STATISTICAL ANALYSIS PLAN

NCT #: NCT02667886

A Phase 1/2 Trial of X4P-001 as Single Agent and in Combination with Axitinib in Patients with Advanced Renal Cell Carcinoma

Protocol Number:	X4P-001-RCCA
Protocol Version and Date:	V7.0 08 June 2018
Study Drug Name:	X4P-001
Phase:	Phase 1/2
Sponsor:	X4 Pharmaceuticals, Inc.
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Protocol Title:	A Phase 1/2 Trial of X4P-001 as Single Agent and in Combination with Axitinib in Patients with Advanced Renal Cell Carcinoma
Protocol Number:	X4P-001-RCCA
Sponsor:	X4 Pharmaceuticals, Inc. 955 Massachusetts Ave, 4th Floor Cambridge, MA 02139

By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidance and guidelines.

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ABBREVIATIONS

Abbreviation	Explaination
AE	Adverse event
ATC	Anatomical Therapeutic Chemical
$AUC_{0\text{-last}}$	Area under the plasma concentration curve from 0 to the last quantifiable concentration post-dose
BID	Twice daily
BLQQ	Below the limit of quantitation
BOR	best overall response
ccRCC	clear cell Renal Cell Carcinoma
CE	Clinically Evaluable
CI	Confidence interval
cm	Centimeter
C_{max}	Maximum observed plasma concentration
C_{min}	Minimum observed plasma concentration
CR	Complete response
CPI	Checkpoint inhibitor
CTCAE/CTC	Common Terminology Criteria for Adverse Events
CV	Coefficient of variation
DCR	Disease Control Rate
DLT	Dose Limiting Toxicity
DOR	Duration of response
DRC	Data Review Committee
ECG	Electrocardiogram
ECOG PS	Eastern Cooperative Oncology Group Performance Scale
eCRF	Electronic Case Report Form
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
ICF	Informed consent form
iCR	CR per iRECIST
IO	Intraosseous infusion
iORR	ORR per iRECIST
iPFS	PFS per iRECIST
iPR	PR per iRECIST
iRECIST	Modified Response Evaluation Criteria in Solid Tumors for immune-based therapeutics

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Abbreviation	Explaination
iSD	SD per iRECIST
ITT	Intent-to-treat
iUPD	unconfirmed progression of disease per iRECIST
kg	Kilogram
MDSC	Myeloid-derived Suppressor Cells
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
MTD	Maximum Tolerated Dose
mTKI	Multi-tyrosine Kinase Inhibitors
NCI	National Cancer Institute
ORR	Objective response rate
PBMC	Peripheral blood mononuclear cells
PD	Pharmacodynamic(s)/ Progression of disease
PFS	Progression-Free Survival
PK	Pharmacokinetics
PR	Partial response
PT	Preferred term
QD	once daily
QRS	Complex containing Q wave, R wave and S wave
QT	Interval between start of the Q wave and the end of the T wave
QTcF	QT corrected by Fridericia's formula
RCC	Renal cell carcinoma
RECIST	Response Evaluation Criteria in Solid Tumors
RP2D	Recommended Phase 2 dose
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Stable disease
SI	International System of Units
STD	Standard deviation
SOC	System Organ Class
TEAE	Treatment-Emergent Adverse Event
TKI	Tyrosine kinase inhibitor
T_{max}	Time to maximum concentration
TTP	Time to progression
uBOR	Unconfirmed best overall response

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Abbreviation	Explaination
VEGFR	Vascular endothelial growth factor receptor
WBC	White Blood Cell Count
WHO	World Health Organization

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1 INTRODUCTION

This statistical analysis plan is designed to outline the statistical methods in evaluating the safety and efficacy of X4P-001 used in combination with axitinib and as a single agent in patients with advanced renal cell carcinoma.

Biomarker analysis will be addressed in separate analysis plans.

This document has been prepared based on protocol version 7.0 dated 08 June 2018 and Electronic Case Report Form (eCRF) dated 12th December 2021.

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2 STUDY DESIGN OVERVIEW

2.1 Overall Study Design

The study will be conducted in patients with advanced clear cell renal cell carnimoa (ccRCC) and includes Part A, Part B and Part C.

- **Part A** will assess the safety and tolerability of escalating doses levels of X4P-001 in combination with axitinib. The X4P-001 dose level for the initial cohort is 200 mg BID. Subsequent cohorts will be administered X4P-001 QD. The initial QD dose level will be 400 mg QD (representing the same total daily exposure as 200 mg BID), and then progressing to 600, 800, and 1200 mg. A safe maximum tolerated dose (MTD) and/or recommended phase 2 dose (RP2D) will be identified in Part A. The RP2D may be the same as the MTD or may be lower.
- **Part B** is an expansion cohort assessing the safety, tolerability, and treatment effect of X4P-001 at RP2D in combination with axitinib in approximately 45 patients. If the RP2D is determined before the MTD is reached in Part A, Part B may be initiated while Part A is ongoing.
- **Part C** will assess the safety, tolerability, and treatment effect of X4P-001 as monotherapy in patients with advanced ccRCC and may be initiated after the MTD of X4P-001 with axitinib is defined in Part A. If that MTD was ≤800 mg QD, then the MTD as monotherapy will be defined by enrolling additional dose-escalation cohorts to receive X4P-001 as a single agent up to, but not exceeding, 1200 mg QD.

The study schedule is presented in Table 1.

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Table 1: Schedule of Events

Procedure[1]	Screening Visit[2]	Cycle 1		Cycle 2		Cycle 3		Cycle 4		Subsequent Odd-Numbered Cycles 5-19	Subsequent Even-Numbered Cycles 6-20	Repeats every 12 weeks[4]			EOT[5]	EOS[6]
		D1[3]	D15	D1	D15	D1	D15	D1	D15	D1	D1	Cycle 21 D1	Cycle 22 D1	Cycle 23 D1		
Informed Consent	X															
Inclusion/Exclusion Criteria	X															
Medical History	X															
History of Renal Cell Carcinoma	X															
Vital Signs[7]	X	X	X	X	X	X		X		X	X	X			X	X
Body weight & height[8]	X	X		X		X				X		X			X	X
ECOG PS	X					X				X		X			X	
Physical Examination	X	X		X		X				X		X			X	X
Ophthalmologic Examination[9]	X[10]			X		X		X		X		X			X	
12-Lead ECG	X	X	X[11]			X				X		X			X	X
Safety Laboratory Tests[12, 13]	X[14]	X	X	X	X	X	X	X	X	X	X	X			X	X
Serology	X[14]															
Pregnancy Test[13, 15]	X[14]	X[15]													X	X
Thyroid Function Test[13, 16]	X[14]	X		X		X		X		X		X			X	X
Blood Biomarker Collection[13, 17]		X		X		X		X		X		X			X	X
PK Collection[18]		X[19]	X[19]	X[20]	X[20]											
PD Collection[18]		X[19]	X[19]													
CT Imaging[21]	X					X				X		X			X[22]	
Administration of Study Drug(s) in clinic[23]		X	X	X	X											
Dispense eye drops and nasal spray[24]		X														
AE & Concomitant Med Monitoring[25]	X	X	X	X	X	X	X	X	X	X	X	X	X[26]	X[26]	X	X

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1. The schedule is presented relative to Study Cycle, Day within Cycle, and Time of Dosing. The calendar day of the first administration of study drug is designated Day 1. Each Cycle represents 4 weeks (28 days). Pre- and post-dose intervals are relative to the time of oral administration, designated 0 hr.
2. Screening activities may be initiated up to 28 days prior to Day 1.
3. To allow for holidays and scheduling flexibility, on-treatment visits may be performed within ± 3 calendar days of the day indicated; ophthalmology exams and CT imaging within ± 4 calendar days.
4. For cycles >23, perform assessments as indicated for Cycle 21-23 every 12 weeks until EOT visit.
5. The EOT visit will be performed within 6 days after the last dose of study drug or the decision to terminate treatment prematurely.
6. The EOS visit is scheduled for 30 days (± 4 days) after the last dose of study drug. In the event the EOT visit is delayed, the EOS visit will be performed at least 14 days after the EOT visit.
7. Vital signs comprise heart rate, blood pressure, and temperature. For patients dosed in clinic on PK collection days, vital signs will be performed pre-dose.
8. Body height needs to be measured at screening only.
9. Ophthalmologic exam – see Protocol Section 7.1.1.5. for details. Note: an optometrist may complete the exam if all requirements can be met, including use of appropriate equipment to obtain the retinal photographs.
10. Screening ophthalmologic exam reports and retinal photos must be submitted to the sponsor at least 5 business days prior to Cycle 1 Day 1 to allow central review for eligibility.
11. ECG should be performed at 2 hr (± 15 mins) post-dose.
12. Safety laboratory tests – hematology and chemistry (see Protocol Section 7.2.1 for details).
13. Safety laboratory tests should be drawn and sent to central laboratory for analysis.
14. All laboratory tests required for screening will be performed by the central laboratory. Specimens should be submitted no more than 14 days prior to Day 1.
15. Women of child-bearing potential only (see Protocol Section 7.4.1.3). On Day 1, a urine or serum pregnancy test will be done at the site and the results obtained prior to dosing.
16. Thyroid Function Tests are performed for Parts A and B only; Protocol Section 7.2.1 for details.
17. Blood samples for tumor-related biomarkers; see Protocol Section 7.1.3.2 for details.
18. PK and PD samples will be collected for all patients in Part A and Part C, and for at least 15 patients in Part B.
19. PK and PD samples to be taken from 0-4 hr on Cycle 1 Day 1 and from 0-8 hr on Cycle 1 Day 15. See Protocol Section 7.1.2 and Protocol Section 7.1.3.1 for details of times for PK and PD dense sampling. For Part B subjects who do not complete PK/PD dense sampling (e.g. after the minimum 15 patients' samples are collected), a pre-dose PK sample will be collected at these visits.
20. PK sample is collected at Pre-dose only.
21. CT imaging of chest, abdomen, and pelvis; see Protocol Section 7.1.4.1 for details. Patients with history or current evidence of CNS disease should also have brain imaging by MRI.
22. CT imaging is not required at the EOT visit if performed within the previous 4 weeks and patient is being terminated for disease progression.
23. Study drugs will be self-administered by the patient daily, except at PK visits, when study drugs will be administered in the clinic.
24. See Protocol Section 7.4.4.1 for details.
25. Concomitant illnesses that worsen or illnesses with onset in screening period will be recorded as AEs (see Protocol Section 8).
26. Can be completed via telephone.

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2.2 Sample Size

The maximum numbers of patients planned to be enrolled in Parts A and C are as follows:

- **Part A,** Dose-escalation: 6 patients per dose level (5 planned dose levels)
- **Part B**, A RP2D expansion cohort: approximately 45 patients will be enrolled.
- **Part C**, Dose-escalation (to be done only if the MTD for X4P-001 from Part A (combination treatment) is ≤800 mg QD): up to 6 patients per single agent dose- escalation level (maximum 3 dose levels).
- **Part C**, Expansion: maximum 15 patients

For **Part A**, Table 2 presents the probability of escalation from a lower dose to the next higher dose, for true rates of DLT ranging from 10% to 90%.

Table 2: Relationship between Underlying DLT Rate and Probability of Dose Escalation

Underlying DLT Rate	10%	20%	30%	40%	50%	60%	70%	80%	90%
Probability of Dose Escalation	91%	71%	49%	31%	17%	8%	3%	1%	0.1%

For **Part B**, with 45 patients at the RP2D, the two-sided 90% confidence interval width for any binary response rate (e.g., DLT or binary PD markers) will be approximately 0.24, assuming a 40% response rate. If a dose de-escalation occurs after the first 12 patients, the remaining 33 patients will be dosed at a lower dose level. With 33 patients, the confidence interval width will be approximately 0.28 for a binary response rate.

For **Part C**, with 15 patients, there is a 79% chance of observing at least one AE with the true underlying rate of 10%, and a 54% chance of observing at least one AE with true underlying rate of 5%.

2.3 Randomization and Blinding

This is an open-label Phase 1/2 study. Patients will not be randomized to study treatment.

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3 STUDY OBJECTIVES

3.1 Primary Objectives

- To evaluate the safety and tolerability of escalating dose levels of X4P-001, both in combination with axitinib and as single agent, in patients with advanced ccRCC.

3.2 Secondary Objectives

- To assess the treatment effect (clinical activity) of X4P-001, both in combination with axitinib and as single agent, in patients with advanced ccRCC using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, including progression free survival (PFS).
- To characterize the pharmacokinetics of escalating dose levels of X4P-001 administered orally.

3.3 Exploratory Objectives

- To investigate associations between the treatment effect of X4P-001 (in combination with axitinib and as a single agent) and selected pharmacodynamic and disease-related biomarkers (e.g., circulating CD34+ cells, plasma levels of soluble VEGFR).
- To assess the treatment effect (clinical activity) of X4P-001, both in combination with axitinib and as single agent, in patients with advanced ccRCC using modified Response Evaluation Criteria in Solid Tumours for immune-based therapeutics (iRECIST).

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4 STUDY ENDPOINTS AND EVALUATIONS

4.1 Safety Evaluations

- Treatment emergent adverse events (TEAEs)
- Clinical laboratory assessments
  - Hematology
  - Serum chemistry
  - Coagulation
  - Thyroid function tests (Parts A and B only)
  - Urinalysis
- Physical examination findings
- Ophthalmologic examination
- Vital signs including weight and height
- ECG findings
- ECOG performance status (ECOG PS)

4.2 Efficacy Endpoints and Evaluations

- Objective response rate (ORR), defined as proportion of patients with best overall response of complete response (CR) or partial response (PR)
- Time to objective response, defined as time from first administration of combination regimen to first CR or PR whichever comes first.
- Duration of response (DOR), defined as the time from first CR or PR whichever comes first until the time of disease progression or death by any cause.
- Disease control rate (DCR), defined as proportion of patients with best overall response of CR, PR or stable disease (SD)
- Time to progression (TTP), defined as the time from first administration of combination regimen until progression of disease (PD)
- PFS, defined as the time from first administration of combination regimen until disease progression or death from any cause

4.3 Exploratory Endpoints and Evaluations

- Identification of potential biomarkers, including serum biomarkers and peripheral blood mononuclear cells (PBMC) that may predict response to treatment for combination of X4P-001 and axitinib, and X4P-001 as a single agent
- Tumor response assessed using the iRECIST with bidimensional and/or unidimensional measurements

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4.4 Pharmacokinetics Evaluations

- Plasma or serum concentrations
- Pharmacokinetics parameters
  - Area under the concentration-versus-time-curve from time 0 to the last value above the limit of quantification (AUC_{0-t})
  - Maximum concentration (C_{max})
  - Time to reach maximum concentration (T_{max})

4.5 Pharmacodynamic Evalutions

- Effect of X4P-001 (in combination with axitinib and as a single agent) in white blood cell counts (WBCs) including
  - WBC counts
  - Counts of circulating CD34+ positive cells

4.6 Other Evaluations

- Baseline and demographic characteristics
- Serology test at baseline
- Medical history
- Prior cancer treatment/procedure
- Prior and concomitant medications
- Prognosis factors
- Pregnancy test

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5 DEFINITIONS AND CONVENTIONS FOR DATA HANDLING

5.1 Definition of Baseline

For all evaluations unless otherwise noted, baseline is defined as the most recent non-missing measurement prior to the first administration of study drug.

5.2 Study Event Days and Times

Study events will be recorded using the calendar date and (where applicable) the time to the nearest minute. For purposes of post-study analysis (e.g., tables and listings), study days will be designated as follows:

- Day 1 is defined as the calendar day of the first dose of study drug.
- The days prior to Day 1 are designated Day -1, Day -2, etc.; there is no Day 0.
- The days following the day of the first dose of study drug are designated Day 2, Day 3, etc.
- The day of the dose of study drug is indicated by adding the suffix "L", e.g., if the last dose is administered on Day 43, it will be displayed as "Day 43L". The days following the last administration of study drug are designated Day 1P, Day 2P, etc.

The times of events related to dosing of study drug will be designated as minutes or hours before or after the time of dosing, which is designated as t=0 (zero). Thus, 15 minutes prior to dosing is t = -15 min; 2 hours after dosing is designated t =2 h.

5.3 First Dose Date of Study Treatment

The date of first dose of study treatment is defined as the earliest dose date of study drugs in the treatment regimen.

5.4 Analysis Visit Window

For safety parameters as described in Section 4.1 excluding clinical laboratory data, measurements collected from unscheduled visits will not be included in the by-visit summary tables but will be included in the listings. Early termination visits for safety measurements will not be mapped to any scheduled post-baseline visit but will be used as the last assessment during treatment period.

5.5 Safety Data Handling

For all safety data, only observed data will be used for analyses, and missing data will not be imputed.

Missing values for safety measures at baseline such as laboratory data, vital signs and ECG data will be substituted by values from the screening visit, where available.

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5.5.1 Handling of Repeated Clinical Laboratory Tests

For laboratory results at unscheduled visits, it will be treated as repeated laboratory results for the closest previous visit. The worst results within the visit will be used in the summary tables for that visit. If the lab results are out of the normal range, the higher or lower values will be the worst result. If both results are within normal range, then lab results at unscheduled visit will not be used for summary.

Lab results beyond the detectable limits will be reported as detectable limits for calculating descriptive statistics.

All the laboratory test results will be included in the data listings as reported.

5.5.2 Pharmacokinetic Data Handling

Concentrations below the limit of quantitation (BLQQ) will be reported as zero (0.00) for calculating descriptive statistics. Individual values that are BLQQ will be presented as BLQQ in the concentration data listing.

Unless otherwise specified, no imputation will be performed for missing observations. All data recorded on the eCRF will be included in data listings for the CSR.

5.5.3 Handling of Partial Dates

Partial or missing dates will be handled as follows:

- For adverse events, imputation of missing or partial dates will only be performed to determine treatment emergence. Unless the partial portion of the date or the corresponding end date indicates otherwise, partial and missing start dates will be assumed to be the date of first dose of study medication to conservatively report the event as treatment emergent. If the partial date or the corresponding end date indicates otherwise, the rules for all other data types should be followed as described below.
- For medications, imputation of partial dates will only be performed to determine whether a medication is concomitant. Unless the partial portion of the date indicates otherwise, partial start and end dates will be assumed to be the date of first dose of study medication to conservatively report the medication as concomitant. If the partial dates indicate otherwise, the rules for all other data types should be followed as described below.
- For all other data types (e.g. date of initial diagnosis), if there are partial dates which require imputation for calculations, the day and/or month and/or year will be imputed in a conservative manner; i.e. for the start dates, if only the day is missing, it will be imputed with the first day of the month and if the month is also missing, it will be imputed with the 1st January. For the end dates, if only the day is missing, it will be imputed with the last day of the month and if the month is also missing, it will be imputed with the 31st December.

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6 PLANNED ANALYSIS

6.1 Changes from Planned Analyses in the Protocol

There is no change as planned in the protocol.

6.2 Interim Analysis

There is no formal interim analysis planned. However, safety data will be reviewed at the DRC meeting prior to each dose cohort escalation and after the 1st 12 patients enrolled in Part B are treated for one cycle.

6.3 Final Analyses and Reporting

All final planned analyses per protocol and this analysis plan will be performed only after database lock.

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7 ANALYSIS POPULATIONS AND APPLICATIONS

7.1 All Patients Population

All Patients Population includes all patients who sign an informed consent form (ICF).

7.2 Safety Population

The Safety Population is defined as all patients who receive at least one dose of study drug.

7.3 Intent-to-Treat Population

The Intent-to-Treat (ITT) Population is defined as all patients who receive at least one dose of study drug.

7.4 Clinically Evaluable Population

The Clinically Evaluable (CE) population is defined as all patients who receive at least one dose of study medication, who have at least one valid post-baseline response (CR/PR/SD/PD) and have no major protocol deviations which will impact the efficacy assessment. The CE population will be the primary population for efficacy analysis.

7.5 Pharmacokinetic Population

The pharmacokinetic (PK) population is defined as all patients who have at least one evaluable concentration.

7.6 Application of Analysis Populations

Unless otherwise noted, the analysis populations that will be used for creating the summary table(s) and figures of each type is provided Table 3. Listing will be provided for apporociate population.

Table 3: Application of Populations on Tables and Figures

Type	Safety	ITT	CE	PK
Disposition	X			
Protocol deviations	X			
Demographics	X			
Renal cell carcinoma history and treatment	X			
Prognosis factors	X		X	
Treatment exposure	X			
Safety evaluations	X			
Efficacy evaluations		X	X	
PK evaluations				X

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8 STATISTICAL CONSIDERATIONS

All analyses described in this plan are considered a priori analyses in that they have been defined prior to locking the database. All other analyses, if any, designed subsequently to locking the database, will be considered post hoc analyses and will be described as exploratory analyses in the Clinical Study Report.

All summaries and statistical analysis will be performed by SAS v9.3 or later.

8.1 General Statistical Procedures

Frequency distributions for categorical variables will be provided as number of patients with a response in the category and the percentages of the total number of patients in that column. Percentages will be based on number of patients in the given population as noted. Percentages will be reported to one decimal place.

A 2-sided 95% exact binomial (Clopper-Pearson) confidence interval (CI) for categorical variables without multiplicity adjustment will be provided where appropriate for efficacy analysis.

The descriptive statistics for continuous variables will be number of patients, mean, standard deviation (STD), median, minimum, and maximum. Mean and median will be reported to 1 more decimal place than the raw data, while the STD will be reported to 2 more decimal places than the raw data. Minimum and maximum will be reported the same as the original data.

In addition to the above descriptive statistics, geometric mean with 95% CI and coefficient of variation (CV%) will also be used for the summaries of concentration data and pharmacokinetic parameter values.

Time-to-event analyses will be performed using Kaplan-Meier methods.

Parts A and B will be summarized together and will be presented by dose group and overall. Part C will be summarized separately if there are enough number of subjects enrolled. Otherwise, Part C data will be listed only.

In general, listings will be provided and ordered by patient number and visit for available data unless otherwise specified in the text.

8.2 Subgroup Analyses

Analyses will be performed for selected endpoints for Parts A and B for following subgroups:

- Receiving immediate prior checkpoint inhibitor (CPI) Treatment
- Receiving immediate prior tyrosine kinase inhibitor (TKI) Treatment
- Receiving immediate prior intraosseous infusion (IO) Treatment

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Immediate prior treatment is defined as the immediate treatment prior to first dose of study drug.

Table 4: List of Subgroup Analysis

Type	Safety Population	ITT Population	CE Population
Demographics	X		
Renal cell carcinoma history and treatment	X		
Prognosis factors	X		X
Adverse events (selected*)	X		
Efficacy evaluations (selected**)		X	X

*includes overall summary of TEAE, summary of TEAE by SOC and PT.
**includes ORR, time to response, duration of response and progression free survival.

8.3 Patient Disposition

Patient disposition in Part A and B will be summarized separately from Part C for Safey Population including the following variables:

- Number of patients who are treated
- Number of patients who completed the study
- Number of patients who are still on treatment
- Number of patients included in each analysis population
- Number of patients who discointued treatment and primary reasons for discontinuation in Safety Population and Clinically Evaluable Population
- Number of patients from dose escalation Part A (Part A and B disposition only)
- Number of patients from dose expansion Part B (Part A and B disposition only)

8.4 Protocol Deviations

Major protocol deviations are defined as those deviations from the study protocol that may have the ability to impact the interpretation of the safety and efficacy results.

Major protocol deviations for Part A and Part B of the study include (but are not limited to):

- Received study treatment without meeting eligibility criteria (unless a specific waiver was issued prior to first dose)
- Received wrong treatment or incorrect dose
- Failure to collect data necessary to determine the safety/tolerability of X4P-001
- Received excluded concomitant treatment
- Met withdrawal criteria and was not withdrawn by the site PI nor discussed with the Medical Monitor

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If a reported protocol deviation does not meet classification criteria for major deviation, the protocol deviation will be reported as a protocol deviation without a classification. All protocol deviations will be identified and finalized prior to database lock and documented.

Number and percentage of patients with a major protocol deviation will be tabulated for Safety Population.

8.5 Demographics and Baseline Characteristics

8.5.1 Demographics and Baseline Characteristics

Demographic and baseline parameters will be tabulated using descriptive statistics for Safety Population including following variables:

- Age (years), calculated as (date of screening - date of birth) / 365.25
- Age category (18 to < 65, ≥ 65 and missing)
- Sex
- Race
- Ethnicity
- Height (cm)
- Screening weight (kg)
- Screening ECOG status

Subgroup analysis for demographic and baseline parameters will also be provided.

8.5.2 Serology Tests

Blood samples will be collected for analysis of the following: Hepatitis B surface antigen (HBsAg), antibody to HIV-1 and HIV-2, antibody to hepatitis C virus (HCV).

Serology tests will be listed only.

8.5.3 Medical History

Medical history will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA) dictionary version in effect at the time of database freeze.

The number and percentage of patients with a medical history will be presented by system organ class (SOC) and preferred term (PT) for Safety Population.

8.5.4 Prior Cancer Treatment/Procedures

Prior anticancer treatment and procedures for renal cell carcinoma will be tabulated for Safety Population including:

- Any prior systemic treatment for RCC

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- Number of prior system treatments by category (1, 2, 3 and > 3)
- Any prior procedures
- Number of patients with prior CPI treatment
- Number of patients with prior TKI treatment
- Number of patients with prior IO treatment
- Number of patients with immediate prior CPI treatment
- Number of patients with immediate prior TKI treatment
- Number of patients with immediate prior IO treatment
- Time from initial diagnosis to first dose date in months, defined as (date of first dose – date of first diagnosis +1)/30.4375
- Duration on last treatment (months), defined as (last date of last treatment – first date of last treatment + 1)/30.4375
- Best response to last systemic treatment before entering study

Subgroup analysis will be performed for Safety Population.

8.5.5 Prior and Concomitant Medication

All medications as documented by the investigator will be coded using Anatomical Therapeutic Chemical (ATC) classification based on the World Health Organization (WHO) Drug Dictionary (WHO-DD March 2016).

Concomitant medications will be summarized according to whether they were being taken pre-study (prior medications) and/or during the study (concomitant medications). Prior medications are any that were being taken prior to the first dose of study medication (i.e., the medication stop date is prior to the first dose of study medication). Concomitant medications are any that were being taken on or after the first dose of study medication. If the start and stop dates of the concomitant medications do not clearly define the period during which a medication was taken, it will be assumed to be a concomitant medication.

Prior and concomitant medications will be summarized by preferred term and Anatomical Therapeutic Chemical (ATC) level 3 term (chemical level) for Safety Population.

8.5.6 Prognosis Factors

Patients' survival status before entering the study will be classified into three groups based on IDMC score: poor (score ≥ 3), intermediate (score =1, 2), and favorable prognosis (score=0) [Daniel Y.C. H 2009].

Prognosis will be summarized for Safety Population and Clinically Evaluable Population. Subgroup analysis will also be provided.

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8.6 Efficacy Analysis

Tumor response assessments will be conducted every 8 weeks for 80 weeks (20 cycles) and then every 12 weeks thereafter, at End of Treatment, and as indicated based on new signs, symptoms or laboratory findings.

The efficacy analysis will be performed for RP2D.

8.6.1 RECIST Based Assessment

The following metrics defined in Section 4.2 will be tabulated based on RECIST 1.1 assessment from central review:

- ORR including unconfirmed ORR (CR + PR) and confirmed ORR (confirmed CR + confirmed PR)
- DCR including unconfirmed DCR (CR + PR + SD) and confirmed DCR (confirmed CR + confirmed PR + SD)
- Time to objective response
- DOR
- TTP
- PFS

In addition to the overall analysis, subgroup analysis including tables and figures will also be provided for each assessment whenever it is applicable.

8.6.1.1 Response Summary

Tumor response, ORR and DCR will be tabulated using best overall response for RP2D in Part A and B, as well as Part C if there are enough number of patients enrolled, by dose level, incorporating 95% exact Clopper-Pearson confidence intervals (CIs) for ORR and DCR. The overall response summary will be presented both for confirmed and unconfirmed responses.

Summary of DCR after 24 weeks will also provided.

In addition, the following plots will be provided for both Intent-to-Treat Population and Clincal Evaluable Population:

- Waterfall plots of the best percentage change in tumor size (i.e. maximum tumor reduction, or minimum increase in the absence of any reduction)
- Spider plots of the percentage change from baseline in the sum of diameters over time connected with a line
- Swim lane plots of time on study treatment and on prior axitinib treatment with symbols indicating response start, progression, and withdrawal from study, where applicable.

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Details of target lesions, non-target lesions, new lesions and overall tumor response will be listed.

8.6.1.1.1 Best Overall Response When Confirmation Is Not Required

For each patient, the unconfirmed best overall response (uBOR) is defined as the best time-point overall response that are recorded from the date of first dose until the date of first documented progression/recurrence, or the date of subsequent anti-cancer therapy, or the date of study discontinuation, whichever occurs first.

8.6.1.1.2 Best Overall Response When Confirmation Is Required

To confirm CR or PR response, tumor imaging may be performed at the earliest 4 weeks after the first indication of response or at the next scheduled scan, whichever is clinically indicated. Tumor imaging for confirmation of response occurred less than 4 weeks after the first indication of response of CR or PR may be used for clinical decision, but it will NOT be used for determination of best overall response (BOR).

- For confirmed responses, responses must be confirmed by an image that shows the same response or better, at least 28 days after the original response. A response of PR followed by a response of CR will be considered as a confirmed PR if there is no subsequent CR.
- SD does not require confirmation. If SD is the best response ever seen, to claim SD as the BOR it must last for 6 weeks since start of treatment.

The following table presents the scenarios for determining the BOR.

Table 5: Derivation of Confirmed Best Overall Response

Overall Response at 1st Time Point	**Overall Response at 2nd Time Point**	**Overall Response at 3rd Time Point**	**Overall Response at 4th Time Point**	**Best Overall Response**
CR	CR	Any		CR*
CR	NE	CR	Any	CR*
CR	PR	Any		Not allowed**. Flag as a data issue: cannot be PR after CR.
CR	SD	Any		Not allowed**. Flag as a data issue: cannot be SD after CR.
CR	PD	Any		SD if the 1st time point ≥ 6 weeks, otherwise PD***
PR	**CR**	CR	Any	CR*
PR	CR	Any		PR*. Flag as a data issue if PR or SD is the overall

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Overall Response at 1st Time Point	Overall Response at 2nd Time Point	Overall Response at 3rd Time Point	Overall Response at 4th Time Point	Best Overall Response
				response at the 3rd time point.
PR	PR	Any		PR*
PR	NE/missing	PR	Any	PR*
PR	**SD**	PD		SD if the 2nd time point ≥ 6 weeks, otherwise PD***
		Any other than PD		SD if the the 2nd time point ≥ 6 weeks, otherwise NE***
PR	PD	Any		SD if the 1st time point ≥ 6 weeks, otherwise PD***
SD	PD	Any		SD if the 1st time point ≥ 6 weeks, otherwise PD***
	Any other than PD			SD if the 1st time point ≥ 6 weeks, otherwise NE***
PD	Any			PD
NE				NE

* The best overall response is CR/PR, if the assessments with PR/CR is ⩾ 4 weeks apart (NE is allowed between the assessments of PR/CR); otherwise, it is SD if the 6-week duration of SD is met, else it is PD.
** If a CR is truly met at first time point, then any disease seen at a subsequent time point, even disease meeting PR criteria relative to baseline, makes the disease PD at that point (since disease must have reappeared after CR). Best response would depend on whether minimum duration for SD was met. Review of the CR at first time point is recommended as it is likely the patient had PR, not CR, at the first time point. Under this circumstance, the original CR should be changed to PR and the best response is PR.
*** Unconfirmed responses are considered as stable disease if the SD duration criterion is met.
The bolded assessment is the time point when the BOR is achieved.

8.6.1.2 Time to Objective Response

Median time to objective response in months with 95% CI for RP2D in Part A and Part B will be derived from Kaplan-Meier estimate. Confirmed response will be used in the analysis.

Time to objective response in months is calculated as (earliest dated of CR or PR – first dose date + 1)/30.4375.

For patients without objective response, the date will be censored with the last date of evaluation. However, if patients have at least two sequential missing assessments, patients will be censored at the last assessment prior to the missing assessments.

In addition, similar analysis will be performed for time to objective response only for patients with objective response.

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8.6.1.3 Duration of Response

DOR as well as duration of CR and PR for Part A and Part B will be summarized as median with 95% CI and interquartile range estimated using Kaplan-Meier method with corresponding 95% CIs for RP2D. Confirmed response will be used in the analysis.

DOR in months is calculated as (date of disease progression – date of first CR or PR + 1)/30.4375.

DOR will be calculated ONLY for patients who responded to the study treatment. For patients without disease progression, the date will be censored with the last date of evaluation. However, if patients have at least two sequential missing assessments, patients will be censored at the last assessment prior to the missing assessments.

8.6.1.4 Time to Progression

TTP in months will be calculated as (date of disease progression – date of first dose + 1)/30.4375.

For patients without disease progression, the date will be censored with the last date of assessment. However, if patients missed two or more sequential assessments, patients will be censored at the last assessment prior to the missing assessments.

TTP for Part A and B at RP2D will be summarized as median and interquartile range estimated using the Kaplan-Meier method with corresponding 95% CI and number (%) of censored patients, along with the number and percentage of patients with events due to progression. In addition, the proportion of patients who have not progressed by 6, 9 and 12 months (with 95% CI) will be derived from the Kaplan-Meier estimates.

A Kaplan-Meier plot will also be provided.

8.6.1.5 Progression Free Survival

PFS in months is calculated as (earlier date of PD or death – date of first dose + 1) / 30.4375.

The following censoring rules will be used:

- For patients without disease progression or death, the date will be censored with the last date of assessment.
- Patients who discontinue treatment for any reason and start another treatment for their malignancy will be censored at the date of the last evaluation prior to this new treatment.

However, if patients missed at least two sequential assessments prior, patients will be censored at the last assessment prior to the missing assessments.

PFS will be summarized for Part A and B at RP2D as median and interquartile range estimated using the Kaplan-Meier method with corresponding 95% CI and number (%) of censored patients, along with the number and percentage of patients with events due to progression and due to death.

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Additionally, the proportion of patients' progression-free at 6 and 12 months (with 95% CI) will be derived from the Kaplan-Meier estimates.

A Kaplan-Meier plot of these data will also be presented.

8.6.2 iRECIST Based Assessment

The exploratory objective of treatment effect (tumor response) will also be analyzed by central review using iRECIST criteria for the following metrics (CR or PR are not required to be confirmed):

- iORR
- iPFS

Summaries of iORR for the iRECIST data will be the same as ORR described in Section 8.6.1.1 for the RECIST data.

iPFS in months is calculated as (earlier date of iUPD or death – date of first dose + 1) / 30.4375.

The following rules will be applied:

- If an initial iUPD is confirmed as an iCPD by the next assessment, then date of the initial iUPD will be used.
- If an iUPD is not confirmed
  - If there is no subsequent iSD, iPR or iCR, then iUPD date will be used.
  - If later criteria of iSD, iPR or iCR are met, then later iCR/iPR/iSD will be evaluated in the determination of best response.
- If there is no disease progression or death, the date will be censored at last date of assessment or last date of assessment prior to new treatment.

However, if subjects missed two or more sequential assessments prior, then date of last assessment prior to the missing assessments will be used.

8.7 Safety Analysis

8.7.1 Treatment Exposure

Details of X4P-001 and axitinib administration will be listed. This will include details of drug administration, treatment dispensed and returned, and the frequency and timing of any dose modifications.

Exposure to X4P-001 will be summarized using the following parameters for the Safety Population per each dose group:

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- Time on treatment (months) defined as (last dose date of X4P-001 – first dose date X4P-001 +1) / 30.4375
- Actual time on treatment (months) defined as (number of days on treatment – number of X4P-001 dose interruption days) / 30.4375

A categorical summary of duration of treatment (< 6 months; ≥ 6 months and < 12 months; and ≥ 12 months) will be provided based on total time on treatment for Safety Population.

Dose modification for X4P-001 will be tabulated in each dose group with any, 1, 2 and 3 or more

- Dose increases
- Dose decreases
- Dose interrupted
- Dose modifications (increases or decreases)

for Safety Population.

8.7.2 Adverse Events

AEs will be coded using MedDRA v19.0 or later and will be classified by SOC and PT of MedDRA. Severity of AEs will be assessed by investigators according to CTCAE (v4.03).

Adverse events with onset after administration of the first dose of study drug up to 10 days after last dosing date will be considered treatment emergent adverse events (TEAEs).

All summaries of AEs described in this section will be on TEAEs.

Related AEs are defined as possibly related or related to study drug as assessed by the Investigator, or with missing relationship.

In genearll, both number of events and number of patients will be tabulated, and percentages will be based on the total number of patients in each dose group.

All analysis will be for Part A and Part B. If there is enough number of patients enrolled in Part C, separated analysis will be provided.

An overall AE summary will be presented for the following categories:

- Any TEAEs
- Drug-related TEAEs
  - Any X4P-001 related TEAEs
  - Any axitinib related TEAEs
  - Any X4P-001 or axitinib related TEAEs
- Any Grade ≥ 3 TEAEs

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- Any drug-related Grade ≥ 3 TEAEs
  - Any X4P-001 related Grade ≥ 3 TEAEs
  - Any axitinib related Grade ≥ 3 TEAEs
  - Any X4P-001 or axitinib related Grade ≥ 3 TEAEs
- Any TEAEs leading to death
- Any drug-related TEAEs leading to death
  - Any X4P-001 related TEAEs leading to death
  - Any axitinib related TEAEs leading to death
  - Any X4P-001 or axitinib related TEAEs leading to death
- Any SAE
- Any drug-related SAEs
  - Any X4P-001 related SAEs
  - Any axitinib related SAEs
  - Any X4P-001 or axitinib related SAEs
- Any TEAEs leading to study drug discontinuations
  - Any TEAEs leading to X4P-001 discontinuations
  - Any TEAEs leading to axitinib discontinuations
  - Any TEAEs leading to X4P-001 or axitinib discontinuations
- Any drug related TEAEs leading to study drug discontinuation
  - Any drug-related TEAEs leading to X4P-001discontinuation
  - Any drug-related TEAEs leading to axitinib discontinuation
  - Any drug-related TEAEs leading to X4P-001 or axitinib discontinuation
- Any DLTs

Summaries of TEAEs by SOC and PT sorted by decreasing frequency of PT within SOC include the following:

- TEAEs
- Drug-related TEAEs
- SAEs
- Drug-related SAEs
- Non-serous TEAEs
- TEAEs leading to discontinuation of either study drug
- TEAEs leading to death
- TEAEs leading to X4P-001 reduction
- TEAEs leading to X4P-001 interruption
- DLTs (by initial dose level)

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A summary of TEAEs by SOC, PT and maximum severity, sorted by decreasing frequency of preferred term within SOC, will also be provided for:

- TEAEs
- TEAEs with CTCAE Grade ≥ 3 split by maximum grade and overall
- Drug-related TEAEs with CTCAE Grade ≥ 3 split by maximum grade and overall

Summaries of TEAEs by decreasing frequency of preferred term will be provided for Part A and Part B for:

- TEAEs
- SAEs
- Most frequent TEAEs (>10%)
- CTCAE Grade ≥ 3 TEAEs
- Drug-related TEAEs
- Drug-related SAEs
- Drug-related CTCAE Grade ≥ 3 TEAEs

Subgroup analysis will be provided for overall summary of TEAEs and TEAEs by SOC and PT.

The following listing will be provided:

- All AEs (flagging those that are treatment emergent)
- Related AEs (flagging those related to X4P-001, related to axitinib or both)
- Serious adverse events (SAEs)
- AEs leading to discontinuation (flagging those leading to discontinuation of X4P-001, axitinib or both)
- AEs leading to death
- DLTs
- Details of any deaths

8.7.3 Clinical Laboratory Tests

All laboratory parameters collected will be normalized by converting values in original units to values in International System of Units (SI) and classified as normal, low, or high based on normal ranges supplied by the local laboratories and upon employing standardization.

8.7.3.1 Hematology, Clinical Chemistry, Coagulation and Thyroid function

The result and the change from baseline will be listed and tabulated for all continous hematology (including coagulation) and chemistry, and thyroid parameters by scheduled timepoint.

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Laboratory values will also be categorized according to their NCI-CTCAE (V4.03) toxicity grade. For applicable parameters, shift tables will be presented from the baseline toxicity grade to the worst post-baseline visit value (scheduled or unscheduled). For parameters which can have toxicity in both high and low values, increases and decreases will be summarized separately.

For non-NCI-CTC laboratory parameters, shift tables of normal/abnormal results will be presented from the baseline value to the worst post-baseline visit value (scheduled or unscheduled).

8.7.3.2 Pregancy Test and Unrianalysis

Pregnancy testing and unrianalysis results will be listed only.

8.7.4 Physical Examination Findings

Physical examination will be presented in listing visit. The value and change from baseline in weight will be summarized descriptively for each scheduled time-point during the study.

8.7.5 Ophthalmologic Examination

Ophthalmologic examination will be performed throughout the study. Details of ophthalmologic results will be listed, and ophthalmologic findings will be tabulated by scheduled time-point. In addition, shift tables will be presented showing the change from baseline to the worst post-baseline and last on study findings. These will be repeated for both local and central review. A discordance summary will also be presented by scheduled time-point comparing local and central review data.

8.7.6 Vital Signs

Vitals signs will be collected throughout the study. The value and change from baseline for vital sign parameters will be listed and summarized descriptively for each scheduled time-point during the study.

8.7.7 Electrocardiogram (ECG)

ECG data will be collected by using a digital 12-lead ECG machine throughout the study.

The value and change from baseline in ECG parameters (heart rate, RR, PR, QRS, QT and corrected QT) will be listed and summarized descriptively for each scheduled time-point during the study. RR interval in seconds is calculated as 60 divided by HR in beats/min. QT corrected by Fridericia's formula (QTcF) may be collected and will be summarized. It will be derived if it is not collected for a patient, using the following equations:

- $QTcF=QT/\sqrt[3]{RR}$

For QTcF, tables will be presented to indicate the number of patients by visit with values ≥ 450 msec, ≥ 480 msec, ≥ 500 msec, an increase from baseline >30 msec and an increase from baseline >60msec.

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ECG data will be listed.

8.7.8 ECOG performance status

Details of ECOG PS will be listed.

8.8 Pharmacokinetic Analysis

Plasma concentrations of X4P-001 and axitinib will be expressed in ng/mL.

Plasma concentrations will be listed and summarized by dose, day, and nominal time for Part A and B, and for Part C. In addition, individual plasma concentration-time plots, and mean plasma concentration-time plots by dose will be provided.

Plasma concentrations at pre-dose on Cycle 1 Day 15, Cycle 2 Day 1, and Cycle 2 Day 15 will be summarized by dose, day, and nominal time for Part A and B, and for Part C. Individual plasma concentration-time plots, and mean plasma concentration-time plots by dose will be provided.

For patients who have intensive PK collections on Cycle 1 Day 1 and Cycle 1 Day 15, PK parameters will be derived from the plasma concentration data of X4P-001 and axitinib using standard non-compartmental methods. The actual sampling times will be used in the derivation of the PK parameters. The derived PK parameters, including $AUC_{0\text{-}t}$, C_{max}, and T_{max}, will be summarized descriptively by dose and day.

8.9 Pharmacodynamic Analysis

The value and change from baseline for pharmacodynamic parameters, including WBC and counts of its subsets (neutrophils, lymphocytes, and monocytes), will be listed, and summarized descriptively for each scheduled time-point during the study. PK/PD correlation may be explored, and details will be described separately.

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9 REFERENCES

Daniel Y.C. H, Wanling X, Meredith M. R, et al. Prognostic Factors for Overall Survival in Patients with Metastatic Renal Cell Carcinoma Treated with Vascular Endothelial Growth Factor–Targeted Agents: Results from a Large, Multicenter Study. Journal of Clinical Oncology. 2009; 27:34-39.

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