6.5. Prior and Concomitant Medication

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 WHO drug class in the FAS. For the summary of concomitant medication, only medications starting on or after the first dose of study drug and no later than 90 days after the last dose of INCMGA00012 will be included. Medications with missing start/end date will be considered as concomitant medications in summary. Other medications will be provided in the listing. Medications intended to manage irAEs as well as prophylaxis/premedication used to prevent infusion reactions may be summarized separately. Post-therapy and nondrug therapy will also be listed per CRF.

7. EFFICACY

Appendix A provides a list of planned tables, figures, and listings.

7.1. General Considerations

Efficacy endpoints of this study include ORR together with DCR, DOR, and PFS as determined by the investigator based on RECIST v1.1, and OS. Listings of response assessments at each visit will be provided. All efficacy analysis will be presented by disease-specific cohort

7.2. Efficacy Hypotheses

Not applicable.

7.3. Analysis of the Efficacy Parameters

The efficacy parameters will be analyzed using FAS.

7.3.1. Response Criteria

Overall disease status will be categorized using RECIST v1.1. Participants will have their overall response evaluated as CR, PR, SD, PD, or NE at each postbaseline radiological assessment based on changes in target lesions, nontarget lesions, and appearance of new lesions.

7.3.2. Primary Analysis

7.3.2.1. Overall Response Rate

The primary endpoint of the study is ORR, defined as the percentage of participants with CR or PR at any postbaseline visit before the first assessment of PD or new anticancer therapy, according to RECIST v1.1 (Eisenhauer et al 2009) as determined by the investigator. Participants who do not have sufficient baseline data to ascertain a response will be included in the denominators in the calculation of ORR. The analysis of ORR will be based on the FAS. Overall response rate and its exact 95% CI will be presented.

For participants with measurable disease at baseline, the RECIST v1.1 assessment criteria presented in Table 3 can be used to determine the overall response at a given timepoint based on the target lesion, nontarget lesion, and new lesion assessments.

Table 3: RECIST Evaluation Criteria for Overall Response

Target Lesions	Nontarget Lesions	New Lesions	Overall Response
CR	CR	No	CR
CR	Non-CR/Non-PD	No	PR
CR	NE	No	PR
PR	Non-PD or NE	No	PR
SD	Non-PD or NE	No	SD
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

7.3.2.2. Best Overall Response

The BOR is the best response recorded from the start of the treatment until the first PD, in the order of CR, PR, SD, PD, and NE. Responses of CR, PR, or SD after a response of PD will not be considered in determining best response. The BOR will be determined from response assessments before 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 BOR determination. In the case of SD, measurements must meet the SD criteria at least after the date of first dose at a minimum of 7 weeks.

7.3.3. Secondary Analysis

7.3.3.1. Duration of Response

Duration of response is defined as the time from first objective response (CR or PR) to the time of first documented PD or death due to any cause. If a participant does not have an event before data cutoff or new anticancer therapy, DOR is censored at the date of the last adequate tumor assessment before data cutoff or new anticancer therapy following the same algorithm as censoring of PFS (see Table 4). If there are sufficient observations for the responders, then a Kaplan-Meier estimate of the distribution function will be constructed for DOR, and the median

DOR along the 95% CI will be reported. If the number of observed responders in each treatment group is not sufficient to estimate median DOR, a swimmer plot and listing for DOR may be generated in place of the summary table.

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 in the absence of death prior to first scheduled tumor assessment	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 or missing)
Study withdrawal for undocumented progression	Censored	Date of last valid radiologic assessment (not NE or missing)
Study withdrawal for toxicity or other reason	Censored	Date of last valid radiologic assessment (not NE or missing)
New anticancer treatment started	Censored	Date of last valid radiologic assessment (not NE or 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 documented progression immediately after missing 2 or more consecutive scheduled tumor assessment	Censored	Date of last valid radiologic assessment (not NE or missing) prior to missed assessments

7.3.3.2. Disease Control Rate

Disease control rate is defined as the proportion of participants with an overall response (CR and PR) or SD at any postbaseline visit before first PD or new anticancer therapy. The DCR will be calculated, and exact 95% CI will be reported.

7.3.3.3. Progression-Free Survival

Progression-free survival is defined as the time from the first dose of study drug to the date of the first PD according to RECIST v1.1 or death due to any cause. Progression-free survival will be analyzed by the Kaplan-Meier method, including estimated median with 95% CI and KaplanMeier estimated probabilities at several timepoints. If participants have no observed death or disease progression before data cutoff or new anticancer therapy, the participants will be treated as censored at their last adequate tumor assessment before data cutoff or new anticancer

therapy according to Table 4. Date of death will be determined using the Death Report, Survival Follow Up, and Subject Status eCRFs.

7.3.3.4. Overall Survival

Overall survival is defined as the time from first dose of study drug to the date of death due to any cause. Date of death will be determined using the Death Report, Survival Follow Up, and Subject Status eCRFs. Participants who are lost to follow-up or still alive at the time of analysis will be censored at the last known alive date. The last known alive date is defined as the later of the last study visit and the date the participant was last known alive from the Survival Follow-Up and Subject Status eCRFs or any datasets with data entry that could reflect participant status. Kaplan Meier curves, medians, and 95% CIs of the medians will be presented for OS.

7.3.3.5. Tumor Size Change Over Time

Tumor size is defined as the sum of diameters of target lesions. The best percentage change from baseline, defined as the largest decrease in tumor size for each participant, will be summarized descriptively. In addition, the best percentage change may be presented by a waterfall plot. The analysis will be performed in all participants in the FAS with baseline tumor size available.

Per RECIST v1.1, target lesions considered "too small to measure" will be assigned a default value of 5 mm for the 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 timepoint.

8. SAFETY AND TOLERABILITY

Appendix A provides a list of planned tables, figures, and listings.

8.1. General Considerations

The clinical safety data (eg, vital signs, ECGs, routine laboratory tests, physical examinations, and AEs) will be summarized using descriptive statistics (eg, mean, frequency) by disease-specific cohort in safety evaluable population. Overall summaries combining all 4 disease-specific cohorts will be presented. If sufficient HIV-positive participants are enrolled into the study, safety data for those participants will be presented.

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 dose of study drug. Analysis of AEs will be limited to TEAEs, but data listings will include all AEs regardless of their timing to study drug administration. Adverse events will be tabulated by MedDRA SOC and PT. Severity of AEs will be based on the NCI CTCAE v5.0 using Grades 1 through 5 (NCI 2017). 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 have a relationship to the study drug will be considered to be treatment-related AEs. If the investigator does not specify the relationship of the AEs to any component of study drug, the AE will be considered treatment-related. The incidence of AEs and treatment-related AEs will be tabulated.

An overall summary of AEs will include number (%) of participants reporting any TEAEs, any serious TEAEs, any Grade 3 or higher TEAEs, any treatment-related TEAEs, any fatal TEAEs, and any TEAEs leading to study drug interruption, dose reduction, or discontinuation and study withdrawal.

Number (%) of participants reporting any TEAEs, any serious TEAEs, any Grade 3 or higher TEAEs, any treatment-related TEAEs, any fatal TEAEs, and any TEAEs leading to treatment interruption, dose reduction, or discontinuation will be tabulated by MedDRA SOC and PT. 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.

Infusion-related reactions as well as irAEs (ie, AESIs) may be summarized separately.

8.2.2. Adverse Events of Special Interest

Immune-related AEs as well as infusion reactions will be considered AESIs in this study. Predefined PTs will be grouped into AESI categories and used to identify irAEs or infusion reactions without consideration of investigator's assessment of causality. Diagnosis of infusion

reactions occurring anytime during the treatment period, symptoms of infusion reactions that occur within 1 day of infusion, and resolve within 2 days from onset, will be considered infusion reactions. Adverse events of special interest identified by the investigator in the AE dataset will also be listed.

Immune-related AEs and infusion reactions will be summarized in separate tables. They will also be combined in an AESI overall summary table. An overall summary of AESIs will include the number (%) of participants reporting any AESIs, any ≥ Grade 3 AESIs, any treatment-related AESIs, any fatal AESIs, and any AESIs leading to infusion interruption, delay in planned treatment, or study drug discontinuation.

8.2.3. Adverse Event Summaries

An overall summary of AEs may include the following:

- Number (%) of participants reporting any TEAEs
- Number (%) of participants reporting any serious TEAEs
- Number (%) of participants reporting any Grade 3 or higher TEAEs
- Number (%) of participants reporting any TEAEs related to study drug
- Number (%) of participants reporting any serious TEAEs related to study drug
- Number (%) of participants reporting any Grade 3 or higher TEAEs related to INCMGA00012
- Number (%) of participants who temporarily interrupted study drug infusion because of TEAEs
- Number (%) of participants who delayed next scheduled dose because of TEAEs
- Number (%) of participants who permanently discontinued INCMGA00012 because of TEAEs
- Number (%) of participants who had a fatal TEAE
- Number (%) of participants who withdrew from study because of TEAEs The following summaries may be produced by MedDRA term:
- 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 Grade 3 or higher TEAEs by SOC and PT
- Summary of Grade 3 or higher TEAEs by PT in decreasing order of frequency
- Summary of serious TEAEs by SOC and PT
- Summary of serious TEAEs by PT in decreasing order of frequency
- Summary of treatment-related TEAEs by SOC and PT
- Summary of treatment-related TEAEs by PT in decreasing order of frequency
- Summary of treatment-related Grade 3 or higher TEAEs by SOC and PT

- Summary of treatment-related serious TEAEs by SOC and PT
- Summary of TEAEs with a fatal outcome by SOC and PT
- Summary of TEAEs leading to infusion interruption by SOC and PT
- Summary of TEAEs leading to infusion delay in next scheduled dose by SOC and PT
- Summary of leading to study drug discontinuation by SOC and PT
- Summary of infusion-related reactions by SOC and PT
- Signs/symptoms of infusion-related reactions
- Summary of nonserious TEAEs by PT in decreasing order of frequency The following summaries for AEs of special interest will be included:
- Overall summary of TEAEs of special interest
- Summary TEAEs of special interest by group term and PT
- Summary TEAEs of special interest by group term, PT, and maximum severity
- Summary of Grade 3 or higher TEAEs of special interest by group term and PT
- Summary of TEAEs of special interest with a fatal outcome by group term and PT
- Summary of TEAEs of special interest leading to infusion interruption by group term and PT
- Summary of TEAEs of special interest leading to infusion delay in next scheduled dose by group term and PT
- Summary of TEAEs of special interest leading to study drug discontinuation by group term 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. Baseline will be determined according to Section 4.1.4. If there are multiple values that meet the criteria for baseline, Table 5 will delineate which value will be defined as baseline.

Table 5: Baseline Laboratory Identification

Priority	Laboratory Visit	Proximity to Visit Window	Tiebreaker
1	Scheduled	In-window	Use smallest laboratory sequence number
2	Unscheduled	In-window	
3	Scheduled	Out-of-window	

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 will be listed.

8.3.2. Laboratory Value Summaries

All test results and associated normal ranges from laboratories will be reported in SI units. Any laboratory test results and associated normal ranges from local laboratories will be converted to SI units. For test results that will be summarized with available normal ranges, the number and percentage of participants with the laboratory values being low (but never high), normal, high (but never low), and both low and high will be calculated for each test. This shift summary may be produced for each test for safety evaluable population. 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 treatment period. For numeric laboratory values, baseline value, postbaseline value, change from baseline, and percentage change from baseline will be summarized by visit.

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 following summaries will be produced for laboratory data (by laboratory parameter) reported on-treatment.

- Number and percentage of participants with worst postbaseline CTC grade (regardless of the baseline status). Each participant will be counted only for the worst grade observed postbaseline.
- Shift tables using CTCAE grades comparing baseline with the worst postbaseline value will be produced for hematology and biochemistry laboratory parameters with CTCAE grades.

- For laboratory parameters where CTCAE grades are not defined, shift tables to the worst postbaseline value will be produced using the low/normal/high classifications based on laboratory reference ranges.
- For laboratory parameters with any worsening postbaseline CTC grades than baseline, the worst postbaseline CTC grades will be summarized according to CTC severity grade levels. If baseline grade is missing, any postbaseline abnormality (Grade 1-4) is considered worsening from baseline.
- Number and percentage of participants meeting categorical liver function test criteria, including ALT, AST, and ALT or AST (> 3, 5, 8, 10, and 20 × ULN), total bilirubin (> 1 and 2 × ULN), ALP (> 1.5, 2, 3, 5, 8, and 10 × ULN), combined categories of ALT/AST and total bilirubin (eg, ALT or AST > 3 × ULN and total bilirubin > ULN) as well as laboratory Hy's Law criteria without medical adjudication (ALT or AST > 3 × ULN and total bilirubin > 2 × ULN and ALP < 2 × ULN at the same visit or within a specified number of days). The worst values observed postbaseline for each participant will be used for each of the categories. The summary will be presented by baseline liver metastases status.

8.4. Vital Signs

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

Criteria for clinically notable vital sign abnormalities are defined in Table 6. 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 absolute percentage change from baseline greater than 25%. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 6: 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

8.5. Electrocardiograms

Twelve-lead ECGs including HR, PR, QRS, QT, QTc, QTcF, and QTcB intervals will be obtained for each participant during the study. Values at each scheduled visit, change, and percentage change from baseline will be summarized for each ECG parameter at baseline will be determined as the last nonmissing ECG measurements taken before the first administration of the study drug.

Criteria for clinically notable ECG abnormalities are defined in Table 7. Participants exhibiting clinically notable ECG abnormalities will be listed by study visit and disease-specific cohort.

Abnormal values for participants with alert ECG values, defined as both the absolute value and the percentage change from baseline being outside normal ranges, will be identified and listed.

Table 7: Criteria for Clinically Notable Electrocardiogram Abnormalities

Parameter	High Threshold	Low Threshold
QTcF/QTcB/ QTc	> 460 ms	< 295 ms
PR	> 220 ms	< 75 ms
QRS	> 120 ms	< 50 ms
QT	> 500 ms	< 300 ms
HR	≥ 100 bpm and increase from baseline of ≥ 25%	≤ 50 bpm and decrease from baseline of ≥ 25%

QTcB = Bazett correction; QTcF = Fridericia correction.

A summary of outliers of QT, QTcB, and QTcF will be presented by study visit.

9. PHARMACOKINETIC [redacted] ANALYSES

9.1. Bioanalysis Materials and Methods

All the bioanalysis work will be performed by Incyte or its designee. Plasma concentrations of INCMGA00012 will be measured using an MSD-ECL method. [redacted]

9.2. Pharmacokinetic Assessments

Assessment of PK is an important objective of this study, representing the first clinical experience with administration of INCMGA00012 as a 30-minute infusion.

Trough serum concentrations by treatment cycles and/or across cycles ≥ 2 will be summarized. Serum PK parameters for INCMGA00012 including C_{max}, T_{max}, and AUC_{0-t} after single dose administration will be derived from serum concentrations versus time data using model independent noncompartmental analysis methods. The descriptive statistical analyses of serum concentrations and/or pharmacokinetic parameters will be performed with regard to 1 or several group variables such as cohort and/or visit, as a secondary endpoint of the study.

Population PK analyses will be conducted using data from this study alone or combined with data from other studies, as deemed appropriate. The planning and the execution of population PK analyses will be reported separately.

[redacted]

[redacted]

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 8.

Table 8: Statistical Analysis Plan Versions

SAP Version	Date
Original	05 FEB 2020
Amendment 1	23 JUN 2020

10.1. Changes to Protocol-Defined Analyses

Not applicable.

10.2. Changes to the Statistical Analysis Plan

10.2.1. Amendment 1

- Added Section 4.2.2 Creatinine Clearance as a variable to be calculated if not reported on the eCRF.
- Clarified analysis of AESIs in Section 8.2.2 to include immune-related AEs and infusion reactions.
- Updated AESI summaries in Section 8.2.3 to have AESIs summarized by group term.
- Updated the plasma concentrations of INCMGA00012 to be measured using an MSD-ECL method in Section 9.1.
- Updated Appendix A to include infusion reactions and summaries by group term.
- Minor administrative changes have been incorporated throughout and are noted in the redline version of the amendment.

11. REFERENCES

Cockcroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. Nephron 1976; 16:31–41.

Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumors: revised RECIST guideline (version 1.1). Eur J Cancer 2009;45:228-247.

National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. 2017.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. Standard tables will follow the conventions in the Standard Safety Tables. 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 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
Baseline and Demographic Characteristics		
1.1 Disposition		
1.1.1	Analysis Populations	Enrolled
1.1.2	Summary of Participant Disposition	FAS
1.1.3	Number of Participants Enrolled by Site and Country	FAS
1.1.4	Summary of Protocol Deviations	FAS
1.2 Demographics		
1.2	Summary of Demographics and Baseline Characteristics	FAS
1.3 Baseline Disease Characteristics (refine per data collection)		
1.3.1	Summary of Cancer History and Baseline Disease Characteristics: Melanoma	FAS
1.3.2	Summary of Cancer History and Baseline Disease Characteristics: NSCLC	FAS
1.3.3	Summary of Cancer History and Baseline Disease Characteristics: Urothelial Cancer	FAS
1.3.4	Summary of Cancer History and Baseline Disease Characteristics: Renal Cell Carcinoma	FAS
1.4 Prior Medication and Concomitant Medication (refine per data collection)		
1.4.1	Summary of Prior Medications	FAS
1.4.2	Summary of Concomitant Medications	FAS
1.4.3	Summary of Prior Therapy	FAS
1.5 Others		
1.5	Summary of General Medical History	FAS
2 Efficacy		
2.1.1	Summary of Best Overall Response According to RECIST v1.1	FAS
2.2.1	Summary of Duration of Response According to RECIST v1.1	FAS
2.2.2	Summary of Progression-Free Survival According to RECIST v1.1	FAS
2.2.3	Summary of Overall Survival	FAS
2.2.4	Summary of Largest Percentage Reduction in Sum of Diameters of Target Lesions	FAS
Safety		
3.1 Dose Exposure		
3.1.1	Summary of Exposure to INCMGA00012	Safety Evaluable
3.1.2	Summary of INCMGA00012 Dose Delay/Interruption	Safety Evaluable

Table No.	Title	Population
3.2 Adverse Events		
3.2.1.1	Overall Summary of Treatment-Emergent Adverse Events	Safety Evaluable
3.2.1.2	Overall Summary of Treatment-Emergent Adverse Events of Special Interest	Safety Evaluable
3.2.1.3	Overall Summary of Treatment-Emergent Infusion Reaction	Safety Evaluable
3.2.1.4	Overall Summary of Treatment-Emergent Immune Related Adverse Events	Safety Evaluable
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.2.2	Summary of Treatment-Emergent Infusion Reaction by Group Term and Preferred Term	Safety Evaluable
3.2.2.3	Summary of Treatment-Emergent Immune Related Adverse Events by Group Term and Preferred Term	Safety Evaluable
3.2.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety Evaluable
3.2.4.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Safety Evaluable
3.2.4.2	Summary of Treatment-Emergent Infusion Reaction by Group Term, Preferred Term, and Maximum Severity	Safety Evaluable
3.2.4.3	Summary of Treatment-Emergent Immune Related Adverse Events by Group Term, Preferred Term, and Maximum Severity	Safety Evaluable
3.2.6.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.6.2	Summary of Grade 3 or Higher Treatment-Emergent Infusion Reaction by Group Term and Preferred Term	Safety Evaluable
3.2.6.3	Summary of Grade 3 or Higher Treatment-Emergent Immune Related Adverse Events by Group Term and Preferred Term	Safety Evaluable
3.2.7	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety Evaluable
3.2.8	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.9	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety Evaluable
3.2.10	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.11	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety Evaluable
3.2.14	Summary of Treatment-Related Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.15	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.16.1	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Safety Evaluable

3.2.16.2	Summary of Treatment-Emergent Infusion Reaction With a Fatal Outcome by Group Term and Preferred Term	Safety Evaluable
3.2.16.3	Summary of Treatment-Emergent Immune Related Adverse Events With a Fatal Outcome by Group Term and Preferred Term	Safety Evaluable

Table No.	Title	Population
3.2.19.1	Summary of Treatment-Emergent Adverse Events Leading to Infusion Interruption by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.19.2	Summary of Treatment-Emergent Infusion Reaction Leading to Infusion Interruption by Group Term and Preferred Term	Safety Evaluable
3.2.19.3	Summary of Treatment-Emergent Immune Related Adverse Events Leading to Infusion Interruption by Group Term and Preferred Term	Safety Evaluable
3.2.19.4	Summary of Treatment-Emergent Adverse Events Leading to Next Scheduled Dose Delay by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.19.5	Summary of Treatment-Emergent Infusion Reaction Leading to Next Scheduled Dose Delay by Group Term and Preferred Term	Safety Evaluable
3.2.19.6	Summary of Treatment-Emergent Immune Related Adverse Events Leading to Next Scheduled Dose Delay by Group Term and Preferred Term	Safety Evaluable
3.2.20.1	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	Safety Evaluable
3.2.20.2	Summary of Treatment-Emergent Infusion Reaction Leading to Discontinuation of Study Drug by Group Term and Preferred Term	Safety Evaluable
3.2.20.3	Summary of Treatment-Emergent Immune Related Adverse Events Leading to Discontinuation of Study Drug by Group Term and Preferred Term	Safety Evaluable
3.2.24	Summary of Nonserious Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency	Safety Evaluable
3.3 Laboratory		
3.3.1.1	Summary of Laboratory Values - Hematology	Safety Evaluable
3.3.1.2	Summary of Laboratory Values - Chemistry	Safety Evaluable
3.3.1.3	Summary of Laboratory Values - Coagulation	Safety Evaluable
3.3.1.4	Summary of Laboratory Values - Urinalysis	Safety Evaluable
3.3.1.5	Summary of Laboratory Values - Endocrine	Safety Evaluable
3.3.2.1	Shift Summary of Hematology Laboratory Values - to the Worst Abnormal Value	Safety Evaluable
3.3.2.2	Shift Summary of Chemistry Laboratory Values - to the Worst Abnormal Value	Safety Evaluable
3.3.2.3	Shift Summary of Coagulation Laboratory Values - to the Worst Abnormal Value	Safety Evaluable
3.3.3.1	Shift Summary of Hematology Laboratory Values in CTC Grade - to the Worst Abnormal Value	Safety Evaluable
3.3.3.2	Shift Summary of Chemistry Laboratory Values in CTC Grade - to the Worst Abnormal Value	Safety Evaluable

3.3.3.3	Shift Summary of Coagulation Laboratory Values in CTC Grade - to the Worst Abnormal Value	Safety Evaluable
3.3.3.4	Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology	Safety Evaluable
3.3.3.5	Treatment-Emergent Worsening of Laboratory Abnormalities - Chemistry	Safety Evaluable
3.3.3.6	Treatment-Emergent Worsening of Laboratory Abnormalities - Coagulation	Safety Evaluable
Table No.	**Title**	**Population**
3.3.6	Summary of Liver Chemistry	Safety Evaluable
3.4 Vital Signs		
3.4.1	Summary of Systolic Blood Pressure	Safety Evaluable
3.4.2	Summary of Diastolic Blood Pressure	Safety Evaluable
3.4.3	Summary of Pulse	Safety Evaluable
3.4.4	Summary of Respiration Rate	Safety Evaluable
3.4.5	Summary of Body Temperature	Safety Evaluable
3.4.6	Summary of Body Weight	Safety Evaluable
3.5 ECG		
3.5.1	Summary of PR Interval (ms) From 12-Lead ECG	Safety Evaluable
3.5.2	Summary of QRS Interval (ms) From 12-Lead ECG	Safety Evaluable
3.5.3	Summary of QT Interval (ms) From 12-Lead ECG	Safety Evaluable
3.5.4	Summary of QTc Interval (ms) From 12-Lead ECG	Safety Evaluable
3.5.5	Summary of QTcF Interval (ms) From 12-Lead ECG	Safety Evaluable
3.5.6	Summary of QTcB Interval (ms) From 12-Lead ECG	Safety Evaluable
3.5.7	Summary of Heart Rate (bpm) From 12-Lead ECG	Safety Evaluable
3.5.8	Summary of Outliers of QT, QTcB, and QTcF Interval Values (ms) from 12-Lead ECG by Visit	Safety Evaluable

Figures

Figure No.	Title
Efficacy (by disease-specific cohort. Laboratory figures may be added as needed)	
4.1	Kaplan-Meier Estimates of Duration of Response According to RECIST v1.1 – by Disease-Specific Cohort (Optional Pending Data Availability)

4.2	Kaplan-Meier Estimates of Progression Free Survival According to RECIST v1.1 – by Disease-Specific Cohort
4.3	Kaplan-Meier Estimates of Overall Survival – by Disease-Specific Cohort
4.4	Waterfall Plot of Best Percentage Change in Sum of Target Lesions – by Disease-Specific Cohort
4.5	Swimmer Plot of Duration of Response According to RECIST v1.1 – by Disease-Specific Cohort
5.1	Mean and Standard Error of Laboratory Parameters – by Disease-Specific Cohort (Optional)

Listings (data dump listings may be added)

Listing No.	Title
2.1 Discontinued Participants (Participant Disposition)	
2.1.1	Participant Enrollment and Disposition Status
2.1.2	Participant Inclusion and Exclusion Criteria Deviations
2.2 Protocol Deviations	
2.2	Protocol Deviations
2.3 Data Excluded From PK, Efficacy, and/or Safety Analyses	
2.3	Analysis Populations
2.4 Demography and Baseline (Including Prior and Concomitant Medications)	
2.4.1	Demographics and Baseline Characteristics
2.4.2	Cancer History and Baseline Disease Characteristics by Cancer Type
2.4.3	Prior Radiotherapy
2.4.4	Prior Systemic Cancer Therapy
2.4.5	Prior Surgery or Surgical Procedure
2.4.6	Medical History
2.4.7	Prior and Concomitant Medications
2.4.8	Procedures and Nondrug Therapy
2.4.9	Post Anticancer Therapy
2.5 Drug Exposure	
2.5	Study Drug Exposure
2.6 Efficacy	
2.6.1	Overall Survival Events and Assessments
2.6.2	Progression-Free Survival Events and Assessments According to RECIST v1.1
2.6.3	Overall Response Assessment According to RECIST v1.1
2.6.4	Duration of Response According to RECIST v1.1
2.6.5	Response Assessment: Target Lesions
2.6.6	Response Assessment: Nontarget Lesions
2.6.7	Response Assessment: New Lesions
2.6.8	Sum of Diameters of Target Lesions
2.6.9	Overall Response Assessment According to iRECIST
2.7 Adverse Events	
2.7.1	Adverse Events
2.7.2	Serious Adverse Events
2.7.3	Fatal Adverse Events
2.7.4	Adverse Events Leading to Study Drug Discontinuation
2.7.5	Adverse Events Leading to Study Drug Interruption

2.7.6	Adverse Events of Infusion Reaction
2.7.7	Immune Related Adverse Events
2.7.8	Grade 3 or Higher Adverse Events
2.7.9	Investigator Identified Adverse Events of Special Interest
2.8 Laboratory Data	
2.8.1	Clinical Laboratory Values – Hematology
2.8.2	Clinical Laboratory Values – Chemistry
2.8.3	Clinical Laboratory Values – Urinalysis
Listing No.	**Title**
2.8.4	Clinical Laboratory Values – Coagulation
2.8.5	Clinical Laboratory Values – Endocrine
2.8.6.1	Abnormal Clinical Laboratory Values – Hematology
2.8.6.2	Abnormal Clinical Laboratory Values – Chemistry
2.8.6.3	Abnormal Clinical Laboratory Values – Urinalysis
2.8.6.4	Abnormal Clinical Laboratory Values – Coagulation
2.8.7	Clinical Laboratory Values – Pregnancy
2.8.8	Clinical Laboratory Values – Liver Chemistry
2.8.9	HIV-Related Parameters
2.8.10	PK Blood Sampling Times
2.9 Vital Signs	
2.9.1	Vital Signs
2.9.2	Abnormal Vital Sign Values
2.9.3	Alert Vital Sign Values
2.10 Electrocardiograms	
2.10.1	12-Lead ECG Values
2.10.2	Abnormal 12-Lead ECG Values
2.10.3	Alert 12-Lead ECG Values
2.11 Other	
2.11.1	ECOG Performance Status
2.11.2	Tobacco Use
2.11.3	Alcohol Consumption

Signature Manifest

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