Official Title:	**Phase 1/2 Safety and Efficacy Study of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies**
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STATISTICAL ANALYSIS PLAN

INCAGN 1876-202

A Phase 1/2 Safety and Efficacy Study of INCAGN01876 in Combination With Immune Therapies in Subjects With Advanced or Metastatic Malignancies

IND Number:	[redacted]
EudraCT Number:	**2017-001951-29**
Sponsor:	**Incyte Biosciences International Sàrl** **Route de la Corniche 1** **1066 Epalinges, Switzerland**
Protocol Version:	**Protocol Amendment 1 dated 24 AUG 2017**
CRF Approval Date:	**29 NOV 2017**
SAP Version:	**Original**
SAP Author:	[redacted]
Date of Plan:	**01 JUN 2018**

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

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LIST OF ABBREVIATIONS

Abbreviation	Term
AE	adverse event
[redacted]	[redacted]
BID	twice daily
[redacted]	[redacted]
[redacted]	[redacted]
CR	complete response
CRF	case report form
CRR	complete response rate
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DCR	disease control rate
DLT	dose-limiting toxicity
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
FAS	full analysis set
GEJ	gastroesophageal junction
GITR	glucocorticoid-induced tumor necrosis factor receptor
HCC	hepatocellular carcinoma
irAE	immune-related adverse event
MedDRA	Medical Dictionary for Regulatory Activities
mRECIST	modified Response Evaluation Criteria in Solid Tumors
MSI-H	microsatellite instability-high
MTD	maximum tolerated dose
NA	not applicable
NCI	National Cancer Institute
NE	not evaluable
NSCLC	non-small cell lung cancer
ORR	objective response rate
OS	overall survival
[redacted]	[redacted]
PD	progressive disease

Abbreviation	Term
PFS	progression-free survival
[redacted]	[redacted]
PR	partial response
PT	preferred term
Q3W	every 3 weeks
QTcB	QT interval corrected using the Bazett formula
QTcF	QT interval corrected using the Fridericia formula
RCC	renal cell carcinoma
RP2D	recommended Phase 2 dose
SD	stable disease
SAP	Statistical Analysis Plan
SCCHN	squamous cell carcinoma of the head and neck
SCLC	small cell lung cancer
SOC	system organ class
TEAE	treatment-emergent adverse event
[redacted]	[redacted]
TMF	trial master file
TNBC	triple-negative breast cancer
UC	urothelial carcinoma
WHO	World Health Organization

1. INTRODUCTION

This is an open-label, nonrandomized, Phase 1/2 study to determine the safety, tolerability, and efficacy of INCAGN01876 when given in combination with immune therapies. Phase 1 will consist of 2 parts. Dose Escalation (Part 1), will consist of a 3 + 3 + 3 design to determine the MTD [redacted] The Safety Expansion (Part 2) will further explore tolerated doses of INCAGN01876 from Part 1 given as a single-dose run-in followed by concomitant immune therapy. Subjects with advanced or metastatic cervical cancer, endometrial cancer, gastric cancer (including stomach and GEJ), esophageal cancer, HCC, melanoma (mucosal or cutaneous), Merkel cell carcinoma, mesothelioma, MSI-H solid tumors, NSCLC, ovarian cancer, SCCHN, SCLC, RCC, TNBC, and UC who have progressed after treatment with available therapies that are known to confer clinical benefit, who are intolerant to treatment, or who refuse standard of care will be enrolled in both parts of Phase 1.

The Phase 2 Dose Expansion will further evaluate the safety, tolerability, and efficacy of the recommended dose(s) of INCAGN01876 selected in Phase 1 when given in combination with immune therapies. Subjects with advanced or metastatic melanoma, RCC, and UC will be enrolled in Phase 2. Section 1 of the Protocol provides a detailed description of the study drug, target patient population, rationale for doses to be examined, and potential risks and benefits of treatment with INCAGN01876.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the Study INCAGN 1876-202 Protocol. The scope of this plan includes the final analyses that are planned and will be executed by the Department of Biostatistics or designee. [redacted]

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCAGN 1876-202 Protocol Amendment 1 dated 24 AUG 2017 and CRFs approved 29 NOV 2017. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and eCRF versions.

2.2. Study Objectives

2.2.1. Primary Objectives

Phase 1

- To evaluate the safety, tolerability, and DLTs of INCAGN01876 in combination with immune therapies and to define the RP2D(s) of INCAGN01876 when given in combination with immune therapies.

Phase 2

- To evaluate the efficacy of INCAGN01876 when given in combination with immune therapies by assessing ORR or CRR per RECIST v1.1.

2.2.2. Secondary Objectives

Phase 1 and Phase 2

- To evaluate the efficacy of INCAGN01876 when given in combination with immune therapies by assessing ORR, DOR, DCR, duration of disease control, and PFS per RECIST v1.1 and mRECIST.
- To evaluate the efficacy of INCAGN01876 when given in combination with immune therapies with respect to 1-year and 2-year OS.
- To evaluate the safety and tolerability of INCAGN01876 when given in combination with immune therapies.

[redacted]

[redacted]

2.3. Study Endpoints

2.3.1. Primary Endpoints

- Safety and tolerability will be assessed by monitoring frequency, duration, and severity of AEs (Phase 1).
- ORR, defined as the percentage of subjects having CR or PR, will be determined by investigator assessment of radiographic disease assessments per RECIST v1.1 (Phase 2).
- CRR, defined as the percentage of checkpoint inhibitor–naive melanoma subjects who have a CR as determined by investigator assessment of radiographic disease assessments per RECIST v1.1 (Phase 2).

2.3.2. Secondary Endpoints

- ORR, defined as the percentage of subjects having CR or PR, will be determined by investigator assessment of radiographic disease assessments per RECIST v1.1 (Phase 1) and mRECIST (Phases 1 and 2).
- DCR, defined as the percentage of subjects having CR, PR, or SD, will be determined by investigator assessment of a radiographic disease assessments per RECIST v1.1 and mRECIST (Phases 1 and 2).
- DOR, defined as the time from the earliest date of disease response (CR or PR) until earliest date of disease progression or death due to any cause, if occurring sooner than progression, will be determined by investigator assessment of radiographic disease assessment per RECIST v1.1 and mRECIST (Phases 1 and 2).
- Duration of disease control (CR, PR, and SD) as measured from first report of SD or better until disease progression or death from any cause, if occurring sooner than progression, will be determined by investigator assessment of radiographic disease per RECIST v1.1 and mRECIST (Phases 1 and 2).
- PFS, defined as the time from the start of combination therapy until the earliest date of disease progression or death due to any cause, if occurring sooner than progression, as determined by investigator assessment of objective radiographic disease assessments per RECIST v1.1 and mRECIST (Phases 1 and 2).
- OS determined from the start of combination therapy until death due to any cause. Survival analyses will occur at 1 year, 2 years, and at the end of the study (Phases 1 and 2).
- Safety and tolerability will be assessed by monitoring frequency, duration, and severity of AEs (Phase 2).

[redacted]

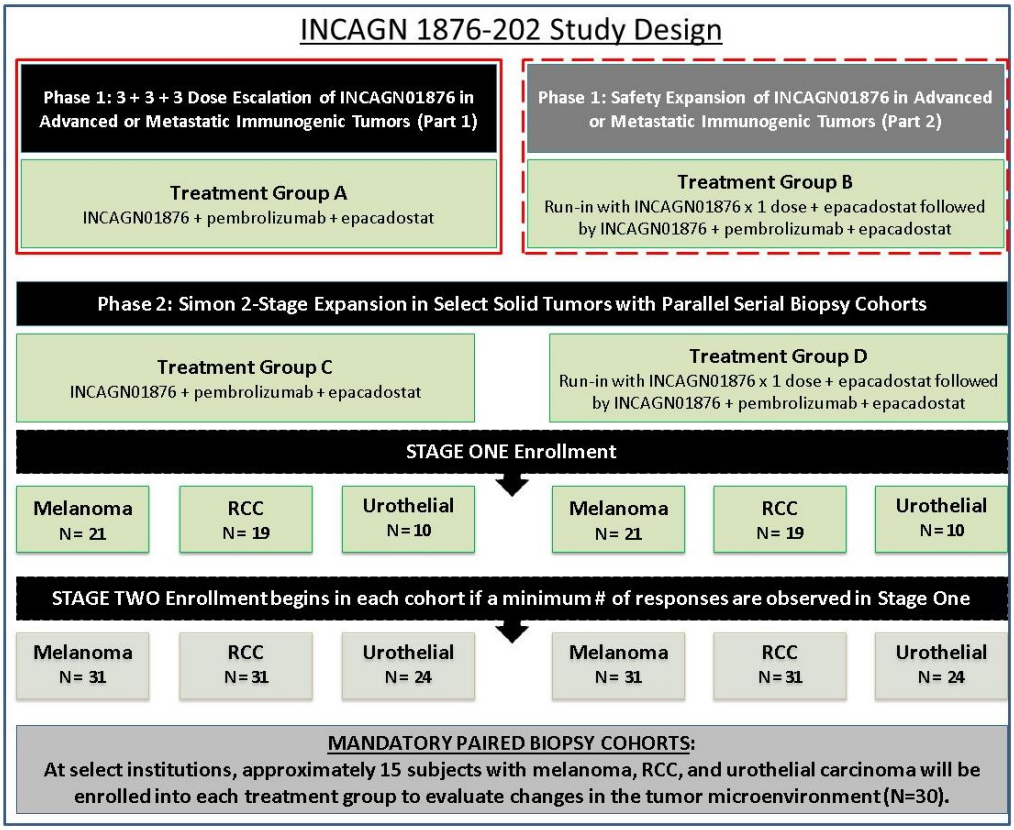
3. STUDY DESIGN

3.1. Overall Study Design

This is an open-label, nonrandomized, Phase 1/2 study to determine the safety, tolerability, and efficacy of INCAGN01876 when given in combination with immune therapies. Phase 1 will consist of 2 parts. Dose Escalation (Part 1) will consist of a 3 + 3 + 3 design to determine the MTD, [redacted] The Safety Expansion (Part 2) will further explore tolerated doses of INCAGN01876 from Part 1 given as a single-dose run-in followed by concomitant immune therapy. Subjects with advanced or metastatic cervical cancer, endometrial cancer, gastric cancer (including stomach and GEJ), esophageal cancer, HCC, melanoma (mucosal or cutaneous), Merkel cell carcinoma, mesothelioma, MSI-H solid tumors, NSCLC, ovarian cancer, SCCHN, SCLC, RCC, TNBC, and UC who have progressed after treatment with available therapies that are known to confer clinical benefit, who are intolerant to treatment, or who refuse standard of care will be enrolled in both parts of Phase 1.

The Phase 2 Dose Expansion will further evaluate the safety, tolerability, and efficacy of the recommended dose(s) of INCAGN01876 selected in Phase 1 when given in combination with immune therapies. Subjects with advanced or metastatic melanoma, RCC, and UC will be enrolled in Phase 2. See Figure 1 for overall study design.

Figure 1: Overall Study Design



3.1.1. Phase 1 – Dose Escalation (Part 1)

A minimum of 3 evaluable subjects will be enrolled in Treatment Group A (see Table 2), beginning with INCAGN01876 Dose Cohort 1 (1.0 mg/kg; starting dose; see Table 1). A higher starting dose of INCAGN01876 may be used if safety data are available from the monotherapy study (INCAGN 1876-101), but it will not exceed 1 dose level below the highest tolerated dose of INCAGN01876 monotherapy. If a higher dose is used, the dose will be communicated to investigational sites with an administrative letter. The first 3 evaluable subjects enrolled within an INCAGN01876 dose cohort will be observed for a minimum of 28 days before the next dose cohort begins enrollment. If 0 DLTs occur in a cohort of 3 evaluable subjects, a new cohort of 3 evaluable subjects will be treated at the next higher dose level. If 1 of 3 evaluable subjects experiences a DLT, that cohort will be expanded to 6 evaluable subjects. If 1 of 6 evaluable subjects experiences a DLT, a new cohort of 3 evaluable subjects will be treated at the next higher dose level. If 2 of 6 evaluable subjects experience a DLT, that cohort will be expanded to 9 evaluable subjects. If ≥ 2 of 3, 3 of 6, or 3 of 9 evaluable subjects experience DLTs within a cohort, then that dose level will be determined to have exceeded the MTD, and the previous dose level will be considered the MTD. If only 3 evaluable subjects were treated at the MTD [redacted], then a minimum of 3 additional evaluable subjects will be enrolled before this dose is administered in Phase 2 of the study.

Additional subjects will be enrolled in a dose cohort to achieve the minimum of 3 evaluable subjects. Subjects who drop out for reasons other than a DLT (eg, events clearly associated with the underlying disease, disease progression, concomitant medication, or comorbidity) during the DLT observation period will result in the subjects being nonevaluable and replaced. Dose modifications should not be made during the DLT observation period without discussion with the medical monitor. The doses of INCAGN01876 to be evaluated in each treatment group are summarized in Table 1.

Table 1: INCAGN01876 Dose Cohorts

Dose Cohort	Dose of INCAGN01876
-1	0.3 mg/kg
1 (Starting Dose)	**1.0 mg/kg**[a]
2	3.0 mg/kg
3	5.0 mg/kg
4	10.0 mg/kg

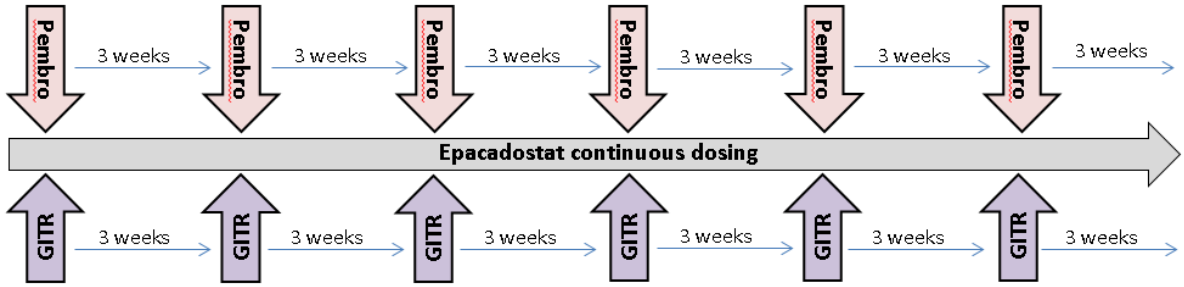
[a] A higher starting dose of INCAGN01876 [redacted] was used based on safety data from the monotherapy study (INCAGN 1876-101), but it did not exceed 1 dose level below the highest tolerated dose of INCAGN01876 monotherapy. The higher dose was communicated to investigational sites with an administrative letter.

3.1.1.1. Treatment Group A: INCAGN01876 + Pembrolizumab

Treatment Group A will treat subjects with INCAGN01876 at the assigned dose level administered Q3W in combination with 200 mg of pembrolizumab administered Q3W and [redacted] epacadostat administered orally BID (see Table 2). **There will be a waiting period of 48 hours between dose administration of the first subject and second subject of each dosing cohort.** The first 3 evaluable subjects enrolled within a cohort will be observed for 28 days before the next cohort begins enrollment. Dose escalation of INCAGN01876 will proceed as outlined in Table 1 until the MTD[redacted] of INCAGN01876 in combination with pembrolizumab and epacadostat is determined. Subjects must receive at least 1 dose of the cohort-specified dose of INCAGN01876, 1 dose of pembrolizumab, and at least 75% of planned doses of epacadostat (42 doses) or have had a DLT during the DLT observation period to be considered evaluable.

Table 2: Phase 1 Dose Escalation of Treatment Group A

Treatment Group A	INCAGN01876 Concurrent Dose Administration	Pembrolizumab	Epacadostat
	See INCAGN01876 dose cohorts (Table 1) Q3W starting at Cycle 1	200 mg Q3W starting at Cycle 1	[redacted] starting at Cycle 1

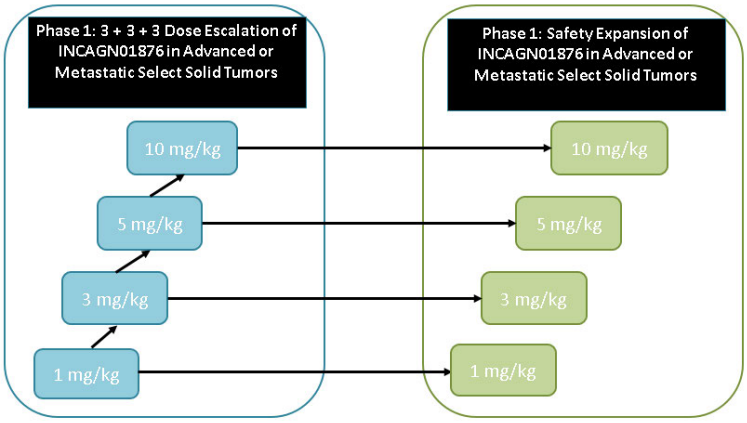


3.1.2. Phase 1 – Safety Expansion (Part 2)

Once an INCAGN01876 dose cohort in Treatment Group A is deemed tolerable (ie, no DLTs or unacceptable toxicities were observed within the defined DLT observation period of at least 28 days), up to 6 evaluable subjects will be enrolled in Treatment Group B at the same dose of INCAGN01876 (see Figure 2). For example, if 3.0 mg/kg of INCAGN01876 is tolerated in Treatment Group A, then 3.0 mg/kg will be explored in up to 6 evaluable subjects in Treatment Group B. Doses of INCAGN01876 in Treatment Group B will be escalated in parallel to those explored in Treatment Group A, but will not exceed the MTD of INCAGN01876 established in Treatment Group A. Alternate dose administration schedules may also be explored depending on [redacted] safety results. The sponsor may elect to prioritize (or deprioritize) enrollment to specific dose cohorts based on emerging safety or efficacy data in collaboration with investigational sites.

If the cumulative incidence of Grade 3 or higher INCAGN01876-related AEs occurs in > 40% of subjects in a particular treatment group, then further enrollment will be interrupted until the sponsor, investigators, and regulatory authorities (if applicable) determine the appropriate course of action (eg, lower the dose of INCAGN01876, change dose frequency, etc).

Figure 2: Phase 1 Safety Expansion (Part 2)

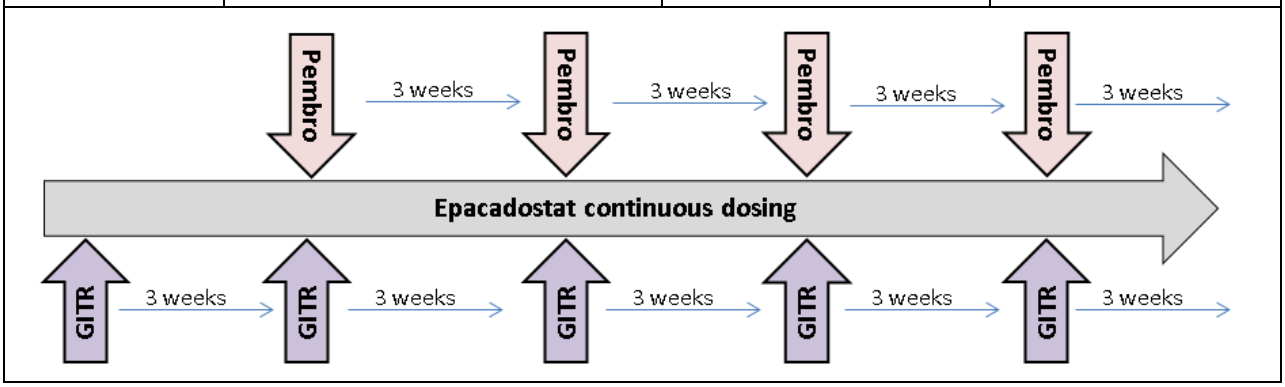


3.1.2.1. Treatment Group B: INCAGN01876 + Epacadostat Run-In Followed by INCAGN01876 + Pembrolizumab + Epacadostat

Treatment Group B will treat subjects with a single-dose run-in of INCAGN01876 at the assigned dose level in combination with [redacted] epacadostat administered orally BID, followed by the combination of INCAGN01876 Q3W, 200 mg of pembrolizumab Q3W starting at Cycle 2, and [redacted] epacadostat administered orally BID (see Table 3).

Table 3: Phase 1 Safety Expansion of Treatment Group B

Treatment Group B	INCAGN01876 Run-In Followed by Concurrent Dose Administration	Pembrolizumab	Epacadostat
	See INCAGN01876 dose cohorts (Table 1) Q3W starting at Cycle 1	200 mg Q3W starting at Cycle 2	[redacted] starting at Cycle 1



3.1.3. Phase 2 – Dose Expansion

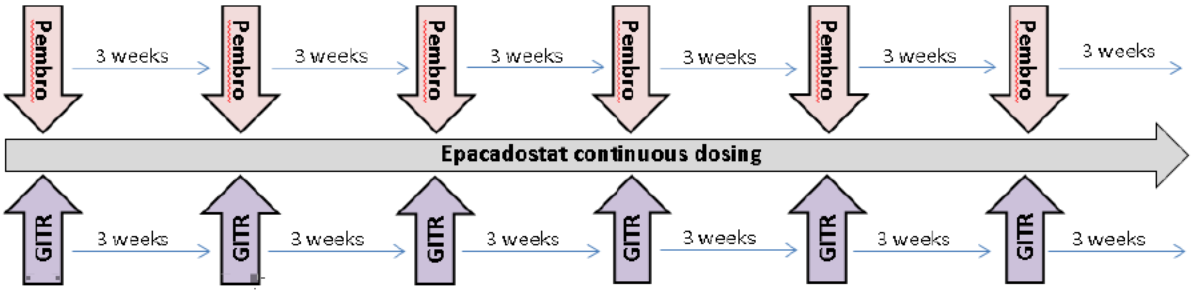
Phase 2 will further evaluate the safety, tolerability, efficacy, [redacted] in subjects with advanced or metastatic melanoma, RCC, and UC. Additional tumor-specific cohorts may be added, by protocol amendment, based on emerging data.

Biopsy cohorts will be added at specific institutions for each treatment group (C and D), where serial mandatory pretreatment and on-treatment biopsies will be collected to evaluate changes in the tumor microenvironment. Approximately 15 evaluable subjects who have tumor lesions that are amenable to percutaneous biopsy will be enrolled in each biopsy cohort. The biopsy-specific cohorts will be limited to subjects with melanoma (mucosal or cutaneous), RCC, and UC (refer to the Protocol, Section 7.10.4).

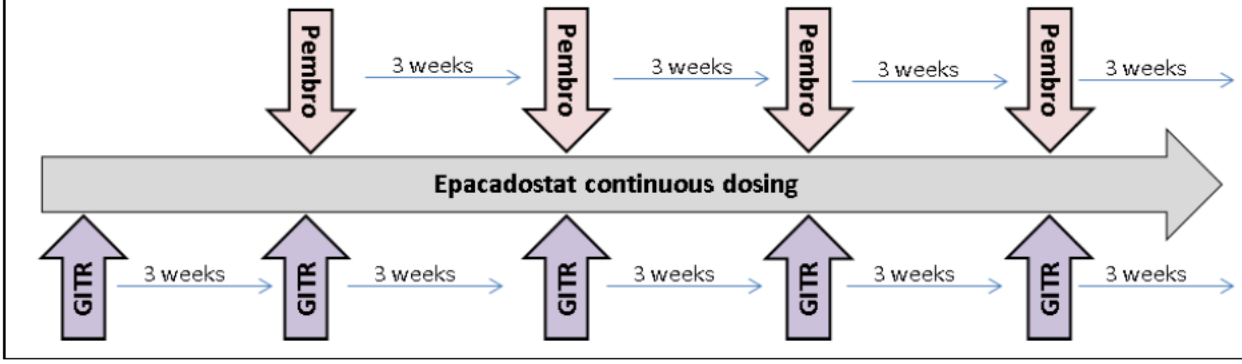
The Phase 2 dose expansion treatment groups and tumor-specific cohorts for each treatment group are outlined in Table 4. A Simon 2-stage design will be used with a stopping rule to allow for early termination of a particular cohort at the end of Stage 1 if there are insufficient responses observed (Simon 1989). The approximate number of subjects for Stage 1 and Stage 2 for each treatment group and tumor type is described in Table 6. Enrollment in Phase 2 will begin when the MTD[redacted] of INCAGN01876 for a given treatment group in Phase 1 has been determined.

Table 4: Phase 2 Dose Expansion Treatment Groups

Dose Expansion Treatment Groups				
	INCAGN01876 Concurrent Dose Administration	**Pembrolizumab**	**Epacadostat**	**Tumor Cohorts**
Treatment Group C	MTD [redacted] of Treatment Group A Q3W starting at Cycle 1	200 mg Q3W starting at Cycle 1	[redacted] starting at Cycle 1	Cohort 1 – Biopsy Cohort 2 – Melanoma Cohort 3 – RCC Cohort 4 – UC



	INCAGN01876 Run-In Followed by Concurrent Dose Administration	**Pembrolizumab**	**Epacadostat**	**Tumor Cohorts**
Treatment Group D	MTD [redacted] of Treatment Group A Q3W starting at Cycle 1	200 mg Q3W starting at Cycle 2	[redacted] starting at Cycle 1	Cohort 1 – Biopsy Cohort 2 – Melanoma Cohort 3 – RCC Cohort 4 – UC



In Phase 2 of the study, toxicities will continue to be monitored. If the cumulative incidence of Grade 3 or higher INCAGN01876-related AEs occurs in > 40% of subjects in a particular treatment group after 6 subjects have been enrolled, then further enrollment in that treatment group will be interrupted until the sponsor, investigators, and regulatory authorities (if applicable) determine the appropriate course of action (eg, lower the dose of INCAGN01876, change dose frequency, etc). If a treatment group is discontinued due to toxicity, it may be re-initiated at a previously tested lower dose level and/or alternate dosing schedule. All AEs, regardless of the time of occurrence on study, may be considered for DLT determination purposes.

3.2. Randomization

Not applicable.

3.3. Control of Type I Error

For the primary efficacy endpoints, the 1-sided Type I error will be controlled at 0.05 for each individual cohort expansion. Note that this level of significance does not account for the multiple expansion cohorts. For other endpoints, CIs will be reported at a 95% confidence level.

3.4. Sample Size Considerations

3.4.1. Sample Size in Phase 1 Part 1

The primary objective of Phase 1 of the study is to evaluate the safety, tolerability, and DLTs of INCAGN01876 in combination with immune therapies and to determine the RP2Ds of INCAGN01876 when given in combination with immune therapies. The total number of subjects will depend on the number of dose levels tested before the recommended dose(s) are established. Dose escalation will follow the 3 + 3 + 3 design algorithm (see Section 3.1.1). Based on this algorithm, a minimum of 3 evaluable subjects will be enrolled in each cohort with a maximum of 9 evaluable subjects in each cohort.

The probabilities of dose escalation from a given dose level for the various DLT rates are provided in Table 5.

Table 5: Probability of Dose Escalation for Various Dose-Limiting Toxicity Rates

True DLT Rate	Probability of Dose Escalation
20%	78.4%
30%	56.1%
40%	35.0%
50%	18.9%
60%	8.8%

For example, if the true DLT rate is 50% at a given dose level, there is an 18.9% chance that the dose would be escalated. Further, if the true DLT rate is 20%, there is a 78.4% chance that the dose would be escalated. If the MTD is not determined at the highest dose level tested during the study, then the MTD is at or above the highest dose level. The MTD is below the lowest dose level of INCAGN01876 if the Cohort 1 dose is not well-tolerated.

3.4.2. Sample Size in Phase 1 Part 2

Once an INCAGN01876 dose cohort in Treatment Group A is deemed tolerable, up to 6 evaluable subjects will be enrolled in Treatment Group B at the same dose of INCAGN01876. For example, if 3.0 mg/kg of INCAGN01876 is tolerated in Treatment Group A, then 3.0 mg/kg will be explored in up to 6 evaluable subjects in Treatment Group B.

3.4.3. Sample Size for Phase 2

Phase 2 will further evaluate the safety, tolerability, preliminary efficacy, [redacted] of the immune therapy combinations as part of dose expansion cohorts in Treatment Groups C and D. In Phase 2, a Simon 2-stage design will be run for each tumor type within a given treatment group.

The sample size for each tumor type within a given treatment group will be guided by the Simon 2-stage design. The planned Simon 2-stage designs are summarized in Table 6. Each Simon 2-stage design will have a stopping rule to allow early termination of a particular cohort at the end of Stage 1 if there are insufficient responses observed, while enrolling enough subjects to predict possible target responses worthy of cohort expansion and potentially further evaluation in future studies.

The individual Simon 2-stage designs run for each tumor type within each treatment group will have design parameters that are determined by historical response rates. For the RCC and UC cohorts, the insufficient response rates are obtained from historical data, and the Simon 2-stage designs allowing early termination are based on ORR. For the melanoma cohort, the insufficient response rate is obtained from historical data, and the primary endpoint for the Simon 2-stage design allows for early termination based on CRR. The same Simon 2-stage design parameters will be used for the alternative dosing sequences represented by Treatment Groups C and D in the same tumor type. For example, the RCC cohorts in Treatment Groups C and D will use the same Simon 2-stage parameters.

In order to determine whether the target response rate (p_1) is likely, an initial number of evaluable subjects (n_1 subjects) will be treated at the MTD [redacted] and schedule of INCAGN01876 within the corresponding tumor type and treatment group and will be enrolled in a cohort (Stage 1). If there are r_1 or fewer responses in the cohort, it will be concluded that the true response rate is unlikely to be greater than or equal to the target rate, and no more subjects will be enrolled in that tumor type cohort for that treatment group in Stage 2. In the cohorts in which greater than r_1 responses are observed among the Stage 1 subjects, n_2 additional evaluable subjects will be treated in Stage 2 to estimate the response rate. At the end of Stage 2, if $\leq r$ subjects have responded among the n evaluable subjects, the triplet combination dosing sequence will be declared nonpromising for that cohort. In other words, after the study is finished, if there is a sufficient number of responses in the 2 stages combined, the triplet combination dosing sequence is considered promising; otherwise it is considered nonpromising.

The detailed calculations for each tumor-specific cohort are based on a 1-sided Type I error of 0.05 and power of 85%. The individual p_0 and p_1 values for the tumor types are listed in Table 6.

A second approach to determining whether the treatment is active across the cohorts will use an integrated Bayesian futility analysis of tumor and dosing strategies specific to Treatment Groups C and D.

Formal quarterly safety reviews will be conducted to review efficacy and safety data with the obligation to hold a safety review meeting every 6 months.

[redacted].

Table 6: Planned Simon 2-Stage Designs for Phase 2

Indication	Combination	r_1	n_1	r	n_2	n	p_0	p_1
Melanoma (CRR)	GITR + Pembro + Epacadostat	6	21	18	31	52	26%	45%
RCC (ORR)	GITR + Pembro + Epacadostat	8	19	25	31	50	40%	60%
UC (ORR)	GITR + Pembro + Epacadostat	3	10	14	24	34	30%	55%

3.5. Schedule of Assessments

See Protocol Amendment 1 dated 24 AUG 2017 for a full description of all study procedures and assessment schedules for this study.

4. DATA HANDLING DEFINITIONS AND CONVENTIONS

4.1. Scheduled Study Evaluations and Study Periods

4.1.1. Day 1

Day 1 is the date that the first dose of study drug (INCAGN01876, pembrolizumab, or epacadostat) is administered to the subjects.

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 INCAGN01876, pembrolizumab, or epacadostat, 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.

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.

Missing or partial date of last dose will be handled as follows:

- If only the day is missing, then the imputed date of the last dose will be the earlier date of the first day of the month or the date that the subject discontinued treatment.
- Otherwise, the date that the subject discontinued treatment will be used as the date of the last dose.

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.

4.1.5. Cycle Length and Duration

Cycle 1 Day 1 is the day that the first dose of study drug is administered. Scheduled cycle length is 21 days. Actual Day 1 of subsequent cycles will correspond with the first day of administration of INCAGN01876 in that cycle; thus, treatment cycles may become out of sync with the originally planned schedule and cycle length may be different from 21 days. The date of the Day 1 of subsequent cycles recorded on the eCRF will be used as the Day 1 of the subsequent cycles.

4.2. Variable Definitions

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

4.2.1. Age

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

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

4.2.2. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of INCAGN01876, pembrolizumab, or epacadostat.

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

- Before the date of first administration of INCAGN01876, pembrolizumab, or epacadostat 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 INCAGN01876, pembrolizumab, or epacadostat and is ongoing or ends during the course of study drug.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first dose of INCAGN01876, pembrolizumab, or epacadostat. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, or both prior and concomitant medication.

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

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9 or later) will be used for the generation of all tables, graphs, and statistical analyses. 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 subjects in each category.

5.2. Treatment Groups

This is an open-label, nonrandomized, Phase 1/2 study to determine the safety, tolerability, and efficacy of INCAGN01876 when given in combination with immune therapies.

In Phase 1 (Dose Escalation), a higher starting dose of INCAGN01876 [redacted] was used based on safety data from the monotherapy study (INCAGN 1876-101) in Treatment Group A, but it did not exceed 1 dose level below the highest tolerated dose of INCAGN01876 monotherapy. The higher dose was communicated to investigational sites with an administrative letter. Phase 1 Treatment Group A serves as a safety run-in phase for Phase 2 Treatment Group C.

In Phase 2 (Dose Expansion), melanoma, RCC, and UC subjects will be enrolled into Treatment Group C [redacted].

[redacted].

[redacted].

5.3. Analysis Populations

5.3.1. Full Analysis Set

The FAS includes all subjects enrolled in the study who received at least 1 dose of INCAGN01876, pembrolizumab, or epacadostat.

Specific FAS populations to be used for drug-specific tables include the following subgroups:

- INCAGN01876 FAS population.
- Pembrolizumab FAS population.
- Epacadostat FAS population.

5.3.2. Response Evaluable Populations

The response evaluable population includes all subjects enrolled in the study who have received at least 1 dose of INCAGN01876, pembrolizumab, or epacadostat; completed a baseline scan; and met at least 1 of the following criteria:

- The subject has $\geq$ 1 postbaseline scan OR
- The subject has been on the study for a minimum of 70 days of follow-up OR
- The subject has discontinued from treatment.

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Appendix A provides a list of data displays. Sample data displays will be provided in a separate document.

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

6.1.1. Demographics

The following demographics will be summarized for the FAS population [redacted]: age, sex, race, ethnicity, weight, and height.

6.1.2. Baseline Disease Characteristics and Disease History

Disease histology, stage at initial diagnosis, current stage, and primary site of disease will be summarized for all subjects in the FAS population [redacted]. ECOG performance status will also be summarized for all subjects in the FAS population [redacted].

6.1.3. Prior Therapy

Number of prior systemic cancer therapy regimens will be summarized for all subjects in the FAS population [redacted]. Regimen name, component drugs, start and stop date, route of the medication, purpose of the regimen, best response, reason for discontinuation, and date of relapse/progression will be listed.

Number of subjects who received prior radiation and number of subjects who had prior surgery or surgical procedure for the malignancies under study will be listed.

6.1.4. Medical History

Medical history recorded on the eCRF will be presented in the subject data listings.

6.2. Disposition of Subjects

The number and percentage of subjects who were enrolled, treated, discontinued study treatment with a primary reason for discontinuation, and withdrawn from the study with a primary reason for withdrawal will be summarized for the FAS population [redacted].

6.3. Protocol Deviations

Protocol deviations recorded on the eCRF will be presented in the subject data listings.

6.4. Exposure

6.4.1. Exposure for INCAGN01876

For subjects in the FAS population, exposure to INCAGN01876 will be summarized descriptively as the following:

- **Total number of infusions:** Total number of infusions per subject with a nonzero dose of INCAGN01876.

6.4.2. Exposure for Pembrolizumab

The exposure for pembrolizumab will be summarized the same as that for INCAGN01876 in Section 6.4.1.

6.4.3. Exposure for Epacadostat

For subjects in the FAS population, exposure to epacadostat will be summarized descriptively as the following:

- **Duration of treatment (days):** Date of last dose of epacadostat – date of first dose of epacadostat + 1.

6.5. Prior and Concomitant Medication

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

7. EFFICACY

Appendix A provides a list of data displays. Sample data displays will be provided in a separate document.

7.1. General Considerations

Due to the early discontinuation of study enrollment, only ORR using RECIST v1.1 will be summarized for the FAS population [redacted].

7.2. Analysis of the Objective Response Rate

7.2.1. Objective Response Rate and Best Overall Response by RECIST v1.1

Best overall response is defined as the best response recorded postbaseline prior to and including the first PD, in the order of CR, PR, SD, PD, and NE. In the case of SD, measurements must meet the SD criteria at least once after the date of first dose of study treatment at a minimum interval of 56 (63 – 7) days. Subjects who fail to meet this criterion will have a best overall response of PD if the next available assessment indicates PD or NE if there is no additional assessment available.

Objective response rate, defined as the proportion of subjects with overall responses, will be summarized for all subjects in the FAS population [redacted].

For subjects with measurable disease at baseline, the RECIST v1.1 assessment criteria presented in Table 7 can be used to determine the overall disease status at a given timepoint based on the target lesion, nontarget lesion, and new lesion assessment.

Table 7: RECIST v1.1 Evaluation Criteria for Overall Response: Measurable Disease at Baseline

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

8. SAFETY AND TOLERABILITY

Appendix A provides a list of data displays. Sample data displays will be provided in a separate document.

8.1. General Considerations

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

Unless otherwise stated, table summaries will be limited to TEAEs.

8.2. Adverse Events

8.2.1. Adverse Event Definitions

A TEAE is any AE either reported for the first time or worsening of a pre-existing event after 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. The CTCAE v4.03 is used for this study. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website.

The subset of AEs considered by the investigator to be related to INCAGN01876, pembrolizumab, or epacadostat will be considered to be treatment-related AEs. If the investigator does not specify the relationship of the AE to study treatment, the AE will be considered to be treatment-related. The incidence of AEs and treatment-related AEs will be tabulated. In addition, serious AEs will also be tabulated.

A grading (severity) scale is provided for each AE term. If the toxicity is not included in the CTCAE v4.03 criteria, it will be rated on a scale of 1 to 5 as follows: 1 = mild, 2 = moderate, 3 = severe, 4 = life threatening, and 5 = death related to AE. All toxicities will be graded based on the worst level reached, not the level they may have reached if they had not been treated. When the intensity of an AE changes over time for a reporting period (eg, between visits), each change in intensity will be collected as an AE until the event resolves. Only the worst grade will be reported in AE summaries. Also, the Grade 3 or higher AEs will be reported in a listing.

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

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

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

8.2.2. Dose-Limiting Toxicities

The number of subjects with DLTs and the type of DLT will be listed. An AE for a subject will be identified as a DLT if the event is recorded as a Protocol-defined DLT on the AE eCRF.

8.2.3. Adverse Events of Special Interest

8.2.3.1. Immune-Related Adverse Events

The subjects with irAEs and type of irAE will be listed. Adverse event terms will be reviewed periodically without respect to treatment group by the medical monitor and clinical scientist to determine which AE terms correspond to irAEs. This periodic review may also occur after database lock. The medical monitor and clinical scientist will also review investigator-reported AEs to determine whether they qualify as irAEs. For example, a rash will be counted as an irAE even if the investigator did not report it as an irAE.

8.2.3.2. Infusion-Related Reactions

Infusion-related reactions, defined as AEs that are identified as infusion-related reaction by the investigator on the infusion-related reaction case report form, will be listed. The listing will include the treatment group, dose level, cycle number, study day, date of onset of AE, date of the associated infusion, and signs and symptoms of the infusion related reaction.

8.2.4. Adverse Event Summaries

An overall summary of AEs for the FAS population [redacted] will include:

- Number (%) of subjects reporting any TEAEs
- Number (%) of subjects reporting any serious TEAEs
- Number (%) of subjects reporting any Grade 3 or higher TEAEs
- Number (%) of subjects reporting any TEAEs related to INCAGN01876
- Number (%) of subjects reporting any TEAEs related to pembrolizumab
- Number (%) of subjects reporting any TEAEs related to epacadostat
- Number (%) of subjects who permanently discontinued study treatment because of TEAEs
- Number (%) of subjects who had a fatal TEAE

The following summaries will be produced by MedDRA term:

- Summary of TEAEs by SOC and PT
- Summary of TEAEs by PT in decreasing order of frequency
- Summary of TEAEs by SOC, PT, and maximum severity
- Summary of Grade 3 or higher TEAEs by SOC and PT
- Summary of INCAGN01876 treatment-related AEs by SOC and PT

- Summary of pembrolizumab treatment-related AEs by SOC and PT
- Summary of epacadostat treatment-related AEs by SOC and PT
- Summary of TEAEs with a fatal outcome by SOC and PT
- Summary of serious TEAEs by SOC and PT
- Summary of serious TEAEs by PT in descending order of frequency
- Summary of nonserious TEAEs by SOC and PT
- Summary of INCAGN01876 treatment-related serious TEAEs by SOC and PT
- Summary of pembrolizumab treatment-related serious TEAEs by SOC and PT
- Summary of epacadostat treatment-related serious TEAEs by SOC and PT
- Summary of TEAEs leading to discontinuation of study treatment by SOC and PT

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

Laboratory baseline values will be determined according to Section 4.1.3. If there are multiple values that meet the criteria for baseline, additional rules may be provided after consultation with the medical monitor to delineate which value will be defined as baseline.

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

8.3.2. Laboratory Value Summaries

All test results and associated normal ranges from local laboratories will be reported in SI units. All tests with numeric values will have a unique unit per test. Any laboratory test results and associated normal ranges from local laboratories will be converted to SI units. For the limited number of cases where the associated normal ranges from a local laboratory cannot be obtained despite due diligence, if query is unsuccessful at resolving the issue and analysis is mandatory then the clinical scientist and medical monitor can provide a suitable normal range to be used in determining CTC grading and flags for above and below normal.

When there are multiple laboratory nonmissing values for a subject's particular test within a visit window, the convention described in Table 8 will be used to determine the record used for by-visit tabulations and summaries.

Table 8: Identification of Records for Postbaseline By-Visit Summaries

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	

For test results that will be summarized with available normal ranges, the number and percentage of subjects 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 will be produced for each test for the FAS population. The denominator for the percentage calculation will use the number of subjects in the baseline category (ie, low, high, normal, missing) as the denominator for the percentage in each of the categories during the treatment period.

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

8.4. Vital Signs

Values at each scheduled visit including systolic blood pressure, diastolic blood pressure, pulse, respiration rate, body temperature, and pulse oximetry will be listed.

Criteria for clinically notable vital sign abnormalities are defined in Table 9. The abnormal values for subjects exhibiting clinically notable vital sign abnormalities will be listed along with their assigned treatment group. 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 subjects exhibiting alert vital sign abnormalities will be listed.

Table 9: 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
Temperature	> 38ºC	< 35.5ºC
Respiratory rate	> 24 breaths/min	< 8 breaths/min
Pulse oximetry	NA	< 90

8.5. Electrocardiograms

Twelve-lead ECGs including PR, QRS, QT, QTcF, QTcB, RR, and JTc intervals will be obtained for each subject during the study. Values at each scheduled visit will be listed for each ECG parameter. Baseline will be determined as the average of all nonmissing values before the first administration of INCAGN01876, pembrolizumab, or epacadostat.

Criteria for clinically notable ECG abnormalities are defined in Table 10. Subjects exhibiting clinically notable ECG abnormalities will be listed with study visit and assigned treatment group. Abnormal values for subjects 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 10: Criteria for Clinically Notable Electrocardiogram Abnormalities

Parameter	High Threshold	Low Threshold
QTcF	> 460 ms	< 295 ms
PR	> 220 ms	< 75 ms
QRS	> 120 ms	< 50 ms
QT	> 500 ms	< 300 ms
RR	> 1330 ms	< 600 ms
JTc	> 340 ms	< 245 ms

QTcF = Fridericia correction.
Note: QTcB uses the same thresholds as those for QTcF.

8.6. Physical Examinations

Weight at each scheduled visit will be obtained and listed for each subject during the study.

9. INTERIM ANALYSES

Since study enrollment discontinued prior to the interim analyses, no interim analyses will be conducted.

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	01 JUN 2018

10.1. Changes to Protocol-Defined Analyses

10.1.1. Sample Size Deviation

10.1.1.1. Sample Size in Phase 1 Part 1

In Phase 1 Part 1, a flat dose of 300mg INCAGN01876 Q3W is selected as the RP2D. A minimum of 6 evaluable subjects was enrolled in Treatment Group A before proceeding to Part 2 of the Protocol. Phase 1 Treatment Group A served as a safety run-in phase for Phase 2 Treatment Group C. No dose escalation or dose de-escalation was conducted.

[redacted]

10.1.1.2. Sample Size in Phase 2

[redacted] A limited number of subjects was enrolled in Phase 2 Treatment Group C. No subjects were enrolled in Treatment Groups B and D.

The letter to stop screening and enrollment can be found in the TMF.

10.1.2. Efficacy Analyses

Only ORR will be summarized per RECIST v1.1. The analyses for other efficacy endpoints and analyses per mRECIST will be eliminated.

10.1.3. Safety Analyses

- Only shift tables will be provided for clinical laboratory tests.
- No summary tables will be tabulated for vital signs and ECGs. A listing with alert values asterisked for vital signs and ECGs respectively will be provided.

10.1.4. Interim Analyses

Simon 2-stage design with integrated Bayesian futility analysis implemented and analyses for the Data Monitoring Committee will not be performed.

11. REFERENCES

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

APPENDIX A. PLANNED TABLES AND FIGURES

Due to the early termination of study enrollment, a synoptic CSR will be provided. This appendix provides a list of the planned tables and listings for the synoptic CSR. Standard tables will follow the conventions in the Standard Safety Tables initial version. Shells are provided for nonstandard tables. In-text tables are not needed for the synoptic CSR.

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

Tables

Table No.	Title	Population	Standard
Baseline and Demographic Characteristics			
1.1 Disposition			
1.1.1	Analysis Populations	FAS	X
1.1.2	Summary of Subject Disposition	FAS	X
1.2 Demography			
1.2.1	Summary of Demographics	FAS	X
1.3 Baseline Characteristics			
1.3.1	Summary of Baseline Disease Characteristics and Disease History	FAS	
1.4 Prior Medication and Concomitant Medication			
1.4.1	Summary of Prior Cancer Therapy	FAS	
1.4.2	Summary of Prior Medications	FAS	X
1.4.3	Summary of Concomitant Medications	FAS	X
Efficacy			
2.1.1	Summary of Objective Response Rate Under RECIST v1.1	Response Evaluable	
Safety			
3.1 Dose Exposure			
3.1.1	Summary of Drug Exposure to INCAGN01876	INCAGN01876 FAS	
3.1.2	Summary of Drug Exposure to Pembrolizumab	Pembrolizumab FAS	
3.1.3	Summary of Drug Exposure to Epacadostat	Epacadostat FAS	
3.2 Adverse Events			
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
3.2.5	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X

Table No.	Title	Population	Standard
3.2.6.1	Summary of INCAGN01876 Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	INCAGN01876 FAS	X
3.2.6.2	Summary of Pembrolizumab Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Pembrolizumab FAS	X
3.2.6.3	Summary of Epacadostat Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Epacadostat FAS	X
3.2.7	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.8	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.9	Summary of Serious Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency	FAS	X
3.2.10[a]	Summary of Nonserious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	FAS	X
3.2.11.1	Summary of INCAGN01876 Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	INCAGN01876 FAS	X
3.2.11.2	Summary of Pembrolizumab Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Pembrolizumab FAS	X
3.2.11.3	Summary of Epacadostat Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Epacadostat FAS	X
3.2.12	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of Study Treatment by MedDRA System Organ Class and Preferred Term	FAS	X
3.3 Laboratory			
3.3.1	Shift Summary of Hematology Laboratory Values in CTC Grade - To the Worst Abnormal Value	FAS	X
3.3.2	Shift Summary of Chemistry Laboratory Values in CTC Grade - To the Worst Abnormal Value	FAS	X

[a] Nonserious TEAE table will be generated for the study with expressed purpose of clinical trial results posting.

Listings

Listing No.	Title
2.1 Discontinued Subjects (Subject Disposition)	
2.1.1	Subject Enrollment and Disposition Status
2.1.2	Subject Inclusion and Exclusion Criteria Violations
2.2 Protocol Deviations	
2.2.1	Protocol Deviations and Violations
2.3 Data Excluded From [redacted], Efficacy, and/or Safety Analyses	
2.3.1	Analysis Population
2.4 Demography and Baseline (Including Prior and Concomitant Medications)	
2.4.1	Demographic Characteristics
2.4.2	Baseline Disease Characteristics for Solid Tumor Types
2.4.3	Disease History
2.4.4	Prior Radiation Treatment
2.4.5	Prior Systemic Therapy
2.4.6	Prior Surgery or Surgical Procedure
2.4.7	Medical History
2.4.8	Prior and Concomitant Medication
2.6 Efficacy	
2.6.1	Best Overall Response Under RECIST v1.1
2.6.2	ECOG Performance Status
2.7 Adverse Events (and Exposure)	
2.6.1.1	Study Drug Administration for INCAGN01876
2.6.1.2	Study Treatment Administration for Pembrolizumab
2.6.1.3	Study Treatment Administration for Epacadostat
2.6.2	Adverse Events
2.6.3	Dose-Limiting Toxicities
2.6.4	Serious Adverse Events
2.6.5	Fatal Adverse Events
2.6.6	Adverse Events Leading to Discontinuation of INCAGN01876
2.6.7	Immune-Related Adverse Events
2.6.8	Infusion Reactions
2.8 Laboratory Data	
2.7.1	Clinical Laboratory Values - Hematology
2.7.2	Clinical Laboratory Values - Chemistry
2.7.3	Clinical Laboratory Values - Coagulation
2.7.4	Clinical Laboratory Values - Urinalysis
2.7.5	Clinical Laboratory Values - Endocrine
2.7.6	Clinical Laboratory Values - Serology
2.7.7	Pregnancy
2.9 Vital Signs	
2.8.1	Vital Signs
2.10 ECGs	
2.9.1	12-Lead ECG Values
2.11 Physical Examinations	
2.11.1	Body Weight