Official Title:	**A Phase1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies (FIGHT-101)**
NCT Number:	NCT02393248
Document Date:	Statistical Analysis Plan Amendment 1: 12 June 2019

STATISTICAL ANALYSIS PLAN

INCB 54828-101

A Phase 1/2, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB054828 in Subjects With Advanced Malignancies (FIGHT-101)

IND Number:	[redacted]
EudraCT Number:	**2016-002831-14**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803**
Protocol Version:	**Protocol Amendment 8 (11 DEC 2018)**
CRF Approval Date:	**05 FEB 2019**
SAP Version:	**Amendment 1**
SAP Author:	[redacted]
Date of Plan:	**12 JUN 2019**

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

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LIST OF ABBREVIATIONS

Abbreviation	Term
AE	adverse event
ALT	alanine aminotransferase
aPTT	activated partial thromboplastin time
AST	aspartate aminotransferase
$AUC_{(0-\tau)}$	AUC from time zero (predose) to time of last observed quantifiable concentration within a subject across all treatments
BMI	body mass index
BOR	best overall response
BSA	body surface area
CL/F	apparent oral dose clearance
C_{max}	maximum observed concentration
C_{min}	minimum observed concentration
CR	complete response
CRF	case report form
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DLT	dose-limiting toxicity
[redacted]	[redacted]
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EOT	end of treatment
FDA	Food and Drug Administration
FGF	fibroblast growth factor
FGFR	fibroblast growth factor receptor
IMWG	International Myeloma Working Group
LLN	lower limit of normal
MedDRA	Medical Dictionary for Regulatory Activities
MPN	myeloproliferative neoplasm
MTD	maximum tolerated dose
NE	not evaluable
ORR	overall response rate
PAD	pharmacologically active dose
PD	pharmacodynamics or progressive disease
[redacted]	[redacted]
PK	pharmacokinetics
PR	partial response
QD	once daily

Abbreviation	Term
RECIST	Response Evaluation Criteria in Solid Tumors
RP2D	recommended Part 2 dose
SD	stable disease
SAP	Statistical Analysis Plan
SI	International System of Units
TEAE	treatment-emergent adverse event
ULN	upper limit of normal

1. INTRODUCTION

This is a Phase 1, open-label, dose-escalation, safety and tolerability study of the FGFR inhibitor INCB054828 in subjects with advanced malignancies. The study will be conducted in 3 parts. Part 1 (monotherapy dose escalation) will determine the MTD of INCB054828 and/or doses/regimen that produce substantial evidence of pharmacologic target inhibition (increased serum phosphate). Approximately 20 subjects with moderate and severe renal impairment will be enrolled in Part 1 for safety and PK evaluation. Part 2 (monotherapy dose expansion) will evaluate the dose(s) selected in Part 1 as a monotherapy in specific indications where activity of FGFR is particularly relevant. Approximately 8 subjects enrolled in Part 2 will participate in a food-effect study. Part 3 will begin with dose-finding to determine recommended expansion doses of INCB054828 in combination with gemcitabine + cisplatin, docetaxel, pembrolizumab, trastuzumab, or INCMGA00012 in subjects for which these treatments or PD-1–directed treatment is relevant. Dose-expansion will further evaluate the dose(s) selected in these populations harboring FGF/FGFR alterations.

A detailed description of the investigational product, target patient population, rationale for doses to be examined, and potential risks and benefits of treatment with INCB054828 is provided in the Protocol, Section 1. The purpose of this SAP is to define the methodology for analyzing and summarizing the data collected during the conduct of Study INCB 54828-101.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 54828-101 Protocol Amendment 8 (11 DEC 2018) and CRFs approved on 05 FEB 2019. 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

- To evaluate the safety, tolerability, and DLTs and to determine the PAD and MTD of INCB054828, alone as a monotherapy and in combination with other therapies.
- To assess the pharmacodynamics of INCB054828.

2.2.2. Secondary Objectives

- To assess preliminary efficacy by assessing the ORR of INCB054828 in subjects with measurable disease, alone as a monotherapy and in combination with other therapies.
- To evaluate the PK of INCB054828 and the effect of food and other therapies on the PK of INCB054828.

[redacted]

2.3. Study Endpoints

2.3.1. Primary Endpoints

- 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.
- Pharmacodynamics of INCB054828 including serum phosphorus level.

2.3.2. Secondary Endpoints

- Tumor response rates in those subjects with measurable disease as determined by investigator assessment of response.
- C_{max}, t_{max}, C_{min}, AUC_{0-t}, $t_{½}$, and Cl/F.

[redacted]

3. STUDY DESIGN

This is an open-label, dose-escalation study of the FGFR inhibitor INCB054828 in subjects with advanced malignancies. Subjects will receive QD doses of INCB054828 on a 2-weeks-on therapy and 1-week-off therapy schedule; a continuous administration regimen will also be explored. The study will be conducted in 3 parts (see Figure 1). Part 1 (monotherapy dose escalation) will determine the MTD of INCB054828 and/or doses/regimen that produce substantial evidence of pharmacologic target inhibition (increased serum phosphate). Part 2 (monotherapy dose expansion) will evaluate the dose(s) and/or regimen selected in Part 1 as a monotherapy in specific indications where activity of FGFR is particularly relevant and that have amplification, mutation, or translocation of FGFR 1, 2, or 3, or alteration of FGF 1 through 23. In Part 1, approximately 20 subjects with moderate ($n \approx 10$) and severe ($n \approx 10$) renal impairment will be enrolled for safety and PK evaluation, with subjects with moderate renal impairment enrolled first.

Additionally, as part of the dose expansion (Part 2), all subjects enrolling in the tumor-specific cohorts ($n = 20$ total, $n = 5$ per cohort) will have mandatory biopsies, and approximately 8 subjects will participate in a food-effect study. Part 3 will begin with dose-finding to determine RP2Ds of INCB054828 in combination with gemcitabine + cisplatin, docetaxel, pembrolizumab, trastuzumab, or INCMGA00012 in subjects for which these treatments or PD-1–directed treatment is relevant. Dose-expansion will further evaluate the RP2Ds selected in these populations harboring FGF/FGFR alterations, including up to 6 subjects per combination for mandatory baseline and on-treatment biopsies.

Treatment may continue as long as subjects are receiving benefit and have not met any criteria for study withdrawal. Subjects who discontinue study drug will continue to be followed for subsequent anticancer treatments and survival.

3.1.1. Part 1 Dose Escalation

Approximately 40 subjects will be enrolled in Part 1. The study will begin with an open-label dose escalation with an accelerated titration design based on observing each dose level for a period of 21 days before enrolling the next cohort and administering the next dose level. In Part 1, subjects who receive at least 11 out of 14 doses of study drug at the level assigned to that cohort or have a DLT will be considered evaluable for determining tolerability of the dose. Subjects enrolling but not meeting these criteria may be replaced in order to fill the cohort.

The starting dose of INCB054828 will be 1 mg QD. The initial cohorts will consist of at least 1 subject each, and the doses may be increased up to 2-fold in successive cohorts until a Grade 2 or greater toxicity (excepting toxicities with a clear alternative explanation [eg, due to disease progression] or transient [$\leq$ 72 hours] abnormal laboratory values without clinically significant signs or symptoms) or HP (serum phosphate $>$ 5.5 mg/dL) is observed, at which time that cohort will be expanded to at least 3 subjects. From the point where a single-subject cohort is first expanded to 3 subjects, subsequent cohorts will enroll at least 3 subjects, and increases to study drug dose will be limited to no more than 50% in successive cohorts. If no DLTs are observed in the initial 3 subjects, the next cohort will begin enrollment. If 1 DLT is observed in the first 3 subjects, 3 additional subjects will be enrolled in the cohort. If a DLT occurs in 2 or more

subjects in a cohort of 3 or 6, then the MTD will be deemed to have been exceeded, and the next lower dose level will be deemed to be the MTD. 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 a DLT. If a DLT is observed at the initial dose of 1 mg QD, then a dose decrease to 0.5 mg may be considered. An intermediate dose level may also be explored. If toxicities specifically relevant to a type of malignancy are observed, a separate dose escalation or de-escalation group will be initiated for subjects with this malignancy.

3.1.1.1. Continuous Administration of INCB054828

Continuous study drug administration will be tested in separate dose-escalation cohorts both in monotherapy cohorts and combination cohorts. The starting dose of continuous administration will be lower than the MTD identified in the 2-weeks-on therapy/1-week-off therapy schedule. Subjects who receive at least 18 of 21 doses of study drug at the level assigned to that cohort or who have a DLT will be considered evaluable for determining tolerability of the dose. Subjects enrolling but not meeting these criteria may be replaced in order to fill the cohort.

3.1.1.2. Renal Impairment

A subgroup of approximately 20 subjects (approximately 10 subjects with moderate renal impairment and 10 with severe renal impairment) will be enrolled in Part 1 at the 13.5 mg continuous administration regimen to assess the effect of renal impairment on the safety and PK of INCB054828.

3.1.1.3. Pharmacodynamic Target

Dose escalation will proceed in the absence of an MTD to a PAD. The PAD is defined as the point where approximately 67% of subjects (2 out of 3) attain HP; in a cohort of 3 subjects, if 2 out of 3 have HP, the cohort will be expanded to 6 (while dose escalation continues as described above). Once the PAD is achieved, a new cohort will be enrolled where subjects will be treated with diet modification (decreased phosphate intake) and phosphate binders, and dose escalation will continue to determine the dose at which at least one-third of subjects attain HP and an MTD is identified. Alternative PAD can be defined by molecular endpoint such as the inhibition of FGFR and/or at least a 1.5-fold increase of serum phosphate.

3.1.1.4. Recommended Part 2 Dose for Monotherapy

The RP2D (dose and/or regimen) will be the lower of the MTD or the PAD with or without concomitant phosphate binders; different RP2Ds may be determined for interval administration and continuous administration. Multiple RP2Ds may be used going into Part 2 and Part 3.

3.1.1.5. Lower Dose Level Expansion

Up to 3 additional subjects may be enrolled at any dose level for the interval and continuous administration monotherapy regimens, as well as the combination regimens, that is deemed to be pharmacodynamically active (HP observed in two-thirds of treated subjects) if that dose level is below the MTD. Subjects must have FGF/FGFR alteration and are required to have a baseline and on-treatment tumor biopsy and at least 1 on-treatment biopsy (recommended at Cycle 2 Day 14 but allowed to be performed at any cycle; must be performed on a study drug administration day, preferably between Day 8 and Day 14). Additionally, an end of treatment (EOT)/at time of progression biopsy is requested but not required. [redacted]

3.1.2. Part 2 Dose Expansion

When the recommended doses and/or regimen for the investigation in Part 2 have been determined, enrollment will proceed for Part 2. It is possible that a different dose and/or regimen will be chosen for subjects with different types of malignancies.

Approximately 140 subjects will be treated in expansion groups to further determine safety, tolerability, efficacy, PK, food effect ($n \approx 8$), and PD in specific populations. In addition, all subjects enrolling in the tumor-specific cohorts ($n = 20$ total, $n = 5$ per cohort) will have mandatory biopsies.

Subjects who attain HP should follow guidelines for HP management guidelines as per Protocol. Subjects that do not attain HP or at least a 1.5-fold increase in serum phosphate after the first cycle of treatment should have their dose increased each cycle to the previously study assessed dose until HP or the maximum safely tested dose/MTD is reached.

3.1.3. Part 3 Combination Dose Finding and Expansion

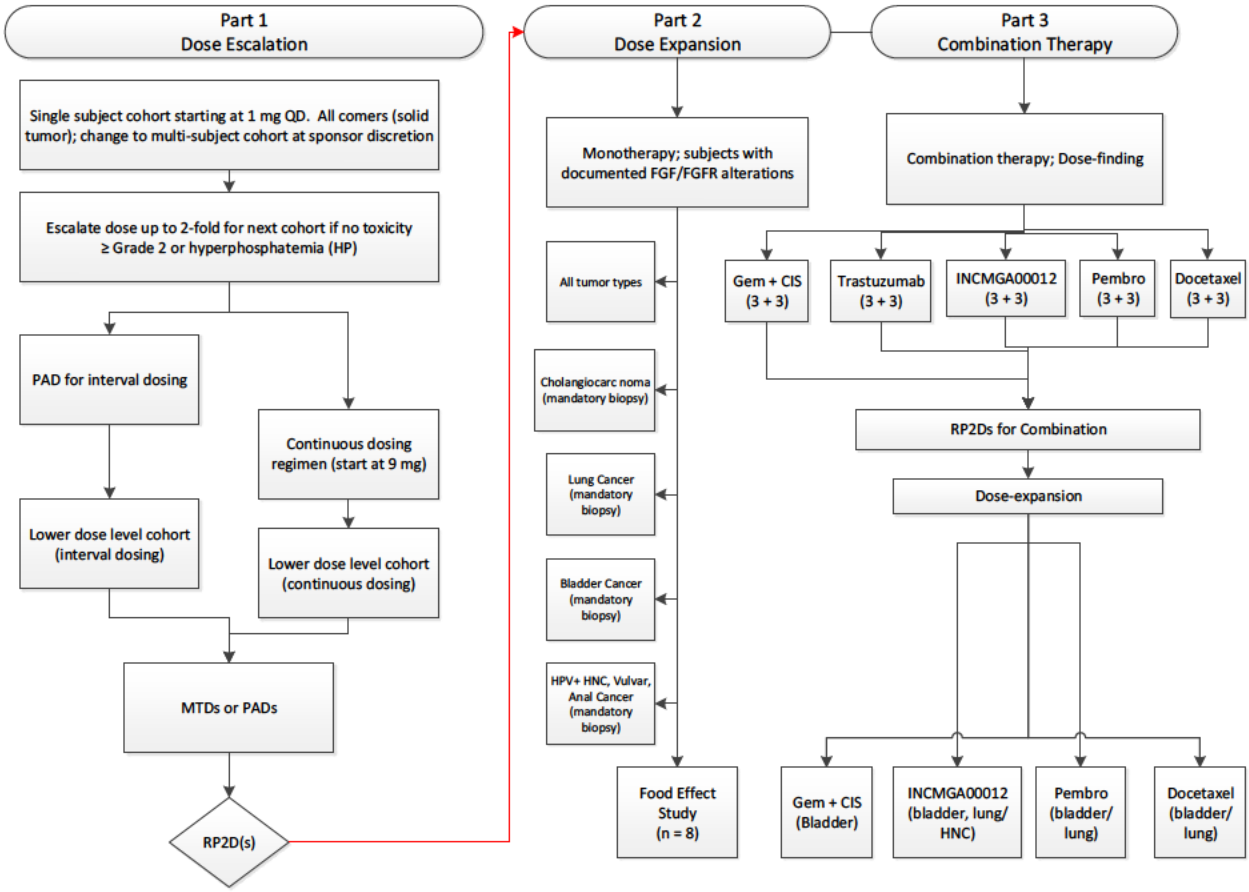
Part 3 will comprise treatment groups evaluating INCB054828 when administered in combination with standard therapies for select solid tumors. Part 3 will include dose finding and dose expansion. Dose finding will be a 3 + 3 enrollment design that will evaluate different doses of INCB054828 in combination with agents utilized in the treatment of solid tumors. The dose expansion is to further evaluate the safety and preliminary efficacy of the combination in select tumor types at the selected INCB054828 dose.

Approximately 60 subjects will be enrolled in the dose-finding group. The starting dose for Part 3 will be the RP2D(s).

Initially, at least 3 subjects will be enrolled in each treatment group for dose finding. The treatment groups include INCB054828 in combination with gemcitabine/cisplatin, docetaxel, pembrolizumab, trastuzumab, or INCMGA00012. If in each group no DLTs are observed, then enrollment of the corresponding expansion will begin. If 1 DLT is observed, then at least 6 subjects will be enrolled in the dose-finding treatment group. If DLTs are observed in 2 or more subjects in a 3- or 6-subject group, then the dose of INCB054828 will be reduced by 25% to 50%. Dose assessment and de-escalation may be repeated once more. The combination MTD will be the highest dose of INCB054828 in each combination at which $\leq 0/3$ or 1/6 subjects experience DLTs. The recommended combination expansion dose will be a dose less than or equal to the MTD/PAD dependent on emergent pharmacodynamics, PK, and safety data and may

be specific to the different combination therapies. Up to 3 additional subjects with known FGF/FGFR alterations may be enrolled at any Part 3 dose level if that dose level is below the MTD/PAD. In addition, the subjects enrolled in lower dose level cohort per treatment combination are required to have baseline biopsy and at least 1 on-treatment biopsy (recommended at Cycle 2 Day 14 but allowed to be performed at any cycle; must be performed on a study drug administration day, preferably between Day 8 and Day 14). Additionally, an EOT/at time of progression biopsy is requested but not required. [redacted] In the Part 3 combination expansion treatment group, a total of approximately 75 subjects will be enrolled across 4 treatment groups (trastuzumab will not be expanded), including up to 6 subjects per combination for mandatory baseline and on-treatment biopsies.

Figure 1: Study Design



3.2. Randomization

Not applicable.

3.3. Control of Type I Error

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

3.4. Sample Size Considerations

Approximately 325 subjects will be enrolled into this study. Part 1 of the study is a standard dose-escalation design, and the sample size depends on the occurrence of safety findings such as DLTs. Approximately 1 to 6 subjects will be enrolled in each dose level. For Part 2, approximately 140 subjects will be enrolled, which will provide > 90% chance of detecting at least 17 responders if the underlying response rate is 30%. For Part 3, approximately 3 to 6 subjects will be enrolled per combination therapy for dose finding, and approximately 24 subjects per combination therapy for dose expansion (except for the docetaxel and trastuzumab cohorts), which will provide > 90% chance of detecting at least 4 responders in expansion group if the underlying response rate is 30%.

3.5. Schedule of Assessments

See Protocol Amendment 8 (11 DEC 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

Day 1 is the date that the first dose of study drug (INCB054828 or combination agent) 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 non-missing measurement obtained before the first administration of INCB054828 or combination agent, 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. Cycle Length and Duration

Cycle 1 Day 1 is defined as the day of the first dose of INCB054828. One treatment cycle consists of 21 days, with first day of each cycle corresponding with the first day of INCB054828 administration in that cycle.

4.1.5. Analysis Window

For parameters that will be summarized by visit, the nominal visit as recorded on the electronic CRF will be used. There will be no additional analysis windowing done based on the assessment date.

4.1.6. Handling of Missing and Incomplete Data

In general, values for missing data will not be imputed unless methods for handling missing data are specified in this section or relevant sections.

Partial disease/cancer diagnosis date will be handled as follows:

- If only the day is missing, then the imputed day will be the first of the month.
- If both the month and day are missing, then the imputed day and month will be 01 JAN.
- No imputation will be done if the date is completely missing.

For relevant efficacy endpoints, partial death date will be imputed as follows:

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

4.2. Variable Definitions

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

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. Body Mass Index

Body mass index will be calculated as follows:

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

4.2.3. Body Surface Area

Body surface area will be calculated based on the Mosteller (1987) formula as follows:

BSA (m^2) = {[weight (kg) × height (cm)] / 3600}^{½}

Sites will also record the BSA calculated per institutional standards.

4.2.4. Prior and Concomitant Medication

Prior medication is defined as any nonstudy medication started before the first dose of INCB054828 or combination agent.

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

- Before the date of first administration of INCB054828 or combination agent 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 INCB054828 or combination agent 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 INCB054828/combination agent. In the listing, it will be indicated whether a medication is prior-only, concomitant-only, or both prior and concomitant medication.

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

5. STATISTICAL METHODOLOGY

5.1. General Methodology

Unless otherwise noted, SAS® software (SAS Institute Inc, Cary, NC; v9.4 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. Analyses of PK endpoints are described in Section 7.3, and will be performed by the Incyte pharmacokineticist.

5.2. Treatment Groups

This is a Phase 1, open label, dose escalation and expansion study.

Safety data from Part 1 and Part 2 will be combined and summarized overall and by dose levels/regimen based on actual treatment received on Day 1. In the event that several dose levels tested are deemed substantially below the MTD, these doses may be combined for summary purposes.

Safety data from Part 3a and Part 3b will be combined and summarized by dose levels/regimen/combination therapy based on actual treatment received on Day 1. In the event that several dose levels tested are deemed substantially below the MTD, these doses may be combined for summary purposes.

Efficacy data from Part 2 and Part 3b will be summarized separately.

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 INCB054828 or combination agent. Treatment groups for this population will be determined according to the actual treatment the subject received on Day 1. Demographics, baseline characteristics, subject disposition, and all the efficacy analyses will be conducted using the efficacy evaluable population.

5.3.2. Safety Population

The Safety Population includes all subjects enrolled in the study who received at least 1 dose of INCB054828 or combination agent. Treatment groups for this population will be determined according to the actual treatment the subject received on Day 1. All safety analyses will be conducted using the safety population.

5.3.3. Pharmacokinetic/Pharmacodynamic Population

The PK/pharmacodynamics population will include all subjects who received at least 1 dose of INCB054828 or combination agent and provided at least 1 postdose plasma sample (1 PK/pharmacodynamics measurement). The study pharmacokineticist will review data listings of subject dosing and sample records to identify subjects to be excluded from analyses of PK data. The study research investigator will review data listings of pharmacodynamics data and sample records to identify subjects to be excluded from analyses of pharmacodynamics data.

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

Appendix C provides a list of planned tables, figures, and listings.

6.1. Demographics and Baseline Characteristics, and Disease History

Demographic and baseline characteristics, disease history, and prior therapy will be summarized for the efficacy evaluable population and listed.

6.1.1. Demographics and Baseline Characteristics

Demographic and baseline characteristics includes age, sex, race, ethnicity, weight, height, BMI, BSA, ECOG performance status, FGFR status, and baseline phosphate.

6.1.2. Disease History

Cancer type, time since initial diagnosis, and staging at diagnosis will be summarized.

Time since diagnosis will be calculated as:

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

6.1.3. Prior Therapy

Number of subjects who received prior systemic therapy and number of prior systemic therapies will be summarized for the efficacy evaluable population. 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 for the efficacy evaluable population. Radiotherapy type, body site, start and stop dates, total dose, and best response will be listed.

Number of subjects who had prior surgery or surgical procedure for the malignancies under study will be summarized for the efficacy evaluable population. Date and description of the surgery/procedure will be listed.

6.1.4. Medical History

For subjects in the efficacy evaluable population, medical history will be summarized by SOC and PT and will be 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 discontinued from the study with a primary reason for withdrawal will be summarized for the efficacy evaluable population.

6.3. Protocol Deviations

Protocol deviations collected on the CRFs will be summarized descriptively and listed.

6.4. Exposure

For subjects in the safety population, exposure to INCB054828 will be summarized descriptively as the following:

- **Number of treatment cycles with INCB054828:** The number of cycles with a nonzero dose of INCB054828.
- **Duration of treatment with INCB054828:**

  Duration of treatment (days) = Date of last dose of INCB054828 – Date of first dose of INCB054828 + 1
- **Average daily dose of INCB054828:**

  Average daily dose of INCB054828 (mg/day) = [total actual INCB054828 dose taken (mg)] / [duration of treatment with INCB054828]

Combination agent gemcitabine, cisplatin, docetaxel, pembrolizumab, trastuzumab, and INCMGA00012 in part 3 will be summarized descriptively as the following:

- **Number of treatment cycles:** The number of cycles with a nonzero dose of study drug.
- **Average number of doses administered per cycle:** Total number of doses administered divided by number of cycles.
- **Relative dose intensity:** The ratio of the total actual dose administered to total assigned dose.

  Relative dose intensity (%) = 100 × [total actual dose] / [total assigned dose]

  Total actual dose (mg) administered is the sum of the dose that has been administered to the subject.

  Total assigned dose (mg) is the total dose expected if the subject had taken all doses as initially assigned.

6.5. Study Drug Compliance

For subjects in the safety populations, overall compliance (%) for INCB054828 will be calculated for all subjects as:

Overall 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.

The total actual dose taken will be calculated based on information entered on the drug accountability CRF. If there is dispensed drug that have not been returned yet, 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 CRF.

Compliance of INCB054828 will be summarized descriptively and listed.

6.6. Prior and Concomitant Medication

Prior medications and concomitant medications will be coded using the WHO Drug Dictionary. For subjects in the safety population, the number and percentage of subjects with prior and concomitant medications will be summarized by WHO drug class and WHO drug term. In the data listing, each medication will be recorded as prior, concomitant, or both prior and concomitant.

7. EFFICACY

Appendix C provides a list of planned tables, figures, and listings.

7.1. Efficacy Hypotheses

Not applicable.

7.2. Analysis of Efficacy Parameters

7.2.1. Response Assessment

Objective assessment of tumor status is required using appropriate disease-specific techniques, and the investigator's assessment will be used to determine responses and will be logged into the CRF. For solid tumors, RECIST v1.1 will be used (Eisenhauer et al 2009).

For multiple myeloma, the assessments will be based on the IMWG Multiple Myeloma response criteria (see Appendix A; Durie et al 2006).

For subjects with MPNs, the response criteria in Appendix B will be used to assess response.

The schedule for efficacy assessments will be at screening (this will be considered the baseline scan) and every 3 cycles (starting with Cycle 3) throughout the study. Efficacy assessments should occur at the end of the cycle. Multiple myeloma subjects should have response assessments performed on Day 14 of every cycle (± 2 days). Subjects with MPN should have a bone marrow aspirate and biopsy performed approximately 3, 6, and 12 months after Day 1 and then every 12 months on the nearest Cycle Day 14 (± 2 days) after the first dose of treatment and as clinically indicated.

For subjects who discontinue treatment for reasons other than disease progression, every effort should be made to continue monitoring disease status until (1) start of new antineoplastic therapy, (2) documented disease progression, (3) death, or (4) the end of study, whichever occurs first.

Response status per investigator's assessment will be recorded at each response assessment visit as CR, PR, SD, PD, NE for solid cancer and MPN; recorded as sCR, CR, VGPR, PR, SD, PD, and clinical relapse for myeloma.

7.2.2. Best Overall Response and Overall Response Rate

Best overall response is the best response postbaseline prior to and including the first PD, in the order of CR, PR, SD, PD, and NE for solid tumor and MPN, and in the order of sCR, CR, VGPR, PR, SD, and PD/relapse for myeloma. In the case of SD for solid tumors, measurements must meet the SD criteria 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 tumor assessment after the initial scan indicates PD, or have a BOR of NE if there are no additional tumor assessments available.

A subject with solid tumor or MPN is considered a responder if they have a BOR of CR or PR; a subject with myeloma is considered a responder if they have BOR of sCR, CR, VGPR, or PR.

The ORR 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 calculation of ORR.

The ORR will be estimated with 95% CIs for the efficacy evaluable population. Confidence intervals will be calculated based on the exact method for binomial distributions.

The BOR will be summarized for the efficacy evaluable population. Response assessment data on target and nontarget lesions and data leading to overall response assessment by visit will be listed.

7.2.3. Change in Target Lesion Size

For subjects with measurable lesions at baseline, target lesion sizes will be measured by sum of diameters. The best percent change from baseline, defined as the largest decrease in target lesion size during the study, will also be summarized, and a waterfall plot of best percent change will be generated. Note that for subjects who only have increases in target lesion size 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 a target lesion is unaccounted for in a particular postbaseline timepoint (ie, the assessment is missing or NE), then the overall sum of diameters for target lesions will not be evaluable for that postbaseline timepoint.

[redacted]

[redacted]

7.2.4.3. ECOG Performance Status

ECOG performance status at scheduled assessment times will be summarized.

7.3. Pharmacokinetic Analyses

The PK parameters of C_{max}, t_{max}, C_{min}, AUC_{0-t}, $t_{½}$, and Cl/F (INCB054828) will be calculated from the blood plasma concentrations of INCB054828 using standard noncompartmental (model-independent) PK methods and will be summarized by treatment group for the PK population. 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.

8. SAFETY AND TOLERABILITY

Appendix C provides a list of planned tables, figures, and listings.

8.1. General Considerations

The analyses for this section will be provided for the safety population. 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.

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 and within 30 days of the last dose of study drug. Analysis of AEs (as discussed below) will be limited to TEAEs, but data listings will include all AEs regardless of their timing to study drug administration.

Adverse Events will be tabulated by the MedDRA preferred term and system organ class. Severity of AEs will be graded using the NCI CTCAE v4.03. The CTCAE reporting guidelines and grading details are available on the Cancer Therapy Evaluation Program website.

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

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.

Serious AEs will also be tabulated.

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

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

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

8.2.2. Dose-Limiting Toxicities

The number of subjects with DLTs during the first cycle of study drug will be summarized, and DLTs will be listed by dose level.

8.2.3. Clinically Notable Treatment-Emergent Adverse Events

Specific groupings of clinically notable TEAEs will be considered, and the number of subjects with at least 1 event will be reported. Such groups consist of TEAEs for which there are specific clinical interests in connection with the study drug or TEAEs that are similar in nature (although not identical). All clinically notable TEAEs are defined through reviewing preferred terms according to MedDRA v21.1.

8.2.4. Adverse Event Summaries

An overall summary of AEs by treatment group will include:

- Number (%) of subjects reporting any TEAEs
- Number (%) of subjects reporting any DLTs in Cycle 1
- Number (%) of subjects reporting any serious TEAEs
- Number (%) of subjects reporting any Grade 3 or Higher TEAEs
- Number (%) of subjects reporting any TEAEs related to INCB054828
- Number (%) of subjects reporting any TEAEs related to combination agent (for Part 3 only)
- Number (%) of subjects who temporarily interrupted INCB054828 due to TEAEs
- Number (%) of subjects with INCB054828 dose reductions due to TEAEs
- Number (%) of subjects who permanently discontinued INCB054828 due to TEAEs
- Number (%) of subjects who withdrew from study due to TEAEs
- Number (%) of subjects who had a fatal TEAE

The following summaries will be produced by MedDRA term (if ≤ 10 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 higher TEAEs by SOC and PT
- Summary of Grade 3 or higher TEAEs by PT in decreasing order of frequency
- Summary of INCB054828 treatment-related TEAEs by SOC and PT
- Summary of INCB054828 treatment-related TEAEs by PT in decreasing order of frequency
- Summary of INCB054828 treatment-related Grade 3 or higher TEAEs by PT in decreasing order of frequency
- Summary of combination agent treatment-related TEAEs by SOC and PT

- Summary of combination agent treatment-related Grade 3 or higher TEAEs by SOC and PT
- Summary of TEAEs with a fatal outcome by SOC and PT
- Summary of serious TEAEs by SOC and PT
- Summary of serious TEAEs by PT in decreasing order of frequency
- Summary of INCB054828 treatment-related serious TEAEs by SOC and PT
- Summary of TEAEs leading to INCB054828 dose interruption by SOC and PT
- Summary of TEAEs leading to INCB054828 dose interruption by PT in decreasing order of frequency
- Summary of TEAEs leading to INCB054828 dose reduction by SOC and PT
- Summary of TEAEs leading to INCB054828 dose reduction by PT in decreasing order of frequency
- Summary of TEAEs leading to discontinuation of INCB054828 by SOC and PT
- Summary of TEAEs leading to discontinuation of INCB054828 by PT in decreasing order of frequency
- Summary of TEAEs leading to withdrawal from the study by SOC and PT
- Summary of TEAEs and Grade 3 or higher TEAEs by PT in decreasing order of frequency
- Summary of INCB054828 treatment-related TEAEs and Grade 3 or higher TEAEs by PT in decreasing order of frequency
- Summary of clinically notable TEAEs by category and PT
- Summary of Grade 3 or higher clinically notable TEAEs by category and PT
- Summary of clinically notable serious TEAEs by category and PT
- Summary of clinically notable TEAEs leading to INCB054828 dose reduction by category and PT
- Summary of clinically notable TEAEs leading to INCB054828 dose interruption by category and PT
- Summary of clinically notable TEAEs leading to discontinuation of INCB054828 by category and PT
- Summary of treatment-emergent nonserious TEAEs by SOC and PT

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

For numeric laboratory results, the change and percentage change from baseline values will be summarized descriptively by visit. Baseline will be determined according to Section 6. If there are multiple values that meet the criteria for baseline, then the value from the central laboratory has priority over value from the local laboratory. Thereafter, 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.

8.3.2. Laboratory Value Summaries

Laboratory parameters identified in Table 2 will be summarized.

Table 2: Laboratory Parameters to Be Summarized

Panel	Summary
Serum chemistry	Albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, bicarbonate, blood urea nitrogen, calcium, chloride, creatinine[a], direct bilirubin, glucose, lactate dehydrogenase, parathyroid hormone[a], phosphate[a], potassium, sodium[a], total bilirubin, total serum protein, uric acid, vitamin D (25-hydroxyvitamin D[a] and 1,25-dihidroxyvitamin D[a])
Hematology	Hematocrit, hemoglobin, platelet count, WBCs, red blood cells, basophils, eosinophils, lymphocytes, monocytes, neutrophils
Coagulation	PT, activated partial thromboplastin time, international normalized ratio
Lipid	Total cholesterol, triglycerides, low-density lipoprotein, high-density lipoprotein
Urinalysis	pH and specific gravity

[a] Line graph will be provided.

All test results and associated normal ranges from central laboratories will be reported in SI units. For numeric laboratory values, baseline value, postbaseline value, change from baseline, and percent change from baseline will be summarized by visit. In addition, mean change from baseline will be plotted over time for selected laboratory parameters including but not limited to the following: phosphate, sodium, calcium, 25-Hydroxyvitamin D, 1, 25-Dihydroxyvitamin D, parathyroid hormone, and creatinine.

For the laboratory parameters that have CTCAE grading, shift tables will also be presented showing change in CTCAE severity 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.

Categorical laboratory data will be tabulated by visit at baseline and postbaseline visits where appropriate.

8.4. Vital Signs

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

Criteria for clinically notable vital sign abnormalities are defined in Table 3. The abnormal values for subjects exhibiting clinically notable vital sign abnormalities will be listed along with their assigned treatment group. Alert vital signs are defined as an absolute value outside the defined range and percentage change from baseline greater than 25%. The abnormal values for subjects exhibiting alert vital sign abnormalities will also be listed.

Table 3: Criteria for Clinically Notable Vital Sign Abnormalities

Parameter	High Threshold	Low Threshold
Systolic blood pressure	> 155 mmHg	< 85 mmHg
Diastolic blood pressure	> 100 mmHg	< 40 mmHg
Pulse	> 100 bpm	< 45 bpm
Temperature	> 38ºC	< 35.5ºC
Respiratory rate	> 24 breaths/min	< 8 breaths/min

8.5. Electrocardiograms

Twelve-lead ECGs including heart rate, PR, QRS, QT, QTcF, and RR intervals will be obtained for each subject during the study. Values at each scheduled visit, change, and percent change from baseline will be summarized for each ECG parameter. Change and percent change from baseline will be calculated using the average of all nonmissing values before the first dose of study drug as the baseline value.

Criteria for clinically notable ECG abnormalities are defined in Table 4. The abnormal values for subjects exhibiting clinically notable ECG abnormalities will be listed. Alert ECG are defined as an absolute value outside the defined range and percentage change greater than 25% (QRS 30%). The abnormal values for subjects exhibiting alert ECG abnormalities will be listed.

Table 4: Criteria for Clinically Notable Electrocardiogram Abnormalities

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

QTcF = Fridericia correction.

9. INTERIM ANALYSES

No interim analysis is planned.

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 5.

Table 5: Statistical Analysis Plan Versions

SAP Version	Date
Original	13 APR 2017
Amendment 1	12 JUN 2019

10.1. Changes to Protocol-Defined Analyses

Not applicable.

10.2. Changes to the Statistical Analysis Plan

10.2.1. Amendment 1

The original SAP has been updated to incorporate updates made to the study in Protocol Amendments 6, 7, and 8. Specific changes include the following:

- Sections 1, 2, and 3 (introduction, objectives and endpoints, and study design) to reflect the updates in Protocol Amendments 6, 7, and 8.
- Section 5 was revised for consistency in treatment group definitions.
- Section 6.1.2 was revised to reflect disease history that will be summarized.
- Section 6.4 was revised to reflect accurate exposure summaries.
- Sections 7 and 8 were updated to align with updated lists of planned tables, figures, and listings.
- Appendix C was revised to update the list of planned tables, figures, and listings and to remove the sample data displays, as they will be included in a separate document.

11. REFERENCES

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Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumors: Revised RECIST guideline (version 1.1). Eur J Cancer 2009;45:228-247.

Food and Drug Administration. Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics. 2018. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071590.pdf. Accessed June 3, 2019.

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

Appendix A. RESPONSE ASSESSMENT CRITERIA FOR MULTIPLE MYELOMA

Table 5 International Myeloma Working Group uniform response criteria: CR and other response categories

Response subcategory	*Response criteria*[a]
sCR	CR as defined below plus Normal FLC ratio and Absence of clonal cells in bone marrow[b] by immunohistochemistry or immunofluorescence[c]
CR	Negative immunofixation on the serum and urine and Disappearance of any soft tissue plasmacytomas and $\leqslant$5% plasma cells in bone marrow[b]
VGPR	Serum and urine M-protein detectable by immunofixation but not on electrophoresis or 90% or greater reduction in serum M-protein plus urine M-protein level $<$100 mg per 24 h
PR	$\geqslant$50% reduction of serum M-protein and reduction in 24-h urinary M-protein by $\geqslant$90% or to $<$200 mg per 24 h If the serum and urine M-protein are unmeasurable,[d] a $\geqslant$50% decrease in the difference between involved and uninvolved FLC levels is required in place of the M-protein criteria If serum and urine M-protein are unmeasurable, and serum free light assay is also unmeasurable, $\geqslant$50% reduction in plasma cells is required in place of M-protein, provided baseline bone marrow plasma cell percentage was $\geqslant$30% In addition to the above listed criteria, if present at baseline, a $\geqslant$50% reduction in the size of soft tissue plasmacytomas is also required
SD (not recommended for use as an indicator of response; stability of disease is best described by providing the time to progression estimates)	Not meeting criteria for CR, VGPR, PR or progressive disease

Abbreviations: CR, complete response; FLC, free light chain; PR, partial response; SD, stable disease; sCR, stringent complete response; VGPR, very good partial response.
[a]All response categories require two consecutive assessments made at anytime before the institution of any new therapy; all categories also require no known evidence of progressive or new bone lesions if radiographic studies were performed. Radiographic studies are not required to satisfy these response requirements.
[b]Confirmation with repeat bone marrow biopsy not needed.
[c]Presence/absence of clonal cells is based upon the k/λ ratio. An abnormal k/λ ratio by immunohistochemistry and/or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting presence of an abnormal clone is k/λ of $>$4:1 or $<$1:2.
[d]Refer to Table 4 for definitions of measurable disease.

Table 6 International Myeloma Working Group uniform response criteria: disease progression and relapse

Relapse subcategory	*Relapse criteria*
Progressive disease[a] To be used for calculation of time to progression and progression-free survival end points for all patients including those in CR (includes primary progressive disease and disease progression on or off therapy)	Progressive Disease: requires any one or more of the following: Increase of ⩾25% from baseline in Serum M-component and/or (the absolute increase must be ⩾0.5 g/dl)[b] Urine M-component and/or (the absolute increase must be ⩾200 mg/24 h Only in patients without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels. The absolute increase must be >10 mg/dl. Bone marrow plasma cell percentage: the absolute % must be ⩾10%[c] Definite development of new bone lesions or soft tissue plasmacytomas or definite increase in the size of existing bone lesions or soft tissue plasmacytomas Development of hypercalcemia (corrected serum calcium >11.5 mg/dl or 2.65 mmol/l) that can be attributed solely to the plasma cell proliferative disorder
Clinical relapse[a]	Clinical relapse requires one or more of: Direct indicators of increasing disease and/or end organ dysfunction (CRAB features)[b] It is not used in calculation of time to progression or progression-free survival but is listed here as as something that can be reported optionally or for use in clinical practice 1. Development of new soft tissue plasmacytomas or bone lesions 2. Definite increase in the size of existing plasmacytomas or bone lesions. A definite increase is defined as a 50% (and at least 1 cm) increase as measured serially by the sum of the products of the cross-diameters of the measurable lesion 3. Hypercalcemia (>11.5 mg/dl) [2.65 mmol/l] 4. Decrease in hemoglobin of ⩾2 g/dl [1.25 mmol/l] (see Table 3 for further details) 5. Rise in serum creatinine by 2 mg/dl or more [177 μmol/l or more]
Relapse from CR[a](To be used only if the end point studied is DFS)[d]	Any one or more of the following: Reappearance of serum or urine M-protein by immunofixation or electrophoresis Development of ⩾5% plasma cells in the bone marrow[c] Appearance of any other sign of progression (i.e., new plasmacytoma, lytic bone lesion, or hypercalcemia see below)

Abbreviations: CR, complete response; DFS, disease-free survival.
[a]All relapse categories require two consecutive assessments made at anytime before classification as relapse or disease progression and/or the institution of any new therapy.
[b]For progressive disease, serum M-component increases of ⩾1 gm/dl are sufficient to define relapse if starting M-component is ⩾5 g/dl.
[c]Relapse from CR has the 5% cutoff versus 10% for other categories of relapse.
[d]For purposes of calculating time to progression and progression-free survival, CR patients should also be evaluated using criteria listed above for progressive disease.

Source: Durie et al 2006.

APPENDIX B. RESPONSE ASSESSMENT CRITERIA FOR SUBJECTS WITH MYELOPROLIFERATIVE NEOPLASMS

Response Criteria for Myeloproliferative Neoplasms With Genetic Alterations in FGF or FGFR Genes

Complete Response	**Criteria**
Hematologic	Durable peripheral blood count remission, defined as: absence of circulating blasts, hemoglobin ≥ 100 g/L and < ULN, platelet count ≥ 100×10^9/L and < ULN, WBC and neutrophil count within institutional normal range. For subjects with baseline eosinophilia: eosinophils < 1.5×10^9/L.
Bone marrow	Cellularity appropriate for age, resolution of abnormal morphology, blasts ≤ 5%.
Spleen	For subjects with splenomegaly at baseline: < 25% increase in spleen size by palpation or imaging if baseline spleen is < 10 cm or < 50% if baseline spleen is ≥ 10 cm.
Lymph nodes	For subjects with lymph node disease: target nodes/nodal masses must regress to ≤ 1.5 cm in longest transverse diameter of lesion, no extralymphatic sites of disease, no new lesions present. Must be PET negative, if positive at baseline.
Cytogenetic CR	Meets above criteria and MPN-associated cytogenetic abnormalities are no longer detected (requires that abnormalities were found at baseline).
Molecular CR	Meets above criteria and MPN-associated molecular abnormalities (eg, by PCR) are no longer detected (requires that abnormalities were found at baseline)
Partial Response	**Criteria**
Hematologic	Hemoglobin ≥ 100 g/L and < ULN, 50% reduction in WBC and neutrophil count, 50% reduction in circulating blasts. For subjects with eosinophilia: > 50% reduction in eosinophil count.
Bone marrow	> 50% reduction in blasts.
Spleen	For subjects with splenomegaly: < 25% increase in spleen size by palpation or imaging if baseline spleen is < 10 cm or < 50% if baseline spleen is ≥ 10 cm.
Lymph nodes	For subjects with lymph node disease: ≥ 50% decrease in the sum of the product of the perpendicular diameters of up to 6 target measureable nodes and extranodal sites, no new lesions present.
Cytogenetics	No new abnormalities detected.
Molecular markers	No new abnormalities detected.
Stable Disease	**Criteria**
Stable disease	Failure to achieve at least Partial Remission, but no evidence of progression for at least 9 weeks.
Progressive Disease	**Criteria**
Hematologic	WBC: > 2 times increase compared with baseline count in the absence of a concurrent acute or subacute medical illness. For subjects with circulating blasts: ≥ 50% increase in circulating blasts.
Bone marrow	≥ 50% increase in blasts.
Spleen	For subjects with splenomegaly: > 25% increase in spleen size by palpation or imaging if baseline spleen is < 10 cm and > 50% if baseline spleen is ≥ 10 cm or appearance of new splenomegaly.
Lymph nodes	If lymph node disease is present: a single node must be abnormal with the longest transverse diameter > 1.5 cm and ≥ 50% increase in the sum of measureable lesions or new or clear progression of preexisting nonmeasured lesions.

CR = complete response; MPN = myeloproliferative neoplasm; PCR = polymerase chain reaction; PET = positron emission tomography; ULN = upper limit of normal; WBC = white blood cell.

APPENDIX C. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the CSR. Standard tables will follow the conventions in the Standard Safety Tables initial version. Shells are provided for nonstandard tables in a separate document.

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

For each baseline and demographic characteristics, safety, laboratory, vital sign, and ECG table and figure listed below, 2 sets of tables and figures will be produced: Part 1 and Part 2 combined and Part 3a and Part 3b combined. For each efficacy table listed below, 2 sets of tables will be produced: Part 2 and Part 3b. For each listing listed below, 4 sets of listings will be produced for Part 1, Part 2, Part 3a, and Part 3b.

Tables

Table No.	Title	Population	Standard	In-Text
Baseline and Demographic Characteristics				
1.1.1	Analysis Populations	All Enrolled	X	
1.1.2	Summary of Subject Disposition	Efficacy	X	X
1.1.3	Summary of Number of Subjects Enrolled by Country and Site	Efficacy	X	
1.1.4	Summary of Protocol Deviations	Efficacy	X	
1.2.1	Summary of Demographics and Baseline Characteristics	Efficacy	X	X
1.2.2	Summary of Disease History	Efficacy	X	X
1.2.3	Summary of Prior Cancer Therapy	Efficacy	X	X
1.3	Summary of Medical History	Efficacy	X	
1.4.1	Summary of Prior Medications	Efficacy	X	
1.4.2	Summary of Concomitant Medications	Efficacy	X	
Efficacy				
2.1	Summary of Best Overall Response and Overall Response Rate	Efficacy		X
[redacted]	[redacted]	[redacted]		[redacted]
[redacted]	[redacted]	[redacted]		[redacted]
2.2.3	Summary of Best Change in Target Lesion Size	Efficacy		X
2.3.1	Summary of ECOG Performance Status	Efficacy	X	
Safety				
3.1.1	Summary of Study Drug Exposure	Safety	X	X
3.1.2	Summary of Study Drug 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	

Table No.	Title	Population	Standard	In-Text
3.2.5	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.6	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	X	X
3.2.7	Summary of INCB054828 Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.8	Summary of INCB054828 Treatment- Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	X	X
3.2.9	Summary of INCB054828 Treatment-Related Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.10	Summary of Combination Agent Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.11	Summary of Combination Agent Treatment-Related Grade 3 or Higher Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.12	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.13	Summary of Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.14	Summary of Serious Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	X	
3.2.15	Summary of INCB054828 Treatment-Related Serious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
3.2.16	Summary of Treatment-Emergent Adverse Events Leading to INCB054828 Dose Interruption by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.17	Summary of Treatment-Emergent Adverse Events Leading to INCB054828 Dose Interruption by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	X	
3.2.18	Summary of Treatment-Emergent Adverse Events Leading to INCB054828 Dose Reduction by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.19	Summary of Treatment-Emergent Adverse Events Leading to INCB054828 Dose Reduction by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	X	
3.2.20	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCB054828 by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.21	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCB054828 by MedDRA Preferred Term in Decreasing Order of Frequency	Safety	X	

Table No.	Title	Population	Standard	In-Text
3.2.22	Summary of Treatment-Emergent Adverse Events Leading to Withdrawal From the Study by MedDRA System Organ Class and Preferred Term	Safety	X	
3.2.23	Summary of Treatment-Emergent Adverse Events and Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety		
3.2.24	Summary of INCB054828 Treatment-Related Treatment-Emergent Adverse Events and Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety		
3.2.25	Summary of Clinically Notable Treatment-Emergent Adverse Events by Category and Preferred Term	Safety		
3.2.26	Summary of Grade 3 or Higher Clinically Notable Treatment-Emergent Adverse Events by Category and PT	Safety		
3.2.27	Summary of Clinically Notable Serious Treatment-Emergent Adverse Events by Category and Preferred Term	Safety		
3.2.28	Summary of Clinically Notable Treatment-Emergent Adverse Events Leading to INCB054828 Dose Reduction by Category and Preferred Term	Safety		
3.2.29	Summary of Clinically Notable Treatment-Emergent Adverse Events Leading to INCB054828 Dose Interruption by Category and Preferred Term	Safety		
3.2.30	Summary of Clinically Notable Treatment-Emergent Adverse Events Leading to Discontinuation of INCB054828 by Category and Preferred Term	Safety		
3.2.31	Summary of Treatment-Emergent Nonserious Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety	X	X
Laboratory				
3.3.1	Summary of Laboratory Values - Hematology	Safety	X	
3.3.2	Shift Summary of Hematology Values in CTC Grade - to the Worst Abnormal Value	Safety	X	
3.3.3	Summary of Treatment-Emergent Worsening of Laboratory Abnormalities - Hematology	Safety	X	
3.3.4	Summary of Laboratory Values - Chemistry	Safety	X	
3.3.5	Shift Summary of Chemistry Values in CTC Grade - to the Worst Abnormal Value	Safety	X	
3.3.6	Summary of Treatment-Emergent Worsening of Laboratory Abnormalities – Chemistry	Safety	X	
3.3.7	Summary of Laboratory Values - Coagulation	Safety	X	
3.3.8	Shift Summary of Coagulation Values in CTC Grade - to the Worst Abnormal Value	Safety	X	
3.3.9	Summary of Treatment-Emergent Worsening of Laboratory Abnormalities - Coagulation	Safety	X	
3.3.10	Summary of Laboratory Values - Urinalysis	Safety	X	
Vital Signs				
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	

Table No.	Title	Population	Standard	In-Text
3.4.4	Summary of Body Temperature	Safety	X	
3.4.5	Summary of Respiratory Rate	Safety	X	
3.4.6	Summary of Body Weight	Safety	X	
ECG				
3.5.1	Summary of RR Interval (ms) From 12-Lead ECG	Safety	X	
3.5.2	Summary of PR Interval (ms) From 12-Lead ECG	Safety	X	
3.5.3	Summary of QRS Interval (ms) From 12-Lead ECG	Safety	X	
3.5.4	Summary of QT Interval (ms) From 12-Lead ECG	Safety	X	
3.5.5	Summary of QTcF Interval (ms) From 12-Lead ECG	Safety	X	
3.5.6	Summary of Heart Rate (bpm) From 12-Lead ECG	Safety	X	
3.5.7	Summary of Outliers of QT, QTcB, and QTcF Interval Values (ms) From 12-Lead ECG	Safety	X	
3.5.8	Summary of Clinically Significant ECG Abnormalities	Safety	X	

Figures

Figure No.	Title
[redacted]	[redacted]
[redacted]	[redacted]
4.2.3	Waterfall Plot of Best Percent Change of Target Lesion Size From Baseline (Efficacy)
4.6	Line Graph of Mean Change From Baseline for Selected Laboratory Values (Safety)

Listings

Listing No.	Title
2.1.1	Analysis Populations
2.1.2	Subject Enrollment and Disposition Status
2.1.3	Subject Inclusion and Exclusion Criteria
2.2	Protocol Deviations
2.4.1	Demographic and Baseline Characteristics
2.4.2	Oncology Disease History
2.4.3	FGF and FGFR Status
2.4.4	Prior Systemic Therapy
2.4.5	Prior Surgery
2.4.6	Prior Radiotherapy
2.4.7	Medical History
2.4.8	Prior and Concomitant Medications
2.5	Study Drug Compliance
2.6.1	Best Overall Response, [redacted]
2.6.2	Investigator-Reported Assessment by RECIST v1.1
2.6.3	Response Assessment: Target Lesions
2.6.4	Response Assessment: Non-Target Lesions
2.6.5	Response Assessment: New Lesions
2.6.6	Investigator Reported Assessment for Myeloma
2.6.7	Investigator Reported Assessment for MPN
2.6.8	Bone Marrow Testing Results

Listing No.	Title
2.6.9	Flow Cytometry Results
2.6.10	Tumor Tissue
2.6.11	ECOG Status
2.7.1	Study Drug Administration
2.7.3	Adverse Events
2.7.4	Dose-Limiting Toxicities
2.7.5	INCB054828 Treatment-Related Adverse Events
2.7.6	Adverse Events Leading to Interruption, Reduction, or Discontinuation of INCB054828
2.7.7	Adverse Events Leading to Discontinuation of INCB054828
2.7.8	Serious Adverse Events
2.7.9	Adverse Events Leading to Death
2.7.10	Adverse Events Leading to Withdrawal From Study
2.7.11	Clinically Notable Adverse Events
2.8.1.1	Clinical Laboratory Values - Hematology
2.8.1.2	Clinical Laboratory Values - Chemistry
2.8.1.3	Clinical Laboratory Values - Coagulation
2.8.1.4	Clinical Laboratory Values - Urinalysis
2.8.2.1	Abnormal Clinical Laboratory Values - Hematology
2.8.2.2	Abnormal Clinical Laboratory Values - Chemistry
2.8.2.3	Abnormal Clinical Laboratory Values - Coagulation
2.8.2.4	Abnormal Clinical Laboratory Values - Urinalysis
2.8.3	PK Blood Sampling Times
2.8.4	PK Urine Sampling Times
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
2.11.1	Eye Examinations
2.11.2	Skeletal Examinations