Official Title: **A Phase 2 Study of INCMGA00012 in Participants With Squamous Carcinoma of the Anal Canal Who Have Progressed Following Platinum-Based Chemotherapy (POD1UM-202)**

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STATISTICAL ANALYSIS PLAN

INCMGA 0012-202

A Phase 2 Study of INCMGA00012 in Participants With Squamous Carcinoma of the Anal Canal Who Have Progressed Following Platinum-Based Chemotherapy (POD1UM-202)

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Protocol Version:	**Protocol Amendment 4 dated 08 JUL 2019**
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SAP Version:	**Amendment 1**
SAP Author:	[redacted]
Date of Plan:	**17 OCT 2019**

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

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LIST OF ABBREVIATIONS

Abbreviation	Term
[redacted]	[redacted]
AE	adverse event
AESI	adverse events of special interest
BMI	body mass index
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
CRF	case report form
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DCR	disease control rate
DMC	Data Monitoring Committee
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
ELISA	enzyme-linked immunosorbent assay
[redacted]	[redacted]
[redacted]	[redacted]
FAS	full analysis set
FDA	Food and Drug Administration
HIV	human immunodeficiency virus
ICF	informed consent form
[redacted]	[redacted]
[redacted]	[redacted]
ICR	independent central review
IEC	independent ethics committee
[redacted]	[redacted]
irAE	immune-related adverse event
IRB	institutional review board
IRC	Independent Review Committee

Abbreviation	Term
[redacted]	[redacted]
[redacted]	[redacted]
IV	intravenously
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
NE	not evaluable
ORR	overall response rate
OS	overall survival
PD	progressive disease
PD-L1	programmed death-ligand
PFS	progression-free survival
PK	pharmacokinetics
PR	partial response
PRO	patient reported outcome
PT	preferred term
Q4W	every 4 weeks
[redacted]	[redacted]
QTcF	QT interval corrected by Fridericia
QTcB	QT interval corrected by Bazett
RECIST	Response Evaluation Criteria In Solid Tumors
SAP	Statistical Analysis Plan
SCAC	squamous carcinoma of the anal canal
SD	stable disease
SOC	system organ class
TEAE	treatment-emergent adverse event
T_{max}	time to maximum concentration
TPR	timepoint response
WHO	World Health Organization

1. INTRODUCTION

This study is an open-label, single-group, multicenter, Phase 2 study that will enroll participants with locally advanced or metastatic SCAC who have progressed on or after a standard-of-care platinum-based chemotherapy regimen. Participants with well-controlled HIV infection will be eligible. The study will enroll approximately 81 participants. All participants will receive INCMGA00012 at the recommended Phase 2 dose of 500 mg IV Q4W. The primary endpoint is ORR as determined by ICR using RECIST v1.1.

The study consists of 3 periods: screening, study drug treatment, and follow-up. Treatment may continue for up to 2 years in the absence of clinical disease progression, intolerable toxicity, death, withdrawal of consent, lost to follow-up, or premature discontinuation for any other reason. Participants who are treated for at least 6 months and achieve a confirmed CR may discontinue INCMGA00012 after 2 additional cycles upon consultation with the medical monitor.

The follow-up period will begin once a participant has completed 2 years of study drug or prematurely discontinued from study drug. Participants will be evaluated for irAEs for 90 days after the last dose of study drug, regardless of whether a new anticancer therapy is started.

Once participants discontinue treatment, they enter the follow-up period and will be assessed for survival until study completion. Participants who discontinue study treatment without experiencing disease progression will enter the follow-up period and continue to undergo tumor assessments according to the schedule of activities until they experience disease progression, the start of a new anticancer treatment, withdrawal of consent, lost to follow-up, the end of the study, or death.

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 will be executed by the Department of Clinical Pharmacokinetics and the Department of Translational Sciences, respectively.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on Study INCMGA 0012-202 Protocol Amendment 4 dated 08 JUL 2019 and CRFs approved on 11 MAR 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 efficacy of INCMGA00012 in terms of the ORR in participants with locally advanced or metastatic SCAC who have progressed after platinum-based chemotherapy.	ORR, defined as the percentage of participants having a CR or PR, according to RECIST v1.1 as determined by ICR.
Secondary	
To determine additional measures of clinical benefit, specifically, DOR, DCR, PFS, and OS.	DOR, defined as the time from an initial objective response (CR or PR) according to RECIST v1.1 until disease progression as determined by ICR or death due to any cause.
	DCR, defined as the number of participants maintaining either an ORR or stable disease.
	PFS, defined as the time from the first dose of study treatment until disease progression by ICR or death due to any cause.
	OS, defined as the time from the start of therapy until death due to any cause.
To evaluate the safety of INCMGA00012 in participants with previously-treated SCAC.	Safety, determined by the number of participants; the frequency, duration, and severity of AEs per CTCAE v5.0; laboratory tests; vital signs; and ECGs.
To determine the PK of INCMGA00012 administered to participants with SCAC.	Population PK, including C_{max}, T_{max}, C_{min}, and AUC_{0-t}, will be summarized.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
[redacted]	

3. STUDY DESIGN

3.1. Overall Study Design

This study is an open-label, single-group, multicenter, Phase 2 study that will enroll participants with locally advanced or metastatic SCAC who have progressed on or after a standard-of-care platinum-based chemotherapy regimen. Participants with well-controlled HIV infection will be eligible. All participants will receive INCMGA00012 at the recommended Phase 2 dose of 500 mg IV Q4W. The primary endpoint is ORR as determined by ICR using RECIST v1.1.

The study consists of 3 periods: screening, study drug treatment, and follow-up. Treatment may continue for up to 2 years in the absence of clinical disease progression, intolerable toxicity, death, withdrawal of consent, lost to follow-up, or premature discontinuation for any other reason.

Treatment will be administered by IV infusion over 60 minutes (± 15 minutes) on Day 1 of each 28-day cycle. Subsequent treatment cycles should be delayed (for up to 12 weeks) until certain criteria are met. The follow-up period will begin once a participant has completed 2 years of study drug or prematurely discontinued from study drug.

Participants unable to restart study drug treatment ≤ 12 weeks from the start of the treatment delay due to toxicity will be permanently discontinued from study treatment. Treatment interruptions of > 12 weeks for reasons other than toxicity (eg, for targeted radiotherapy or surgical resection of oligometastatic disease) will be considered on a case-by-case basis by the medical monitor.

Participants who have been treated for at least 6 months and achieve a confirmed CR may discontinue INCMGA00012 after 2 additional cycles upon consultation with the medical monitor.

3.1.1. Survival Follow-Up Period

All participants will be followed for survival assessment until study completion. During this time, participants will be followed via telephone or other electronic contact at least every 12 weeks for follow-up of overall survival.

3.1.2. Treatment Discontinuation

Participants **must** be withdrawn from study treatment for the following reasons:

- Clinical disease progression.
- Unacceptable toxicity as noted in Protocol Section 6.5.2.
- Consent is withdrawn.
- Further study treatment would be injurious to the participant's health or well-being, in the investigator's medical judgment.
- The study is terminated by the sponsor.
- The study is terminated by the local health authority, IRB, or IEC.

A participant **may** be discontinued from study drug as follows:

- If a participant is noncompliant with study procedures or study drug administration in the investigator's opinion, the sponsor should be consulted for instruction on handling the participant.
- The participant becomes pregnant. If the female participant is no longer pregnant and meets the treatment continuation criteria within 12 weeks of the scheduled start of a cycle, study treatment may be resumed after approval has been received from the medical monitor, per Protocol Section 9.7.

3.1.3. 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 all participants have completed at least 2 years of treatment with INCMGA00012 or discontinued.

A participant is considered to have completed the study if he/she has completed all periods/parts of the study including survival follow-up.

3.1.4. Response Assessment

Objective assessment of disease status will be evaluated according to RECIST v1.1 (Eisenhauer et al 2009) and entered into the eCRF. [redacted]

Efficacy assessments of response should be performed according to the schedule of activities. Scans should follow calendar days and remain on the 8-week schedule, established on Cycle 1 Day 1 (date of first dose of study drug), and should not be delayed for treatment holds or interruptions. Confirmation of CR or PR should be confirmed by imaging at least 4 weeks after initial documentation. For participants who discontinue study treatment for reasons other than disease progression, every effort should be made to continue monitoring their disease status by radiographic imaging according to the follow-up schedule.

Participants who continue study participation in the follow-up period without experiencing disease progression will continue to have efficacy assessments every 12 weeks until they complete participation in the study, start a new anticancer therapy, experience disease progression, or death.

3.2. Randomization

Not applicable.

3.3. Control of Type I Error

There is no formal hypothesis testing in this study. For analysis of response rate, 2-sided 95% CI will be reported.

3.4. Sample Size Considerations

In a recent single-arm Phase 2 study, nivolumab achieved an ORR of 24% in participants with unresectable metastatic anal cancer (Morris et al 2017).

Based on a target ORR of 25% and a sample size of 81, the study has 80% power to exclude a lower confidence limit of 13% with alpha equal to 0.025 (1-sided). Response rate and associated 95% CI are provided in Table 2. The sample size calculation is based on the FAS (see Section 5.3.1).

Table 2: Response Rates and 95% Confidence Intervals

Sample Size	Number of Responses	Response Rate (%)	95% CI (%)
81	10	12.3	6.1-21.5
81	15	18.5	10.8-28.7
81	20	24.7	15.8-35.5
81	25	30.9	21.1-42.1
81	30	37.0	26.6-48.5

3.5. Schedule of Assessments

Refer to Protocol Amendment 4 dated 08 JUL 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

INCMGA00012 is the only study drug in this study.

4.1.2. Day 1

Day 1 is the date that the first dose of INCMGA00012 is administered to the participants.

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 conventions 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.
- No imputation will be done if the date is completely missing.

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.

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

4.1.6. Cycle Length and Duration

One cycle is defined as 28 days (4 weeks) for participants in this study. Cycle 1 Day 1 is the day of first infusion of INCMGA00012. Day 1 of subsequent cycles will correspond with the infusion date of INCMGA00012 within the cycle. Scheduled visits will have a ± 3-day window. Tumor assessments will have ± 7-day 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 following time interval:

> Date of first administration of study drug through the date of last administration of study drug + 90 days.

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

If the last date of study drug is missing, on-treatment assessments/events include any assessment/event recorded in the database that occurred after the start date of study drug.

Data listings will include all assessments/events, and those which are not on-treatment assessments/events will be flagged.

4.2. Variable Definitions

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

4.2.1. Body Mass Index

Body mass index will be calculated as follows:

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

4.2.2. Prior and Concomitant Medication

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

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

For the purposes of analysis, all medications will be considered concomitant medications unless the medications can unequivocally be defined as not concomitant, that is, if the start date and end date are all missing, then the medication is considered as concomitant medication.

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.

Interim analysis is planned for this study as defined in Section 11.

5.2. Treatment Groups

There is only 1 treatment group in this study, that is, INCMGA00012.

5.3. Analysis Populations

5.3.1. Full Analysis Set

The FAS includes all participants enrolled in the study who received at least 1 dose of study drug. The FAS will be used for the summary of demographics, baseline characteristics, and participant disposition as well as efficacy analysis.

5.3.2. Safety Evaluable Population

The safety evaluable population includes all enrolled participants who received at least 1 dose of study drug.

All safety analyses will be conducted using the safety evaluable population.

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 serum sample (1 PK measurement). The study pharmacokineticist will review data listings of study drug administration and sample records to identify subjects to be excluded from analyses of PK data. The study research investigator will review data listings of pharmacodynamic data and sample records to identify subjects to be excluded from analyses of pharmacodynamic data.

[redacted]

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

The FAS will be used for all baseline disease characteristics and demographic summaries and data listings.

6.1.1. Demographics and Baseline Characteristics

Demographic and baseline characteristics will be listed in detail. The following demographics will be summarized using the safety evaluable population and FAS: age, sex, race, ethnicity, body weight, height, and BMI. Qualitative data will be summarized by contingency tables while quantitative data will be summarized by descriptive summary statistics.

6.1.2. Baseline Disease Characteristics and Disease History

According to data collected in the eCRF, time since initial diagnosis, tumor stage at initial diagnosis, site of primary tumor at initial diagnosis, PD-L1 assessment, MSI status, HPV status, HIV infection, ECOG performance status, and current sites of disease will be summarized for all participants in FAS.

6.1.3. Prior Therapy

The number and percentage of participants recording any prior systemic cancer therapy, prior radiation, or prior surgery will be summarized. 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. Detailed information on prior systemic cancer therapy, prior radiation, and prior surgery will be listed in 3 separate listings.

6.1.4. Medical History

Medical history will be summarized for all participants in the FAS. This summary will be presented by primary SOC and PT.

6.2. Disposition of Participants

The number and percentage of participants who are on treatment, who discontinue study treatment with a 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 the FAS.

6.3. Protocol Deviations

Protocol deviations recorded on the eCRF will be presented in the participant data listings. If data warrant, protocol deviations will be summarized descriptively.

6.4. Exposure

For participants in the safety evaluable population, exposure to INCMGA00012 will be summarized descriptively as follows:

- **Total number of infusions:** Total number of infusions of INCMGA00012 per participant.
- **Total dose administered (mg):** Estimated volume delivered / prepared volume × 500 mg.
- **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.

Infusion information collected in the eCRF will be listed. Dose delay and temporary infusion interruption may be summarized/listed as needed.

6.5. Prior and Concomitant Medication

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary and summarized by ATC drug class and WHO drug term. Results will be summarized as number and percentage of participants with prior and concomitant medications by ATC class and WHO drug term in safety population. 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 study drug will be included. Medications with missing start/end dates will be considered as concomitant medication in the summary. Post-treatment anti-cancer therapy will be summarized. Other medications will be provided in the listing. Drugs intended to manage irAEs as well as prophylaxis/premedication used to prevent infusion reactions may be summarized separately. Procedures and nondrug therapies will also be summarized/listed per CRF.

7. EFFICACY

A list of planned tables, figures, and listings is provided in Appendix A.

7.1. General Considerations

Efficacy endpoints of this study include ORR, DOR, DCR, and PFS based on RECIST v1.1 as determined by ICR, and OS. [redacted] Response assessment on RECIST v1.1 by investigator may be provided as a sensitivity analysis. Listings of response assessment at each visit will be provided.

7.2. Efficacy Hypotheses

Not applicable.

7.3. Analysis of the Efficacy Parameters

7.3.1. Response Criteria

Overall response will be categorized using RECIST v1.1 [redacted] Participants will have their overall response evaluated as CR, PR, SD, PD, or NE for RECIST v1.1 [redacted] 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 PD or new anticancer therapy, according to RECIST v1.1 (Eisenhauer et al 2009) as determined by an ICR. The primary analysis of ORR will be performed at least 6 months after the last participant is enrolled in the study. Participants who do not have sufficient baseline data to ascertain a response will be included in the denominators in the calculation of ORR. The primary analysis of ORR will be based on the FAS. Overall response rate and its exact 95% CI will be presented. In addition, ORR by investigator assessment will be provided as sensitivity analysis for the primary endpoint.

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 assessment.

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. Handling of Missing Data in Primary Analysis

The study requires measurable disease at baseline per RECIST v1.1 as part of the inclusion criteria. However, if a participant did not have measurable disease and was administered study drug, the participant will also be counted as denominator in the calculation of ORR. For this study, participants without measurable disease at baseline will be considered nonresponders. Participants with subsequent missing assessments that prevent the evaluation of the primary endpoint will be considered nonresponders. No data imputation will be applied.

A response assessment of CR or PR reported before any additional anticancer therapy will be considered as a response in the calculation of ORR irrespective of the number of missed assessments before response.

7.3.2.3. Best Overall Response

The best overall response 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 participant's best response assignment will depend on the achievement of both measurement and confirmation criteria. The best overall response 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 best overall response determination. The best overall response for each participant is determined from the sequence of overall responses according to the following rules:

- CR = at least 2 consecutive determinations of CR at least 4 weeks apart before progression
- PR = at least 2 consecutive determinations of PR or better at least 4 weeks apart before progression (and not qualifying for a CR)
- SD = at least 1 SD assessment (or better) ≥ 7 weeks after start of treatment (and not qualifying for CR or PR)

- PD = meet progression criteria comparing with nadir (and not qualifying for CR, PR, or SD)
- NE = all other cases (ie, not qualifying for confirmed CR or PR and without SD after more than 7 weeks or PD)

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 (49 days). Participants who fail to meet this criterion will have a best overall response of PD if the next available assessment indicated PD or NE if there is no additional assessment available. Table 4 lists the scenarios of responses that can occur after an unconfirmed CR or PR in the 4-week follow-up time and provides a rule for determining the best overall response in each scenario.

Table 4: Confirmed Response Based on Subsequent Assessments

First Timepoint Response[a]	Second Timepoint Response	Confirmed Response[b]
CR	PR/SD/PD	SD or NE[b]
CR	CR	CR[a]
CR	NE[a]	SD or NE[b]
PR	CR/PR	PR[a]
PR	SD/PD	SD or NE[b]
PR	NE[a]	SD or NE[b]
SD	CR/PR/SD/PD/NE	SD or NE[b]
PD	No further evaluation	PD

[a] 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 TPR 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.

[b] A confirmed response of SD can only be made after the participant is on study for a minimum of 49 days. If the participant is on study less than 49 days, any tumor assessment indicating SD before this time period will have a confirmed response of NE unless PD is identified.

7.3.3. Secondary Analysis

7.3.3.1. Duration of Response

Duration of response is defined as the time from first documented response (CR or PR, which is confirmed subsequently) to the time of first documented disease progression 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 5). The DOR endpoint will be analyzed at least 6 months after the last participant is enrolled in the study. The Kaplan-Meier estimate of the distribution function will be constructed for DOR. The estimated median along with 95% CIs will be reported. A swim plot for DOR may be generated. Analysis of DOR will be according to RECIST v1.1 as determined by ICR in the FAS.

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 per RECIST v1.1, according the ICR. The DCR will be estimated, and the 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 treatment to the date of the first documented progression per RECIST v1.1 according to ICR or death due to any cause. Progression-free survival will be analyzed by the Kaplan-Meier method, including estimated median with 95% CI and Kaplan-Meier 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 5, which is based on the FDA Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (2007). Date of death will be determined using the Death Report, Survival Follow-Up, and Subject Status eCRFs.

Table 5: 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 discontinuation for undocumented progression	Censored	Date of last valid radiologic assessment (not NE or missing)
Study discontinuation 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

7.3.3.4. Overall Survival

Overall survival is defined as the time from first dose of study treatment 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. Kaplan-Meier curves, medians, and 95% CIs of the medians will be presented for OS.

7.3.4. 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.

7.3.5. Subgroup Analysis

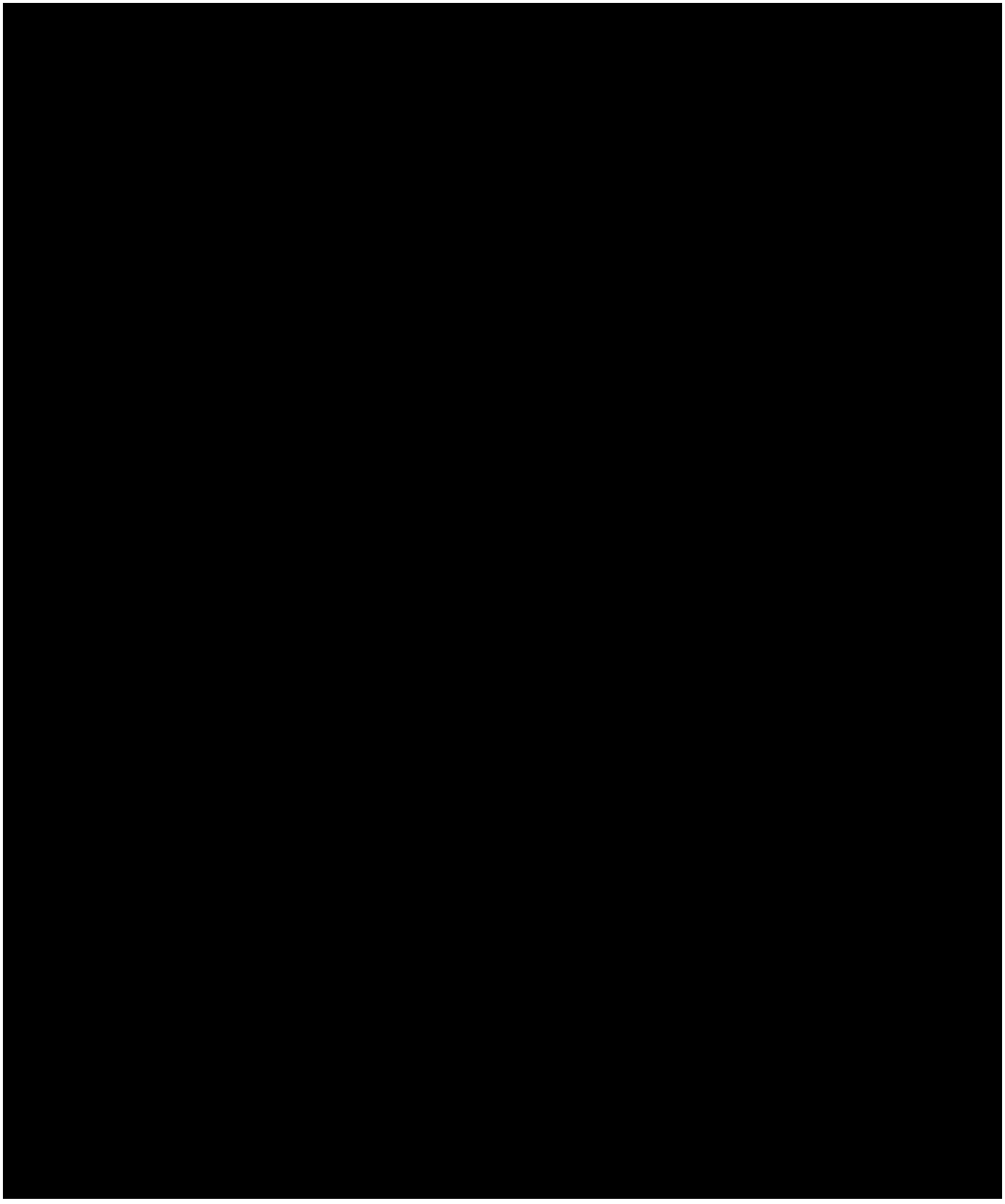
Subgroup analyses will be performed on the following based on the participant's baseline status:

- Sex: Male, Female
- Baseline ECOG performance status: 0 vs 1
- Age: < 65 years, ≥ 65 years and < 75 years, ≥ 75 years
- Race: Caucasian, non-Caucasian
- Ethnicity: Hispanic or Latino, Not Hispanic or Latino
- HIV status: Known HIV-positive, negative, or unknown
- Prior lines of therapy: less than 2 lines of prior therapy vs more than 2 lines of prior therapy
- Liver metastatic: Yes, No
- HPV, MSI, and/or PD-L1 assessment (if tumor tissue is available at screening): $< 1\%$, $\geq 1\%$

Subgroup analyses will only be performed if at least 5 participants are present in each subgroup. Some grouping of classes will be considered if there are too few participants in some subgroups.

Efficacy analyses in subgroups will generally be exploratory and are intended to explore the intrinsic consistency of any treatment effects found overall.

Subgroup analyses of the primary endpoint (ORR) will be performed on the FAS by presenting the point estimates in the subgroup with the exact 95% CIs. Summary tables and forest plots may be presented.



[redacted]

8. SAFETY AND TOLERABILITY

A list of planned tables, figures, and listings is provided in Appendix A.

8.1. General Considerations

The clinical safety data (eg, vital signs, ECGs, routine laboratory tests, and AEs) will be summarized using descriptive statistics (eg, mean, frequency) using the safety evaluable population. Some safety analyses such as AEs and laboratory values may be performed within a known HIV-positive subgroup if a sufficient number of participants are enrolled.

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

8.2. Adverse Events

8.2.1. Adverse Event Definitions

A TEAE 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.

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

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

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.

Cumulative toxicity including cumulative adverse event rates may be provided at specific timepoints including 3, 6, and 12 months.

8.2.2. Adverse Events of Special Interest

Adverse events that are potentially immune-related will be assessed as AESIs. Adverse events of special interest identified in the AE dataset will be summarized. In addition, predefined PTs may be used to summarize AESIs.

An overall summary of AESIs will include number (%) of participants reporting any AESIs, any ≥ Grade 3 AESIs, any treatment-related AESIs, any fatal AESIs, and any AESIs leading to treatment interruption/delay in planned treatment/dose reduction/discontinuation.

Time of the first onset of the AESI, time to the first onset of AESI, defined as from study Day 1 to the date of first onset of each AESI, as well as duration of AESI may be summarized.

Immune-related AEs are to be collected for 90 days after the last dose of study drug, regardless of whether a new anticancer therapy is started. Reasonable efforts should be made to align the first 12-week follow-up visit with the end of the 90-day irAE reporting period.

8.2.3. Adverse Event Summaries

An overall summary of AEs will include:

- 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 who temporarily interrupted study drug infusion because of TEAEs
- Number (%) of participants who delayed the next scheduled study drug infusion because of TEAEs
- Number (%) of participants who permanently discontinued study drug because of TEAEs
- Number (%) of participants who had a fatal TEAE
- Number (%) of participants reporting any infusion-related reactions

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

- Overall summary of TEAEs
- 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 treatment-related TEAEs by SOC and PT
- Summary of treatment-related TEAEs by PT in decreasing order of frequency
- Summary of TEAEs with a fatal outcome by SOC and PT
- Summary of serious TEAEs by SOC and PT
- Summary of treatment-related serious TEAEs by SOC and PT
- Summary of serious TEAEs by PT in decreasing order of frequency
- Summary of TEAEs leading to dose delay by SOC and PT
- Summary of TEAEs leading to infusion interruption by SOC and PT
- Summary of TEAEs 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 AESIs will be included:

- Overall summary of TEAEs of special interests
- Summary of TEAEs of special interest by SOC and PT
- Summary of TEAEs of special interest by PT in decreasing order of frequency
- Summary of TEAEs of special interest with a fatal outcome by SOC and PT
- Summary of TEAEs of special interest leading to dose delay by SOC and PT
- Summary of TEAEs of special interest leading to infusion interruption by SOC and PT
- Summary of TEAEs of special interest leading to study drug discontinuation by SOC and PT
- Summary TEAEs of special interest by SOC, PT, and maximum severity
- Summary of Grade 3 or higher TEAEs of special interest by SOC and PT
- Summary of time of first onset and duration of identified TEAEs of special interest
- Summary of clinical interventions used to manage TEAEs of special interest

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 7 may be referred as tiebreaker to delineate which value will be defined as baseline.

Table 7: 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 and shift tables relative to baseline will be tabulated.

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 the safety 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.

Shift tables will be presented showing change in CTCAE grade from baseline to worst postbaseline grade. 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. All laboratory assessments will be listed, and those collected later than 90 days after the last treatment/exposure date will be flagged in the listings.

- Number and percentage of participants with worst postbaseline CTCAE grade (regardless of the baseline status) will be summarized. Each participant will be counted only for the worst grade observed after baseline.
- 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.
- Number and percentage of participants meeting categorical liver function test criteria, including ALT, AST, and ALT/AST (> 3 ×, 5 ×, 8 ×, 10 ×, 20 × ULN), total bilirubin (> 1 ×, 2 × ULN), ALP (> 1.5 ×, 2 ×, 3 ×, 5 ×, 8 ×, 10 × ULN), combined categories of ALT/AST and total bilirubin (eg, ALT/AST > 3 × UNL & total bilirubin > ULN) as well as Hy's Law criteria (ALT or AST > 3 × ULN and total bilirubin > 2 × ULN and ALP < 2 × ULN at the same visit). The worst values observed postbaseline for each participant will be used for each of the categories.

8.4. Vital Signs

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

Criteria for clinically notable vital sign abnormalities are defined in Table 8. The abnormal values for participants exhibiting clinically notable vital sign abnormalities will be listed. Alert vital signs are defined as an absolute value outside the defined range and percentage change from baseline greater than 25%. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 8: 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, RR, 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. Baseline will be determined as the last nonmissing ECG measurements taken on or before the first administration of study drug.

Criteria for clinically notable ECG abnormalities are defined in Table 9. Participants exhibiting clinically notable ECG abnormalities will be listed with study visit. 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 9: Criteria for Clinically Notable Electrocardiogram Abnormalities

Parameter	High Threshold	Low Threshold
QTcF/QTcB	> 460 ms	< 295 ms
PR	> 220 ms	< 75 ms
QRS	> 120 ms	< 50 ms
QT	> 500 ms	< 300 ms
RR	> 1330 ms	< 600 ms
HR (bpm)	≥ 100 and ≥ 25% increase from baseline	≤ 50 and ≥ 25% decrease from baseline

QTcB = Bazett correction; QTcF = Fridericia correction.

Twelve-lead ECGs will be obtained for each participant during the study. Electrocardiogram abnormalities, both at baseline and postbaseline visits, will be tabulated. Incidences of abnormalities will be listed with study visit and a description of the abnormality.

9. PHARMACOKINETIC [redacted] ANALYSES

9.1. Pharmacokinetic Assessments

Serum concentrations of INCMGA00012 will be monitored using a quantitative sandwich ELISA method. Single and multiple dose PK parameters for INCMGA00012, C_{max}, T_{max}, AUC_{tau}, C_{trough}, CL, V_{ss}, and $t_{½}$ will be derived from INCMGA00012 serum concentration versus time data. Population PK analyses may be conducted using data from this study alone or combined with data from other studies. Pharmacokinetic parameters will be summarized as a secondary endpoint of the study.

[redacted]

11. INTERIM ANALYSES

An analysis is planned after approximately 25 participants are assessable for investigator-assessed response according to RECIST v1.1. The primary intent of this analysis is to minimize unnecessary exposure of participants to INCMGA00012 in the event of futility. An ICR will be used for interim analysis if available; otherwise, investigator response assessment may be used. The study will be stopped for futility at the interim analysis if conditional power based on interim result is lower than 20%, which is equivalent to less than 2 participants responded. All participants enrolled with a postbaseline response assessment or participants who discontinued early will be included in the futility analysis. Participants enrolled in the study without any postbaseline response assessment but are ongoing in the study will not be included in the futility analysis for calculation of conditional power. Enrollment will continue while the analysis is being conducted. This futility analysis will be reviewed by an independent DMC as specified in the DMC Charter. The process by which the DMC will review data and make recommendations and decisions will be documented in the DMC Charter.

12. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 10.

Table 10: Statistical Analysis Plan Versions

SAP Version	Date
Original	14 MAY 2019
Amendment 1	17 OCT 2019

12.1. Changes to Protocol-Defined Analyses

Not applicable.

12.2. Changes to the Statistical Analysis Plan

12.2.1. Amendment 1

The following changes were made to the SAP:

- Clarification regarding the timing of analysis of the ORR and DOR endpoints was added in Sections 7.3.2.1 and 7.3.3.1.
- Clinical notable vital sign criteria for body temperature were removed in Table 8.
- Minor administrative changes have been incorporated throughout and are noted in the redline version of the amendment.

13. REFERENCES

Morris VK, Salem ME, Nimeiri H, et al. Nivolumab for previously treated unresectable metastatic anal cancer (NCI9673): a multicentre, single-arm, phase 2 study. Lancet Oncol 2017;18:446-453.

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.

Food and Drug Administration. Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics. 2007. www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071590.pdf. Accessed May 9, 2019.

[redacted]

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the CSR. 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. Analysis to support the DMC will be performed as marked pending data availability.

Tables

Table No.	Title	Population	DMC
Baseline and Demographic Characteristics			
1.1 Disposition			
1.1.1	Analysis Populations	Enrolled	
1.1.2	Summary of Participant Disposition	FAS	Y
1.1.3	Summary of Number of Participants Enrolled by Country and Site	Enrolled	
1.1.4	Summary of Protocol Deviations	FAS	
1.2 Demography			
1.2.1	Summary of Demographics	FAS	Y
1.3 Baseline Disease Characteristics (refine per data collection)			
1.3.1	Summary of Cancer History and Baseline Disease Characteristics	FAS	Y
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 Systemic Cancer Therapy	FAS	Y
1.4.4	Summary of Prior Radiotherapy	FAS	
1.4.5	Summary of Prior Surgery/Procedure	FAS	
1.4.6	Summary of Nondrug Procedure	FAS	
1.4.7	Summary of Post Anticancer Therapy	FAS	
1.5 Others			
1.5.1	Summary of General Medical History	FAS	
Efficacy (additional subgroup analysis may be performed if data permitted)			
2.1.1	Summary of Best Overall Response by ICR	FAS	Y
2.2.1	Summary of Duration of Response by ICR	FAS	
2.2.2	Summary of Disease Control Rate by ICR	FAS	
2.2.3	Summary of Progression Free Survival by ICR	FAS	
2.2.4	Summary of Overall Survival	FAS	
2.2.5	Summary of Largest Percentage Reduction in Sum of Diameters of Target Lesions	FAS	
2.3.1	Summary of Best Overall Response by ICR by Gender	FAS	
2.3.2	Summary of Best Overall Response by ICR by Age Group	FAS	
2.3.3	Summary of Best Overall Response by ICR by Race	FAS	
2.3.4	Summary of Best Overall Response by ICR by Ethnicity	FAS	
2.3.5	Summary of Best Overall Response by ICR by ECOG Status at Baseline	FAS	
2.3.6	Summary of Best Overall Response by ICR by HIV Status at Baseline	FAS	
2.3.7	Summary of Best Overall Response by ICR by Prior Lines of Therapy	FAS	
2.3.8	Summary of Best Overall Response by ICR by Liver Metastatic Status	FAS	
2.3.9	Summary of Best Overall Response by ICR by PD-L1 status	FAS	
[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	
2.5.1	Summary of Best Overall Response by Investigator	FAS	Y
2.5.2	Summary of Duration of Response by Investigator	FAS	

Table No.	Title	Population	DMC
Safety			
3.1 Dose Exposure			
3.1.1	Summary of Exposure to INCMGA00012	Safety	Y
3.1.2	Summary of Dose Delay/Interruption	Safety	
3.2 Adverse Events			
3.2.1	Overall Summary of Treatment-Emergent Adverse Events	Safety	Y
3.2.1.1	Overall Summary of Treatment-Emergent Adverse Events of Special Interest	Safety	Y
3.2.2.1	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.2.2	Summary of Treatment-Emergent Adverse Events of Special Interest by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.3.1	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	Y
3.2.3.2	Summary of Treatment-Emergent Adverse Events of Special Interest by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	Y
3.2.4	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Safety	Y
3.2.4.1	Summary of Treatment-Emergent Adverse Events of Special Interest by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Safety	
3.2.6	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.6.1	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events of Special Interest by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.7	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	
3.2.8	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.9	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	
3.2.10	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.11	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	
3.2.12	Summary of Treatment-Emergent Adverse Events Leading to Dose Delay by MedDRA System Organ Class and Preferred Term	Safety	
3.2.12.1	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Dose Delay by MedDRA System Organ Class and Preferred Term	Safety	
3.2.15	Summary of Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	
3.2.16	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.16.1	Summary of Treatment-Emergent Adverse Events of Special Interest With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Safety	
3.2.19	Summary of Treatment-Emergent Adverse Events Leading to Infusion Interruption by MedDRA System Organ Class and Preferred Term	Safety	
3.2.19.1	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Infusion Interruption by MedDRA System Organ Class and Preferred Term	Safety	
3.2.20	Summary of Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by MedDRA System Organ Class and Preferred Term	Safety	Y

Table No.	Title	Population	DMC
3.2.20.1	Summary of Treatment-Emergent Adverse Events of Special Interest Leading to Study Drug Discontinuation by MedDRA System Organ Class and Preferred Term	Safety	Y
3.2.22	Summary of Infusion-Related Reaction by MedDRA System Organ Class and Preferred Term	Safety	
3.2.23	Signs/Symptoms of Infusion-Related Reaction	Safety	
3.2.24	Summary of Nonserious Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency	Safety	
3.2.25	Summary of Time of First Onset and Duration of Treatment-Emergent Adverse Events of Special Interest	Safety	
3.2.26	Summary of Clinical Intervention of Adverse Events of Special Interest	Safety	
3.3 Laboratory			
3.3.1	Summary of Laboratory Values - Hematology	Safety	Y
3.3.2	Shift Summary of Hematology Laboratory Values in CTC Grade - to the Worst Abnormal Value	Safety	
3.3.3	Shift Summary of Hematology Laboratory Values - to the Worst Abnormal Value	Safety	
3.3.4	Summary of Laboratory Values - Chemistry	Safety	Y
3.3.5	Shift Summary of Chemistry Laboratory Values in CTC Grade - to the Worst Abnormal Value	Safety	
3.3.6	Shift Summary of Chemistry Laboratory Values - to the Worst Abnormal Value	Safety	
3.3.7	Summary of Laboratory Values - Coagulation	Safety	
3.3.8	Shift Summary of Coagulation Laboratory Values in CTC Grade - to the Worst Abnormal Value	Safety	
3.3.9	Shift Summary of Coagulation Laboratory Values - to the Worst Abnormal Value	Safety	
3.3.10	Summary of Liver Chemistry	Safety	
3.4 Vital Signs			
3.4.1	Summary of Systolic Blood Pressure	Safety	
3.4.2	Summary of Diastolic Blood Pressure	Safety	
3.4.3	Summary of Pulse	Safety	
3.4.4	Summary of Respiration Rate	Safety	
3.4.5	Summary of Body Temperature	Safety	
3.4.6	Summary of Weight	Safety	
3.5 ECG			
3.5.1	Summary of PR Interval (ms) From 12-Lead ECG	Safety	
3.5.2	Summary of QRS Interval (ms) From 12-Lead ECG	Safety	
3.5.3	Summary of QT Interval (ms) From 12-Lead ECG	Safety	
3.5.4	Summary of QTcF Interval (ms) From 12-Lead ECG	Safety	
3.5.5	Summary of QTcB Interval (ms) From 12-Lead ECG	Safety	
3.5.6	Summary of RR Interval (ms) From 12-Lead ECG	Safety	
3.5.7	Summary of Heart Rate From 12-Lead ECG	Safety	
3.5.8	Summary of Outliers of QT, QTcB, and QTcF Interval Values (ms) From 12-Lead ECG	Safety	
3.5.9	Summary of Clinically Significant ECG Abnormality	Safety	
[redacted]			

Table No.	Title	Population	DMC
[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	

Figures

Figure No.	Title
Efficacy (Lab figures may be added as needed. Kaplan-Meier plots may be added per investigator and for different analysis populations)	
4.1	Kaplan-Meier Estimates of Duration of Response by IRC
4.2	Kaplan-Meier Estimates of Progression-Free Survival by IRC
4.3.1	Kaplan-Meier Estimates of Overall Survival
4.3.2	Waterfall Plot of Best Percentage Change in Sum of Target Lesions
4.3.3	Swimmer Plot of Duration of Response by IRC
4.3.4	Forest Plot of Overall Response and 95% CI by IRC
[redacted]	[redacted]
4.5.X	Mean and Standard Error of Laboratory Parameters
4.6.X	Mean and Standard Error of HIV Parameters

Listings (Data Dump Listings May Be Added)

Listing No.	Title	DMC
2.1 Discontinued Participants (Participant Disposition)		
2.1.1	Participant Enrollment and Disposition Status	Y
2.1.2	Participant Inclusion and Exclusion Criteria Violations	
2.2 Protocol Deviations		
2.2	Protocol Deviations	Y
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	Demographic and Baseline Disease Characteristics	Y
2.4.2	Cancer Disease History	Y
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	Y
2.6 Efficacy		
2.6.1	Overall Survival Events and Assessments	
2.6.2	Progression-Free Survival Events and Assessments by IRC	
2.6.3	Overall Response Assessment by IRC	
2.6.4	Duration of Response by IRC	
2.6.5	Response Assessment: Target Lesions	
2.6.6	Response Assessment: Nontarget Lesions	
2.6.7	Response Assessment: New Lesions	
2.6.8	Largest Percentage Reduction in Sum of Diameters of Target Lesions by IRC	
2.6.9	ECOG Performance Status	
[redacted]	[redacted]	
[redacted]	[redacted]	
2.6.12	Overall Response Assessment by Investigator per RECIST	

Listing No.	Title	DMC
2.7 Adverse Events		
2.7.1	Adverse Events	Y
2.7.2	Serious Adverse Events	Y
2.7.3	Fatal Adverse Events	Y
2.7.4	Adverse Events Leading to Study Drug Discontinuation	Y
2.7.5	Adverse Events Leading to Study Drug Interruptions or Delays	
2.7.6	Adverse Events of Special Interest	
2.7.7	Adverse Events Grade 3 or Higher	Y
2.7.8	Infusion-Related Reactions	
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	
2.8.4	Clinical Laboratory Values – Coagulation	
2.8.5	Abnormal Clinical Laboratory Values	
2.8.6	PK Blood Sampling Times	
[redacted]	[redacted]	
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 Physical Examinations		
2.11.1	Physical Examinations	
2.11.2	Body Weight	