STATISTICAL ANALYSIS PLAN

INCB 54329-101 / NCT02431260

A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054329 in Subjects With Advanced Malignancies

IND Number:	**124,657**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803**
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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
AML	acute myeloid leukemia
ANOVA	analysis of variance
AUC_{0-t}	AUC from time zero (predose) to time of last observed quantifiable concentration within a subject across all treatments
BET	bromodomain extra-terminal
BID	twice daily
BOR	best overall response
CCyR	complete cytogenetic response
CI	confidence interval
Cl/F	oral dose clearance
CLL	chronic lymphocytic leukemia
C_{max}	maximum observed concentration
C_{min}	minimum observed concentration
CMR	complete molecular response
c-MYC	cellular form of a regulator gene that can act as an oncogene (MYC)
CR	complete response
CRF	case report form
CRi	complete remission with incomplete recovery
CTCAE	Common Terminology Criteria for Adverse Events
DLBCL	diffuse large B-cell lymphoma
DLT	dose-limiting toxicity
DOR	duration of response
DSS	Durie Salmon stage
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EFS	event-free survival
ELN	European LeukemiaNet
FDA	Food and Drug Administration
HI	hematologic improvement
HI-E	hematologic improvement-erythroid response
HI-N	hematologic improvement-neutrophil response
HI-P	hematologic improvement-platelet response
ICF	informed consent form

Abbreviation	Term
IPSS	International Prognostic Scoring System
ISS	International Staging System
IWG	International Working Group
MDS	myelodysplastic syndrome
MDS/MPN	myelodysplastic/myeloproliferative neoplasms
MedDRA	Medical Dictionary for Regulatory Activities
MF	myelofibrosis
MLFS	morphologic leukemia-free state
MM	multiple myeloma
MR	minimal response
MTD	maximum tolerated dose
NA	not assessed
NCI	National Cancer Institute
ND	not done
NE	not evaluable
NSCLC	non–small cell lung cancer
ORR	objective response rate
OS	overall survival
PAD	pharmacologically active dose
PCyR	partial cytogenetic response
PD	progressive disease
PFS	progression-free survival
PK	pharmacokinetic
PMR	partial molecular response
PR	partial response
PT	preferred term
QD	once daily
QTcF	QT interval corrected using Fridericia's formula
RECIST	Response Evaluation Criteria in Solid Tumors
RP2D	recommended Phase 2 dose
SAE	serious adverse event
SAP	statistical analysis plan
sCR	stringent complete response
SD	stable disease
SLL	small lymphocytic lymphoma
SOC	system organ class

Abbreviation	Term
TEAE	treatment-emergent adverse event
TGA	Treatment Group A
TGB	Treatment Group B
TGC	Treatment Group C
T_{max}	time of occurrence of C_{max}
VGPR	very good partial response
WHO	World Health Organization

1. INTRODUCTION

This is a Phase 1/2, open-label, dose-escalation study of the BET inhibitor INCB054329 in subjects with advanced malignancies. Subjects will receive QD doses of INCB054329 in 21-day cycles until withdrawal criteria are met (eg, toxicity, disease progression). Alternative dosing regimens may be explored based on emerging PK, pharmacodynamics, and safety data.

The study will be conducted in 3 parts: Part 1 Dose Escalation will determine the MTD of INCB054329 and/or a tolerated dose that reaches the desired target inhibition (ie, a PAD). Part 2 Dose Titration will determine the feasibility of intrasubject dose titration using Protocol-defined criteria. Part 3 Dose Expansion will evaluate the doses and schedules selected in Part 1 and Part 2 in subjects with select tumor types postulated to be particularly susceptible to BET inhibition.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the Study INCB 54329-101 Protocol. The scope of this plan includes analyses that are planned and will be executed by the Department of Biostatistics or designee, and the analyses of PK data. The [redacted] pharmacodynamics data are not described in this SAP.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on Study INCB 54329-101 Amendment 2 dated 08 DEC 2016 and CRFs approved on 01 MAY 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 Objective

- To evaluate the safety and tolerability of INCB054329 in subjects with advanced malignancies.

2.2.2. Secondary Objectives

- To evaluate the PK and pharmacodynamics of INCB054329 in subjects with advanced malignancies.
- To evaluate preliminary efficacy of INCB054329 in subjects with advanced malignancies.

[redacted]

2.3. Study Endpoints

2.3.1. Primary Endpoint

- Safety and tolerability will be 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.

2.3.2. Secondary Endpoints

- Pharmacokinetics of INCB054329, including C_{max}, T_{max}, C_{min}, AUC_{0-t}, and Cl/F at Days 1, 2, 8, 15, and 16 of Cycle 1, for subjects in Parts 1, 2 and 3 and any cycle where dose escalation occurs.
- Pharmacodynamic profile of INCB054329 using a whole blood pharmacodynamics assay.
- Evaluation of ORR, PFS, DOR, and OS for subjects in Part 2 and Part 3.

[redacted]

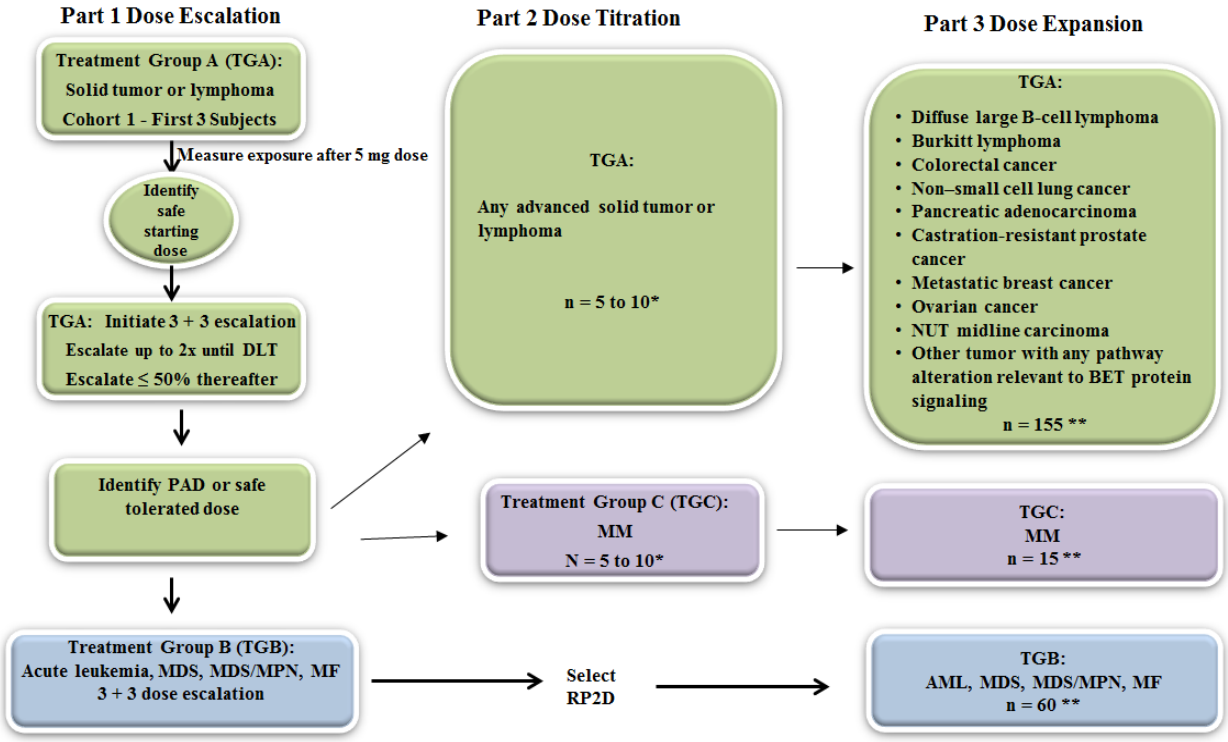
3. STUDY DESIGN

This is a Phase 1/2, open-label, dose-escalation study of INCB054329 in subjects with advanced malignancies. Subjects will receive QD doses of INCB054329 in 21-day cycles until withdrawal criteria are met (eg, toxicity, disease progression). The study will be conducted in 3 parts:

- Part 1 Dose Escalation will determine the MTD of INCB054329 and/or a tolerated dose that reaches the desired target inhibition (ie, a PAD).
- Part 2 Dose Titration will determine the feasibility of intrasubject dose titration using Protocol-defined criteria.
- Part 3 Dose Expansion will evaluate the doses and schedules selected in Part 1and Part 2 in subjects with select tumor types postulated to be particularly susceptible to BET inhibition (refer to Protocol Section 3.2, Subject Inclusion Criteria).

The study design is shown in Figure 1.

Figure 1: Study Design



*Part 2 Dose Titration: TGA and TGC will enroll simultaneously at least 5 subjects and up to approximately 10 subjects per treatment group titrating each subject per Protocol-defined dose titration criteria.
** Part 3 Dose Expansion: TGA, TGB, and TGC, will enroll up to 5 subjects per tumor type in each treatment group, with the exception of 'TGA: Other tumor with c-MYC or SHH pathway activation which is considered an assorted basket and may enroll up to 15 subjects.' If ≥ 1 out of 5 of the select tumor types demonstrates clinically meaningful benefit, enrollment in that select tumor type will then continue to enroll up to approximately 15 subjects with that tumor type. If activity is not demonstrated, no further subjects will be dosed within that particular tumor type.

Part 1 Dose Escalation

The study will begin with open-label dose escalation in TGA, using a 3 + 3 design to determine the tolerated dose over a 21-day cycle. Initially, subjects in Cohort 1 will receive a single dose of INCB054329 followed by a timed PK assessment to confirm exposure approximately 1 week before continuous administration is initiated (referred to as Day 0). The starting dose for continuous administration will be determined based on the exposures assessed at this PK assessment; this dose will be no higher than 15 mg.

The dose-escalation portion of the study will be conducted in the following treatment groups:

- TGA will include subjects with any advanced solid tumor or lymphoma.
- TGB will include subjects with acute leukemia, MDS, MDS/MPN, and MF.

Escalation will begin with Cohort 1 (including the Day 0 single-dose PK assessment) in TGA. Treatment Group B will begin enrollment at the PAD (plasma concentration exceeding the PK which is projected to inhibit c-Myc level ≥ 50% for approximately 10 hours) or a tolerated dose identified in TGA at the discretion of the sponsor, and dose escalation will proceed independently to an MTD in each treatment group using a 3 + 3 design. Treatment Group C will open in Part 2 instead of Part 1 (refer to the rationale in Protocol Section 1.8). Alternative dose regimens may be explored, such as BID or intermittent dose regimens, pending emerging PK,

pharmacodynamics, and safety data. If there is a distinct discrepancy in tolerability among different disease types within the same treatment group, additional disease-specific dose-escalation schedules may be initiated.

Each dose-escalation cohort will initially enroll at least 3 subjects. If no DLTs are observed in the initial 3 subjects, the next cohort will begin enrollment at the next highest dose level. Subjects not receiving at least 80% of the planned study drug doses during the first cycle (ie, ≥ 17 of the 21 QD doses or 34 of the 42 BID doses in Cycle 1) will be considered nonevaluable for the purposes of determining the MTD (unless due to a DLT) and will be replaced. Cohorts may include an additional subject to ensure that enough evaluable subjects reach Day 21.

Dose increases between cohorts may be up to 2-fold until a Grade 2 toxicity is observed, after which dose increases will be limited to no more than 50% above the previous level. If 1 DLT is observed in the first 3 subjects in a cohort, at least 3 additional subjects will be enrolled in that cohort. If a DLT occurs in one-third or more of the total cohort (ie, ≥ 2 of 6 subjects), then the MTD will be deemed to have been exceeded, and the next lower dose level will be deemed to be the tolerated dose. Thus, the MTD will be defined as 1 dose level below that at which one-third or more of subjects in a particular cohort report DLTs. If the Cohort 1 dose is not tolerated (≥ 2 of 6 subjects report a DLT), a dose de-escalation will be considered.

If a PAD is reached before identifying the MTD, the PAD may be selected for use in the expansion cohort (Part 3), at the discretion of the sponsor.

Individual subjects within each cohort will undergo reductions/interruptions in INCB054329 administration according to prescribed safety parameters.

Part 2 Dose Titration

Part 2 will enroll 2 treatment groups to investigate the feasibility of intrasubject dose titration with Protocol-defined criteria. Part 2 TGA will enroll subjects with advanced solid tumors and lymphomas; Part 2 TGC will enroll subjects with MM. The starting dose will be the highest tolerated dose with continuous BID dose administration identified in Part 1 TGA. Based on emerging data, the starting dose for Part 2 TGA and TGC was 20 mg BID. Part 2 TGA and TGC will simultaneously enroll at least 5 subjects and up to approximately 10 subjects each. At the end of Cycle 1, if dose titration criteria are met (refer to Protocol Section 4.1.2.1), the dose may be increased to 25 mg BID on Day 1 of Cycle 2. Dose escalation by ≤ 5 mg BID increments may be permitted after each subsequent cycle of treatment if the subject continues to meet the dose escalation criteria. Dose interruptions, reductions, or termination may be implemented as described in Protocol Section 5.6. Part 2 may also explore 1 or more alternate dose regimens.

Part 3 Dose Expansion

Part 3 of the study will evaluate the dose selected in Part 1 and Part 2 in select tumor types at their respective RP2Ds; based on available data, a dose up to the MTD may be selected as the RP2D for use in each expansion cohort by the sponsor and investigators. There will be 3 treatment groups in Part 3.

Part 3 TGA will enroll up to approximately 155 subjects with specified solid tumors or lymphoma, with a goal of enrolling 5 subjects per tumor type (DLBCL, Burkett lymphoma, colorectal cancer, NSCLC, pancreatic adenocarcinoma, castration-resistant prostate cancer, metastatic breast cancer, ovarian cancer, and NUT midline carcinoma); if ≥ 1 of the 5 subjects with a select tumor type demonstrates clinically meaningful benefit, enrollment for that tumor type would continue up to approximately 15 subjects. An additional group of up to approximately 20 subjects with any tumor known to have c-MYC of sonic hedgehog pathway activation will also be enrolled, of whom no fewer than 5 will have DLBCL with a known aberration of MYC and BCL2 and/or BLC6 (ie, "double-hit" DLBCL) or B-cell lymphoma, unclassifiable with features intermediate between DLBCL and Burkitt lymphoma.

Part 3 TGB will enroll up to 60 subjects with AML, MDS, MDS/MPN, or MF.

Part 3 TGC will enroll up to approximately 15 subjects with MM.

Individual dose modifications (dose interruption, reduction, or termination) will be permitted according to Protocol-defined safety parameters. Subjects will continue to receive INCB054329 in 21-day cycles until withdrawal criteria are met (eg, toxicity, disease progression). Part 3 TGA (solid tumors and lymphoma) will also include a food-effect study for the first 12 subjects enrolled.

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% confidence level.

3.3. Sample Size Considerations

3.3.1. Sample Size in Part 1

In Part 1 of the study, the standard 3 + 3 dose escalation design will be used in 2 disease-specific treatment groups: TGA and TGB. Based on the design, within each treatment group, a minimum of 3 and up to 6 subjects will be enrolled at each dose level. The total sample size in Part 1 will depend on the frequency of DLTs and the number of dose levels tested before the MTD or PAD is reached. Up to 90 subjects will be treated in Part 1 of the study.

During the 3 + 3 dose escalation in Part 1, the probabilities of dose escalation from that dose level for various DLT rates are given in Table 1.

Table 1: Probability of Dose Escalation for Specific Dose-Limiting Toxicity Rates During 3 + 3 Dose Escalation

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%

3.3.2. Sample Size in Part 2

Part 2 will enroll 2 treatment groups, TGA and TGC, to investigate the feasibility of intrasubject dose titration. Both TGA and TGC will simultaneously enroll at least 5 and up to approximately 10 subjects each. With 5 subjects enrolled, there is > 80% chance of observing at least 1 responder if the true underlying response rate is 30%.

3.3.3. Sample Size in Part 3

Part 3 will enroll 3 treatment groups, TGA, TGB, and TGC, to evaluate the dose selected in Part 1 and Part 2 in select tumor types at their recommended Phase 2 doses. Approximately 5 subjects will be initially enrolled for each tumor type in TGA (with the exception of the group including any tumor with a known aberration in c-MYC or other genes in which BET proteins are relevant, which will enroll 20 subjects). With 5 subjects enrolled, there is > 80% chance of observing at least 1 responder if the true underlying response rate is 30%.

For each cancer type in TGB and TGC, at least 5 and up to approximately 15 subjects will be enrolled. With 5 subjects enrolled, there is ≥ 80% chance of observing at least 1 responder if the true underlying response rate is 30%.

3.4. Schedule of Assessments

Refer to Study INCB 54329-101 Protocol Amendment 2 dated 08 DEC 2016 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 analysis purpose, Day 1 is the date that the first dose of study drug (INCB054329) 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 INCB054329, 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 day 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.

For prior and concomitant medications:

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

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

4.1.5. Cycle Length and Duration

For subjects not included in the Day 0 single-dose PK assessment, Cycle 1 Day 1 is the day that the first dose of study drug is administered. For subjects in the Day 0 single-dose PK assessment, that is, the first 3 subjects of Cohort 1 in Part 1 TGA, Cycle 1 Day 1 is the day that the first dose is administered after the Day 0 dose. Scheduled cycle length is 21 days.

Actual Day 1 of subsequent cycles will correspond with the first day of administration of INCB054329 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 INCB054329.

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

- Before the date of first administration of INCB054329 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 INCB054329 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 INCB054329. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, or both prior and concomitant.

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

5. STATISTICAL METHODOLOGY

5.1. General Methodology

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

5.2. Treatment Groups

This is a Phase 1/2, open-label, dose-escalation study. The efficacy endpoints will be summarized by the appropriate disease subtype. All other data, including baseline, disposition, and safety, will be summarized overall and by treatment group based on the dose regimen initially assigned. In the event that several dose regimens tested are deemed substantially below the MTD, these doses may be combined for summary purposes.

5.3. Analysis Populations

5.3.1. Efficacy Evaluable Population

The efficacy evaluable population includes all subjects enrolled in the study who received at least 1 dose of INCB054329 and had at least 1 postbaseline disease assessment or who discontinued treatment. All efficacy analyses will be conducted using the efficacy evaluable population.

Specific analysis populations to be used for analysis by cancer type may include the following subgroups:

- Solid tumor efficacy evaluable population
- Lymphoma efficacy evaluable population
- AML efficacy evaluable population
- MDS efficacy evaluable population
- MDS/MPN efficacy evaluable population
- MF efficacy evaluable population
- MM efficacy evaluable population

5.3.2. Safety Population

The safety population includes all enrolled subjects who received at least 1 dose of INCB054329. All safety analyses will be conducted using the safety population. Analysis for demographics, baseline characteristics, disease history, and subject disposition will also be conducted using the safety population.

Specific analysis populations to be used for analysis by cancer type may include the following subgroups:

- Solid tumor safety population
- Lymphoma safety population
- AML safety population
- MDS safety population
- MDS/MPN safety population
- MF safety population
- MM safety population

5.3.3. Pharmacokinetic and Pharmacodynamic Evaluable Populations

The PK evaluable population includes all subjects who received at least 1 dose of INCB054329 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 PK analyses.

The pharmacodynamic evaluable population includes all subjects who received at least 1 dose of INCB054329 and provided at least 1 postdose sample (1 pharmacodynamic measurement). The study research investigator will review data listings of pharmacodynamic data and sample records to identify subjects to be excluded from pharmacodynamic analyses.

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Appendix A provides a list of data displays.

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

6.1.1. Demographics

The following demographics will be summarized and listed for the safety population: age, sex, race, ethnicity, height, and weight.

6.1.2. Baseline Disease Characteristics and Disease History

Baseline disease characteristics and disease history will be summarized and listed for all subjects in the safety population.

For all subjects, ECOG performance status will be summarized and listed. Manual palpation of the spleen and the result (for subjects with the applicable disease) and manual palpation of liver and the result (for subjects with the applicable disease) will also be summarized and listed.

For subjects with solid tumors, time since initial diagnosis, solid tumor cancer type, stage at initial diagnosis, current stage, MYC rearrangement status and other tumor marker test results will be summarized and listed. Summary may be provided by disease subtype if appropriate.

For subjects with lymphoma, disease subtype, time since diagnosis, results from cytogenetic testing, Ann Arbor staging, presence of B-symptoms at baseline, and tumor marker test results will be summarized and listed. For subjects with DLBCL subtype, International Prognostic Index will also be summarized and listed; for subjects with CLL or SLL subtypes, Rai staging will also be summarized and listed.

For subjects with AML, time since initial diagnosis, AML disease category, WHO classification, ELN risk classification, presence of extramedullary disease, FLT3 and other tumor marker test results will be summarized and listed.

For subjects with MDS, time since initial diagnosis, WHO classification, IPSS risk group, IPSS-R prognostic variable for bone marrow blasts, IPSS-R prognostic variable for cytogenetics, IPSS-R prognostic variable for hemoglobin/platelets/absolute neutrophils, and tumor marker test results will be summarized and listed.

For subjects with MDS/MPN, time since initial diagnosis, MDS/MPN disease type, presence of extramedullary disease, and tumor marker test results will be summarized and listed.

For subjects with MF, time since initial diagnosis, MF disease category, prior splenic irradiation, prognostic factors (only for primary MF), IWG risk level, and tumor marker test results will be summarized and listed.

For subjects with MM, time since initial diagnosis, initial DSS, initial ISS stage, current DSS, current ISS stage, current myeloma type, light chain, light chain type, and tumor marker test results will be summarized and listed.

Time since diagnosis will be calculated as:

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

6.1.3. Prior Therapy

Prior therapy will be summarized and listed for all subjects in the safety population.

Number of prior systemic cancer therapy regimens will be summarized. 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.

Number of subjects who received prior radiation will be summarized. Radiotherapy type, location of administration, start and stop dates, total dose, and best response will be listed.

Number of subjects who had prior surgery or surgical procedure for disease under study will be summarized. Date, type, and description of the surgery/procedure will be listed.

Number of subjects who had hematopoietic stem cell transplant will be summarized. Date of transplant, type of transplant, source cell, line of therapy, best response, and the medication used with the transplant will be listed.

6.1.4. Medical History

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

6.2. Disposition of Subjects

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

6.3. Protocol Deviations and Violations

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

6.4. Exposure

For subjects in the safety population, exposure to INCB054329 will be summarized descriptively as the number of cycles, duration of treatment, and average daily dose. Study drug administration data will be listed.

- **Number of cycles with INCB054329:** Number of cycles with a nonzero dose of INCB054329.
- **Duration of treatment with INCB054329 (days):** Duration of treatment (days) = date of last dose of INCB054329 – date of first dose of INCB054329 + 1.

- **Average daily dose of INCB054329 (mg/day):** total actual INCB054329 dose taken (mg) / duration of treatment with INCB054329 (days).

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

6.5. Study Drug Compliance

For subjects in the safety population, overall compliance (%) for INCB054329 will be calculated for all subjects as

Compliance (%) = 100 × [total dose actually taken (mg)] / [total prescribed dose (mg)]

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

6.6. Prior and Concomitant Medication

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

7. EFFICACY

Appendix A provides a list of data displays.

7.1. General Considerations

All efficacy analyses will be performed using the efficacy evaluable population. If there are less than 5 subjects for a disease subtype, efficacy data may be presented in data listings only.

7.2. Efficacy Hypotheses

Not applicable.

7.3. Analysis of the Efficacy Parameter

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.

Response status per investigator's assessment for solid tumors will be recorded at each response assessment visit as CR, PR, SD, PD, NE, or NA.

7.3.1.2. Best Overall Response and Objective Response Rate

Best overall response for subjects with solid tumors is the best response recorded 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 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 95% CIs. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.1.3. Progression-Free Survival

Progression-free survival for solid tumors is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or PD. The date of PD will be the timepoint at which PD is first recorded. Censoring for PFS will follow the algorithm outlined in Table 2, which is based on US FDA guidance (FDA 2007).

The number of subjects who had PD or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median PFS will be presented with its 95% CI.

Table 2: Evaluation and Censoring of Progression-Free Survival

Situation	Outcome	Date of Progression or Censoring
No baseline tumor assessments	Censored	Date of enrollment
Progression documented between scheduled visits	Progressed	Earliest of: • Date of radiological assessment showing new lesion (if progression is based on new lesion); or • Date of last radiological assessment of measured lesions (if progression is based on increase in sum of measured lesions)
No progression	Censored	Date of last valid radiologic assessment (not NE and not missing)
Treatment discontinuation for undocumented progression	Censored	Date of last valid radiologic assessment (not NE and not missing)
Treatment discontinuation for toxicity or other reason	Censored	Date of last valid radiologic assessment (not NE and not missing)
New anticancer treatment started	Censored	Date of last valid radiologic assessment (not NE and not missing)
Death before first progression assessment	Progressed	Date of death
Death between adequate assessment visits	Progressed	Date of death
Death or progression after more than 1 missed assessment	Censored	Date of last valid radiologic assessment (not NE and not missing)

7.3.1.4. Duration of Response

For responders, DOR for solid tumors is the time from the first response of CR or PR to the earlier of death or PD occurring after the first response of CR or PR. The date of PD will be the timepoint at which PD is first recorded. Censoring of DOR will follow the same algorithm as the censoring of PFS (Section 7.3.1.3).

The total number of responders, the number of subjects who had PD or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.3.1.5. Best Change in Target Lesion Size

For subjects with measurable lesions at baseline, target lesion sizes will be measured by sum of longest 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.

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 postbaseline timepoint.

7.3.2. Lymphoma

7.3.2.1. Response Assessment

Disease assessment for lymphoma subjects with subtypes other than CLL/SLL will be performed following Response Criteria for Lymphoma – The Lugano Classification (Cheson et al 2014). The investigator's assessment will be used to determine responses and will be logged into the eCRF.

Response status per investigator's assessment by PET and/or CT/MRI for lymphoma will be recorded at each response assessment visit as CR, PR, SD, PD, NE, or ND.

7.3.2.2. Best Overall Response and Objective Response Rate

Best overall response for lymphoma is the best response recorded 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 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 95% CIs. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.2.3. Progression-Free Survival

Progression-free survival for lymphoma is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or PD. The date of PD will be the timepoint at which PD is first recorded. Censoring for PFS will follow the algorithm outlined in Table 2.

The number of subjects who had PD or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median PFS will be presented with its 95% CI.

7.3.2.4. Duration of Response

For responders, DOR for lymphoma is the time from the first response of CR or PR to the earlier of death or PD occurring after the first response of CR or PR. The date of PD will be the timepoint at which PD is first recorded. Censoring of DOR will follow the same algorithm as the censoring of PFS (Section 7.3.2.3).

The total number of responders, the number of subjects who had PD or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.3.2.5. Best Change in Target Lesion Size

For subjects with measurable lesions at baseline, target lesion sizes will be measured by sum of product 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.

Target lesions considered "too small to measure" will be assigned a default value of 5 mm × 5 mm for purposes of this analysis. Likewise, target lesions identified as "not present" at postbaseline assessments will be assigned 0 mm × 0 mm for this analysis. In the event that a target lesion 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 postbaseline timepoint.

7.3.3. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

7.3.3.1. Response Assessment

Disease assessment for lymphoma subjects with CLL/SLL subtype will be performed using the International Workshop on CLL criteria for CLL (Hallek et al 2008, Cheson et al 2012). The investigator's assessment will be used to determine responses and will be logged into the eCRF.

Response status per investigator's assessment for CLL/SLL will be recorded at each response assessment visit as CR, PR, SD, PD, or NE.

7.3.3.2. Best Overall Response and Objective Response Rate

Best overall response for CLL/SLL is the best response recorded prior to and including the first PD, in the order of CR, PR, SD, PD, and NE.

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 95% CIs. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.3.3. Progression-Free Survival

Progression-free survival for CLL/SLL is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or PD. The date of PD will be the timepoint at which PD is first recorded. Censoring for PFS will follow the algorithm outlined in Table 2.

The number of subjects who had PD or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median PFS will be presented with its 95% CI.

7.3.3.4. Duration of Response

For responders, DOR for CLL/SLL is the time from the first response of CR or PR to the earlier of death or PD occurring after the first response of CR or PR. The date of PD will be the timepoint at which PD is first recorded. Censoring of DOR will follow the same algorithm as the censoring of PFS (Section 7.3.3.3).

The total number of responders, the number of subjects who had PD or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.3.3.5. Change in Peripheral Blood Leukemic Cells

For subjects with CLL/SLL, changes in peripheral blood leukemic cells, including neutrophils, platelets, hemoglobin, and lymphocytes, from baseline to each post-treatment assessment will be listed.

7.3.4. Acute Myeloid Leukemia

7.3.4.1. 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 into the eCRF.

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 complete remission, CRi, MLFS, partial remission, peripheral blood blast

response, SD, treatment failure, relapse, or PD. For cytogenetic response, response status will be recorded at each response assessment visit as CCyR, PCyR, no response, NA, or not applicable. For molecular response, response status will be recorded at each response assessment visit as CMR, PMR, no response, NA, or not applicable.

7.3.4.2. Best Overall Response and Objective Response Rate

7.3.4.2.1. Altering the Natural History of the Disease

For AML, BOR based on altering the natural history of the disease is the best response recorded prior to and including the first progression, which consists of treatment failure, relapse, or PD, in the order of complete remission, CRi, MLFS, partial remission, peripheral blood blast response, SD, and progression.

A subject is considered a responder if the subject has a BOR of complete remission, CRi, MLFS, or partial remission.

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 95% CIs. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.4.2.2. Cytogenetic Response

Cytogenetic response is applicable for subjects with abnormal karyotype at baseline. Best overall response for cytogenetic response is the best response recorded prior to and including the time when first progression based on altering the natural history of the disease occurs, in the order of CCyR, PCyR, no response, or NA.

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

7.3.4.2.3. Molecular Response

Molecular response is applicable for subjects with molecular abnormality at baseline. Best overall response for molecular response is the best response recorded prior to and including the time when first progression based on altering the natural history of the disease occurs, in the order of CMR, PMR, no response, or NA.

Best overall response will be summarized descriptively. Subjects with molecular abnormality at baseline will be included in the denominators in the summary of BOR.

7.3.4.3. Event-Free Survival

Event-free survival for AML is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or progression. The date of progression will be the timepoint at which progression is first recorded. Censoring of EFS for AML will follow the algorithm outlined in Table 3.

The number of subjects who had progression or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median EFS will be presented with its 95% CI.

Table 3: Evaluation and Censoring of Event-Free Survival

Situation	Outcome	Date of Progression or Censoring
No baseline disease assessments	Censored	Date of Day 1
No valid postbaseline response assessments	Censored	Date of Day 1
Event documented between scheduled response assessments	Event	Date of first overall assessment of event
No event	Censored	Date of last valid disease assessment (not NE and not missing)
Treatment discontinuation for undocumented event	Censored	Date of last valid disease assessment (not NE and not missing)
Treatment discontinuation for toxicity or other reason	Censored	Date of last valid disease assessment (not NE and not missing)
New anticancer treatment started	Censored	Date of last valid disease assessment (not NE and not missing) on/before starting a new anticancer treatment
Death before first event response assessment or discontinuation from study	Event	Date of death
Death between adequate response assessments	Event	Date of death

7.3.4.4. Duration of Response

For responders, DOR for AML is the time from the first response of complete remission, CRi, MLFS, or partial remission to the earlier of death or progression (ie, treatment failure, relapse, or PD) occurring after the first response of complete remission, CRi, MLFS, or partial remission. The date of progression will be the timepoint at which progression is first recorded. Censoring of DOR will follow the same algorithm as the censoring of EFS (Section 7.3.4.3).

The total number of responders, the number of subjects who had progression or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.3.5. Myelodysplastic Syndrome

7.3.5.1. Response Assessment

Disease assessment for subjects with MDS 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 into the eCRF.

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) HI. For altering the natural history of the disease, response status will be recorded at each response assessment visit as complete remission, partial remission, marrow complete remission, SD, treatment failure, disease progression, disease transformation, or relapse after complete remission or partial remission. For cytogenetic response, response status will be recorded at each response assessment visit as CCyR, PCyR, no response, or not applicable. For HI, response status will be recorded at each response assessment visit as HI-E, HI-P, HI-N, or not applicable.

7.3.5.2. Best Overall Response and Objective Response Rate

7.3.5.2.1. Altering the Natural History of the Disease

For MDS, BOR based on altering the natural history of the disease is the best response recorded prior to and including the time when first progression which consists of treatment failure, disease progression, disease transformation, and relapse after complete remission or partial remission occurs, in the order of complete remission, partial remission, marrow complete remission, SD, and progression. When analysis requires the confirmation of complete remission, partial remission, or marrow complete remission, responses must be at least 4 weeks in duration, and the rule in Table 4 should be applied.

Table 4: 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
complete remission	complete remission	complete remission
partial remission	complete remission, or partial remission	partial remission
marrow complete remission	complete remission, partial remission, or marrow complete remission	marrow complete remission

A subject is considered a responder if the subject has a BOR of complete remission, partial remission, or marrow complete remission.

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.

For non-confirmatory response, BOR will be summarized descriptively, and ORR will be estimated with 95% CIs.

For confirmatory response, the best confirmed response of complete remission, partial remission, and marrow complete remission will be summarized descriptively, and the confirmed ORR will be estimated with 95% CIs.

Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.5.2.2. Cytogenetic Response

Cytogenetic response is applicable for subjects with abnormal karyotype at baseline. Best overall response for cytogenetic response is the best response recorded prior to and including the time when the first progression based on altering the natural history of the disease occurs, in the order of CCyR, PCyR, or no response.

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

7.3.5.2.3. Hematological Improvement

The number of subjects who had at least 1 HI in postbaseline assessments along with the corresponding subcategories (ie, HI-E, HI-P, or HI-N) will be summarized descriptively.

7.3.5.3. Event-Free Survival

Event-free survival for MDS is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or progression. The date of progression will be the timepoint at which progression is first recorded. Censoring of EFS for MDS will follow the algorithm outlined in Table 3.

The number of subjects who had progression or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median EFS will be presented with its 95% CI.

7.3.5.4. Duration of Response

For responders, DOR for MDS is the time from the first response of complete remission, partial remission, or marrow complete remission to the earlier of death or progression occurring after the first response of complete remission, partial remission, or marrow complete remission. The date of progression will be the timepoint at which progression is first recorded. Censoring of DOR will follow the same algorithm as the censoring of EFS (Section 7.3.5.3).

The total number of responders, the number of subjects who had progression or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.3.6. Myelodysplastic Syndrome/Myeloproliferative Neoplasms

7.3.6.1. Response Assessment

Disease assessment for subjects with MDS/MPN will be performed following the International Consortium Proposal of Uniform Response Criteria for MDS/MPN in Adults (Savona et al 2015). The investigator's assessment will be used to determine responses and will be logged into the eCRF.

Response status per investigator's assessment for MDS/MPN will be recorded in terms of 2 aspects: (1) altering the natural history of the disease and (2) cytogenetic response. For altering the natural history of the disease, response status will be recorded at each response assessment visit as complete remission, partial remission, marrow response, clinical benefit, and

PD. For cytogenetic response, response status will be recorded at each response assessment visit as CCyR, no response, or not applicable.

7.3.6.2. Best Overall Response and Objective Response Rate

7.3.6.2.1. Altering the Natural History of the Disease

For MDS/MPN, BOR based on altering the natural history of the disease is the best response recorded prior to and including the first PD in the order of complete remission, partial remission, marrow response, clinical benefit, and PD.

A subject is considered a responder if the subject has a BOR of complete remission, partial remission, or marrow response. A subject who has an erythroid response, platelet response, neutrophil response, or spleen response (as described by Savona et al 2015) in the absence of progression or remission and independent of marrow response is considered to be receiving clinical benefit but not considered a responder.

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 95% CIs. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.6.2.2. Cytogenetic Response

Cytogenetic response is applicable for subjects with abnormal karyotype at baseline. Best overall response for cytogenetic response is the best response recorded prior to and including the time when the first PD based on altering the natural history of the disease occurs, in the order of CCyR or no remission.

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

7.3.6.3. Event-Free Survival

Event-free survival for MDS/MPN is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or PD. The date of PD will be the timepoint at which PD is first recorded. Censoring of EFS for MDS/MPN will follow the algorithm outlined in Table 3.

The number of subjects who had PD or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median EFS will be presented with its 95% CI.

7.3.6.4. Duration of Response

For responders, DOR for MDS/MPN is the time from the first response of complete remission, partial remission, or marrow response to the earlier of death or PD occurring after the first response of complete remission, partial remission, or marrow response. The date of PD will be the timepoint at which PD is first recorded. Censoring of DOR will follow the same algorithm as the censoring of EFS (Section 7.3.6.3).

The total number of responders, the number of subjects who had PD or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.3.7. Myelofibrosis

7.3.7.1. Response Assessment

Disease assessment for subjects with MF will be performed following the revised Response Criteria for MF in the IWG–Myeloproliferative Neoplasms Research and Treatment and ELN consensus report (Tefferi et al 2013). The investigator's assessment will be used to determine responses and will be logged into the eCRF.

Response status per investigator's assessment for MF will be recorded in terms of 3 aspects: (1) altering the natural history of the disease, (2) anemia response, and (3) spleen response. For altering the natural history of the disease, response status will be recorded at each response assessment visit as CR, PR, clinical improvement, SD, PD, or relapse. For anemia response, response status will be recorded at each response assessment visit as a $\geq$ 20 g/L increase in hemoglobin level (for transfusion-independent subjects) or becoming transfusion-independent (for transfusion-dependent subjects). For spleen response, response status will be recorded at each response assessment visit as baseline splenomegaly palpable at 5 to 10 cm below the LCM becoming not palpable or baseline splenomegaly palpable at > 10 cm below the LCM decreasing by $\geq$ 50%.

7.3.7.2. Best Overall Response and Objective Response Rate

7.3.7.2.1. Altering the Natural History of the Disease

For subjects with MF, BOR based on altering the natural history of the disease is the best response recorded prior to and including the time of first progression which consists of PD or relapse, in the order of CR, PR, clinical improvement, SD, and progression. When analysis requires the confirmation of CR or PR, responses must be at least 12 weeks in duration. In this case, CR or PR can be confirmed only if the same or better responses as compared with the previous ones are met at each subsequent timepoint as specified in the Protocol until benefit lasts for $\geq$ 12 weeks.

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

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.

For non-confirmatory response, BOR will be summarized descriptively, and ORR will be estimated with 95% CIs.

For confirmatory response, the best confirmed response of CR and PR will be summarized descriptively, and the confirmed ORR will be estimated with 95% CIs.

Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.7.2.2. Anemia Response

Anemia response is applicable for subjects who are transfusion-dependent at baseline. Best overall response for anemia response is the best anemia response recorded prior to and including the time when the first progression occurs for altering the natural history of disease, and in the order of: transfusion-independent subjects (a ≥ 20 g/L increase in hemoglobin level), transfusion-dependent subjects (becoming transfusion-independent), or no anemia response.

Best overall response will be summarized descriptively. Subjects who are transfusion-dependent at baseline will be included in the denominators in the summary of BOR.

7.3.7.2.3. Spleen Response

Spleen response is applicable for subjects with baseline splenomegaly that is palpable at ≥ 5 cm below the LCM. The number of subjects who had baseline splenomegaly palpable at 5 to 10 cm below the LCM that becomes not palpable or baseline splenomegaly palpable at > 10 cm below the LCM decreasing by ≥ 50% will be summarized. Subjects with baseline splenomegaly that is palpable at ≥ 5 cm below the LCM will be included in the denominators in the summary of spleen response.

7.3.7.3. Event-Free Survival

Event-free survival for MF is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or progression. The date of progression will be the timepoint at which progression is first recorded. Censoring of EFS for MF will follow the same algorithm outlined in Table 3.

The number of subjects who had progression or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median EFS will be presented with its 95% CI.

7.3.7.4. Duration of Response

For responders, DOR for MF is the time from the first response of CR, or PR to the earlier of death or progression occurring after the first response of CR or PR. The date of progression will be the timepoint at which progression is first recorded. Censoring of DOR will follow the same algorithm as the censoring of EFS (Section 7.3.7.3).

The total number of responders, the number of subjects who had progression or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.3.8. Multiple Myeloma

7.3.8.1. Response Assessment

Disease assessment for subjects with MM will be performed following the International Uniform Response Criteria for MM (Durie et al 2006) and Criteria for Evaluating Disease Response and Progression in Patients With MM Treated by High-Dose Therapy and Haemopoietic Stem Cell Transplantation (Blade et al 1998), which is for assessing MR only. The investigator's assessment will be used to determine responses and will be logged into the eCRF.

Response status per investigator's assessment for MM will be recorded at each response assessment visit as sCR, CR, VGPR, PR, MR, SD, or PD.

7.3.8.2. Best Overall Response and Objective Response Rate

Best overall response for MM is the best response recorded prior to and including the first PD, in the order of sCR, CR, VGPR, PR, MR, SD, and PD. A subject is considered a responder if they have a best overall response of sCR, CR, VGPR, 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 95% CIs. Confidence intervals will be calculated based on the exact method for binomial distributions.

7.3.8.3. Event-Free Survival

Event-free survival for MM is defined as the length of time between the start of the study drug (Day 1) and the earlier of death or PD. The date of PD will be the timepoint at which PD is first recorded. Censoring for PFS will follow the algorithm outlined in Table 3.

The number of subjects who had PD or who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median EFS will be presented with its 95% CI.

7.3.8.4. Duration of Response

For responders, DOR for MM is the time from the first response of sCR, CR, VGPR, or PR to the earlier of death or PD occurring after the first response of sCR, CR, VGPR, or PR. The date of PD will be the timepoint at which PD is first recorded. Censoring of DOR will follow the same algorithm as the censoring of EFS (Section 7.3.8.3).

The total number of responders, the number of subjects who had PD or who died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI.

7.4. Analysis of Other Efficacy Variables

7.4.1. Overall Survival

Overall survival is defined as the time from the start of the study drug (Day 1) until death from any cause. Date of death will be determined using the Death Report eCRFs. Subjects who are lost to follow-up or still alive at the time of analysis will be right-censored at the date the subject was last known to be alive. The last known alive date is defined as the later of the last study visit and the date the subject was last known to be alive.

The number of subjects who died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median OS will be presented with its 95% CI.

7.4.2. Eastern Cooperative Oncology Group Performance Status

Eastern Cooperative Oncology Group Performance status at scheduled assessment times will be summarized.

7.5. Pharmacokinetic Analyses

Pharmacokinetic analysis of INCB054329, including C_{max}, T_{max}, C_{min}, AUC_{0-t}, and Cl/F, will be performed on samples collected at the specified timepoints. The parameters will be calculated from the blood plasma concentrations of INCB054329 using standard noncompartmental (model-independent) PK methods and commercial software. The PK parameters will be summarized by descriptive statistics by part and cohort.

The log-transformed PK parameters will be compared among the dose levels by using a 1-factor ANOVA. Dose-dependent parameters (C_{max} and AUC) will be normalized to the lowest common dose before statistical comparisons. C_{max} and AUC will be evaluated using a power model, for example, $AUC = \alpha \cdot (dose^{\beta})$ or, equivalently, $\log(AUC) = \log(\alpha) + \beta \cdot \log(dose)$, where linear dose proportionality is accepted if β is not significantly different from 1. Attainment of steady-state will be assessed separately for each cohort by comparing trough plasma concentrations on Days 8 and 15.

For the food-effect assessment, the log-transformed PK parameters will be compared between the fed and fasted treatments using an ANOVA for a 1-way crossover design. The geometric mean relative bioavailability and 90% CIs will be calculated for comparing C_{max} and AUC between the fed (test) and fasted (reference) treatments. Population PK methods may be employed if there are a sufficient number of plasma PK samples.

7.6. Pharmacodynamic Analyses

Separate pharmacodynamic analyses may be provided by the Incyte Translational Sciences group.

8. SAFETY AND TOLERABILITY

Appendix A provides a list of data displays.

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.

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 (NCI 2010). The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website. If an event is not classified by CTCAE, the severity of the AE will be graded according to the scale below to estimate the grade of severity:

Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
Grade 2	Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate activities of daily living.
Grade 3	Severe or medical significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living.
Grade 4	Life-threatening consequences; urgent intervention indicated.

The subset of AEs considered by the investigator to be related to study drug will be considered to be treatment-related AEs. If the investigator does not specify the relationship of the AE to study drug, the AE will be considered to be treatment-related. The incidence of AEs and treatment-related AEs will be tabulated. In addition, 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. Therefore, an unresolved missing onset date will be considered treatment emergent, with the following exceptions:

- If the stop/resolution date is before the first dose administration date on Day 1, then the AE will be considered as not being treatment emergent.
- If both the month and day are missing, and the last day of the year is before the first dose administration date on Day 1, then the AE will not be considered treatment emergent.
- If only the day is missing, and the last day of the month is before the first dose administration date on Day 1, then the AE will not be considered treatment emergent.

8.2.2. Dose-Limiting Toxicities

Subjects with DLTs and the type of DLT will be listed.

8.2.3. Maximum Tolerated Dose

Maximum tolerated dose will be defined as 1 dose level below that at which one-third or more of subjects in a particular cohort have DLTs.

8.2.4. 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 INCB054329
- Number (%) of subjects who temporarily interrupted INCB054329 because of TEAEs
- Number (%) of subjects who permanently discontinued INCB054329 because of TEAEs
- Number (%) of subjects with INCB054329 dose reductions because of TEAEs
- 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 INCB054329 treatment-related TEAEs by SOC and PT

- Summary of INCB054329 treatment-related TEAEs by SOC, PT, and maximum severity
- 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 descending order of frequency
- Summary of INCB054329 treatment-related SAEs by SOC and PT
- Summary of TEAEs leading to INCB054329 dose reduction by SOC and PT
- Summary of TEAEs leading to INCB054329 dose interruption by SOC and PT
- Summary of TEAEs leading to discontinuation of INCB054329 by SOC and PT
- Summary of nonserious TEAEs by SOC and PT

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

Laboratory values and change from baseline values will be summarized descriptively by visit. Baseline will be determined according to Section 4.1.3. 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 incidence of abnormal laboratory values and shift tables relative to baseline will be tabulated.

8.3.2. Laboratory Value Summaries

All test results and associated normal ranges from 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, a set of standard normal ranges based on documented reference ranges will be applied to facilitate reporting the test results.

When there are multiple laboratory nonmissing values for a subject's particular test within a visit window, the convention described in Table 5 will be used to determine the record used for by-visit tabulations and summaries.

Table 5: 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	

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

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.

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.

Categorical laboratory data will be tabulated by visit at baseline and postbaseline visits whenever it is appropriate.

8.4. Vital Signs

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

Criteria for clinically notable vital sign abnormalities are defined in Table 6. 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 greater than 25%. The abnormal values for subjects exhibiting alert vital sign abnormalities will be listed.

Table 6: Criteria for Clinically Notable Vital Sign Abnormalities

Parameter	High Threshold	Low Threshold
Systolic blood pressure	> 155 mmHg	< 85 mmHg
Diastolic blood pressure	> 100 mmHg	< 45 mmHg
Pulse	> 100 bpm	< 45 bpm
Temperature	> 38ºC	< 35.5ºC
Respiratory rate	> 24 breaths/min	< 8 breaths/min

8.5. Electrocardiograms

Twelve-lead ECGs including PR, QRS, QT, QTcF, QTcB, and RR intervals will be obtained for each subject during the study. Values at each scheduled visit, change, and percentage change from baseline will be summarized for each ECG parameter. Baseline will be determined as the average of all nonmissing values before the first administration of INCB054329.

Criteria for clinically notable ECG abnormalities are defined in Table 7. 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 7: Criteria for Clinically Notable Electrocardiogram Abnormalities

Parameter	High Threshold	Low Threshold
QTcF	> 480 ms	< 295 ms
PR	> 220 ms	< 75 ms
QRS	> 120 ms	< 50 ms
QT	> 500 ms	< 300 ms
RR	> 1330 ms	< 600 ms

QTcF = Fridericia correction.

9. INTERIM ANALYSES

There are no planned, formal interim analyses for this study. Periodic review of accrued clinical data will be conducted by the sponsor. Based on review of the most current safety data, the sponsor (in consultation with the study investigators and using the dose-escalation/de-escalation rules) will determine if and at what dose(s) additional subjects should be treated in the study.

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 8.

Table 8: Statistical Analysis Plan Versions

SAP Version	Date
Original	05 APR 2018

10.1. Changes to Protocol-Defined Analyses

Not applicable.

10.2. Changes to the Statistical Analysis Plan

Not applicable.

11. REFERENCES

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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 AND FIGURES

This appendix provides a list of the planned tables, listings, and figures for the clinical study report. Standard tables will follow the conventions in the Standard Safety Tables initial version. In-text tables are identical in structure and content to appendix tables, but follow a Rich Text Format.

The lists of tables, listings, and figures 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.

Tables

Table No.	Title	Population	Standard	In-Text
1.1.1	Analysis Populations	Safety	X	X
1.1.2	Summary of Subject Disposition	Safety	X	X
1.2.1	Summary of Demographics	Safety	X	X
1.3.1.1.1	Summary of Baseline Disease Characteristics and Disease History-Breast Cancer	Safety		X
1.3.1.1.2	Summary of Baseline Disease Characteristics and Disease History-Castration-Resistant Prostate Cancer	Safety		
1.3.1.1.3	Summary of Baseline Disease Characteristics and Disease History-Colorectal Cancer	Safety		X
1.3.1.1.4	Summary of Baseline Disease Characteristics and Disease History-Non–Small Cell Lung Cancer	Safety		
1.3.1.1.5	Summary of Baseline Disease Characteristics and Disease History-Nut Midline Carcinoma	Safety		X
1.3.1.1.6	Summary of Baseline Disease Characteristics and Disease History-Ovarian Cancer	Safety		
1.3.1.1.7	Summary of Baseline Disease Characteristics and Disease History-Pancreatic Cancer	Safety		
1.3.1.1.8	Summary of Baseline Disease Characteristics and Disease History-Other Solid Tumor	Safety		
1.3.1.2	Summary of Baseline Disease Characteristics and Disease History-Lymphoma	Safety		X
1.3.1.3	Summary of Baseline Disease Characteristics and Disease History-CLL/SLL	Safety		X
1.3.1.4	Summary of Baseline Disease Characteristics and Disease History-AML	Safety		X
1.3.1.5	Summary of Baseline Disease Characteristics and Disease History-MDS	Safety		X
1.3.1.6	Summary of Baseline Disease Characteristics and Disease History-MDS/MPN	Safety		X
1.3.1.7	Summary of Baseline Disease Characteristics and Disease History-MF	Safety		X
1.3.1.8	Summary of Baseline Disease Characteristics and Disease History-MM	Safety		X
1.3.2	Summary of Prior Cancer Therapy	Safety		
1.3.3	Summary of Prior Cancer Medications	Safety	X	
1.4.1	Summary of Prior Medications	Safety	X	
1.4.2	Summary of Concomitant Medications	Safety	X	
1.5.1	Summary of General Medical History	Safety	X	

Table No.	Title	Population	Standard	In-Text
2.1.1.1	Summary of Best Response and Objective Response Rate-Solid Tumor	Efficacy Evaluable		X
2.1.1.2	Summary of Best Response and Objective Response Rate-Lymphoma	Efficacy Evaluable		X
2.1.1.3	Summary of Best Response and Objective Response Rate-CLL/SLL	Efficacy Evaluable		X
2.1.1.4	Summary of Best Response and Objective Response Rate-AML	Efficacy Evaluable		X
2.1.1.5	Summary of Best Response and Objective Response Rate-MDS	Efficacy Evaluable		X
2.1.1.6	Summary of Best Response and Objective Response Rate-MDS/MPN	Efficacy Evaluable		X
2.1.1.7	Summary of Best Response and Objective Response Rate-MF	Efficacy Evaluable		X
2.1.1.8	Summary of Best Response and Objective Response Rate-MM	Efficacy Evaluable		X
2.2.1	Summary of Overall Survival	Efficacy Evaluable		X
2.2.2.1	Summary of Progression-Free Survival	Efficacy Evaluable		X
2.2.2.2	Summary of Event-Free Survival	Efficacy Evaluable		X
2.2.3	Summary of Duration of Response	Efficacy Evaluable		X
2.2.4	Summary of Best Change in Target Lesion Size	Efficacy Evaluable		X
2.3.1	Summary of ECOG status	Efficacy Evaluable		
3.1.1	Summary of Exposure and Compliance	Safety	X	X
3.2.1	Overall Summary of Treatment-Emergent Adverse Events	Safety	X	X
3.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	X	X
3.2.4	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Safety	X	
3.2.5	Summary of Grade 3 or 4 Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.6	Summary of INCB054329 Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.7	Summary of INCB054329 Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Safety	X	X
3.2.8	Summary of Treatment-Emergent Adverse Events Leading to Death by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.9	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.10	Summary of Serious Treatment-Emergent Adverse Events by Preferred Term in Decreasing Order of Frequency	Safety	X	X

Table No.	Title	Population	Standard	In-Text
3.2.11	Summary of INCB054329 Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.12	Summary of Treatment-Emergent Adverse Events Leading to INCB054329 Dose Reduction by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.13	Summary of Treatment-Emergent Adverse Events Leading to INCB054329 Dose Interruption by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.14	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCB054329 by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.15	Summary of Nonserious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	
3.3.1	Summary of Laboratory Values – Hematology	Safety	X	
3.3.2	Shift Summary of Hematology Laboratory Values in CTC Grade – to the Worst Abnormal Value	Safety	X	X
3.3.4	Summary of Laboratory Values – Chemistry	Safety	X	
3.3.5	Shift Summary of Chemistry Laboratory Values in CTC Grade – to the Worst Abnormal Value	Safety	X	X
3.3.7	Summary of Laboratory Values – Coagulation	Safety	X	
3.3.8	Shift Summary of Coagulation Laboratory Values in CTC Grade – to the Worst Abnormal Value	Safety	X	
3.3.9	Summary of Laboratory Values – Urinalysis	Safety	X	
3.4.1	Summary of Systolic Blood Pressure	Safety	X	
3.4.2	Summary of Diastolic Blood Pressure	Safety	X	
3.4.3	Summary of Pulse	Safety	X	
3.4.4	Summary of Respiratory Rate	Safety	X	
3.4.5	Summary of Body Temperature	Safety	X	
3.4.6	Summary of Body Weight	Safety	X	
3.5.1	Summary of PR Interval (ms) From 12-Lead ECG	Safety	X	
3.5.2	Summary of RR Interval (ms) From 12-Lead ECG	Safety	X	
3.5.3	Summary of QT Interval (ms) From 12-Lead ECG	Safety	X	
3.5.4	Summary of QRS Interval (ms) From 12-Lead ECG	Safety	X	
3.5.6	Summary of QTcF Interval (ms) From 12-Lead ECG	Safety	X	
3.5.7	Summary of Outliers of QT and QTcF Interval Values From 12-Lead ECG	Safety	X	

Figures

Figure No.	Title
4.1.1	Kaplan-Meier Estimates of Overall Survival
4.2.1.1	Kaplan-Meier Estimates of Progression-Free Survival
4.2.1.2	Kaplan-Meier Estimates of Event-Free Survival
4.2.2	Kaplan-Meier Estimates of Duration of Response
4.3.3	Waterfall Plot of Best Percentage Change in Sum of Target Lesions
4.4.1	Line Graph of Selected Laboratory Values by Study Visit
4.4.2	Box-and-Whisker Plot of Selected Laboratory Values by Study Visit

Listings

Listing No.	Title
2.1.1	Subject Enrollment and Disposition Status
2.1.2	Subject Inclusion and Exclusion Criteria Violations
2.2.1	Protocol Deviations and Violations
2.3.1	Analysis Populations
2.4.1	Demographic Characteristics
2.4.2	Baseline Disease Characteristics and Disease History
2.4.3	Prior Radiation Treatment
2.4.4	Prior Systemic Therapy
2.4.5	Prior Surgery or Surgical Procedure
2.4.6	Prior Stem Cell Transplant
2.4.7	Medical History
2.4.8	Prior and Concomitant Medication
2.5.1	Study Drug Administration and Compliance
2.6.1	Deaths
2.6.2.1	Best Overall Response, Duration of Response, Overall Survival, and Progression-Free Survival
2.6.2.2	Best Overall Response, Duration of Response, Overall Survival, and Event-Free Survival
2.6.3	Overall Response Assessment by Visit
2.6.4	Response Assessment: Target Lesions
2.6.5	Response Assessment: Non-Target Lesions
2.6.6	Response Assessment: New Lesions
2.6.7	ECOG Status
2.7.1	Adverse Events
2.7.2	Dose-Limiting Toxicities
2.7.3	Serious Adverse Events
2.7.4	Grade 3 and Higher Adverse Events
2.7.5	Adverse Events Leading to Death
2.7.6	Treatment-Related Adverse Events
2.7.7	Adverse Events Leading to Interruption, Reduction, or Discontinuation of INCB054329
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

Signature Manifest

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