Official Title:	**A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy - (FIGHT-202)**
NCT Number:	NCT02924376
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STATISTICAL ANALYSIS PLAN

INCB 54828-202

A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy

IND Number:	[redacted]
EudraCT Number:	**2016-002422-36**
Sponsor:	**Incyte Corporation** **1801 Augustine Cut-Off** **Wilmington, DE 19803**
Protocol Version:	**Protocol Amendment 6 dated 15 FEB 2018**
CRF Approval Date:	**27 NOV 2018**
SAP Version:	**Amendment 1**
SAP Author:	[redacted]
Date of Plan:	**15 APR 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
BMI	body mass index
CI	confidence interval
CR	complete response
CRF	case report form
CTCAE	Common Terminology Criteria for Adverse Events
DCR	disease control rate
DOR	duration of response
ECG	electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
[redacted]	[redacted]
FDA	Food and Drug Administration
FGF	fibroblast growth factor
FGFR	fibroblast growth factor receptor
MedDRA	Medical Dictionary for Regulatory Activities
NCI	National Cancer Institute
NE	not evaluable
ORR	objective response rate
OS	overall survival
PD	progressive disease
PFS	progression-free survival
PK	pharmacokinetic
PP	per protocol
PR	partial response
[redacted]	[redacted]
[redacted]	[redacted]
QTcF	QT interval corrected using Fridericia's formula
RECIST	Response Evaluation Criteria in Solid Tumors
SD	stable disease
SAE	serious adverse event
SAP	Statistical Analysis Plan
SI	international system of units
TEAE	treatment-emergent adverse event
TNM	TNM Classification of Malignant Tumors
WHO	World Health Organization

1. INTRODUCTION

This is a Phase 2, open-label, monotherapy study of INCB054828 in subjects with advanced/metastatic or surgically unresectable cholangiocarcinoma with FGFR2 translocations, with other FGF/FGFR alterations, or who are negative for 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 are provided in the Protocol, Section 1.

The purpose of this SAP is to provide details of the statistical analyses that have been outlined in the Study INCB 54828-202 Protocol.

2. STUDY INFORMATION, OBJECTIVES, AND ENDPOINTS

2.1. Protocol and Case Report Form Version

This SAP is based on INCB 54828-202 Protocol Amendment 6 dated 15 FEB 2018 and CRFs approved on 27 NOV 2018. 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 efficacy of INCB054828 in subjects with advanced/metastatic or surgically unresectable cholangiocarcinoma with FGFR2 translocation who have failed at least 1 previous treatment.

2.2.2. Secondary Objectives

- To evaluate the efficacy of INCB054828 in subjects with advanced/metastatic or surgically unresectable cholangiocarcinoma within different molecular subgroups.
- To evaluate the safety of INCB054828 in subjects with advanced/metastatic or surgically unresectable cholangiocarcinoma.
- To identify and evaluate covariates that may influence the PK of INCB054828 in this subject population through population PK analysis. Additionally, exposure-response analyses for key efficacy and safety parameters will also be considered if there is sufficient data available.

[redacted]

2.3. Study Endpoints

2.3.1. Primary Endpoint

- To determine the ORR in subjects with FGFR2 translocations based on the central genomics laboratory results. Objective response rate is defined as the proportion of subjects who achieved a CR (disappearance of all target lesions) or a PR (≥ 30% decrease in the sum of the longest diameters of target lesions) based on RECIST v1.1. Clinical response will be determined by an independent radiological review committee.

2.3.2. Secondary Endpoints

- ORR in subjects with other FGF/FGFR alterations (Cohort B).
- ORR in subjects with FGF/FGFR alterations (Cohorts A and B).
- ORR in subjects negative for FGF/FGFR alterations (Cohort C [United States only])
- PFS (PFS = first dose to PD or death; all cohorts).
- DOR (DOR = time from the date of CR or PR until PD; all cohorts).
- DCR (DCR = CR + PR + SD; all cohorts).
- OS (OS = first dose to death of any cause; all cohorts).
- Safety and tolerability will be assessed by evaluating the frequency, duration and severity of AEs; through review of findings of physical examinations, changes in vital signs, and ECGs; and through clinical laboratory blood and urine sample evaluations (all cohorts).
- Population PK (all cohorts).

[redacted]

3. STUDY DESIGN

This is an open-label, monotherapy study of INCB054828 in subjects with advanced/metastatic or surgically unresectable cholangiocarcinoma with FGFR2 translocations, with other FGF/FGFR alterations, or who are negative for FGF/FGFR alterations. The study will enroll approximately 140 subjects total: 100 subjects with FGFR2 translocations (Cohort A), 20 subjects with other FGF/FGFR alterations (Cohort B), and 20 subjects with no FGF/FGFR alterations (Cohort C [United States only]).

Subjects will receive INCB054828 13.5 mg once daily on a 2-weeks-on therapy and 1-week-off therapy schedule. Full study drug administration information can be found in the Protocol, Section 5.2.

Subject eligibility can be based on local genomic testing results, if available. Confirmatory testing through the central genomics laboratory will be performed for all subjects.

Previous therapies may include chemotherapeutic agents and immunotherapies, with or without radiotherapy. Subjects receiving radiotherapy to target the lesion(s) must show progression of the target lesion prior to entry into the study.

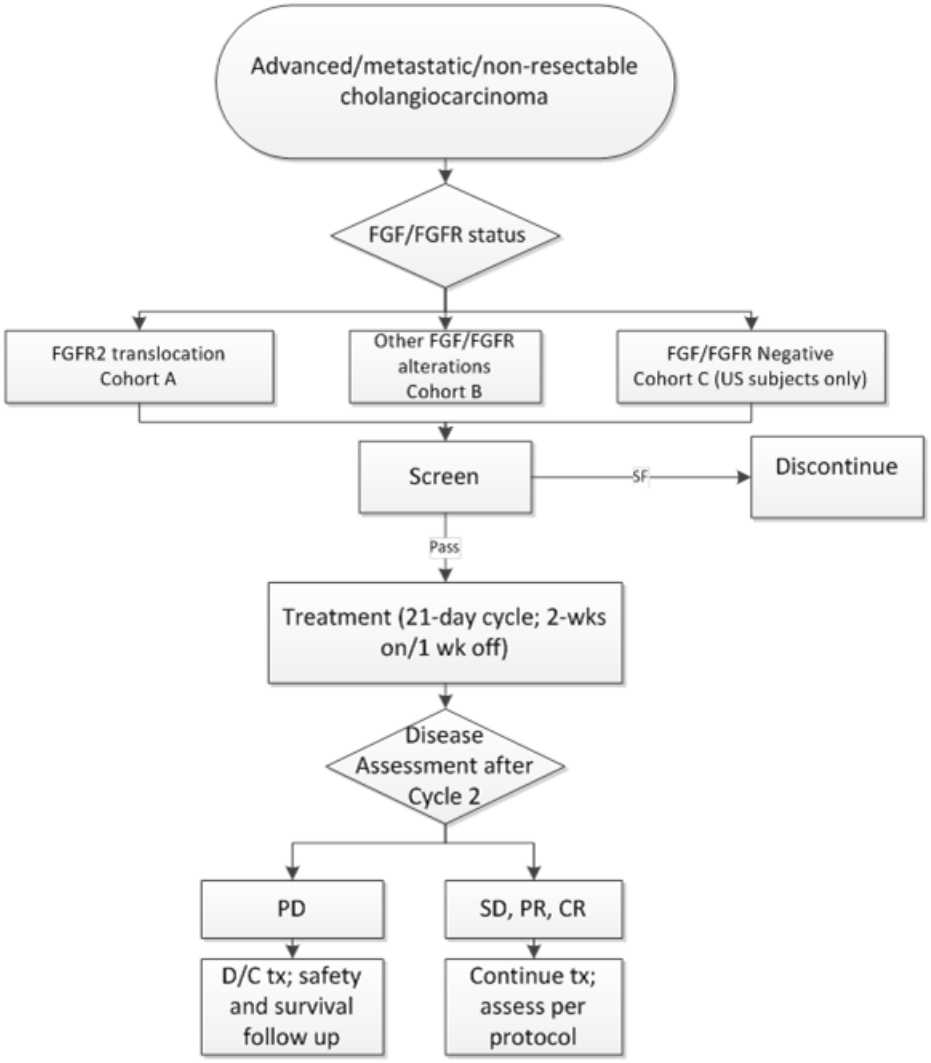
Genomic testing results will allow subjects to be assigned to a cohort as follows:

- Cohort A: FGFR2 translocations with a documented fusion partner in central laboratory report.
- Cohort B: other FGF/FGFR alterations.
- Cohort C (United States only): negative for FGF/FGFR alterations.

Subjects enrolled based on a local sequencing report will be assigned to a cohort based on the local results. However, final cohort assignments for statistical analysis will be based on the central genomic testing results.

Treatment will start on Cycle 1 Day 1. Subjects will undergo regular safety assessments during treatment, as well as regular efficacy assessments. Subjects will be allowed to continue administration in 21-day cycles until documented disease progression or unacceptable toxicity is reported. See Figure 1 for the study design.

Figure 1: Study Design



D/C = discontinue; SF = screen fail; tx = treatment.

3.1. Control of Type I Error

Unless otherwise specified, all CIs provided will be at the 95% confidence level.

3.2. Sample Size Considerations

Approximately 100 subjects with documentation of FGFR2 translocation from the central genomics laboratory are planned for the final analysis of the primary endpoint of ORR. With the assumed rate of 33% for the intervention, a sample size of approximately 100 subjects would provide > 95% probability to have a 95% CI with lower limit of > 15%, assuming 10% lost to follow-up. Up to 20 subjects will be enrolled in Cohort B and Cohort C (United States only), respectively, which will provide > 80% chance of observing at least 4 responders in each cohort, if the underlying ORR is 30%.

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) is administered to the subject.

4.1.2. Study Day

If a visit/reporting date is on or after the Day 1 date, 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 the Day 1 date, 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 defined as the last nonmissing measurement obtained prior to the first administration of INCB054828. When scheduled assessments and unscheduled assessments occur on the same day and time of the assessment or time of first dose is not available, use the following convention to determine baseline:

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

4.1.4. Handling of Missing and Incomplete Data

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

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

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

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

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

4.1.5. Cycle Length and Duration

Cycle 1 Day 1 is the day that the first dose of INCB054828 is administered. Scheduled cycle length is 21 days, with first day of each cycle corresponding with the first day of INCB054828 administration in that cycle.

4.1.6. Analysis Window

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

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 informed consent form, 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. Prior and Concomitant Medication

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

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

- Before the date of first administration of INCB054828 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 and is ongoing or ends during the course of study drug administration.

A prior medication could also be classified as "both prior and concomitant medication" if the end date is on or after first dose of INCB054828. 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; v9.1 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

Subjects will be summarized by cohorts, and cohort determination will be based on FGF/FGFR status from the central genomics laboratory.

5.3. Analysis Populations

5.3.1. Efficacy Evaluable Population

The efficacy evaluable population includes all subjects who have a known FGF/FGFR alteration from the central genomics laboratory and who received at least 1 dose of INCB054828 and all subjects in the United States who have a negative FGF/FGFR alteration from the central genomics laboratory and who received at least 1 dose of INCB054828. The efficacy evaluable population will be used for the summary of demographics, baseline characteristics, subject disposition, and analyses of all efficacy data.

5.3.2. Per Protocol Population

Subjects in the efficacy evaluable population who are considered to be sufficiently compliant with the protocol compose the PP population.

The following procedures will be performed to identify those subjects who are to be excluded from the PP population before the database freeze:

- Clinical review of Protocol deviations.
- Clinical review of concomitant medications as defined in Section 5.6 of the Protocol.
- Clinical review of the dose administration and drug accountability listing.

The determination of subjects being considered for exclusion from the PP population by the clinical team will be prepared and signed before database freeze.

The PP population will be used in the supportive sensitivity analyses for efficacy endpoints.

5.3.3. Safety Population

The safety population includes all enrolled subjects who received at least 1 dose of INCB054828. All safety analyses will be conducted using the safety population.

6. BASELINE, EXPOSURE, AND DISPOSITION VARIABLES AND ANALYSES

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

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

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

6.1.1. Demographics

The following demographic and baseline characteristics will be summarized for the efficacy evaluable population: age, sex, race, geographic region (North America vs Western Europe vs rest of world), ethnicity, weight (by gender), height, and BMI.

6.1.2. Baseline Disease Characteristics

The following baseline disease characteristics will be summarized for the efficacy evaluable population: ECOG performance status and baseline phosphate.

6.1.3. Disease History

Time since diagnosis, stage at diagnosis, cholangiocarcinoma location at diagnosis, current TNM classification, and tumor marker test results will be summarized.

Time since diagnosis will be calculated as:

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

6.1.4. Prior Therapy

Number of subjects who received prior systemic cancer therapy, number of prior systemic cancer therapy regimens, number of subjects who received prior neoadjuvant therapy, number of subjects who received prior adjuvant therapy, as well as number of subjects who received prior platinum therapy, 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.

6.1.5. Medical History

For subjects in the efficacy evaluable population, general medical history, as well as hepatitis history, will be summarized by system organ class and preferred term and will be listed. Preferred terms for hepatitis history include, but are not limited to the following: hepatitis B; hepatitis C; viral hepatitis carrier; hepatitis non-A, non-B, non-C; and fascioliasis.

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 eCRF 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:** Number of cycles with a nonzero dose of INCB054828.
- **Duration of treatment (weeks):** (date of last dose of INCB054828 – date of first dose of INCB054828 + 1) / 7.
- **Number of days with INCB054828:** Number of days with a nonzero dose of INCB054828.
- **Average daily dose (mg/day):** Total actual INCB054828 dose taken (mg) / duration of treatment.

Duration of exposure in months will be calculated based on the assumption that each month has 30.4375 days. The number and percentage of subjects in each duration category (< 1 month, 1-< 3 months, 3-< 6 months, 6-< 9 months, 9-< 12 months, 12-< 15 months, 15-< 18 months, 18-< 21 months, 21-< 24 months, > 24 months as applicable) will be summarized.

Number of subjects without dose reduction, with at least 1 dose reduction, with only 1 dose reduction, as well as with more than 1 dose reduction will be summarized.

Number of subjects without dose interruption, with at least 1 dose interruption, with only 1 dose interruption, as well as with more than 1 dose interruption will be summarized.

Final dose, defined as last nonmissing dose in the study or last nonmissing dose prior to data cutoff date if subject is still ongoing, will be summarized.

6.5. Study Drug Compliance

Overall compliance (%) for INCB054828 will be calculated for all subjects as:

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

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

The total actual dose taken will be calculated based on information entered on the drug accountability eCRF. If there is dispensed drug that has 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 eCRF.

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 A provides a list of planned tables, figures, and listings.

7.1. Efficacy Hypotheses

Not applicable.

7.2. Analysis of the Primary Efficacy Parameter

7.2.1. Primary Efficacy Analysis

The primary endpoint of the study is ORR in subjects with FGFR2 translocations based on the central genomics laboratory results, defined as the proportion of subjects with best response of CR or PR based on review of scans by an independent centralized radiological review committee per RECIST v1.1 (Eisenhauer et al 2009) results. Confirmation of CR and PR is required and documented in the Independent Central Review Charter. This analysis will be based on efficacy evaluable population for subjects with FGFR2 translocations. 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 95% CI for ORR will be calculated using exact method for binomial distribution.

The ORR will also be analyzed based on the PP population as a sensitivity analysis.

7.2.1.1. Response Criteria

Objective assessment of tumor status will be evaluated by an independent centralized radiological review committee based on RECIST v1.1, and response status will be logged into the eCRF.

Response status will be recorded at each response assessment visit as CR, PR, SD, PD, or NE.

7.2.1.2. Objective Response Rate and Best Response

Subjects are considered objective responders if they have a best overall response of CR or PR at any postbaseline visit prior to first PD.

In general, best overall response is the best response recorded postbaseline prior to and including the first PD, in the order of CR, PR, SD, PD, and NE. A best overall response of CR or PR needs to be confirmed, and confirmation method is described in the Independent Central Review Charter. In the case of SD, measurements must meet the SD criteria at least once after the date of first dose at a minimum interval of 39 days. Subjects that fail to meet this criterion will have best overall response of PD if the next available assessment indicates PD or NE if there is no additional assessment available.

7.2.2. Subgroup Analyses for Primary Endpoint

Subgroups will be formed based on the following subject characteristics and baseline variables for those subjects whose data are available:

- Age category (< 65 years vs 65-< 75 years vs ≥75 years)
- Sex (female vs male)
- Region (North America vs Western Europe vs rest of world)
- Baseline ECOG performance score (0 vs 1/2)
- Metastatic disease present (yes vs no)
- Lines of prior therapy (1 line vs 2 lines vs ≥ 3 lines)
- Received previous platinum treatment (yes vs no)
- Renal impairment grade (normal vs mild vs moderate vs severe)
- Hepatic impairment grade (normal vs mild vs moderate vs severe)

The primary endpoint will be summarized for subgroups and a forest plot of ORR and its 95% CI for each subgroup will be provided.

7.2.3. Sensitivity Analyses for Primary Endpoint

The primary endpoint will be analyzed using the PP population as a sensitivity analysis to the efficacy evaluable population.

7.3. Analysis of the Secondary Efficacy Parameters

7.3.1. Secondary Endpoints Involving Objective Response Rate

The secondary endpoints involving ORR in this study includes:

- ORR in subjects with other FGF/FGFR alterations (Cohort B).
- ORR in all subjects with FGF/FGFR alterations (Cohorts A and B).
- ORR in subjects negative for FGF/FGFR alterations (Cohort C [United States only]).

ORR is based on review of scans by an independent centralized radiological review committee, and confirmation of response is required. The second endpoints involving ORR will be analyzed in the same way as the primary endpoint, and the 95% CI for ORR will be calculated using exact method for binomial distribution.

7.3.2. Progression-Free Survival

Progression-free survival is defined as the length of time from the start of the study drug (Day 1) until the earlier of death or PD by RECIST v1.1 as assessed by the independent centralized

radiological review committee. The date of PD will be the timepoint at which progression is first recorded. Censoring for PFS will follow the algorithm outlined in Table 1, which is based on the FDA Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (FDA 2015, FDA 2018)

The number of subjects who progressed or died and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median PFS will be presented with its 95% CI. The 95% CI will be calculated using the Brookmeyer and Crowley's method (Brookmeyer and Crowley 1982). The PFS analysis will be conducted for Cohorts A, B, and C, respectively.

Progression-free survival for Cohort A will be analyzed for each subgroup as described in Section 7.2.2, with the exception of renal/hepatic impairment. If there are sufficient subjects in each subgroup, forest plots of median PFS and its 95% CI for each subgroup will be provided.

Table 1: Evaluation and Censoring of Progression-Free Survival

Situation	Outcome	Date of Progression or Censoring
No baseline tumor assessment	Censored	Day 1
No adequate postbaseline response assessment	Censored	Day 1
Progression documented between scheduled response assessments	Progressed	Date of first overall response of progressive disease
No progression	Censored	Date of last adequate response assessment (not NE and not missing)
Study discontinuation for undocumented progression	Censored	Date of last adequate response assessment (not NE and not missing)
Study discontinuation for toxicity or other reason	Censored	Date of last adequate response assessment (not NE and not missing)
New anticancer treatment started	Censored	Date of last adequate response assessment (not NE and not missing) prior to starting of the new anticancer treatment
Death before first progressive disease 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 adequate response assessment (not NE and not missing)

NE = not evaluable.

7.3.3. Duration of Response

For objective responders, DOR is the time from the first overall response contributing to an objective response as assessed by an independent centralized radiological review committee per RECIST v1.1, to the earlier of death or first overall response of PD occurring after the first overall response contributing to the objective response. Censoring of DOR will follow the same algorithm as the censoring of PFS (see Section 7.3.2).

The total number of responders, the number of subjects who progressed or died, and the number of subjects censored will be summarized. The Kaplan-Meier estimate of median DOR will be presented with its 95% CI. The 95% CI for DOR will be calculated using the Brookmeyer and Crowley's method (Brookmeyer and Crowley 1982). The DOR analysis will be conducted for Cohorts A, B, and C, respectively.

Subgroup analysis of DOR for Cohort A will be conducted for renal impairment grade and for hepatic impairment grade if there are sufficient responders in each subgroup.

7.3.4. Disease Control Rate

Disease control rate is defined as the proportion of subjects with best response of CR, PR, or SD based on review of scans by an independent centralized radiological review committee per RECIST v1.1. Confirmation of CR and PR is required and documented in the Independent Central Review Charter. This analysis will be based on efficacy evaluable population for subjects in Cohorts A, B, and C, respectively. 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 DCR. The 95% CI for DCR will be calculated using exact method for binomial distribution.

7.3.5. Overall Survival

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

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. The 95% CI for OS will be calculated using the Brookmeyer and Crowley's method (Brookmeyer and Crowley 1982). The OS analysis will be conducted for Cohorts A, B, and C, respectively.

7.4. Analysis of Other Efficacy Parameters

7.4.1. Largest Percentage Reduction in Sum of Diameters of Target Lesions

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.

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 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.

7.4.2. Investigator Assessed Efficacy Parameters

Objective response rate, PFS, DOR, and DCR based on review of scans by investigator per RECIST v1.1 will be analyzed in a similar fashion as those parameters assessed by an independent centralized radiological review committee. Confirmation of CR and PR is not required.

Objective response rate, DOR, and DCR assessed by an independent centralized radiological review committee per RECIST v1.1 without requirement of CR and PR confirmation will also be analyzed.

7.4.3. Time to Response

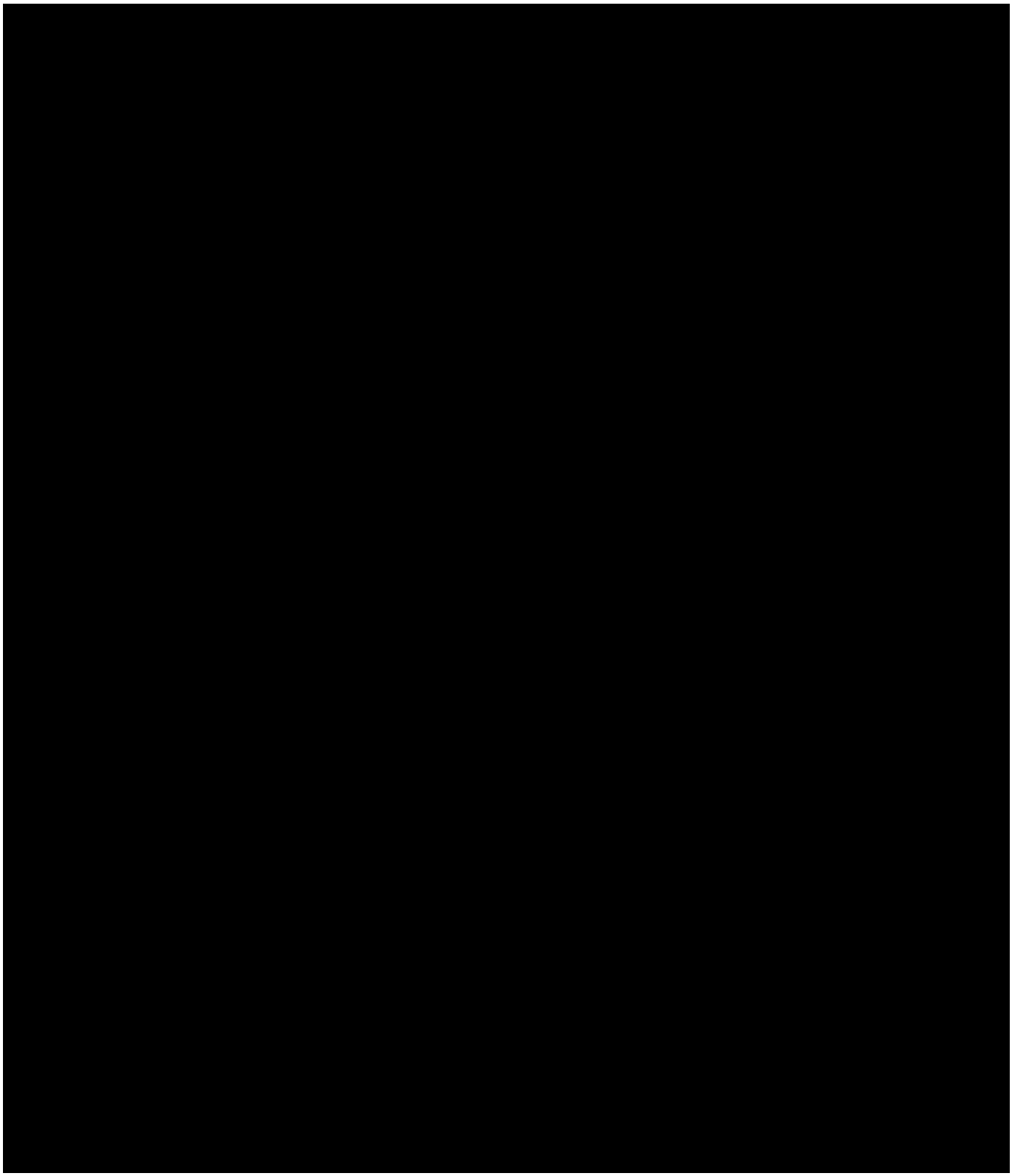
Time-to-onset of response is defined as the time from the start of the study drug (Day 1) until the date of first confirmed CR or PR as assessed by the independent centralized radiological review committee per RECIST v1.1. The date of first confirmed CR or PR is the date when the criteria for CR or PR is first met and the CR or PR is confirmed at a subsequent timepoint.

For responders, time-to-onset of response will be summarized.

7.4.4. Eastern Cooperative Oncology Group Performance Status

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

[redacted]



7.6. Pharmacokinetic Analyses

The data will be analyzed by standard population PK methods using appropriate software (eg, NONMEM®). An attempt will be made to evaluate the effect of demographic characteristics and baseline characteristics (eg, age, weight, sex, race, renal function, FGF/FGFR alteration status) on the population PK profile. Additionally, exposure-response analyses for key efficacy and safety parameters may also be considered if there are sufficient data available.

8. SAFETY AND TOLERABILITY

Appendix A 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 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 MedDRA preferred term and system organ class. Severity of AEs will be described and graded using the NCI CTCAE v4.03. The CTCAE v4.03 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 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. The incidence of AEs and treatment-related AEs will be tabulated. Serious adverse events 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 they can unequivocally be defined as not treatment-emergent.

8.2.2. Clinically Notable Adverse Events

Specific groupings of clinically notable AEs will be considered and the number of subjects with at least 1 event within each grouping will be reported. Such groups consist of AEs for which there is a specific clinical interest in connection with the study drug or AEs that are similar in nature (although not identical). The groups are defined as per Table 4. All clinically notable AEs are defined through reviewing preferred term according to the current MedDRA v21.1.

Table 4: Clinically Notable Adverse Events Groupings

Categories	Preferred Terms
Serous retinal detachment	Serous retinal detachment, detachment of macular retinal pigment epithelium, detachment of retinal pigment epithelium, retinal detachment, subretinal fluid, retinal oedema, chorioretinopathy, retinal pigment epitheliopathy, chorioretinal disorder, retinopathy
Nail toxicity	Nail toxicity, nail bed tenderness, nail bed disorder, nail bed bleeding, nail disorder, nail discolouration, nail discomfort, nail dystrophy, nail hypertrophy, nail ridging, nail infection, onychalgia, onychoclasis, onycholysis, onychomadesis, onychomycosis, paronychia, fungal paronychia
Hyperphosphatemia	Hyperphosphataemia, blood phosphorus increased
Hypophosphatemia	Hypophosphataemia, blood phosphorus decreased

8.2.3. Time-to-First-Event Analyses

For clinically notable AEs identified in Table 4, time-to-first event analyses will be performed.

Time-to-first occurrence of an AE is defined as the time from start of study drug to the date of first occurrence of an AE, that is, time in days is calculated as (start date of first occurrence of AE) – (date of first dose of study drug) + 1. A subject will be censored for time-to-onset if:

- The subject dies with no event.
- The subject receives a new anticancer therapy with no event or before the event has occurred.
- The subject discontinues from the study treatment with no event (up to 30 days after study treatment discontinuation).
- The subject is still ongoing at the cutoff with no event.

In the absence of an event, the censoring date applied will be the earliest from the following dates: date of last dose + 30 days, analysis cutoff, new anticancer therapy start, and death.

The analyses will comprise the following:

- Time-to-onset of first new TEAE (any grade)
- Time-to-onset of first new TEAE of Grade 3 or higher

8.2.4. Adverse Event Summaries

An overall summary of AEs by cohort will include:

- Number (%) of subjects reporting any TEAEs
- Number (%) of subjects reporting any SAEs
- Number (%) of subjects reporting any Grade 3 or higher TEAEs
- Number (%) of subjects reporting any TEAEs related to INCB054828
- Number (%) of subjects who temporarily interrupted INCB054828 because of TEAEs
- Number (%) of subjects who permanently discontinued INCB054828 because of TEAEs
- Number (%) of subjects with INCB054828 dose reductions because of TEAEs
- Number (%) of subjects who had a fatal TEAE

The following summaries for each cohort will be produced by MedDRA term (if ≤ 10 subjects appear in a table, a listing may be appropriate):

- Summary of TEAEs by system organ class and preferred term
- Summary of TEAEs by preferred term in decreasing order of frequency
- Summary of TEAEs by system organ class, preferred term, and maximum severity
- Summary of Grade 3 or higher TEAEs by system organ class and preferred term
- Summary of Grade 3 or higher TEAEs by preferred term in decreasing order of frequency
- Summary of treatment-related TEAEs by system organ class and preferred term
- Summary of treatment-related TEAEs by preferred term in decreasing order of frequency
- Summary of Grade 3 or higher treatment-related AEs by system organ class and preferred term
- Summary of TEAEs with a fatal outcome by system organ class and preferred term
- Summary of serious TEAEs by system organ class and preferred term
- Summary of treatment-emergent SAEs by preferred term in decreasing order of frequency
- Summary of treatment-related serious TEAEs by system organ class and preferred term
- Summary of TEAEs leading to dose reduction by system organ class and preferred term
- Summary of TEAEs leading to dose interruption by system organ class and preferred term
- Summary of TEAEs leading to discontinuation of study drug by system organ class and preferred term
- Summary of treatment-emergent non-SAEs by system organ class and preferred term
- Summary of TEAEs and Grade 3 or higher AEs by preferred term in decreasing order of frequency
- Summary of clinically notable TEAEs by category and preferred term

- Summary of Grade 3 or higher clinically notable TEAEs by category and preferred term
- Summary of serious clinically notable TEAEs by category and preferred term
- Summary of clinically notable TEAEs leading to dose reduction by category and preferred term
- Summary of clinically notable TEAEs leading to dose interruption by category and preferred term
- Summary of clinically notable TEAEs leading to discontinuation of study drug by category and preferred term
- Summary of clinically notable TEAEs by category and preferred term: life-table method
- Summary of Grade 3 or higher clinically notable TEAEs by category and preferred term: life-table method

8.3. Clinical Laboratory Tests

8.3.1. Laboratory Value Definitions

For numeric laboratory results, the change and percentage change from baseline will be calculated. Baseline will be determined according to Section 4.1.3. If there are multiple values that meet the criteria for baseline, the value from the central laboratory has priority over the 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 of 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

All test results and associated normal ranges from central 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 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 phosphate, calcium, sodium, 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, and parathyroid hormone.

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. 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, weight, and body temperature, will be summarized descriptively.

Criteria for clinically notable vital sign abnormalities are defined in Table 5. The abnormal values for subjects exhibiting clinically notable vital sign abnormalities will be listed. Alert vital signs are defined as an absolute value outside of 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 5: 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	> 38°C	< 35.5°C
Respiratory rate	> 24 breaths/min	< 8 breaths/min

8.5. Electrocardiograms

Twelve-lead ECGs including PR, QRS, QT, and QTcF intervals, as well as heart rate, 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 INCB054828 as the baseline value.

Criteria for clinically notable ECG abnormalities are defined in Table 6. The abnormal values for subjects exhibiting clinically notable ECG abnormalities will be listed with study visit. Alert ECG values are defined as both the absolute value outside the defined range and the percentage change greater than 25% (QRS 30%). The abnormal values for subjects exhibiting alert ECG abnormalities will be identified and listed.

Table 6: 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

9. INTERIM ANALYSES

For Cohort A (FGFR2 translocation), a futility analysis will be performed when approximately 25 subjects are enrolled into the cohort and have at least 1 tumor assessment or have permanently discontinued study treatment. Cohort A can be stopped for futility if 2 or fewer responders are observed, for which there is less than a 10% probability of claiming ORR > 15% at final analysis based on a 60-subject cohort, as initially planned before Amendment 5. This rule is just a guidance and is nonbinding.

Cohorts B (other FGF/FGFR alterations) and C (United States only; negative for FGF/FGFR alterations) can be stopped if 1 or less responders are observed within the first 10 subjects enrolled into the cohort who have at least 2 cycles of data. This rule is just a guidance and is nonbinding.

10. CHANGES AND MODIFICATIONS TO THE ANALYSIS PLAN

All versions of the SAP are listed in Table 7.

Table 7: Statistical Analysis Plan Versions

SAP Version	Date
Original	12 JUN 2017
Amendment 1	15 APR 2019

10.1. Changes to Protocol-Defined Analyses

Not applicable.

10.2. Changes to the Statistical Analysis Plan

The original SAP has been updated to incorporate the Protocol Amendments 5 and 6 updates. Specific changes are outlined below:

- Subgroup analyses have been added for the primary endpoint (ORR in Cohort A) and the secondary endpoint (PFS in Cohort A).
- Renal and hepatic subgroup analyses for ORR and DOR have been added.
- Average daily dose has been updated to use duration of treatment as the denominator.
- Move analysis of largest percentage reduction in sum of diameters of target lesions from secondary efficacy parameters section to other efficacy parameters section
- Time-to-response analysis has been added.
- Investigator assessed efficacy parameters have been added as other efficacy analyses.
- Summary of weight has been moved from efficacy section to vital sign section.
- Clinical notable adverse events and time to first occurrence of clinical notable adverse events have been added.

11. REFERENCES

Brookmeyer R, Crowley J. A confidence interval for the median survival time. Biometrics 1982;38:29-41.

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 (FDA). Guidance for Industry: Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics. 2015. https://www.fda.gov/downloads/drugs/guidances/ucm259421.pdf. Accessed April 12, 2019.

Food and Drug Administration (FDA). Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics. 2018. https://www.fda.gov/downloads/Drugs/Guidances/ucm071590.pdf. Accessed April 12, 2019.

APPENDIX A. PLANNED TABLES, FIGURES, AND LISTINGS

This appendix provides a list of the planned tables, figures, and listings for the Clinical Study Report. Standard tables will follow the conventions in the Standard Safety Tables initial version. Shells are provided for nonstandard tables in a separate document. In-text tables are identical in structure and content as appendix tables, but follow a Rich Text Format.

The lists of tables, figures, and listings are to be used as guidelines. Modifications of the lists that do not otherwise affect the nature of the analysis will not warrant an amendment to the SAP. Each table will display Cohorts A, B, and C unless otherwise noted in the title.

Tables

Table No.	Title	Population
Baseline and Demographic Characteristics		
1.1.1	Analysis Populations	All Enrolled
1.1.2	Summary of Subject Disposition	Efficacy, Safety
1.1.3	Summary of Number of Subjects Enrolled by Country and Site	Efficacy, Safety
1.1.4	Summary of Protocol Deviations	Efficacy, Safety
1.1.5	Summary of Cohorts	All Enrolled
1.2.1	Summary of Demographics and Baseline Characteristics	Efficacy, Safety
1.2.2	Summary of Disease History	Efficacy, Safety
1.2.3	Summary of Prior Cancer Therapy	Efficacy, Safety
1.3.1	Summary of Medical History	Efficacy, Safety
1.3.2	Summary of Hepatitis History	Efficacy, Safety
1.4.1	Summary of Prior Medications	Efficacy, Safety
1.4.2	Summary of Concomitant Medications	Efficacy, Safety
Efficacy		
2.1.1	Summary of Best Response and Objective Response Rate – Cohort A	Efficacy
2.1.2	Summary of Best Response and Objective Response Rate – Cohort A	Per Protocol
2.1.3	Subgroup Analysis of Best Response and Objective Response Rate – Cohort A	Efficacy
2.2.1	Summary of Best Response and Objective Response Rate – Cohort B	Efficacy
2.2.2	Summary of Best Response and Objective Response Rate – Cohorts A and B	Efficacy
2.2.3	Summary of Best Response and Objective Response Rate – Cohort C	Efficacy
2.2.4	Summary of Duration of Response	Efficacy
2.2.5	Subgroup Analysis of Duration of Response – Cohort A	Efficacy
2.2.6	Summary of Disease Control Rate	Efficacy
2.2.7	Summary of Progression-Free Survival	Efficacy
2.2.8	Subgroup Analysis of Progression-Free Survival – Cohort A	Efficacy
2.2.8	Summary of Overall Survival	Efficacy
2.3.1	Summary of Best Change in Target Lesion Size (Sum of Diameters, mm)	Efficacy
2.3.2	Summary of Time to Response	Efficacy
2.3.3	Summary of ECOG Performance Status	Efficacy
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Table No.	Title	Population
Safety		
3.1.1	Summary of Study Drug Exposure	Safety
3.1.2	Summary of Study Drug Compliance	Safety
3.1.3	Summary of Study Drug Dose Modification and Final Dose	Safety
3.2.1	Overall Summary of Treatment-Emergent Adverse Events	Safety
3.2.2	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.3	Summary of Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety
3.2.4	Summary of Treatment-Emergent Adverse Events by MedDRA System Organ Class, Preferred Term, and Maximum Severity	Safety
3.2.5	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.6	Summary of Grade 3 or Higher Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety
3.2.7	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.8	Summary of Treatment-Related Treatment-Emergent Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety
3.2.9	Summary of Grade 3or Higher Treatment-Related Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.10	Summary of Treatment-Emergent Adverse Events With a Fatal Outcome by MedDRA System Organ Class and Preferred Term	Safety
3.2.11	Summary of Treatment-Emergent Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.12	Summary of Treatment-Emergent Serious Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety
3.2.13	Summary of Treatment-Related Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.14	Summary of Treatment-Emergent Adverse Events Leading to INCB054828 Dose Reduction by MedDRA System Organ Class and Preferred Term	Safety
3.2.15	Summary of Treatment-Emergent Adverse Events Leading to INCB054828 Dose Interruption by MedDRA System Organ Class and Preferred Term	Safety
3.2.16	Summary of Treatment-Emergent Adverse Events Leading to Discontinuation of INCB054828 by MedDRA System Organ Class and Preferred Term	Safety
3.2.17	Summary of Treatment-Emergent Non-Serious Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
3.2.18	Summary of Treatment-Emergent Adverse Events and Grade 3 or Higher Adverse Events by MedDRA Preferred Term in Decreasing Order of Frequency	Safety
3.2.19	Summary of Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events by Category and Preferred Term	Safety
3.2.20	Summary of Grade 3 or Higher Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events by Category and Preferred Term	Safety
3.2.21	Summary of Serious Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events by Category and Preferred Term	Safety

Table No.	Title	Population
3.2.22	Summary of Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events Leading to Dose Reduction by Category and Preferred Term	Safety
3.2.23	Summary of Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events Leading to Dose Interruption by Category and Preferred Term	Safety
3.2.24	Summary of Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events Leading to Discontinuation of Study Drug by Category and Preferred Term	Safety
3.2.25	Summary of Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events by Category and Preferred Term: Life-Table Method	Safety
3.2.26	Summary of Grade 3 or Higher Sponsor-Defined Clinically Notable Treatment-Emergent Adverse Events by Category and Preferred Term: Life-Table Method	Safety
Laboratory		
3.3.1	Summary of Laboratory Values – Hematology	Safety
3.3.2	Shift Summary of Hematology Values in CTC Grade – To the Worst Abnormal Value	Safety
3.3.3	Summary of Treatment-Emergent Worsening of Laboratory Abnormalities – Hematology	Safety
3.3.4	Summary of Laboratory Values – Chemistry	Safety
3.3.5	Shift Summary of Chemistry Values in CTC Grade – To the Worst Abnormal Value	Safety
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3.3.7	Summary of Laboratory Values – Coagulation	Safety
3.3.8	Shift Summary of Coagulation Values in CTC Grade – To the Worst Abnormal Value	Safety
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3.4.3	Summary of Pulse	Safety
3.4.4	Summary of Body Temperature	Safety
3.4.5	Summary of Respiratory Rate	Safety
3.4.6	Summary of Body Weight	Safety
ECG		
3.5.1	Summary of PR Interval (ms) From 12-Lead ECG	Safety
3.5.2	Summary of QRS Interval (ms) From 12-Lead ECG	Safety
3.5.3	Summary of QT Interval (ms) From 12-Lead ECG	Safety
3.5.4	Summary of QTcF Interval (ms) From 12-Lead ECG	Safety
3.5.5	Summary of Heart Rate (bpm) From 12-Lead ECG	Safety
3.5.6	Summary of Outliers of QT and QTcF Interval Values From 12-Lead ECG	Safety
3.5.7	Summary of Clinically Significant ECG Abnormalities	Safety

Figures

Figure No.	Title
4.1	Forest Plot of Objective Response Rate (Efficacy)
4.2.1	Kaplan-Meier Estimates of Progression-Free Survival (Efficacy)
4.2.2	Kaplan-Meier Estimates of Duration of Response (Efficacy)
4.2.3	Kaplan-Meier Estimates of Overall Survival (Efficacy)
4.3.1	Waterfall Plot of Best Percent Change of Target Lesion Size From Baseline (Efficacy)
4.3.2	Swimmer Plot of Duration of Treatment (Efficacy)
4.3.3	Forest Plot of Progression-Free Survival (Efficacy)
4.3.4	Forest Plot of Duration of Response (Efficacy)
4.5	Kaplan-Meier Estimates of Time to Adverse Event (Safety)
4.6	Line Graph of Mean Change From Baseline for Selected Laboratory Values (Safety)

Listings

Listing No.	Title
2.1.1	Analysis Population
2.1.2	Subject Enrollment and Disposition Status
2.1.3	Subject Inclusion and Exclusion Criteria Violations
2.2.1	Protocol Deviations
2.4.1	Demographic and Baseline Characteristics
2.4.2	Oncology Disease History
2.4.3	Prior Systemic Therapy
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2.4.5	Prior Radiation Treatment
2.4.6	Post Therapy
2.4.7	Medical History
2.4.8	Hepatitis History
2.4.9	Prior and Concomitant Medication
2.4.10	FGF/FGFR Alterations
2.5	Study Drug Compliance
2.6.1	Best Overall Response, Duration of Response, Progression-Free Survival, and Overall Survival
2.6.2	Investigator-Reported Assessment by RECIST v1.1
2.6.3	Response Assessment: Target Lesions
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2.6.5	Response Assessment: New Lesions
2.6.6	Duration of Treatment, Best Overall Response, and Duration of Response
2.6.7	Tumor Tissue
2.6.8	ECOG Performance Status
[redacted]	[redacted]
[redacted]	[redacted]
2.7.1	Study Drug Administration
2.7.2	Adverse Events
2.7.3	INCB054828 Treatment-Related Adverse Events
2.7.4	Adverse Events Leading to Interruption, Reduction, or Discontinuation of INCB054828
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Listing No.	Title
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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
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2.11.1	Eye Examinations

Signature Manifest

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