Official Title: **A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB059872 in Subjects With Advanced Malignancies**

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STATISTICAL ANALYSIS PLAN

INCB 59872-101

A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB059872 in Subjects With Advanced Malignancies

IND Number:	[redacted]
EudraCT Number	**2017-001710-28**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803**
Protocol Version:	**Protocol Amendment (Version) 5 dated 30 JUL 2018**
CRF Approval Date:	**23 APR 2018**
SAP Version:	**Original**
SAP Author:	[redacted]**, PhD** [redacted] **Biostatistics**
Date of Plan:	**01 OCT 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	Definition
AE	adverse event
AML	acute myeloid leukemia
ATRA	all-trans retinoic acid
BMI	body mass index
BOR	best overall response
bpm	beats per minute
BSA	body surface area
CCyR	complete cytogenetic response
CI	confidence interval
CMR	complete molecular response
CR	complete remission/complete response
CRF	case report form
CRi	Complete remission with incomplete hematologic recovery
CT	computed tomography
CTCAE	Common Terminology Criteria for Adverse Events
DLT	dose-limiting toxicity
[redacted]	
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
FAS	Full Analysis Set
FDA	Food and Drug Administration (US)
HI-E	hematologic improvement-erythroid response
HI-N	hematologic improvement-neutrophil response
HI-P	hematologic improvement-platelet response
IPSS-R	International Prognostic Scoring System Risk
irAE	immune-related adverse event
IWG	International Working Group
LSD1	lysine-specific demethylase 1
MDS	myelodysplastic syndrome
MedDRA	Medical Dictionary for Regulatory Activities
MF	myelofibrosis
MLFS	morphologic leukemia-free state
[redacted]	

Abbreviation	Definition
MRI	magnetic resonance imaging
MTD	maximum tolerated dose
NA	not applicable
NE	not evaluable
ORR	objective response rate
PCyR	partial cytogenetic response
PD	progressive disease
[redacted]	
PK	pharmacokinetic
PR	partial remission/partial response
PT	preferred term
QD	once daily
QOD	every other day
RECIST	Response Evaluation Criteria in Solid Tumors
SAE	serious adverse event
SAP	Statistical Analysis Plan
SCLC	small cell lung cancer
SD	stable disease
SOC	system organ class
TEAE	treatment-emergent adverse event
TG	treatment group
TSS	total symptom score
WHO	World Health Organization

1. INTRODUCTION

This is an open-label, dose-escalation/dose-expansion study of the LSD1 inhibitor INCB059872 as a monotherapy and combination therapy in subjects with advanced malignancies. The study will be conducted in 4 parts: Parts 1 and 2 will evaluate INCB059872 as monotherapy, with Part 1 for dose escalation and Part 2 for dose expansion, and Parts 3 and 4 will evaluate INCB059872 in combination with select therapies, with Part 3 for combination dose escalation and Part 4 for combination dose expansion. Dose escalation for Parts 1 and 3 will proceed following a 3 + 3 design. Parts 3 and 4 will evaluate INCB059872 in combination with ATRA, in combination with azacitidine, and in combination with nivolumab in subjects with advanced or metastatic malignancies.

Section 1 of the Protocol provides a detailed description of the investigational product, target patient population, rationale for doses to be examined, and potential risks and benefits of treatment with INCB059872, ATRA, azacitidine, and nivolumab.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the Study INCB 59872-101 Protocol. The scope of this plan includes the final analyses that are planned and will be executed by the Department of Biostatistics or designee, and the analyses of pharmacokinetics. [redacted]

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 59872-101 Protocol Amendment 5 dated 30 JUL 2018 and CRFs approved 23 APR 2018. Unless superseded by an amendment, this SAP will be effective for all subsequent Protocol amendments and CRF versions.

2.2. Study Objectives

2.2.1. Primary Objectives

- **Part 1:** To evaluate the safety and tolerability and determine the recommended dose(s) of INCB059872 for further study in advanced malignancies.
- **Part 2:** To further evaluate the safety and tolerability of INCB059872 for further study in advanced malignancies.
- **Part 3:** To evaluate the safety and tolerability and determine the recommended dose of INCB059872 in combination with other therapies for further study in advanced malignancies.
- **Part 4:** To further evaluate the safety and tolerability of INCB059872 in combination with other therapies in advanced malignancies.

2.2.2. Secondary Objectives

- **Parts 1 and 2:** To assess preliminary antitumor activity of INCB059872 as a monotherapy in subjects with advanced malignancies.
- **Parts 3 and 4:** To assess preliminary antitumor activity of INCB059872 in combination with other therapies in subjects with advanced malignancies.
- To evaluate the PK of INCB059872 and assess the effect of food (TG B1 only) on the PK of INCB059872.

[redacted]

2.3. Study Endpoints

2.3.1. Primary Endpoints

- **Parts 1 and 2:** Safety and tolerability as assessed by monitoring frequency, duration, and severity of AEs, through physical examinations, by evaluating changes in vital signs and ECGs, and through clinical laboratory blood and urine sample evaluations.
- **Parts 3 and 4:** Safety and tolerability as assessed by monitoring frequency, duration, and severity of AEs, through physical examinations, by evaluating changes in vital signs and ECGs, and through clinical laboratory blood and urine sample evaluations in combinations therapies.

2.3.2. Secondary Endpoints

- **Parts 1 and 2:** Tumor response rates in those subjects with measurable disease or spleen volume changes as determined by investigator assessment of response per disease-specific guidelines.
  - Solid tumors: ORR, defined as the percentage of subjects having CR or PR will be determined by the investigator assessment of radiographic disease assessments per RECIST v1.1.
  - AML/MDS: ORR, defined as the proportion of subjects who achieve CR or CRi per the IWG Response Criteria for AML or the IWG Response Criteria for MDS, as applicable.
  - MF: Change and percentage change in spleen volume as measured by MRI (CT scan in subjects who are not a candidate for MRI or when MRI is not readily available) at Week 12 when compared with baseline.
- **Parts 3 and 4:** Tumor response rates in those subjects with measurable disease as determined by investigator assessment of response per disease-specific guidelines.
  - SCLC: ORR, defined as the percentage of subjects having CR or PR will be determined by the investigator assessment of radiographic disease assessments per RECIST v1.1.
  - AML: ORR, defined as the proportion of subjects who achieve CR or CRi per the IWG Response Criteria for AML.
- PK parameters of INCB059872 in plasma: C_{max}, T_{max}, C_{min}, $AUC_{0\text{-}t}$, $t_{½}$, and Cl/F.

[redacted]

3. STUDY DESIGN

This is an open-label, dose-escalation/dose-expansion study of the LSD1 inhibitor INCB059872 as a monotherapy and combination therapy in subjects with advanced malignancies. As illustrated in Figure 1, the study will be conducted in 4 parts: Parts 1 and 2 will evaluate INCB059872 as a monotherapy, with Part 1 for dose escalation and Part 2 for dose expansion, and Parts 3 and 4 will evaluate INCB059872 in combination with select therapies, with Part 3 for combination dose escalation and Part 4 for combination dose expansion. Part 1 (monotherapy dose escalation) will determine the dose(s) of INCB059872 for dose expansion, based on the MTD. The recommended dose(s) will be taken forward into Part 2 (monotherapy dose expansion). The initiation of Part 2 will be based on further review of the ongoing clinical study and preclinical data of INCB059872 and information from literature. Part 3 (dose escalation of INCB059872 in combination therapy) will be initiated after the MTD in Part 1 is determined. Part 4 (dose expansion of INCB059872 in combination therapy) will explore the dose(s) confirmed in Part 3 and may be different based on combination therapy and/or tumor type.

In Part 1, TG A will enroll subjects with AML or MDS. The enrollment in TG B is prioritized for SCLC. Enrollment of subjects with other solid malignancies (eg, endocrine tumors) is allowed with sponsor medical monitor approval. Dose escalation for TG A and TG B in Part 1 will proceed independently, with each treatment group following a 3 + 3 design. The starting dose of INCB059872 for TG A and TG B will be 2 mg QOD. If QOD is well-tolerated, the next dose may be administered at a different dosing regimen (ie, once daily) but will not exceed the 100% dose escalation for a total daily dose. Upon identification of the recommended dose(s), up to 4 expansion cohorts per tumor type of approximately 15 subjects each may begin enrollment in Part 2 to further determine the safety, tolerability, efficacy, PK, and pharmacodynamics of the selected dose(s).

In Part 2, TG A1 will enroll subjects with AML or MDS and subjects in this cohort will have an opportunity to switch their treatment to a combination dose that is tested and found safe. Treatment Group A2 will enroll subjects with primary myelofibrosis or secondary MF (post–polycythemia vera myelofibrosis or post–essential thrombocythemia myelofibrosis).

Treatment Group B1 will enroll subjects with SCLC. Treatment Group B2 will enroll subjects with Ewing's sarcoma and poorly differentiated neuroendocrine tumors.

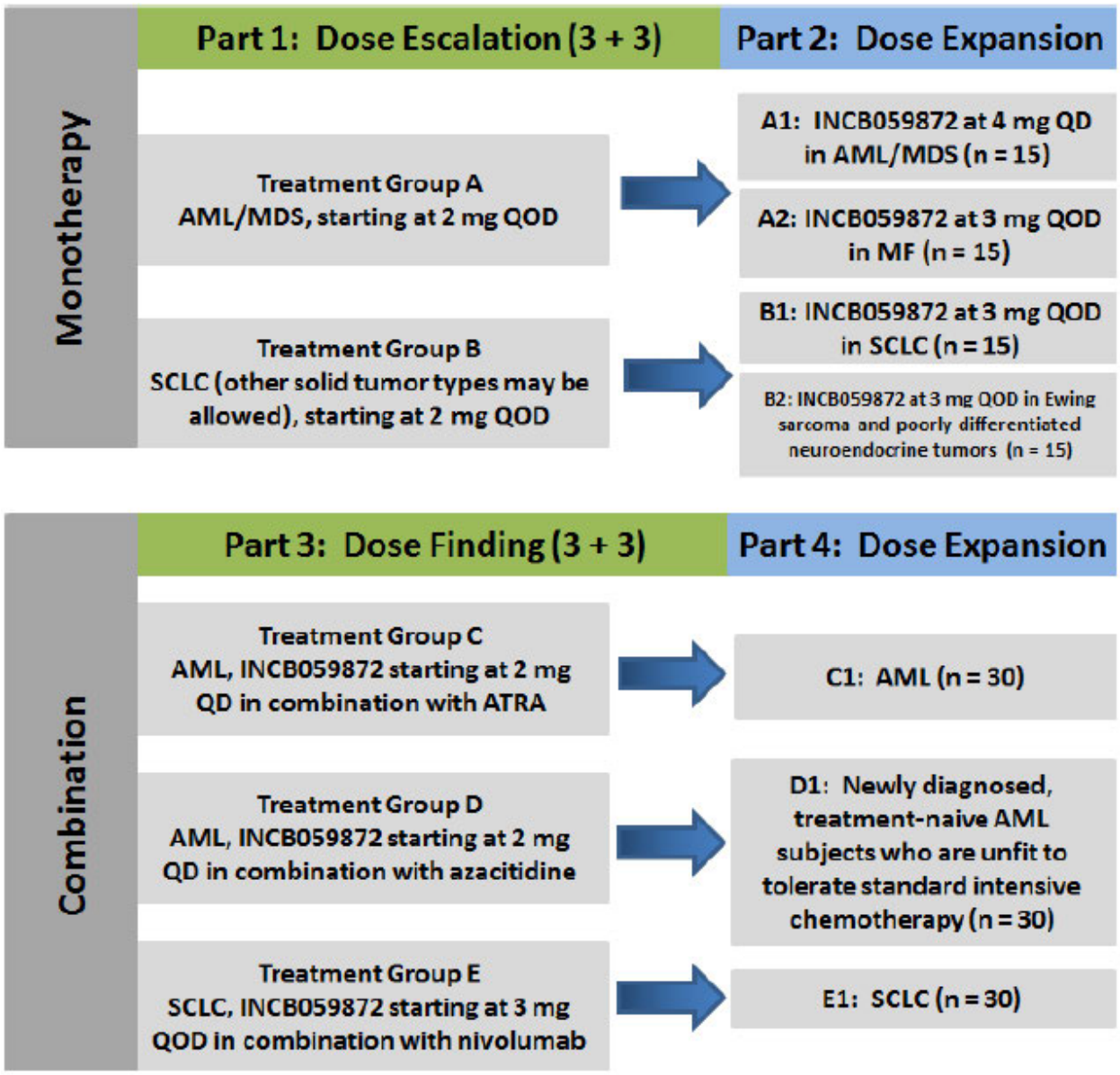
Part 3 enrollment will be initiated after the MTD has been determined in Part 1 and will include dose-finding to evaluate safety and tolerability of the combinations. Dose-finding will use a 3 + 3 design to evaluate different doses of INCB059872 in combination with other therapies in the following treatment groups:

- Combination TG C will evaluate INCB059872 in combination with ATRA in subjects with relapsed/refractory AML. The starting dose for INCB059872 in this cohort will be 2 mg QD (2 dose levels below the recommended dose for monotherapy expansion in TG A1).
- Combination TG D will evaluate INCB059872 in combination with azacitidine in subjects with newly diagnosed, treatment-naive AML who are unfit to tolerate standard intensive chemotherapy at study entry. The starting dose for INCB059872 in this cohort will be 2 mg QD (2 dose levels below the recommended dose for monotherapy expansion in TG A1).
- Combination TG E will evaluate INCB059872 in combination with nivolumab in subjects with advanced SCLC previously progressed on platinum-based treatment. The starting dose for INCB059872 in this cohort will be 3 mg QOD (the recommended dose for monotherapy expansion in TG B1).

Upon identification of the recommended dose(s) for each treatment combination in Part 3, expansion cohorts of approximately 30 subjects in each treatment group may begin enrollment in Part 4 to further determine the safety, tolerability, efficacy, PK, and pharmacodynamics of the selected dose(s). In Part 4, combination TG C1 will evaluate INCB059872 in combination with ATRA using the regimen identified in Part 3 in subjects with relapsed/refractory AML. Combination TG D1 will evaluate INCB059872 in combination with azacitidine using the regimen identified in Part 3 in subjects with newly diagnosed, treatment-naive AML who are unfit to tolerate standard intensive chemotherapy at study entry. Combination TG E1 will evaluate INCB059872 in combination with nivolumab using the regimen identified in Part 3 in subjects with advanced SCLC who previously progressed on platinum based treatment.

In Part 4, a stopping rule for futility is planned for each combination dose expansion treatment group when 15 subjects have been treated and evaluated for response or have permanently discontinued study treatment because of disease progression, withdrawal of consent, or death. Combination TG C1 will be terminated for futility if ≤ 1 of the 15 subjects responded (ie, CR or CRi) based on assessments provided by investigator. Combination TG D1 will be terminated for futility if ≤ 2 of the 15 subjects responded (ie, CR or CRi) based on assessments provided by investigator. Combination TG E1 will be terminated for futility if ≤ 1 of the 15 subjects responded (ie, CR or PR) based on assessments provided by investigator.

Figure 1: Study Design



3.1. Randomization

Not applicable.

3.2. Control of Type I Error

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

3.3. Sample Size Considerations

Parts 1 and 3 of the study will use a standard 3 + 3 dose-escalation design, and the sample size will depend on the frequency of DLTs and the number of dose-escalation cohorts studied before reaching the MTD. Approximately 3 to 6 subjects will be enrolled in each dose level. Using this design, the probability of dose escalation for various DLT rates is given in Table 1.

Table 1: Probability of Dose Escalation by DLT Rate

True DLT Rate	Probability of Dose Escalation
10%	90.6%
20%	70.9%
30%	49.4%
40%	30.9%
50%	17.2%
60%	8.2%

For Part 2, approximately 15 subjects will be enrolled for each expansion cohort. The evaluation of 15 subjects will provide a ≥ 90% chance of observing at least 1 toxicity with a true event rate of ≥ 15%.

For Part 4, for each of the combination cohorts (TGs C1, D1, and E1), up to approximately 30 subjects will be enrolled. The evaluation of 30 subjects will provide approximately 90% chance of observing at least 1 toxicity with a true event rate of ≥ 7%.

3.4. Schedule of Assessments

Refer to Protocol Amendment 5 dated 30 JUL 2018 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

For monotherapy (Parts 1 and 2), Day 1 is the date that the first dose of INCB059872 is administered to the subjects.

For combination therapy (Parts 3 and 4), Day 1 is the date that the first dose of study treatment (INCB059872, ATRA, azacitidine, or nivolumab) 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

For monotherapy (Parts 1 and 2), baseline is the last nonmissing measurement obtained before the first administration of INCB059872, unless otherwise defined.

For combination therapy (Parts 3 and 4), baseline is the last nonmissing measurement obtained before the first administration of INCB059872 and ATRA (TGs C and C1), INCB059872 and azacitidine (TGs D and D1), or INCB059872 and nivolumab (TGs E and E1), 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.

When calculating time since diagnosis of cancer, partial 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 last 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 date of death will be imputed as follows:

- 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

Azacitidine will be administered as an open-label commercial product at a starting dose of 75 mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day or less period (ie, a 2-day break allowed on weekend, if needed) of each 28-day treatment cycle. Nivolumab will be administered at a dose of 3 mg/kg as an intravenous infusion over 60 minutes every 2 weeks (Day 1 and Day 15 of each 28-day treatment cycle).

For combination therapy (Parts 3 and 4), Cycle 1 Day 1 is the day that the first dose of INCB059872, ATRA, azacitidine, or nivolumab is administered. Actual Day 1 of subsequent cycles will correspond with the first day of administration of azacitidine or nivolumab in that cycle; thus, treatment cycles may become out of sync with the originally planned schedule and cycle length may be different from 28 days. The date of Day 1 of subsequent cycles recorded on the eCRF will be used as Day 1 of the subsequent cycles.

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. Body Surface Area

For subjects in TGs C and C1 and TGs D and D1 (Parts 3 and 4), the BSA will be calculated based on the Mosteller (1987) formula as follows:

$$BSA\ (m^2) = \{[weight\ (kg) \times height\ (cm)] / 3600\}^{1/2}.$$

4.2.3. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of INCB059872 (Parts 1 and 2), INCB059872 and ATRA (TGs C and C1), INCB059872 and azacitidine (TGs D and D1), or INCB059872 and nivolumab (TGs E and E1).

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

- Before the date of first administration of INCB059872 (Parts 1 and 2), INCB059872 and ATRA (TGs C and C1), INCB059872 and azacitidine (TGs D and D1), or INCB059872 and nivolumab (TGs E and E1) and is ongoing throughout the study or ends on/after the date of first study treatment administration.
- On/after the date of first administration of INCB059872, ATRA, azacitidine, or nivolumab and is ongoing or ends during the course of study treatment administration.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first dose of INCB059872, ATRA, azacitidine, or nivolumab. 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; Version 9.4 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 subjects in each category.

Interim analyses are planned for this study as defined in Section 10.

5.2. Treatment Groups

This is an open-label, dose-escalation/dose-expansion study of the LSD1 inhibitor INCB059872 as a monotherapy and combination therapy in subjects with advanced malignancies. The study will be conducted in 4 parts: Parts 1 and 2 will evaluate INCB059872 as monotherapy, with Part 1 for dose escalation and Part 2 for dose expansion, and Parts 3 and 4 will evaluate INCB059872 in combination with select therapies, with Part 3 for combination dose escalation and Part 4 for combination dose expansion.

For monotherapy, Parts 1 and 2 will be combined for summary purposes. Disease history and efficacy endpoints will be summarized by tumor types (AML, MF, MDS, SCLC, Ewing's sarcoma, poorly differentiated neuroendocrine, and other solid tumors). Within each tumor type, data will be summarized overall and by dose levels based on the dose regimen initially assigned. Summary tables for some tumor types may be replaced with listings when appropriate. For instance, an efficacy summary table for a cancer type may be replaced with a listing if this cancer type only contains a few subjects. All other data, including demographics, baseline disease characteristics, disposition, and safety, will be summarized separately for hematologic malignancies (TG A/A1/A2 combined as Group A) and solid tumor malignancies (TG B/B1/B2 combined as Group B). Within each group, data will be summarized overall and by dose levels based on the dose regimen initially assigned.

For combination therapy (Parts 3 and 4), all data in dose escalation and dose expansion will be combined and summarized by the following defined groups:

- Group C = TG C + TG C1;
- Group D = TG D + TG D1;
- Group E = TG E + TG E1.

Within each group, data will be summarized overall and by dose levels 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

5.3.1. Full Analysis Set

The FAS includes all subjects enrolled in the study who received at least 1 dose of INCB059872, ATRA, azacitidine, or nivolumab.

The FAS will be used for the summary of demographics, baseline characteristics, subject disposition, and analyses of all efficacy data.

5.3.2. Safety Population

The safety population includes all enrolled subjects who received at least 1 dose of INCB059872, ATRA, azacitidine, or nivolumab.

All safety analyses will be conducted using the safety population.

5.3.3. Pharmacokinetic Evaluable Population

The PK-evaluable population includes all subjects who received at least 1 dose of study treatment and provided at least 1 postdose sample (1 PK measurement). The study pharmacokineticist will review data listings of study drug administration and sample records to identify subjects to be excluded from analyses of PK data.

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

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

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

6.1.1. Demographics and Baseline Characteristics

The following demographics will be summarized for the FAS: age, sex, race, ethnicity, weight, height, BMI, and BSA (TGs C/C1 and TGs D/D1). Size of spleen and liver by manual palpation (for subjects with MF as applicable), and ECOG performance status at baseline will be summarized and listed for the FAS.

6.1.2. Disease History

For AML subjects in the FAS, time since initial diagnosis, AML disease category, current WHO classification, French-American-British classification, European LeukemiaNET risk classification, presence of extramedullary disease, FLT3 status, IDH1 status, and IDH2 status will be summarized and listed.

For MDS subjects in the FAS, time since initial diagnosis, current WHO classification, current IPSS-R group for MDS, and current IPSS-R prognostic variable for cytogenetics will be summarized and listed.

For MF subjects in the FAS, time since initial diagnosis, current MF disease category, availability of bone marrow biopsy result, prior medications for MF, prior splenic irradiation, transfusion dependence per protocol definition, prognostic factors, IWG risk level, and JAK2 status will be summarized and listed.

For SCLC subjects in the FAS, time since initial diagnosis, stage at initial diagnosis, current stage of disease, current sites of disease, MYC rearrangement status, and PD-L1 status will be summarized and listed.

For Ewing's sarcoma subjects in the FAS, time since advanced/metastatic diagnosis, stage at initial diagnosis, grade at initial diagnosis, sites of disease at initial diagnosis, current stage of disease, current sites of disease, cytogenetics status, CDKN2A status, TP53 status, and STAG2 status will be summarized and listed.

For subjects with poorly differentiated neuroendocrine in the FAS, time since initial diagnosis, stage at initial diagnosis, current stage of disease, current sites of disease, MYC rearrangement status, and PD-L1 status will be summarized and listed.

For subjects with other solid tumors in the FAS, time since initial diagnosis, stage at initial diagnosis, current stage of disease, solid tumor cancer type, current sites of disease, MYC rearrangement status, and PD-L1 status will be summarized and listed.

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 Cancer Therapy

The number of prior systemic cancer therapy regimens will be summarized for all subjects in the FAS. The component drugs of prior systemic therapy regimens will be coded using the WHO Drug Dictionary. The number and percentage of subjects with each drug will be summarized by WHO drug class and WHO drug preferred term. 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 subjects who received prior radiation will be summarized for the FAS. Radiotherapy type, location of administration, start and stop dates, reason for regimen, total dose, and best response will be listed.

The number of subjects who had prior surgery or surgical procedure for cancer treatment will be summarized for the FAS. Date and description of the surgery/procedure will be listed.

The number of subjects who had hematopoietic stem cell transplant (for hematologic tumor types as applicable) will be summarized for the FAS. Date of transplant, type of transplant, source cell, line of therapy, best response, date of relapse/progression, and the regimen and drug names used with the transplant will be listed.

6.1.4. Medical History

Medical history will be coded to SOC and PT using MedDRA coding dictionary. For subjects in the FAS, medical history will be summarized by SOC and PT and listed.

6.2. Disposition of Subjects

The number and percentage of subjects who were treated, discontinued study treatment with a primary reason for discontinuation, and withdrew from the study with a primary reason for withdrawal will be summarized and listed for the FAS.

The number of subjects enrolled by country and site will also be provided for the full analysis set.

6.3. Protocol Deviations

Protocol deviations recorded on the eCRF will be summarized and listed for the full analysis set.

6.4. Exposure

For subjects in the safety population, exposure to INCB059872, ATRA, azacitidine, and nivolumab will be summarized descriptively as the following:

6.4.1. Exposure for INCB059872

- **Duration of treatment (days):** Date of last dose of INCB059872 – date of first dose of INCB059872 + 1.
- **Average reported daily dose of INCB059872 (mg/day):** Total reported INCB059872 dose (mg) / duration of treatment with INCB059872 (days).
- **Dose modifications for INCB059872:** Number of subjects who had INCB059872 dose reduction and interruption will be summarized.

6.4.2. Exposure for All-Trans Retinoic Acid

- **Duration of treatment (days):** Date of last dose of ATRA – date of first dose of ATRA + 1.
- **Average reported daily dose of ATRA (mg/day):** Total reported ATRA dose (mg) / duration of treatment with ATRA (days).
- **Dose modifications for ATRA:** Number of subjects who had ATRA dose reduction and interruption will be summarized.

6.4.3. Exposure for Azacitidine

- **Number of cycles**: Number of cycles with a nonzero dose of azacitidine.
- **Relative dose intensity of azacitidine (%):** 100 × [total actual dose] / [total assigned dose].

  Total actual dose (mg/m^2) administered is the sum of the BSA-adjusted cumulative dose of azacitidine that has been administered to the subject.

  Total assigned dose (mg/m^2) is the total dose expected if the subject had taken all doses as initially assigned. Let S be the study day of the last date that the subject is exposed to azacitidine. Let D be the assigned dose level of 75 in mg/m^2. The total assigned dose is defined as

  total assigned dose (mg/m^2) = $D \times 7 \times \{\lfloor S/28 \rfloor + min[(S - 28 \times \lfloor S/28 \rfloor)/7,\ 1]\}$,

  where $\lfloor . \rfloor$ assigns the largest integer not greater than the argument.
- **Azacitidine dose modifications:** Number of subjects who had azacitidine dose reduction and interruption will be summarized.

6.4.4. Exposure for Nivolumab

- **Number of cycles:** Number of cycles with a nonzero dose of nivolumab.
- **Relative dose intensity of nivolumab (%):** 100 × [total actual dose] / [total assigned dose].

  Total actual dose (mg/kg) administered is the sum of the weight-adjusted cumulative dose of nivolumab that has been administered to the subject.

  Total assigned dose (mg/kg) is the total dose expected if the subject had taken all doses as initially assigned. Let S be the study day of the last date that the subject is exposed to nivolumab. Let D be the assigned dose level of 3 in mg/kg. The total assigned dose is defined as

  total assigned dose (mg/kg) = $D \times (\lceil S/28 \rceil + \lceil (S - 14) / 28 \rceil)$,

  where $\lceil . \rceil$ assigns the smallest integer not less than the argument.
- **Nivolumab dose modifications:** Number of subjects who had nivolumab dose reduction and interruption will be summarized.

6.5. Study Drug Compliance

For subjects in the safety population, overall compliance (%) for INCB059872 will be calculated for all subjects as

compliance (%) = 100 × [total dose actually taken] / [total prescribed dose].

The total prescribed dose is defined as the sum of the doses prescribed by the investigator accounting for dose modifications.

The total actual dose taken will be calculated based on information entered on the drug accountability eCRF. If there are dispensed drugs that have not been returned yet, the actual dose taken starting from the dispense date of the unreturned drugs will be imputed by the dose taken as reported on the dosing eCRF.

6.6. Prior and Concomitant Medication

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary. Number and percentage of subjects in the FAS with each prior and concomitant medications will be summarized by WHO drug class and WHO drug preferred term.

7. EFFICACY

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

7.1. General Considerations

For subjects with solid tumors, AML, and MDS, the proportion of subjects who meet the response criteria as appropriate for the tumor type will be summarized with descriptive statistics. [redacted]. For MF subjects, changes and percentage changes in spleen volume from baseline to Week 12 [redacted] will be summarized descriptively. All efficacy analyses will be performed using the FAS.

7.2. Efficacy Hypotheses

Not applicable.

7.3. Analysis of the Efficacy Parameters

7.3.1. Solid Tumors

7.3.1.1. Response Assessment

Tumor assessment for subjects with solid tumors will be performed using RECIST v1.1 (Eisenhauer et al 2009). The investigator's assessment will be used to determine responses and will be logged into the eCRF. The schedule for solid tumor assessment will be at screening, every 8 weeks during the study treatment, at the EOT visit, and every 8 to 9 weeks during the disease status follow-up.

Response status per investigator's assessment for solid tumor will be recorded at each response assessment visit as CR, PR, SD, PD, NE, or not assessed.

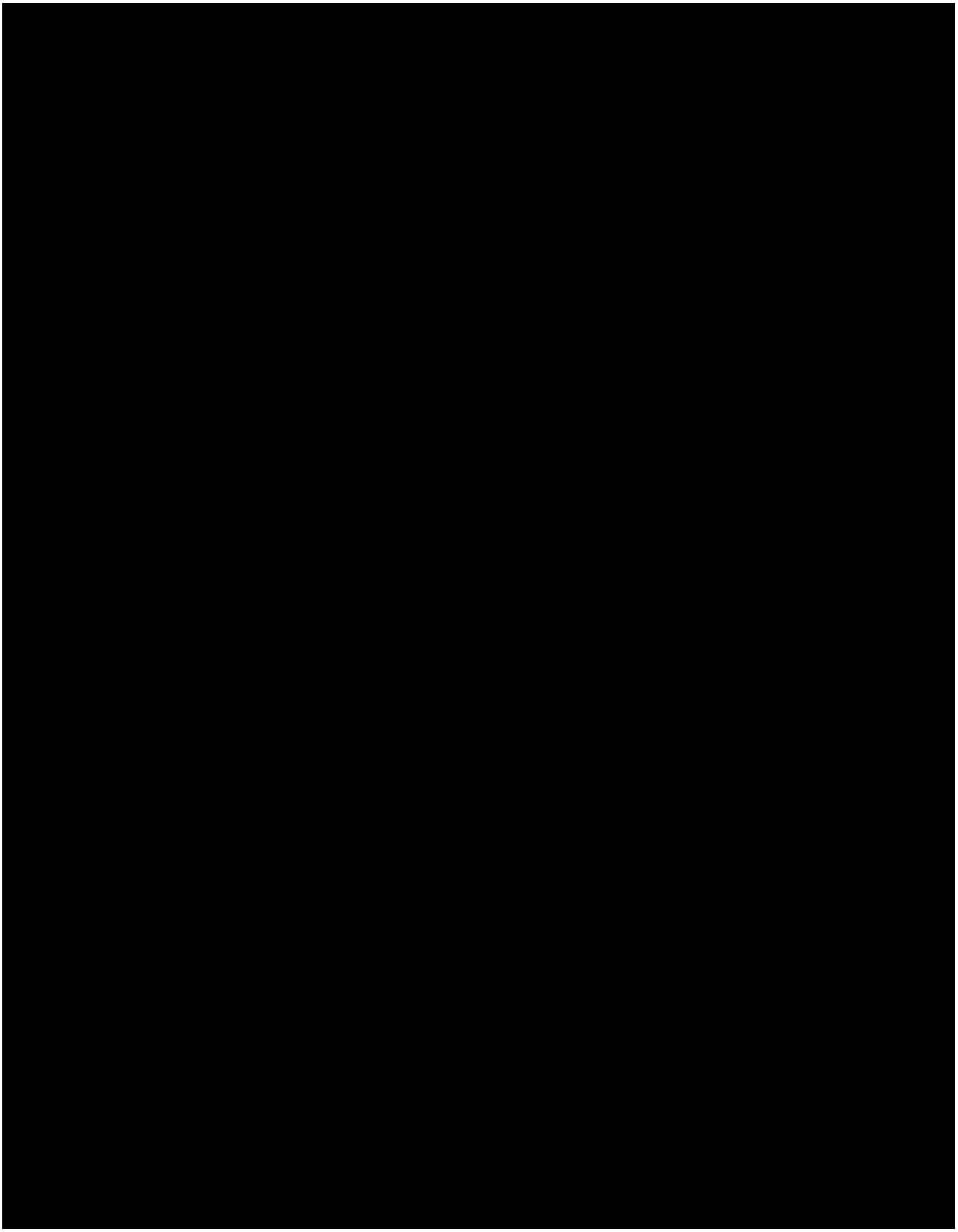
7.3.1.2. Best Overall Response and Objective Response Rate

Best overall response for subjects with solid tumors is the best response recorded before 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 criterion at least once on or after Day 42. Subjects 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.

A subject is considered a responder if the subject has a BOR of CR or PR.

Objective response rate is the proportion of responders. Subjects 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 calculations of ORR.

Best overall response will be summarized descriptively. Objective response rate will be estimated with its 95% CI. Confidence intervals will be calculated based on the exact method for binomial distributions.



7.3.1.6. Best Change in Target Lesion Size

For subjects with measurable lesions at baseline, target lesion sizes will be measured by the sum of diameters. The best percentage change from baseline, defined as the largest decrease in target lesion sizes during the study, will be summarized and a waterfall plot of the best percentage change will be generated. Note that for subjects who only have increases in target lesion sizes from baseline, the smallest increase will be considered as the best change from baseline.

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

7.3.2. Acute Myeloid Leukemia

7.3.2.1. Response Assessment

Disease assessment for subjects with AML will be performed following the IWG Response Criteria for AML (Cheson et al 2003). The investigator's assessment will be used to determine responses and will be logged on the eCRF. The schedule for disease assessment will be at screening, every 4 weeks during the study treatment, at the EOT visit, and every 8 to 9 weeks during the disease status follow-up.

Response status per investigator's assessment for AML will be recorded in terms of 3 aspects: (1) altering the natural history of the disease, (2) cytogenetic response, and (3) molecular response. For altering the natural history of the disease, response status will be recorded at each response assessment as CR, CRi, MLFS, PR, peripheral blood blast response, SD, PD, relapse, or treatment failure. For cytogenetic response, response status will be recorded at each response assessment visit as CCyR, no response, not assessed, or NA (ie, normal karyotype). For molecular response, response status will be recorded at each response assessment visit as CMR, no response, not assessed, or NA (ie, no molecular abnormality identified). Refer to Appendix D in the Protocol for the summarized description of the IWG Response Criteria for AML.

7.3.2.2. Best Overall Response and Objective Response Rate

7.3.2.2.1. Altering the Natural History of the Disease

For AML, BOR based on altering the natural history of the disease is the best response recorded before and including the first progression, which consists of treatment failure, relapse, and PD, in the order of CR, CRi, MLFS, PR, peripheral blood blast response, SD, and progression. In the case of SD, measurements must meet the SD criterion at least once on or after Day 24.

A subject is considered a responder if the subject has a BOR of CR or CRi.

Objective response rate is defined as the proportion of responders based on altering the natural history of the disease. Subjects 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 calculations of ORR.

Best overall response will be summarized descriptively. Objective response rate will be estimated with its 95% CI. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.2.2.2. Cytogenetic Response

Cytogenetic response is applicable for subjects with abnormal karyotype at baseline. Best overall response for cytogenetic response is the best response recorded before and including the time when the first progression based on altering the natural history of the disease occurs, in the order of CCyR, no response, and not assessed.

Best overall response will be summarized descriptively for subjects with abnormal karyotype at baseline.

7.3.2.2.3. Molecular Response

Molecular response is applicable for subjects with molecular abnormality at baseline. Best overall response for molecular response is the best response recorded before and including the time when the first progression based on altering the natural history of the disease occurs, in the order of CMR, no response, and not assessed.

Best overall response will be summarized descriptively for subjects with molecular abnormality at baseline.

7.3.3. Myelodysplastic Syndrome

7.3.3.1. Response Assessment

Disease assessment for MDS subjects will be performed following the IWG Response Criteria for MDS (Cheson et al 2006). The investigator's assessment will be used to determine responses and will be logged on the eCRF. The schedule for disease assessment will be at screening, every 4 weeks during the study treatment, at the EOT visit, and every 8 to 9 weeks during the disease status follow-up.

Response status per investigator's assessment for MDS will be recorded in terms of 3 aspects: (1) altering the natural history of the disease, (2) cytogenetic response, and (3) hematologic improvement. For altering the natural history of the disease, response status will be recorded at each response assessment visit as CR, PR, marrow CR, SD, PD, treatment failure, disease transformation, or relapse after CR or PR. For cytogenetic response, response status will be recorded at each response assessment visit as CCyR, PCyR, or NA. For hematologic improvement, response status will be recorded at each response assessment visit as HI-E, HI-P, HI-N, progression or relapse after hematologic improvement, or NA. Refer to Appendix F in the Protocol for the summarized description of the IWG Response Criteria for MDS.

7.3.3.2. Best Overall Response and Objective Response Rate

7.3.3.2.1. Altering the Natural History of the Disease

For MDS, BOR based on altering the natural history of the disease is the best response recorded before and including the first progression, which consists of treatment failure, PD, disease transformation, and relapse after CR or PR, in the order of CR, PR, marrow CR, SD, and progression. In the case of SD, measurements must meet the SD criterion at least once on or after Day 24. When analysis requires the confirmation of CR, PR, or marrow CR, responses must be at least 4 weeks in duration and the rule in Table 3 should be applied.

Table 3: Confirmation of Complete Remission, Partial Remission, and Marrow Complete Remission for Myelodysplastic Syndrome

First Assessment	Subsequent Assessment at 4 or More Weeks Later	Confirmed Response
CR	CR	CR
PR	PR or CR	PR
Marrow CR	Marrow CR, PR, or CR	Marrow CR

A subject is considered a responder if the subject has a best overall response of CR.

Objective response rate for MDS is defined as the proportion of responders based on altering the natural history of the disease. Subjects 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 calculations of ORR.

Non-confirmatory BOR will be summarized descriptively, and the ORR will be estimated with its 95% CI. Best confirmed response of CR, PR, and marrow CR will be summarized descriptively. The confirmed ORR will be estimated with its 95% CI. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.3.2.2. Cytogenetic Response

Cytogenetic response is applicable for subjects with abnormal karyotype at baseline. Best overall response for cytogenetic response is the best response recorded before and including the time when the first progression based on altering the natural history of the disease occurs, in the order of CCyR or PCyR.

Best overall response will be summarized descriptively. Subjects with abnormal karyotype at baseline will be used as the denominators in the summary of BOR.

7.3.3.2.3. Hematologic Improvement

The number of subjects who had at least one hematologic improvement in post baseline assessments along with the corresponding subcategories (ie, HI-E, HI-P, or HI-N) will be summarized descriptively.

[redacted]

7.3.4. Myelofibrosis

The MF disease assessments will be at screening, every 4 weeks during the study treatment, at the EOT visit, and every 8 to 9 weeks during the disease status follow-up. [redacted]

7.3.4.1. Spleen Volume Reduction

The change and percentage change from baseline as measured by MRI (or CT scan in applicable subjects) at Week 12 [redacted] in spleen volume will be calculated for subjects with MF in the FAS. Descriptive statistics will be calculated by dose levels for the baseline value, Week 12 value, change and percentage change from baseline to Week 12, [redacted].

The number of subjects with spleen volume reduction from baseline to Week 12 [redacted] in pre-defined categories (eg, < 0% reduction, 0% to < 10% reduction, 10% to < 35% reduction, and ≥ 35% reductions) will be summarized by dose levels.

[redacted]

7.4. Analysis of Other Efficacy Variables

7.4.1. Eastern Cooperative Oncology Group Performance Status

The ECOG status at scheduled assessment times will be summarized categorically by dose levels and tumor type.

8. PHARMACOKINETIC ANALYSES

The PK parameters of C_{max}, T_{max}, C_{min}, AUC_{0-t}, $t_{½}$, and Cl/F (INCB059872) will be calculated from the blood plasma concentrations of INCB059872 using standard noncompartmental (model-independent) PK methods. Pharmacokinetic calculations will be performed, if appropriate, using commercial software such as WinNonlin® (Pharsight Corporation, Mountain View, CA). Nominal times will be used in all cases, except when the difference between the actual time and nominal time is greater than 15 minutes for samples collected up to 4 hours after administration and greater than 30 minutes for samples collected more than 4 hours after administration; in these cases, actual time will be used for PK analysis. Refer to Appendix C in the Protocol for a detailed list and description of the PK parameters.

9. SAFETY AND TOLERABILITY

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

9.1. 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 preferred terms reported on relatively few subjects.

9.2. Adverse Events

9.2.1. Adverse Event Definitions

A TEAE is any AE either reported for the first time or worsening of a pre-existing event after the first dose of study treatment (until 30 days after the last dose of study treatment). 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 treatment administration.

Adverse events will be tabulated by MedDRA PT and SOC. Severity of AEs will be graded using the NCI CTCAE version 4.03. 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 treatment 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, SAEs will also be tabulated.

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

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

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

9.2.2. Dose-Limiting Toxicities

The DLTs will be listed by treatment groups defined in Section 5.2 and dose levels for subjects in Parts 1 and 3.

9.2.3. Immune-Related Adverse Events

For subjects receiving INCB059872 in combination with nivolumab (TGs E and E1), the number of subjects who experienced any irAEs will be summarized by SOC, PT, and maximum severity. Refer to Appendix H in the Protocol for details of irAEs.

9.2.4. Adverse Event Summaries

An overall summary of AEs will include:

- Number (%) of subjects reporting any TEAEs
- Number (%) of subjects reporting any SAEs
- Number (%) of subjects reporting any Grade 3 or 4 TEAEs
- Number (%) of subjects reporting any TEAEs related to INCB059872
- [redacted]
- Number (%) of subjects who temporarily interrupted INCB059872 because of TEAEs
- [redacted]
- Number (%) of subjects who permanently discontinued INCB059872 because of TEAEs
- [redacted]
- Number (%) of subjects with INCB059872 dose reductions because of TEAEs
- [redacted]
- Number (%) of subjects who had a fatal TEAE

The following summaries will be produced by MedDRA term (if 10 or fewer subjects 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 4 TEAEs by SOC and PT
- Summary of Grade 3 or 4 TEAEs by PT in decreasing order of frequency
- Summary of INCB059872 treatment-related AEs by SOC and PT

- Summary of INCB059872 treatment-related AEs by PT in decreasing order of frequency
- Summary of INCB059872 treatment-related AEs by SOC, PT, and maximum severity
- Summary of Grade 3 or 4 INCB059872 treatment-related AEs by SOC and PT
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- Summary of TEAEs leading to death by SOC and PT
- Summary of serious TEAEs by SOC and PT
- Summary of serious TEAEs by PT in decreasing order of frequency
- Summary of INCB059872 treatment-related SAEs by SOC and PT
- [redacted]
- Summary of TEAEs leading to INCB059872 dose reduction by SOC and PT
- [redacted]
- Summary of TEAEs leading to INCB059872 dose interruption by SOC and PT
- [redacted]
- Summary of TEAEs leading to discontinuation of INCB059872 by SOC and PT
- [redacted]

9.3. Clinical Laboratory Tests

9.3.1. Laboratory Value Definitions

Laboratory values and change from baseline values will be summarized descriptively by visit. Baseline will be determined according to Section 4.1.3. 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 will be assessed for severity based on the numerical component of CTCAE v4.03.

9.3.2. Laboratory Value Summaries

All 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 subject's particular test at a scheduled visit, the laboratory value with the smallest laboratory sequence number will be used in by-visit summaries.

Numeric laboratory values will be summarized descriptively in SI units, and non-numeric test values will be tabulated when necessary. In addition, line graphs will be provided for hemoglobin, platelet counts, leukocytes, neutrophils, lymphocytes, and blast (for hematologic tumor types as applicable).

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 subjects in the baseline category.

9.4. Vital Signs

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

Normal ranges for vital sign values are defined in Table 4. The abnormal values for subjects exhibiting vital sign abnormalities will be listed along with their assigned dose level. Alert vital signs are defined as an absolute value outside the defined normal range and percentage change greater than 25%. The abnormal values for subjects exhibiting alert vital sign abnormalities will be listed.

Table 4: 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

9.5. Electrocardiograms

Twelve-lead ECGs including PR, RR, QT, QRS, QTcB, and QTcF intervals will be obtained for each subject 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 INCB059872 (Parts 1 and 2), INCB059872 and ATRA (TGs C and C1), INCB059872 and azacitidine (TGs D and D1), or INCB059872 and nivolumab (TGs E and E1).

Normal ranges for ECG values are defined in Table 5. Electrocardiogram values will also be considered abnormal if the absolute percentage change from baseline is more than 25% (30% for QRS interval). Subjects exhibiting ECG abnormalities will be listed with study visit and assigned dose level. 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. Outliers of QT, QTcB, and QTcF values, defined as absolute values > 450 ms, > 500 ms, or change from baseline > 30 ms, will be summarized.

Table 5: Normal Ranges for Electrocardiogram Values

Parameter	High Threshold	Low Threshold
PR	> 220 ms	< 75 ms
RR	> 1330 ms	< 600 ms
QT	> 500 ms	< 300 ms
QRS	> 120 ms	< 50 ms
QTcB, QTcF	> 470 ms	< 295 ms

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

10. INTERIM ANALYSES

10.1. Overview of Interim Analyses

In Part 4, a stopping rule for futility is planned for each combination dose expansion treatment group when 15 subjects have been treated and evaluated for response or have permanently discontinued study treatment because of disease progression, withdrawal of consent, or death. Combination TG C1 will be terminated for futility if ≤ 1 of the 15 subjects responded (ie, CR or CRi based on altering the natural history of the disease) based on assessments provided by the investigator. Combination TG D1 will be terminated for futility if ≤ 2 of the 15 subjects responded (ie, CR or CRi based on altering the natural history of the disease) based on assessments provided by the investigator. Combination TG E1 will be terminated for futility if ≤ 1 of the 15 subjects responded (ie, CR or PR) based on assessments provided by the investigator. No formal TFLs were planned for interim analyses.

An iDSMB will review safety data at regular intervals throughout the study. Details regarding membership, roles, and responsibilities of the committee are specified in the iDSMB charter. The process by which the iDSMB will make recommendations and decisions is documented in the iDSMB charter.

10.2. Derivations and Calculations for Interim Analyses

For each combination expansion group, the futility analysis will be conducted for exactly 15 subjects with the stopping boundary as stated in Section 10.1. There is no efficacy interim analysis planned for the study.

11. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 6.

Table 6: Statistical Analysis Plan Versions

SAP Version	Date
Original	01 OCT 2018

11.1. Changes to Protocol-Defined Analyses

Not applicable.

11.2. Changes to the Statistical Analysis Plan

Not applicable.

12. REFERENCES

Cheson BD, Bennett JM, Kopecky KJ, et al. Revised recommendations of the International Working Group for Diagnosis, Standardization of Response Criteria, Treatment Outcomes, and Reporting Standards for Therapeutic Trials in Acute Myeloid Leukemia. J Clin Oncol 2003;21:4642-4649.

Cheson BD, Greenberg PL, Bennett JM, et al. Clinical application and proposal for modification of the International Working Group (IWG) response criteria in myelodysplasia. Blood 2006;108:419-425.

Eisenhauer E, 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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Mosteller RD. Simplified calculation of body-surface area. N Engl J Med 1987;317:1098.

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Tefferi A, Cervantes F, Mesa R, et al. Revised response criteria for myelofibrosis: International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report. Blood 2013;122:1395-1398.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. For Parts 1 and 2 (monotherapy), the disease history and efficacy TFLs will have ".1.1" at the end of the numbering for AML, ".1.2" for MDS, ".1.3" for MF, ".1.4" for SCLC, ".1.5" for Ewing's sarcoma, ".1.6" for poorly differentiated neuroendocrine, and ".1.7" for other solid tumors; all other TFLs will have ".1.1" at the end of numbering for Group A (TG A/A1/A2 combined) and ".1.2" for Group B (TG B/B1/B2 combined). For Parts 3 and 4 (combination therapy), the TFLs will have ".2.1" at the end of the numbering for Group C (TG C/C1 combined), ".2.2" for Group D (TG D/D1 combined), and ".2.3" for Group E (TG E/E1 combined).

Standard tables will follow the conventions in the Standard Safety Tables initial version. In-text tables are identical in structure and content as appendix tables, but follow a Rich Text Format.

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

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1.3.3	Summary of Prior Systematic Cancer Therapy by WHO Drug Class and Preferred Term	FAS
1.4.1	Summary of Prior Medications	FAS
1.4.2	Summary of Concomitant Medications	FAS
1.5.1	Summary of General Medical History	FAS
2.2.1	Summary of Best Overall Response and Objective Response Rate	FAS
2.2.2	Summary of Spleen Volume Reduction	FAS
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[redacted]		
2.3.4	Summary of Best Change in Target Lesion Size	FAS
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2.3.7	Summary of ECOG Status	FAS
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3.2.11	Summary of ATRA/Azacitidine/Nivolumab Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.12	Summary of ATRA/Azacitidine/Nivolumab Treatment-Related Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety
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[redacted]	
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4.6.1	Line Plot of Mean Values Over Time for Hemoglobin
4.6.2	Line Plot of Mean Values Over Time for Platelets
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[redacted]	
2.6.10	ECOG Status
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2.7.2	Adverse Events
2.7.3	Dose-Limiting Toxicities
2.7.4	Serious Adverse Events
2.7.5	Grade 3 and Higher Adverse Events
2.7.6	Fatal Adverse Events
2.7.7	Treatment-Related Adverse Events
2.7.8	Adverse Events Leading to Interruption, Reduction, or Discontinuation of Study Treatment
2.8.1	Clinical Laboratory Values - Hematology
2.8.2	Clinical Laboratory Values - Chemistry
2.8.3	Clinical Laboratory Values - Coagulation
2.8.4	Clinical Laboratory Values - Urinalysis
2.8.5	Abnormal Clinical Laboratory Values - Hematology
2.8.6	Abnormal Clinical Laboratory Values - Chemistry
2.8.7	Abnormal Clinical Laboratory Values - Coagulation
2.8.8	Abnormal Clinical Laboratory Values - Urinalysis
2.9.1	Vital Signs
2.9.2	Abnormal Vital Sign Values
2.9.3	Alert Vital Sign Values
2.10.1	12-Lead ECG Values
2.10.2	Abnormal 12-Lead ECG Values
2.10.3	Alert 12-Lead ECG Values