Official Title: A Phase 1-2 Study of Combination Therapy With INCMGA00012 (Anti–PD-1), INCAGN02385 (Anti–LAG-3), and INCAGN02390 (Anti–TIM-3) in Participants With Select Advanced Malignancies

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Statistical Analysis Plan

INCAGN 2385-201

A Phase 1-2 Study of Combination Therapy With INCMGA00012 (Anti–PD-1), INCAGN02385 (Anti–LAG-3), and INCAGN02390 (Anti–TIM-3) in Participants With Select Advanced Malignancies

IND Number:	**147,539**
Sponsor:	**Incyte Biosciences International Sàrl** **Route de la Corniche 1** **1066 Epalinges, Switzerland**
Protocol Version:	**Protocol Amendment 4 dated 02 MAR 2023**
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SAP Version:	**Amendment 1**
SAP Author:	[redacted]**, Biostatistics**
Date of Plan:	**23 MAY 2025**

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
ADA	antidrug antibody
AE	adverse event
ALT	alanine 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
BOIN	Bayesian optimal interval
BOR	best overall response
bpm	beats per minute
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
CTCAE	Common Terminology Criteria for Adverse Events
DCR	disease control rate
DLT	dose-limiting toxicity
DMC	Data Monitoring Committee
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
FAS	full analysis set
FDA	Food and Drug Administration (US)
irAE	immune-related adverse event
IRR	infusion-related reaction
MedDRA	Medical Dictionary for Regulatory Activities
mPFS	median progression-free survival
MTD	maximum tolerated dose
NE	not evaluable
ORR	objective response rate
PD	progressive disease
PET	probability of early termination
PFS	progression-free survival
PK	pharmacokinetic

Abbreviation	Term
PR	partial response
PT	preferred term
ORR	objective response rate
QTcB	QT interval corrected using Bazett's formula
QTcF	QT interval corrected using Fridericia's formula
RECIST	Response Evaluation Criteria in Solid Tumors
RNA	ribonucleic acid
RO	receptor occupancy
SAP	Statistical Analysis Plan
SD	stable disease
SOC	system organ class
TEAE	treatment-emergent adverse event
TLFs	tables, listings, and figures
t_{max}	time to maximum concentration
WHO	World Health Organization

1. INTRODUCTION

This is an open-label, nonrandomized, Phase 1-2 study to determine the safety, tolerability, and preliminary efficacy of INCAGN02385 and INCAGN02390 given both as monotherapy as well as in combination with retifanlimab (ie, doublets and triplets) at multiple doses on Q2W, Q3W, and Q4W schedules.

Section 2 of the Protocol provides a detailed description of the investigational product, target participant population, rationale for doses to be examined, and potential risks and benefits of treatment with INCAGN02385, INCAGN02390, and retifanlimab.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the INCAGN 2385-201 Protocol.

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

The analysis of biomarkers and pharmacodynamics will be conducted by the Incyte translational scientist, and the details of the analysis methodology and results will appear in a separate report.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCAGN 2385-201 Protocol Amendment 4 dated 02 MAR 2023 and CRFs approved 08 NOV 2023. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and eCRF versions.

2.2. Study Objectives and Endpoints

Table 1 presents the objectives and endpoints.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary	
Phase 1	
To determine RP2Ds for all study drugs to be used in the following regimens: Part 1 (Q2W): INCAGN02385 + INCAGN02390 Part 2 (Q2W): INCAGN02385 + INCAGN02390 + retifanlimab Part 3 (Q3W): INCAGN02385, INCAGN02390, INCAGN02385 + retifanlimab and INCAGN02390 + retifanlimab Part 4 (Q4W): INCAGN02385 + INCAGN02390 + retifanlimab	• Safety and tolerability as assessed by monitoring the frequency and severity of AEs.
Phase 2	
To determine the preliminary efficacy of INCAGN02385 + INCAGN02390 + retifanlimab in Cohorts A and B. Cohort A: Participants with advanced melanoma who have progressed or relapsed on or after anti–PD-(L)1 therapy. Cohort B: Participants with advanced melanoma naïve to systemic therapy (first line)	• ORR, defined as the percentage of participants having a CR or PR, will be determined by investigator assessment of radiographic disease assessments per RECIST v1.1. • DOR, defined as the time from earliest date of disease response (CR or PR) until earliest date of disease progression, will be determined by investigator assessment of radiographic disease per RECIST v1.1, or death from any cause, if occurring sooner than progression. • DCR, defined as percentage of participants having CR, PR, or SD as best on-study response. • PFS, defined as the time from date of first dose of study treatment until the earliest date of disease progression, as determined by investigator assessment of objective radiographic disease per RECIST v1.1, or death due to any cause.
To determine the safety of INCAGN02385 + INCAGN02390 + retifanlimab	Safety and tolerability as assessed by monitoring the frequency and severity of AEs.

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
Secondary	
Phase 1	
To determine the preliminary efficacy of the combinations of INCAGN02385 + INCAGN02390 and of INCAGN02385 + INCAGN02390 + retifanlimab for both Q2W and Q4W schedules in participants with solid tumors who have failed anti–PD-1 therapy.	• ORR, defined as the percentage of participants having a CR or PR, will be determined by investigator assessment of radiographic disease assessments per RECIST v1.1. • DCR, defined as percentage of participants having CR, PR, or SD as best on-study response. • PFS, defined as the time from date of first dose of study treatment until the earliest date of disease progression, as determined by investigator assessment of objective radiographic disease per RECIST v1.1, or death due to any cause.
[redacted]	

Table 1: Objectives and Endpoints (Continued)

Objectives	Endpoints
[redacted]	

3. STUDY DESIGN

This is an open-label, nonrandomized, Phase 1-2 study to determine the safety, tolerability, and preliminary efficacy of INCAGN02385 and INCAGN02390 given both as monotherapy as well as in combination with retifanlimab (ie, doublets and triplets) at multiple doses on Q2W, Q3W, and Q4W schedules.

- **Phase 1** is to determine safe combination doses given on various schedules. Combination doses for further study will be chosen based on safety. [redacted]
  - **Part 1**: Part 1 will use a BOIN design and will determine whether the doses selected for further study from the respective monotherapy studies (Q2W INCAGN02385 dose is 350 mg and INCAGN02390 dose is 400 mg) are safe when used in the combination of INCAGN02385 and INCAGN02390 ($n \leq 9$). If the safety of doses tested cannot be established, then the dose level will be reduced 1 level from doses tested in monotherapy studies (ie, 250 mg Q2W for INCAGN02385 and 200 mg Q2W for INCAGN02390).
  - **Part 2**: Following confirmation of the safety of the doublet, the safety of the triple combination of INCAGN02385 (350 mg Q2W) + INCAGN02390 (400 mg Q2W) + retifanlimab (500 mg Q4W) will be tested ($n \leq 9$). If safety of doses tested in the triplet cannot be established, the dose levels for INCAGN02385 and INCAGN02390 will be dropped 1 level from doses tested in monotherapy studies (ie, 250 mg Q2W for INCAGN02385 and 200 mg Q2W for INCAGN02390).
  - **Part 3:** Once safety for the Q2W schedule has been established for the PD-1-free doublet (INCAGN02385 + INCAGN02390) and the triplet (INCAGN02385 + INCAGN02390 + retifanlimab), a Q3W schedule will be evaluated in a stepwise manner.
  - **Part 4:** Q4W schedule will be evaluated as alternative schedule to accommodate future combinations with other agents of interest and in a stepwise manner. [redacted]
- **Phase 2** will further assess safety and determine preliminary efficacy for the combination of INCAGN02385 + INCAGN02390 + retifanlimab.
  - **Cohort A:** A population of participants with unresectable/metastatic or adjuvant-treated melanoma ($n = 15$) who progressed or relapsed on or after prior anti–PD-(L)1 therapy will receive INCAGN02385 + INCAGN02390 + retifanlimab Q2W at doses selected in Part 2. If a sufficient number of responses are seen ($\geq 1/15$ responses), the population will be expanded to include additional participants ($+ n = 15$) in a Simon 2-stage expansion to further evaluate safety and efficacy.

- **Cohort B:** Following DMC review of Phase 1 Part 3, a population of participants with advanced melanoma naïve to systemic therapy (1L) will receive INCAGN02385 + INCAGN02390 + retifanlimab Q3W at the doses selected in Phase 1 Part 3 (n = 32 for each dose level). Initially, 14 participants will be enrolled in Cohort B. If a sufficient efficacy signal is seen (eg, ≥ 6/14 responses in a nonbinding analysis) in Stage 1, additional participants (+ n = 18) will be enrolled. Cohort B is designed with 1-sided $\alpha = 0.09$ with an approximate 98% power to observe at least 17 responses in the total population enrolled (N = 32) using a Bayesian predicted probability.

See Figure 1 for the study design schema. Details of the study design are in Section 4 of the Protocol.

Figure 1: Study Design Schema

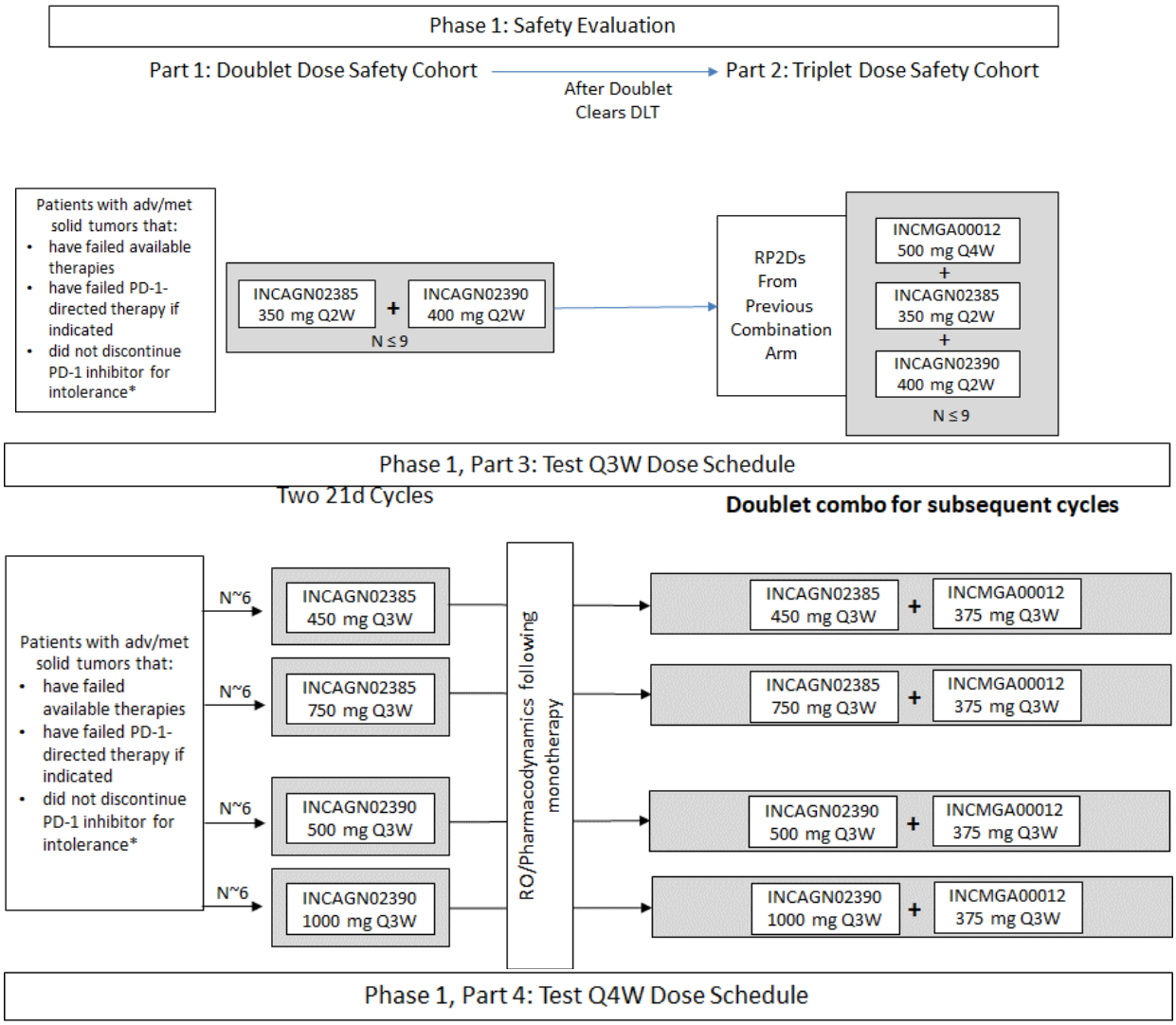
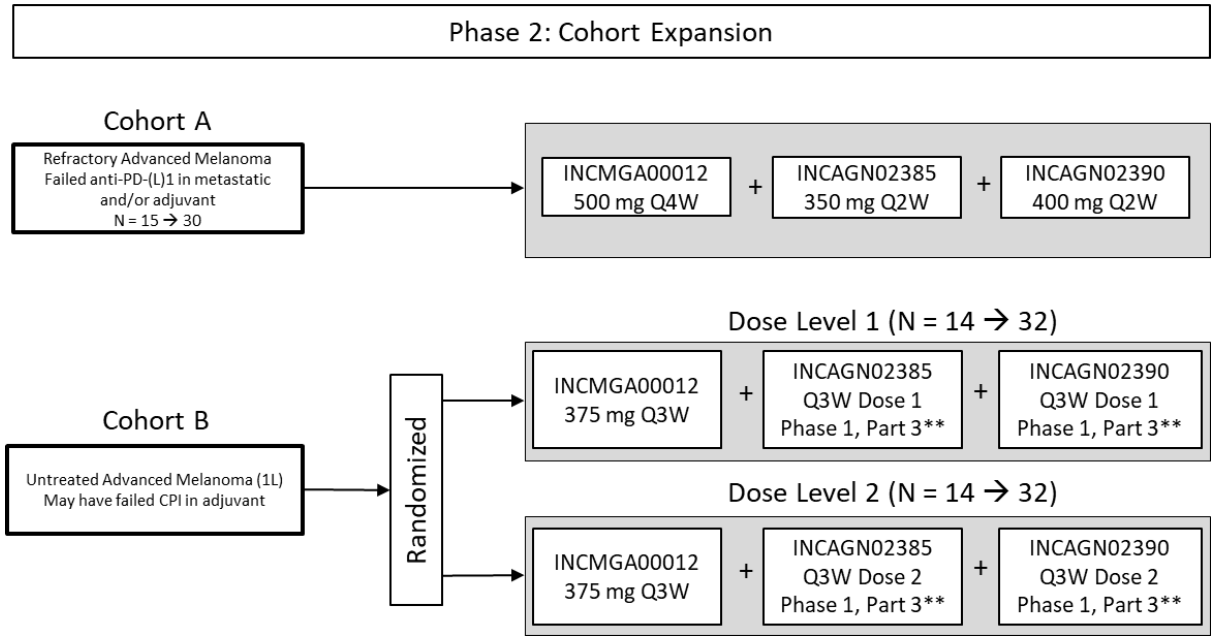


Figure 1: Study Design Schema (Continued)



Note: For Part 1 and 2, if safety of doses tested in either the doublet or the triplet cannot be established, the dose levels for INCAGN02385 and INCAGN02390 will be dropped 1 level from doses tested in monotherapy studies (ie, 250 mg Q2W for INCAGN02385 and 200 mg Q2W for INCAGN02390).
Note: For Part 4, dose(s) for the triple combination on Q4W schedule will be simulated based on [redacted] of monotherapy INCAGN02385 and INCAGN02390 in the Q3W dose evaluation in Part 3.
*See Section 5 of the Protocol for full inclusion and exclusion criteria
**Dose(s) for Phase 2 Cohort B will be based on Phase 1 Part 3. At least 2 doses may be tested for both INCAGN02385 and INCAGN02390. Cohort B will open as soon as Q3W doses are established in Phase 1.

3.1. Randomization

This is an open-label study. Measurements of safety and efficacy are objective measurements, and only comparisons to pretreatment conditions will be made. When there is more than one dose level within a part or cohort of the study, the participant will be randomly assigned into each dose level.

3.2. Control of Type I Error

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

3.3. Sample Size Considerations

3.3.1. Phase 1

For Parts 1 and 2, the BOIN design will be used to determine the RP2D of combination of INCAGN02385 and INCAGN02390 as well as the combination of all 3 drugs (INCAGN02385 + INCAGN02390 + retifanlimab) in participants with immunogenic tumor types. Dose escalation and de-escalation will follow the BOIN design algorithm (Liu and Yuan 2015).

The BOIN design minimizes the probability of making incorrect decision on dose assignments under 3-point hypotheses:

- H_0: the true DLT rate of current dose = ϕ,
- H_1: the true DLT rate of current dose = ϕ_1,
- H_2: the true DLT rate of current dose = ϕ_2,

where ϕ is the target DLT rate, so H_0 indicates that the current dose is the MTD and the dose should be retained for the next cohort of participants; ϕ_1 is the highest DLT rate that is deemed subtherapeutic (ie, below the MTD), so H_1 indicates that dose escalation is required, and ϕ_2 is the lowest DLT rate deemed overly toxic, so H_2 indicates that dose de-escalation is required. For this study, $\phi = 0.28$, $\phi_1 = 0.6 \cdot \phi$, and $\phi_2 = 1.4 \cdot \phi$ are selected for the 3-point hypotheses. An equal prior probability of hypothesis being true are assigned to each of the hypotheses, that is $\pi_0 = \pi_1 = \pi_2 = 1/3$. The value of 0.95 is selected for the cutoff to eliminate an overly toxic dose for safety.

At the end of the dose-escalation part of the study, the estimated MTD is the dose at which the observed DLT rate is closest to the target DLT rate of 28% using an isotonic method that takes the assumption of a monotonic dose-toxicity relationship into account. At each dose level, Table 2 will be used to guide dose escalation/de-escalation decisions.

The dose escalation will continue, based on the rules in Table 2, until at least 1 of the following occurs:

- Enrollment of additional participants in a dose level that already has 9 evaluable participants, or
- Dose escalation to a dose level that has already been eliminated.

At that point, the dose escalation will be stopped. Based on this algorithm, a maximum of 9 evaluable participants will be enrolled at each tested dose level.

Table 2: Planned Dose Escalation, De-Escalation, and Elimination Boundaries for Target DLT Rate of 28% in Phase 1 Part 1 and 2

	Number of Evaluable Participants Treated at the Current Dose								
Action	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9[a]**
Escalate if # of DLTs ≤	0	0	0	0	1	1	1	1	1
De-escalate if # of DLTs ≥	1	1	2	2	2	3	3	3	4
Elimination if # of DLTs ≥	N/A	N/A	3	3	4	4	4	5	5

[a] If 9 evaluable participants are enrolled in a dose cohort and 3 of those participants experience a DLT, the medical monitor and the investigators will review the entirety of the data and decide whether to escalate the dose level, de-escalate the dose level, or stop at that dose level.

In Part 3, for dose optimization purposes for each agent (INCAGN02385 and INCAGN02390), two Q3W doses were selected based [redacted] Two doses of INCAGN02385, 450 mg Q3W and 750 mg Q3W, will be administered to participants (n = 6 each) as monotherapy for 2 21-day cycles. Following 2 monotherapy cycles, these same participants will then remain on their current dose of INCAGN02385 and be given retifanlimab (375 mg Q3W) in combination. Similarly, 2 doses

of INCAGN02390, 500 mg Q3W and 1000 mg Q3W, will be administered to participants (n = 6 each) as monotherapy for 2 21-day cycles. Following 2 monotherapy cycles, these same participants will then remain on their current dose of INCAGN02390 and be given retifanlimab (375 mg Q3W) in combination.

In Part 4, a Q4W schedule of retifanlimab + INCAGN02385 + INCAGN02385 will be evaluated in a single cohort of participants (n = 10) as alternative schedule to accommodate future combinations with other agents of interest and in a stepwise manner. Once [redacted] and [redacted] data from the monotherapy Q3W evaluation in Phase 1 Part 3 are obtained, these data will inform Q4W dose estimations for the triplet combination (INCAGN02385 + INCAGN02390 + retifanlimab 500 mg) to be evaluated on a Q4W schedule.

3.3.2. Phase 2

For Cohort A, a historical control for efficacy of immuno-oncology therapy in participants refractory to anti–PD-1/L1 therapy is estimated to be approximately ORR = 5%. In order for the triple combination to be considered effective, a 15% benefit is required (ie, ORR = 20%). The Simon 2-stage design (Simon 1989) with the minimax design option will be applied to this cohort. An interim analysis will be conducted after 15 participants are enrolled and assessed for response in Stage 1. If ≥ 1 responders are observed, an additional 15 participants will be enrolled for Stage 2. At the end of Stage 2, if ≤ 3 responses are observed among the total 30 participants, the treatment will be considered nonpromising. The design is based on a Type I error of 10% with 86% power to detect a 20% response rate.

For Cohort B, a historical control for efficacy of immuno-oncology therapy in participant with untreated advanced melanoma is estimated to be approximately ORR = 40% (Postow et al 2015, Robert et al 2015, Tawbi et al 2022). In order for the triple combination to be considered effective, a 30% benefit is required (ie, ORR = 70%). To determine whether the target response rate (p_1) of 70% against the historical control response rate (p_0) of 40% is likely, an initial 14 participants (n_1) will be enrolled in each dose cohort for the interim analysis. A nonbinding analysis of efficacy will be conducted after Stage 1. If there a sufficient efficacy signal (eg, ≥ 6 responses (r_1)) is observed, an additional 18 participants may be enrolled into each dose level. The decision by the sponsor to enroll Stage 2 will take into consideration the depth (defined as the decrease in tumor burden) and DORs in addition to the number of responses in Stage 1. A total of ≥ 17 responses (r) will claim treatment efficacy. A total sample size (N) of 32 participants provides a 1-sided Type I error (α) of 9% and an approximate power of 98%. Table 3 lists the detailed design rules, generated by an R-shiny tool using the Bayesian predictive probability (Chen et al 2019).

Table 3: Planned Bayesian Predictive Probability Design for Phase 2 Cohort B

p_0	p_1	n_1	N	r_1	r	α	Power
40%	70%	14	32	≥ 6	≥ 17	9%	98%

3.4. Schedule of Assessments

Refer to Protocol Amendment 4 dated 02 MAR 2023 for a full description of all study procedures and assessment schedules for this study.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1

Day 1 is the date that the first dose of INCAGN02385, INCAGN02390, or retifanlimab is administered to the participants.

4.1.2. Study Day

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

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

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

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

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

4.1.3. Baseline Value

Baseline is the last nonmissing measurement obtained before the first administration of INCAGN02385, INCAGN02390, or retifanlimab (when applicable), unless otherwise defined.

When scheduled assessments and unscheduled assessments occur on the same day and time of the assessment or time of first dose is not available, use the following convention to determine baseline:

- If both a scheduled and an unscheduled visit are available on the day of the first dose and the time is missing, use the scheduled assessment as baseline.
- If all scheduled assessments are missing on the day of the first dose and an unscheduled assessment is available, use the unscheduled assessment as baseline.

4.1.4. 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. The original reported dates collected on the eCRF should be used in all relevant listings. The following rules will be used for handling partial dates for analyses requiring dates.

When calculating time since diagnosis of cancer, partial cancer diagnosis date will be handled as follows in the calculations:

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

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

- If only the day is missing, then the earlier date of the last day of the month or the date that the participant discontinued treatment will be used.
- If both the month and day are missing, then the earlier date of 31 DEC of the year or the date that the participant discontinued treatment will be used.
- Otherwise, the date that the participant discontinued treatment will be used as the date of the last dose.

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

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

4.1.5. Cycle Length and Duration

Cycle 1 Day 1 is the day that the first dose of INCAGN02385, INCAGN02390, or retifanlimab (when applicable) is administered. The scheduled cycle length varies among parts of the study and cohorts (Q2W, Q3W, or Q4W). The actual Day 1 of subsequent cycles will correspond with the first day of administration of INCAGN02385, INCAGN02390, or retifanlimab (when applicable) in that cycle.

4.2. Variable Definitions

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 INCAGN02385, INCAGN02390, or retifanlimab (when applicable).

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

- Before the date of first administration of INCAGN02385, INCAGN02390, or retifanlimab (when applicable) and is ongoing throughout the study or ends on/after the date of first study medication administration.
- On/after the date of first administration of INCAGN02385, INCAGN02390, or retifanlimab (when applicable) and is ongoing or ends during the course of the study.

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

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

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9.4 or later) will be used for the generation of all tables, graphs, and statistical analyses. Descriptive summaries for continuous variables will include but not be limited to the number of observations, mean, standard deviation, median, minimum, and maximum. Descriptive summaries for categorical variables will include the number and percentage of participants in each category.

Interim analyses are planned for this study as defined in Section 9.

Further development of INCAGN02385 and INCAGN02390 was terminated on 24 MAY 2024, due to a strategic decision by the sponsor, not as a result of any safety concerns (see Section 10.1). No analysis on the clinical laboratory tests, vital signs, or ECG will be provided. Other analysis described will be provided according to Appendix A.

5.2. Treatment Groups

This is a Phase 1-2, open-label, nonrandomized study. Data will be summarized by phase and by treatment group based on the dose regimen initially assigned. In the event that several dose regimens tested are deemed substantially below the MTD, these doses may be combined for summary purposes.

5.3. Analysis Populations

Table 4 presents the populations for analysis.

Table 4: Populations for Analysis

Population	Description
FAS	The FAS includes all participants enrolled in the study who received at least 1 dose of assigned study treatment. This population will be used in the analyses of demographic, baseline, safety, study treatment administration, and PFS.
RECIST evaluable	Participants in the RECIST evaluable population includes all participants enrolled in the study who have received at least 1 dose of study treatment and completed a baseline scan and meet at least 1 of the following criteria: • The participant has had ≥ 1 postbaseline scan. • The participant has been on the study for a minimum of 56 days of follow-up. • The participant has discontinued from treatment.

Table 4: Populations for Analysis (Continued)

Population	Description
DLT evaluable	The DLT evaluable population includes all participants from the Phase 1 who received at least 1 dose of assigned study treatment, and either: (1) experienced a DLT during the safety evaluation period or (2) received 2 doses of INCAGN02385 and 2 doses of INCAGN02390, plus 1 dose of retifanlimab (if applicable) during the first 28 days (Q2W and Q4W) or 21 days (Q3W) as applicable per cycle definition, and have sufficient monitoring for the investigator and sponsor to conclude that no DLT occurred.

Table 5 shows how the analysis populations are associated with the primary and secondary endpoints.

Table 5: Endpoints and Analysis Populations

Endpoint	Analysis Population	Population-Level Summary Metric
Phase 1 primary endpoint		
Safety and tolerability will be assessed by monitoring the frequency, duration, and severity of AEs.	FAS	Frequency (%) of any TEAEs, serious TEAEs, Grade 3 or higher TEAEs, treatment-related TEAEs, TEAEs leading to treatment discontinuation, immune-related TEAEs, infusion-related TEAEs, and fatal TEAE.
Phase 2 primary endpoint		
Safety and tolerability will be assessed by monitoring the frequency, duration, and severity of AEs.	FAS	Frequency (%) of any TEAEs, serious TEAEs, Grade 3 or higher TEAEs, treatment-related TEAEs, TEAEs leading to treatment discontinuation, immune-related TEAEs, infusion-related TEAEs, and fatal TEAE.
ORR	RECIST evaluable	ORR
DOR	RECIST evaluable[a]	DOR
DCR	RECIST evaluable	DCR
PFS	FAS	mPFS
Phase 1 secondary endpoint		
ORR	RECIST evaluable	ORR
DCR	RECIST evaluable	DCR
PFS	FAS	mPFS

[a] Responder subpopulation.

6. BASELINE, EXPOSURE, AND DISPOSITION

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

6.1. Demographics, Baseline Characteristics, and Disease History

6.1.1. Demographics

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

6.1.2. Baseline Disease Characteristics and Disease History

Baseline disease characteristics and disease history will be summarized and listed for participants in the FAS. It includes time since initial diagnosis, solid tumor cancer type, baseline ECOG performance status, and relevant biomarkers.

Time since diagnosis will be calculated as follows:

Time since diagnosis (years) = (Day 1 date – date of diagnosis + 1) / 365.25.

6.1.3. Prior Therapy

The number of prior systemic cancer therapy regimens will be summarized for all participants in the FAS. The component drugs of prior systemic therapy regimens will be coded using the WHO Drug Dictionary. The number and percentage of participants who received each drug will be summarized by WHO drug class and WHO drug preferred term. The number and percentage of participants who received prior therapies per disease setting; number of prior lines of systemic therapies overall and per disease setting; and more specifically, prior exposure to checkpoint inhibitors (eg, PD-1/PDL-1, CTLA4, etc) will be summarized. The regimen name, component drugs, start and stop dates, purpose of the regimen, best response, reason for discontinuation, and date of relapse/progression will be listed.

The number of participants who received prior radiation will be summarized for the FAS. The radiotherapy type, body site, start and stop dates, total dose, and best response will be listed.

The number of participants who had prior surgery or surgical procedure for the malignancies under study will be summarized for the FAS. The date and description of the surgery/procedure will be listed.

6.1.4. Medical History

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

6.2. Disposition of Participants

The number and percentage of participants who were treated, who were ongoing with study treatment, who discontinued study treatment with a primary reason for discontinuation, who were still in the study, and who withdrew from the study with a primary reason for withdrawal

will be summarized and listed for participants in the FAS. The number of participants enrolled by country and site will also be provided by treatment group.

6.3. Protocol Deviations

Protocol deviations recorded on the eCRF will be summarized and listed.

6.4. Exposure

For participants in the FAS, exposure to INCAGN02385, INCAGN02390, or INCMGA00012 (when applicable) will be summarized descriptively as the following:

- **Total number of infusions:** total number of infusion per participant with a nonzero dose of study drug.
- **Total dose administered (mg):** sum of the cumulative dose that has been administered to each participant.
- **Average dose per infusion (mg):** total dose administered (mg) / total number of infusions.
- **Duration of treatment with study drug (days):** date of last dose of study drug – date of first dose of study drug + 1.
- **Dose intensity (mg/day):** total dose administered (mg) / (duration of treatment + cycle length – 1).
- **Relative dose intensity:** actual dose intensity (mg/day) / planned dose intensity (mg/day).
- **Dose administered per cycle (mg):** the actual dose administered (mg) per cycle.

6.5. Prior and Concomitant Medication

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary. The number and percentage of participants in the FAS with each prior and concomitant mediations will be summarized by WHO drug class and term.

7. SAFETY AND TOLERABILITY

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

7.1. General Considerations

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

7.2. Adverse Events

7.2.1. 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 until 90 days after the last 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 v5.0 using Grades 1 through 5. 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 or partial dates will be handled using the rules described in Section 4.1.4. 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.

7.2.2. Adverse Event of Special Interest

Adverse events of special interest will include irAEs and IRRs that will be coded according to MedDRA along with all other AEs.

Immune-related AEs will be identified by investigator assessment as well as using sponsor predefined preferred terms based on the immune checkpoint inhibitor class regardless of investigator's assessment of causality. Sponsor-assessed irAEs will be summarized by preferred term and system organ class.

Infusion-related reactions will be identified by investigator assessment as well as using sponsor predefined preferred terms indicating a diagnosis of IRRs or symptoms potentially associated with IRRs. Sponsor-assessed IRRs will be summarized by preferred term and system organ class.

7.2.3. Adverse Event Summaries

An overall summary of AEs by treatment group and/or cohort will 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 who had any treatment-related TEAEs
- Number (%) of participants reporting treatment-related Grade 3 or higher TEAEs
- Number (%) of participants who permanently discontinued treatment because of TEAEs
- Number (%) of participants who had any immune-related TEAEs
- Number (%) of participants who had any infusion-related TEAEs
- Number (%) of participants who had immune-related TEAEs per severity grade (Grades 1, 2, 3, 4, 5)
- Number (%) of participants who had infusion-related TEAEs per severity grade (Grades 1, 2, 3, 4, 5)
- Number (%) of participants who had a fatal TEAE

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

- Summary of TEAEs by 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 PT in decreasing order of frequency
- Summary of serious TEAEs by PT in descending order of frequency
- 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 TEAEs leading to study drug dose interruption by SOC and PT
- Summary of TEAEs leading to discontinuation of study drug by SOC and PT
- Summary of tolerability
- Summary of immune-related TEAEs by SOC and PT
- Summary of infusion-related TEAEs by SOC and PT

7.3. Clinical Laboratory Tests

Further development of INCAGN02385 and INCAGN02390 was terminated on 24 MAY 2024, due to a strategic decision by the sponsor, not as a result of any safety concerns (see Section 10.1). No analysis on the clinical laboratory tests will be provided.

7.3.1. Laboratory Value Definitions

Laboratory values and change from baseline values will be summarized descriptively by visit. The baseline value will be determined using the nonmissing values collected before the first dose using the priority defined in Table 6. The last record before administration in the highest priority will be considered the baseline record. For baseline laboratory candidates with the same date and time in the same priority category, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

Table 6: Identification of Baseline Record

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

Laboratory test values will be assessed for severity based on the numerical component of CTCAE v5.0.

7.3.2. Laboratory Value Summaries

Local laboratories will be used for this study. Any laboratory test results and associated normal ranges from local laboratories will be converted to SI units. When there are multiple laboratory nonmissing values for a participant's particular test at a scheduled visit, the laboratory value with the smallest laboratory sequence number will be used in by-visit summaries. Table 7 will be used to determine the record used for by-visit tabulations and summaries.

Table 7: Identification of Records for Postbaseline By-Visit Summaries

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

Numeric laboratory values will be summarized descriptively in SI units, and non-numeric test values will be tabulated when necessary. In addition, line graphs may be provided for hemoglobin, platelet counts, white blood cell counts, neutrophils, and lymphocytes.

Severity grades will be assigned to laboratory test values based on the numerical component of CTCAE v5.0. Shift tables will be presented showing change in CTCAE grade from baseline to worst grade postbaseline. Separate summaries for abnormally high and abnormally low laboratory values will be provided when the laboratory parameter has both high and low grading criteria. The denominator for the percentage calculation will be the number of participants in the baseline category. The number of participants who experienced worsening of laboratory abnormalities will be summarized by maximum severity.

7.3.3. Potential Hy's Law Events

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

7.4. Vital Signs

Further development of INCAGN02385 and INCAGN02390 was terminated on 24 MAY 2024, due to a strategic decision by the sponsor, not as a result of any safety concerns (see Section 10.1). No analysis on the vital signs will be provided.

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

Normal ranges for vital sign values are defined in Table 8. For participants exhibiting vital sign abnormalities, the abnormal values will be listed along with their assigned treatment group. Alert vital signs are defined as an absolute value outside the defined normal range and percentage change greater than 25%. Note that the definition of alert vital signs does not apply for body temperature and weight. The abnormal values for participants exhibiting alert vital sign abnormalities will be listed.

Table 8: Normal Ranges for Vital Sign Values

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

7.5. Electrocardiograms

Further development of INCAGN02385 and INCAGN02390 was terminated on 24 MAY 2024, due to a strategic decision by the sponsor, not as a result of any safety concerns (see Section 10.1). No analysis on the ECGs will be provided.

Twelve-lead ECGs including PR, QRS, QT, QTcF, QTcB, and RR intervals will be obtained for each participant during the study. Values at each scheduled timepoint, change, and percentage change from baseline will be summarized for each ECG parameter. Baseline will be determined as the average of all nonmissing values before the first administration of study drug.

Normal ranges for ECG values are defined in Table 9. Electrocardiogram values will also be considered abnormal if the absolute percentage change from baseline is more than 25% (30% for QRS interval). Participants exhibiting ECG abnormalities will be listed with study visit and assigned dose level. 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. Outliers of QT, QTcB, and QTcF values, defined as absolute values

> 500 milliseconds, > 460 milliseconds, or change from baseline > 30 milliseconds, will be summarized.

Table 9: Normal Ranges for Electrocardiogram Values

Parameter	High Threshold	Low Threshold
PR	≤ 220 ms	≥ 75 ms
QRS	≤ 120 ms	≥ 50 ms
QT	≤ 500 ms	≥ 300 ms
QTcF, QTcB	≤ 460 ms	≥ 295 ms
RR	≤ 1330 ms	≥ 600 ms

QTcB = Bazett's correction; QTcF = Fridericia's correction.

8. EFFICACY

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

8.1. General Considerations

Progression-free survival analyses will be performed using the FAS population. Objective response rate and DCR will be performed using the RECIST evaluable population. Duration of response will be performed based on RECIST evaluable responders.

8.2. Efficacy Hypotheses

Not applicable.

8.3. Analysis of the Efficacy Parameters

8.3.1. Response Assessment by RECIST

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

8.3.2. Best Overall Response and Objective Response Rate by RECIST

Best overall response for participants with solid tumors is the best response recorded postbaseline prior to and including the first PD, in the order of CR, PR, SD, PD, and NE.

The BOR will be determined from response assessments prior to or on the same day as new anticancer therapy. If any alternative cancer therapy is taken while on study, any subsequent assessments will be excluded from the BOR determination.

In the case of SD, measurements must meet the SD criteria at least once after the date of first dose at a minimum interval of 56 days. Participants who fail to meet this criterion will have a

BOR of PD if the next available assessment after the initial assessment indicates PD, or a BOR of NE if there are no additional assessments available.

Objective response rate is defined as the proportion of participants with a CR or PR as BOR.

Objective response rate is a primary efficacy endpoint for Phase 2 and a secondary endpoint for Phase 1. [redacted]

The ORR will be estimated with 95% CIs for each phase by treatment group and/or cohort ([redacted]). Confidence intervals will be calculated based on the exact method for binomial distributions. Participants who do not have sufficient baseline or on-study response assessment information to be adequately assessed for response status will be included in the denominators in the calculation of ORR.

8.3.3. Duration of Response

Duration of response is defined as the time from earliest date of disease response (CR or PR) until earliest date of disease progression as determined by investigator assessment per RECIST v1.1, or death from any cause, if occurring sooner than progression. Participants with no observed death or disease progression will be censored. Censoring for DOR will follow the algorithm outlined in Table 10. If a participant meets multiple criteria for censoring, the censoring criterion that occurs earliest will be applied.

Duration of response is a primary efficacy endpoint for Phase 2 [redacted]

Kaplan-Meier estimation of median DOR and its 95% CIs will be presented for participants who achieve an objective response for each phase by treatment group and/or cohort ([redacted]).

8.3.4. Disease Control Rate

Disease control rate, defined as the proportion of participants with CR, PR, or SD as the BOR.

Disease control rate is a primary efficacy endpoint for Phase 2 and a secondary endpoint for Phase 1. [redacted]

Disease control rate will be estimated with 95% CIs for participants who achieve an objective response for each phase by treatment group and/or cohort ([redacted]). Confidence intervals will be calculated based on the exact method for binomial distributions. Participants who do not have sufficient baseline or on-study response assessment information to be adequately assessed for response status will be included in the denominators in the calculation of DCR.

8.3.5. Progression-Free Survival by RECIST

Progression-free survival for solid tumors is defined as the time from the date of the first dose of study treatment until the earliest date of disease progression, as determined by investigator assessment of objective radiographic disease per RECIST v1.1, or death from any cause if occurring sooner than progression. Survival data will be analyzed by the Kaplan-Meier method, treating participants with no observed death or disease progression as censored. Partial death dates will be handled using the rules described in Section 4.1.4. Censoring for PFS will follow the algorithm outlined in Table 10, which is based which is based on FDA guidance (FDA 2015, FDA 2018).

Progression-free survival per RECIST v1.1 is a primary efficacy endpoint for Phase 2 and a secondary endpoint for Phase 1. [redacted]

The number of participants who had PD or who died and the number of participants censored will be summarized. The Kaplan-Meier estimate of mPFS will be presented with its 95% CI for participants who achieve an objective response for each phase by treatment group and/or cohort ([redacted]).

Table 10: Evaluation and Censoring of Progression-Free Survival

Situation	Primary Analysis
No baseline tumor assessments	Censored at Day 1
No valid postbaseline response assessments	Censored at Day 1
Progression documented between scheduled visits	Progressed at date of first overall response of PD
Death before first PD assessment	Progressed at date of death
No PD and no death; new anticancer treatment is not initiated	Censored at last disease assessment
No PD and no death; new anticancer treatment is initiated	Censored at last disease assessment before new anticancer treatment
No PD and no death; after ≥ 2 missed disease assessments	Censored at last disease assessment prior to the ≥ 2 missed disease assessment
PD or death documented after ≤ 1 missed disease assessment	Progressed at date of documented PD or death
PD or death documented after ≥ 2 missed disease assessments	Censored at last disease assessment prior to the ≥ 2 missed disease assessment

[redacted]

9. INTERIM ANALYSES

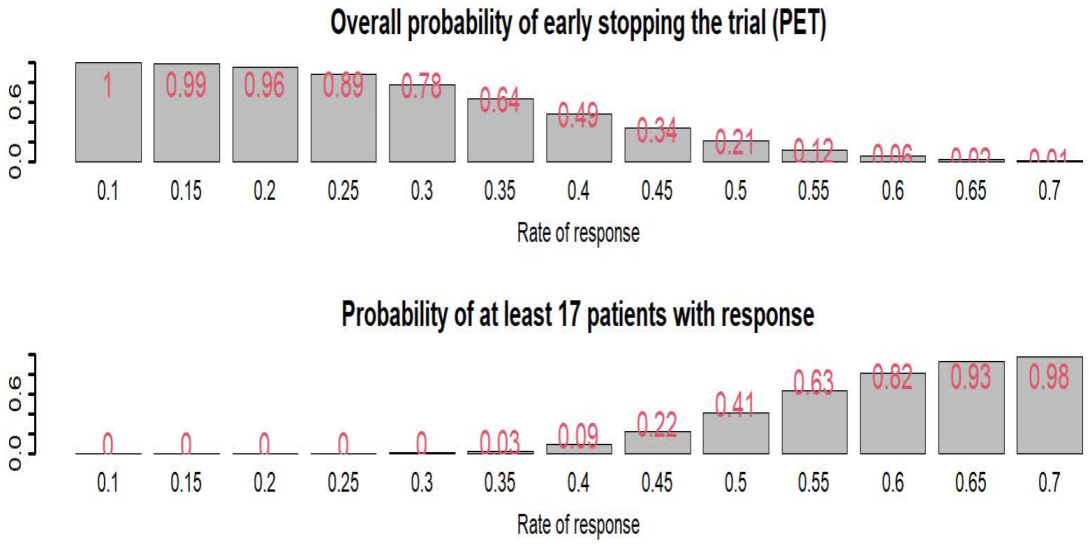
9.1. Overview of Interim Analyses

An interim analysis will be conducted in Phase 2 for each cohort.

For Cohort A, an interim analysis will be conducted after 15 participants are enrolled and 2 postbaseline scans are obtained, and BOR will be summarized. The cutoff date for interim analysis will be once the 15th participant obtains the second postbaseline scan. Nonbinding futility rule will be applied. If no responses are observed, the cohort may be terminated for futility. The enrollment for Cohort A will stop after 15 participants are enrolled except for the participants that were already in screening before the cutoff date and will continue their participation in the study if they are deemed eligible. If 1 or more responses are observed, an additional 15 participants will be enrolled for Stage 2 evaluation. If the true ORR is 5%, the design will have a 46% probability of terminating at the end of Stage 1.

For each dose level of Cohort B, a nonbinding interim analysis using a Bayesian predictive probability will be performed when 14 evaluable participants have at least 2 tumor assessments. Best overall response will be summarized. If a sufficient efficacy signal is not observed (eg,< 6 responses, but also taking into account the depth and duration of response), the sponsor may determine that the treatment will be discontinued given a 9% cutoff of the predictive probability (ie, chance to stop the study in the interim analysis). Otherwise, an additional 18 participants will be enrolled into the study, for a total of 32 participants. With a historical control response rate of 0.4 and posterior probability of 0.9 as the threshold, a total of ≥17 of the 32 participants must have response to claim treatment efficacy. A noninformative beta prior, beta(1,1), is used to calculate the posterior probability and predictive probability for the rate of response. Enrollment will be held during the interim analysis. However, if there is a sufficient efficacy signal observed before having 14 evaluable participants with at least 2 tumor assessments, then there is no need to hold enrollment, and the study can directly continue with enrollment of the additional 18 participants. Performance of the design (see Figure 2) shows that if the true rate of response is 40%, the chance to reach a total of ≥ 17 participants with response at the end of the study is 9% (Type I error); however, the probability to stop the study early is 49%. If the true rate of response is indeed 70%, then the chance to reach ≥ 17 participants with response at the end of the study is 98% (power), and the corresponding probability to stop the treatment early is 1%.

Figure 2: Performance (Probability of Early Termination [PET], Type I Error, and Power) of Cohort B



9.2. Data Cutoff for Interim Analysis

For Cohort A, a cutoff for clinical data used in the interim analysis for BOR will be based on the date of the 15th participant obtains the second postbaseline scan and will include all participant visits occurring on or before this date.

For Cohort B, a cutoff for clinical data used in the interim analysis for BOR will be based on the date of the 14th participant obtains the second postbaseline scan and will include all participant visits occurring on or before this date.

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 11.

Table 11: Statistical Analysis Plan Versions

SAP Version	Date
Original	02 DEC 2022
Amendment 1	23 MAY 2025

10.1. Changes to Protocol-Defined Analyses

Further development of INCAGN02385 and INCAGN02390 was terminated on 24 MAY 2024, due to a strategic decision by the sponsor, not as a result of any safety concerns.

At the time of termination, enrollment in study INCAGN 2385-201 was as follows:

- Phase 1 Part 1: 10 participants
- Phase 1 Part 2: 11 participants
- Phase 1 Part 3: 24 participants
- Phase 2 Cohort A: 16 participants

A synoptic Clinical Study Report will be prepared.

To address the primary and secondary objectives, and considering the enrollment and availability of collected data at the study termination, the planned TLFs have been updated as outlined in Appendix A.

10.2. Changes to the Statistical Analysis Plan

To address the primary and secondary objectives, and considering the enrollment and availability of collected data at the study termination, the planned TLFs have been updated as outlined in Appendix A.

Sections 5.1, 7.3, 7.4 , and 7.5 were updated to include a statement regarding study termination and updated analyses.

In addition, Sections 2.2, 3.3.2, and 9.1 were updated to align with Protocol Amendment 4.

11. REFERENCES

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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.

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Postow MA, Chesney J, Pavlick AC et al. Nivolumab and ipilimumab versus ipilimumab in untreated melanoma. N Engl J Med 2015;372:2006-2017.

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Tawbi HA, Schadendorf D, Lipson E, et al. Relatlimab and nivolumab versus nivolumab in untreated advanced melanoma. N Engl J Med 2022;386:24-34.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. Shells are provided in a separate document for tables that are not in the Standard Safety Tables v2.2.

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.

Each table, figure, or listing may be presented separately by phase and by part or cohort.

Tables

Table No.	Title	Population	Standard
Baseline and Demographic Characteristics			
1.1.1	Analysis Populations	All screened participants	X
1.1.2	Summary of Participant Disposition	FAS	X
1.1.3	Summary of Number of Participants Enrolled by Country and Site	FAS	X
1.1.4	Summary of Protocol Deviations	FAS	X
1.2.1	Summary of Demographic and Baseline Characteristics	FAS	X
1.3.1	Summary of Baseline Disease Characteristics and Disease History for Participants With Solid Tumors	FAS	
1.3.2	Summary of Prior Cancer Therapy	FAS	
1.3.3	Summary of Prior Cancer Medication by Drug Class and Preferred Term	FAS	X
1.4.1	Summary of Prior Medications	FAS	X
1.4.2	Summary of Concomitant Medications	FAS	X
1.5.1	Summary of General Medical History	FAS	X
Efficacy			
2.1.1	Summary of Best Overall Response, Objective Response Rate, and Disease Control Rate by RECIST	FAS	
2.1.2	Summary of Progression-Free Survival by RECIST	FAS	
2.1.5	Summary of ECOG Status	FAS	
Safety			
3.1.1.1	Summary of Exposure - INCAGN02385	FAS	X
3.1.1.2	Summary of Exposure - INCAGN02390	FAS	X
3.1.1.3	Summary of Exposure - Retifanlimab	FAS	X
3.2.1	Overall Summary of Treatment-Emergent Adverse Events	FAS	X
3.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.4	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	FAS	X
3.2.6	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.8	Summary of Serious Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency	FAS	X

Table No.	Title	Population	Standard
3.2.10	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.13	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.15	Summary of Treatment-Emergent Adverse Events Leading to Study Drug Dose Interruption by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.16	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.17.1	Summary of Immune-Related Treatment-Emergent Adverse Events by SOC and PT (Sponsor-Assessed)	FAS	
3.2.18.1	Summary of Infusion-Related Treatment-Emergent Adverse Events by SOC and PT (Sponsor-Assessed)	FAS	
3.2.19	Summary of Tolerability	FAS	

Listings

Listing No.	Title
2.1.1	Participant Enrollment and Disposition Status
2.1.2	Participant Inclusion and Exclusion Criteria Violations
2.1.3	Participants Enrolled by Country and Site
2.2.1	Protocol Deviations
2.3.1	Analysis Populations
2.4.1	Demographic and Baseline Characteristics
2.4.2	Baseline Disease Characteristics and Disease History
2.4.3	Prior Radiation Treatment
2.4.4	Prior Systemic Therapy
2.4.5	Prior Surgery or Surgical Procedure
2.4.7	Medical History
2.4.8	Prior and Concomitant Medication
2.5.2	Study Drug Administration
2.6.1	Deaths
2.6.2	Best Overall Response, Duration of Response, and Progression-Free Survival
2.6.3	Overall Response Assessment by Visit
2.6.7	ECOG Status
2.7.2	Adverse Events
2.7.3	Dose-Limiting Toxicities
2.7.4	Serious Adverse Events
2.7.5	Fatal Adverse Events
2.7.6	Adverse Events Leading to Interruption, Reduction, or Discontinuation of Study Drug
2.7.7	Immune-Related Adverse Events (Sponsor-Assessed)
2.7.8	Infusion-Related Adverse Events (Sponsor-Assessed)