STATISTICAL ANALYSIS PLAN

PHASE 2

VERSION: 1.0

DATE OF PLAN: 14 February 2023

BASED ON:

Protocol Version 4.0: 04 August 2022

STUDY TITLE:

An Open-Label, Safety, Tolerability, and Proof-of-Concept Study of Oral BCX9930 Therapy in Subjects with Complement 3 Glomerulopathy, Immunoglobulin A Nephropathy, or Primary Membranous Nephropathy

STUDY DRUG:

BCX9930

PROTOCOL NUMBER:

BCX9930- 211

SPONSOR:

BioCryst Pharmaceuticals Inc.

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Durham, North Carolina 27703 USA

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

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TECHNICAL SUMMARY REPORT (TSR)

Name of Sponsor/Company **BioCryst Pharmaceuticals, Inc.**	**Individual Study Table Referring to Part of the Dossier:** **Volume:**	***(For National Authority Use Only)*:**
Name of Finished Product: BCX9930	**Page:**	
Name of Active Ingredient: [redacted]		
Title Of Study: An Open-Label, Safety, Tolerability, and Proof-of-Concept Study of Oral BCX9930 Therapy in Subjects with Complement 3 Glomerulopathy, Immunoglobulin A Nephropathy, or Primary Membranous Nephropathy		
Lead or Coordinating Investigator: [redacted]		
Studied period : 52 weeks	**Phase of development:** 2	

Objectives:

Primary:

- To evaluate the therapeutic potential of BCX9930 as assessed by proteinuria

Secondary:

- To evaluate the safety and tolerability of BCX9930
- To evaluate the therapeutic potential of BCX9930 as assessed by other measures of clinical benefit
- To evaluate effects on kidney biopsy morphologic findings (C3G cohort only)

Exploratory:

[redacted]

Methodology:

This was a Phase 2, open-label, multicenter, POC study to evaluate the safety, tolerability, and therapeutic potential of BCX9930, an oral Factor D inhibitor, administered for up to 52 weeks in adult (≥ 18 years old) subjects with C3G, IgAN, or PMN. After up to a 56-day screening qualification period, approximately 14 eligible subjects were to be enrolled into each of three parallel study treatment cohorts. Under protocol versions prior to Protocol Version 4.0, subjects were to receive BCX9930 500 mg twice daily (BID). Each cohort was to be analyzed separately. Under Protocol Version 4.0, subjects were to receive BCX9930 200 mg twice daily (BID) for the first 14 days and 400 mg BID on Day 15 and for the remainder of the treatment period, up to a total duration of 52 weeks.

Note: BioCryst stopped development of BCX9930 in December of 2022 based on changes in the competitive environment. Therefore, this study was discontinued.

Number of Subjects (planned and analyzed):

This study planned to enroll approximately 14 adult subjects in each of the 3 cohorts: C3G, IgAN and PMN for a total enrollment of approximately 42 subjects.

Note: At the time the study was discontinued there were three screened subjects with a C3G history, and among them, two with confirmed C3G diagnosis who received study drug. All subjects were recruited prior to implementation of Protocol version 4.0. No subjects were enrolled under the other two cohorts.

Test product, dose and mode of administration:

Under protocol versions prior to Protocol Version 4.0, subjects were to receive BCX9930 500 mg twice daily (BID). Under Protocol Version 4.0, subjects were to receive BCX9930 200 mg twice daily (BID) for the first 14 days and 400 mg BID on Day 15 and for the remainder of the treatment period, up to a total duration of 52 weeks. The appropriate quantity of BCX9930 tablets were to be taken orally, twice a day, approximately 12 hours apart, without regard to food. Subjects were advised that adequate hydration should be maintained to prevent the formation of highly concentrated urine.

[redacted]

Duration of treatment:

Subjects were to receive open-label BCX9930 for up to 52 weeks.

Reference therapy, dose and mode of administration:

Not applicable.

Statistical methods:

This was a Phase 2, open-label, POC study to estimate the safety, tolerability, and therapeutic potential of BCX9930 administration in subjects with C3G, IgAN, or PMN. As such, no formal power or sample size calculations were performed to determine each cohort size.

Outcome Analyses to be Conducted:

The analyses will be conducted for the following:

- Disposition by C3G cohort and all screened subjects,
- Demographics and baseline characteristics by C3G cohort,
- Concomitant medications by dosing group,
- Exposure by dosing group,
- Key efficacy endpoints: 24-hour uPCR, 24-hour urine protein excretion and eGFR (Descriptive statistics on observed value, change from baseline, percent change from baseline, and ratio to baseline by scheduled visit and dosing group),
- TEAEs by dosing group (Overall summary of TEAEs, and TEAEs by SOC and PT),
- Laboratory tests by dosing group (Maximum elevation in post-baseline liver function tests and serum creatinine)

For continuous variables, descriptive summaries will be presented. For categorical variables, summaries will be presented as counts and frequencies.

Baseline characteristics and all safety data collected in the study will be listed.

Due to the study discontinuation at a total of 2 treated subjects, efficacy analyses will be limited to descriptive statistics for the key efficacy endpoints noted above. Source data collected for all efficacy endpoints (primary, secondary, and exploratory endpoints) will be listed.

PK concentration, PK parameters, PD/ biomarkers, and healthcare outcomes will be listed.

Sample Size Justification:

The proposed sample size of up to approximately 14 subjects per cohort was chosen to provide an estimate of 24-hour urine protein-to-creatinine ratio (uPCR) reduction up to 52 weeks to assess the therapeutic potential for BCX9930 in these renal indications and inform sample sizes for future studies of BCX9930.

Table of Contents

LIST OF TABLES

1. LIST OF ABBREVIATIONS

Table 1: List of Abbreviations

Abbreviation	Term
ADaM	Analysis data model
AE	Adverse event
ALT	Alanine aminotransferase
ALP	Alkaline phosphatase
AP-activated	Alternative pathway activated
[redacted]	[redacted]
AST	Aspartate transferase
ATC	Anatomical therapeutic class
BID	Twice daily
BMI	Body mass index
C3	Complement 3
C3G	Complement 3 glomerulopathy
CFB	Change from baseline
CI	Confidence interval
CKD-EPI	Chronic kidney disease epidemiology collaboration
CP	Classical pathway
CRF	Case report form
CRO	Contract research organization
CSR	Clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
CV	Coefficient of variation
DDI	Drug-drug interaction
DHHS	Department of Health and Human Services
DMC	Data monitoring committee
DNA	Deoxyribonucleic acid
ECG	Electrocardiogram
eCRF	Electronic case report form
eGFR	Estimated glomerular filtration rate
EM	Electron microscopy or “electron micrograph” images
[redacted]	[redacted]

Abbreviation	Term
F/ET	Follow-up/End of Treatment
FSH	Follicle-stimulating hormone
GN	Glomerulonephritis
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDL	High-density lipoprotein
Hib	*Haemophilus influenzae* Type B
HIV	Human immunodeficiency virus
IA	Interim analysis
ICH	International Council for Harmonisation
IgAN	Immunoglobulin A nephropathy
IgG	Immunoglobulin G
INR	International normalized ratio
[redacted]	[redacted]
LDH	Lactate dehydrogenase
LDL	Low-density lipoprotein
LLN	Lower limit of normal006
[redacted]	[redacted]
MedDRA	Medical Dictionary for Regulatory Activities
PD	Pharmacodynamic(s)
[redacted]	[redacted]
[redacted]	[redacted]
PK	Pharmacokinetic(s)
PMN	Primary membranous nephropathy
POC	Proof-of-concept
PRO	Patient-reported outcome
PT	Preferred term
QoL	Quality-of-life
SAE	Serious adverse event
SAP	Statistical analysis plan
SAS	Statistical analysis system
sC5b-9	Soluble c5b-9

Abbreviation	Term
SCr	Serum creatinine
SD	Standard deviation
SDTM	Study data tabulation model
SOC	System organ class
TEAE	Treatment-emergent adverse event
TESAE	Treatment-emergent serious adverse event
uACR	Urine albumin-to-creatinine ratio
ULN	Upper limit of normal
[redacted]	[redacted]
uPCR	Urine protein-to-creatinine ratio
VZV	Varicella-zoster virus
WHO	World health organization

2. INTRODUCTION

BioCryst stopped development of BCX9930 in December of 2022 based on changes in the competitive environment. Therefore, this study was discontinued.

Due to the BCX9930 program discontinuation, data collected in study BCX9930-211 will be reported using an abbreviated Clinical Study Report (CSR). The purpose of this statistical analysis plan (SAP) is to describe the planned analyses for the CSR in study BCX9930-211.

At the time of BCX9930 program discontinuation, there were only three screened subjects with one screen failure and two treated subjects in this study. The focus of the CSR will be on collected safety data. Summary tables will be presented for key safety variables. As this study had only a total of 2 treated subjects, only key efficacy endpoints described in the study protocol will be summarized using descriptive statistics. All data collected in this study including safety, efficacy and exploratory endpoints will be presented in data listings.

The SAP is based on:

- Protocol No. BCX9930-211 Version 4.0, dated 04 August 2022
- ICH guidelines E4 and E9 (Statistical Principles for Clinical Trials)

Table 2: Protocol Revision Chronology:

Version	Date	Change
Protocol v1.0	16 April 2021	Original
Protocol v2.0	23 June 2021	1. Simplified acute kidney injury and acute kidney disorder language 2. N. Meningitidis Type B and H. influenza vaccinations are now strongly encouraged
Protocol v2.1	13 August 2021	1. Preliminary drug-drug interaction (DDI) results from BCX9930-102 (Study 102) in healthy subjects were provided in "Section 5.3.2-Clinical Findings for BCX9930" and corresponding updates were made to "Section 9.2.2-Prohibited and Restricted Medications". 2. Change in title to "Vice President, Clinical Development Sciences".
Protocol v3.0	27 January 2022	1. Study duration increased from 24 weeks to up to 52 weeks 2. On-treatment kidney biopsies were aligned by cohort. 3. Refer to Summary of Changes (Protocol v2.1. to v3.0)

Version	Date	Change
Protocol v4.0	04 August 2022	1. Dose and dosing regimen • Recommended dose of BCX9930 reduced from 500 mg BID to 400 mg BID for all subjects. • For newly randomized subjects, treatment with BCX9930 will begin at 200 mg BID for the first 14 days before escalation to 400 mg BID. 2. Refer to Summary of Changes (Protocol v3.0. to v4.0)

3. STUDY OBJECTIVES AND ENDPOINTS

3.1. Study Objectives

3.1.1. Primary Objective

The primary objective of this study per protocol was:

- To evaluate the therapeutic potential of BCX9930 as assessed by proteinuria

3.1.2. Secondary Objectives

The secondary objectives of this study per protocol were:

- To evaluate the safety and tolerability of BCX9930
- To evaluate the therapeutic potential of BCX9930 as assessed by other measures of clinical benefit
- To evaluate effects of BCX9930 on kidney biopsy morphologic findings (C3G cohort only)

3.1.3. Exploratory Objectives

The exploratory objectives of this study per protocol were:

[redacted]

3.2. Study Endpoints

3.2.1. Primary Endpoint

The primary endpoint of this study per protocol was:

- Change in 24-hour urinary protein excretion normalized to urine creatinine as measured by percentage change in uPCR from baseline

3.2.2. Secondary Endpoints

The secondary endpoints of this study per protocol were:

- Number and proportion of subjects with a uPCR response defined as:
  - Partial remission, ≥ 50% reduction from baseline
  - Complete remission, ≤ 500 mg/g
  - Normalization, ≤ 200 mg/g
- Change from baseline in 24-hour urinary protein excretion as measured by percentage change in urinary protein from baseline
- Change from baseline in eGFR
- Change from baseline in serum albumin
- Number and proportion of subjects with the following parameters:
  - Protein ≥ 3.5 g in a 24-hour urine collection
  - Serum albumin ≤ 2.5 g/dL
- Number and proportion of subjects with a morphologic response in each of the following categories (C3G cohort only at Week 24):
  - Decreased endocapillary hypercellularity, mesangial hypercellularity, active crescents (if present), glomerular leukocyte infiltration, fibrinoid necrosis, membranoproliferative glomerulonephritis pattern
  - Decreased acute tubular injury, interstitial inflammation, interstitial edema
  - Reduction in C3 glomerular staining
  - Reduction in the extent of deposits, clearing of deposits, or no additional active deposits as assessed by electron microscopy (EM)
  - No progression of chronic changes (ie, global, segmental glomerulosclerosis, tubular atrophy/interstitial fibrosis, arteriosclerosis)
- Number and proportion of subjects with a TEAE
- Number and proportion of subjects who discontinue due to a TEAE
- Number and proportion of subjects who experience a treatment-emergent serious adverse event (TESAE)
- Number and proportion of subjects who experience a Grade 3 or 4 TEAE based on Common Terminology Criteria for Adverse Events (CTCAE)
- Number and proportion of subjects who experience a CTCAE treatment-emergent Grade 3 or 4 laboratory abnormality

3.2.3. Exploratory Endpoints

The exploratory endpoints of this study per protocol were:

[redacted]

3.3. Statistical Hypotheses

Protocol states post-baseline measurements were to be assessed against their applicable baseline measurements.

Due to the study discontinuation at a total of 2 treated subjects, formal statistical hypotheses will not be conducted.

4. STUDY DESIGN

4.1. Summary of Study Design

This was a Phase 2, open-label, multicenter, POC study to evaluate the safety, tolerability, and therapeutic potential of BCX9930, an oral Factor D inhibitor, administered for up to 52 weeks in adult (≥ 18 years old) subjects with either C3G, IgAN, or PMN. Under protocol versions prior to Protocol Version 4.0, after up to a 56-day screening qualification period, approximately 14 eligible subjects were to be enrolled into each of 3 parallel study treatment cohorts and receive BCX9930 500 mg twice daily (BID). With protocol Version 4.0, subjects were to receive BCX9930 200 mg twice daily (BID) for the first 14 days and 400 mg BID on Day 15 and for the remainder of the treatment period, up to a total duration of 52 weeks. The appropriate quantity of BCX9930 tablets was to be taken orally, twice a day, approximately 12 hours apart, without regard to food. Subjects were advised that adequate hydration should be maintained to prevent the formation of highly concentrated urine.

The BCX9930 program was discontinued (see Section 2 for details) prior to any subject enrolling under Protocol Version 4.0.

The overall study design is described in section 7.1 in each protocol version.

Study schemas of Protocol Version 3.0 and Version 4.0 are shown in Figure 1. Note: No subjects were enrolled under protocol Version 4.0.

After the Day 1 Visit, subjects were required to return to the clinic at Weeks 1, 2, and 4, and then every 4 weeks thereafter through Week 24. Additional safety assessments were to be performed at Weeks 3, 5, 6, 7, and 10, either at the investigative site, or at a local laboratory more convenient for the subject or via a home health service (where permitted and available). At the Week 24 Visit, the clinical benefit of BCX9930 treatment would be assessed by the investigator. Subjects who were assessed as deriving clinical benefit would continue treatment up to Week 52. described in Table 3 and Table 4.

Subjects who completed BCX9930 dosing through Week 52 or subjects who were discontinued from BCX9930 dosing prior to Week 52 were to return to the clinic approximately 4 weeks (28 ± 3 days) after the date of their last dose of BCX9930 for the Safety Follow-up (FU) Visit prior to study completion/discontinuation.

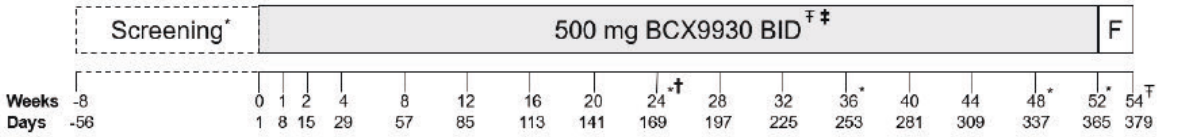
An optional serial PK/PD substudy was to include subjects who provided consent to evaluate the PK and PD of BCX9930 at the Day 1 Visit and/or at a subsequent visit prior to the Week 24 Visit. Serial sampling of urine and blood was to be performed over a period of 6 hours. Subjects who did not participate in the Baseline (Day 1) PK/PD sample collection were eligible to participate at a subsequent clinic visit prior to the Week 24 Visit.

All subjects were to have a single blood sample drawn for PK analysis at each clinic visit ("sparse sampling" to support PPK and PK/PD modeling). For subjects participating in the serial PK/PD substudy, a single blood sample was to be drawn for PK and PD analysis at visits where serial blood samples were not collected through [redacted] post dose.

All subjects who signed a separate informed consent (optional) were to participate in exploratory pharmacogenomics testing at a single visit from Day 1 up to the Week 24 Visit (including the safety FU Visit, if applicable).

Figure 1: Study Schema by Protocol Version

Protocol Version 3.0



*** = Kidney Biopsies:** A screening biopsy may be waived with approval of central pathologist and agreement with the medical monitor for any subject with a prior biopsy ≤ 30 days prior to screening and ≤ 90 days prior to screening for adolescents with C3G.

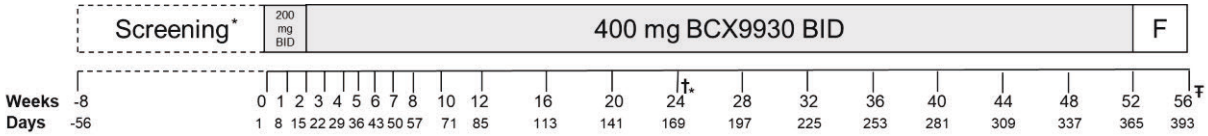
Subjects with C3G will undergo a percutaneous needle biopsy of the kidney at the Week 24 Visit or within 7 days after the visit. The Week 24 biopsy procedure is optional for adolescent subjects with C3G.

Subjects with IgAN will undergo a percutaneous needle biopsy of the kidney at the Week 36 Visit or within 7 days after the visit.

Subjects with PMN will undergo a percutaneous needle biopsy of the kidney at the Week 48 Visit to within 3 days after the Week 52 Visit. Dosing with BCX9930 will continue until the Week 52 Visit or until the day of the biopsy procedure.

† = Clinical Benefit Assessment
‡ = Follow-up/End of Treatment Visit: 14 ± 3 days after last dose of BCX9930 for all subjects
‡ = Safety Follow-up Visit: 28 ± 3 days after last dose of BCX9930 for subjects who discontinue BCX9930 dosing prior to the Week 52 Visit
F= Follow-Up
Note: Additional visits may occur during the study and are not represented (eg, additional screening visits, unscheduled visits, or visits for biopsy procedures)

Protocol Version 4.0



• = Kidney Biopsies: A screening biopsy may be waived with approval of central pathologist and agreement with the medical monitor for any subject who has undergone a renal biopsy procedure as follows: within 3 months prior to screening for the C3G cohort, within 6 months prior to screening for the IgAN or PMN cohorts.
Subjects with C3G will undergo a percutaneous needle biopsy of the kidney at the Week 24 Visit or within 7 days after the visit.

† = Clinical Benefit Assessment
‡ = Safety Follow-up Visit: 28 ± 3 days after last dose of BCX9930 for all subjects
F = Safety Follow-Up
Note: Subjects will return to the clinic at Weeks 1, 2, and 4, and then every 4 weeks thereafter through Week 52. Additional safety assessments will be performed at Weeks 3, 5, 6, 7, and 10, either at the investigative site or at a laboratory local to the subject or via a home health service.
Additional visits may occur during the study and are not represented (eg, additional screening visits, unscheduled visits, or visits for biopsy procedures)

4.2. Definition of Study Drugs

BCX9930 is a small-molecule inhibitor of Factor D and was provided as tablets for oral administration. The active ingredient is BCX9930 drug substance.

BCX9930 tablets contain the active ingredient blended with the excipients microcrystalline cellulose, mannitol, crospovidone, colloidal silicon dioxide, and magnesium stearate, and are film-coated with Opadry white, which is a hydroxypropyl methylcellulose based non-functional coating.

Dosage forms include BCX9930 tablets of 100-, 200-, and 250-mg strength, which are all from a dose proportional blend compressed into tablets of the desired weight.

Additional details of the chemical and physical characteristics of BCX9930 may be found in the Investigator's Brochure for BCX9930 and investigational medication product manual. Please note both IMP and study drug refer to BCX9930 in this protocol.

4.3. Sample Size Considerations

4.3.1. Sample Size Justifications

No formal power or sample size calculations were planned to determine the sample size for each cohort. The proposed sample size of approximately 14 subjects per cohort was expected to provide an estimate of uPCR reduction up to 52 weeks to estimate the safety and therapeutic potential for BCX9930 in these renal indications and inform sample sizes for future studies of BCX9930.

Several recent Phase 2 studies that evaluated investigational products with similar or identical mechanisms of action as BCX9930 enrolled 5 to 7 subjects with C3G per study and reported reductions in proteinuria after treatment durations ranging from 2 to 48 weeks (unpublished data).

4.3.2. Sample Size Re-Estimation

No sample size re-estimations were planned.

4.4. Randomization

This is an open-label, non-randomized study. No study treatments were blinded or masked.

4.5. Clinical Assessments

The planned schedule of assessments for this study is presented in Table 3 (Screening through Week 24) and Table 4 (Week 28 through Week 52). The planned schedule of assessments for the PK/PD substudy is presented in Table 5.

Table 3: Schedule of Assessments (Screening - Week 24)

Assessment/Procedure	Screening [a]	Baseline	Dosing Phase (Study Week)												Safety FU Visit [d]
	(Up to Day - 56)	Day 1 [b]	1 (± 1 d)	2 (± 1 d)	3 [c] (± 1 d)	4 (± 1 d)	5 [c] (± 3 d)	6 [c] (± 3 d)	7 [c] (± 3 d)	8 (± 3 d)	10 [c] (± 3 d)	12 (± 3 d)	16 (± 3 d)	20 (± 3 d)	24 (± 3 d)	28 ± 3 days after last dose
Written informed consent [e]	X															
Review eligibility criteria	X	X														
Demographics	X															
Medical & medication history	X															
Disease Specific Medical History Form [f]	X															
Height, body weight, and BMI [g]	X	X				X				X		X	X	X	X	X
Physical examination [h]	X	X	X	X		X				X		X	X	X	X	X
12-lead ECG [i]	X	X	X	X		X				X		X	X	X	X	X
Vital signs [j]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Hematology and coagulation	X	X	X	X		X				X		X	X	X	X	X
Chemistry	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urinalysis including microscopy [k]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Intended 24-hour urine collection [l]	X	X	X	X		X				X		X	X	X	X	X
eGFR [m]	X	X	X	X		X				X		X	X	X	X	X
Percutaneous renal biopsy [n,o]	X														X [q]	
Urine for biomarker testing [p]		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Drugs of abuse screen	X															
Pregnancy test [q]	X	X	X	X		X				X		X	X	X	X	X
FSH [r]	X															

Assessment/Procedure	Screening [a]	Baseline	Dosing Phase (Study Week)												Safety FU Visit [d]
	(Up to Day - 56)	Day 1 [b]	1 (± 1 d)	2 (± 1 d)	3 [c] (± 1 d)	4 (± 1 d)	5 [c] (± 3 d)	6 [c] (± 3 d)	7 [c] (± 3 d)	8 (± 3 d)	10 [c] (± 3 d)	12 (± 3 d)	16 (± 3 d)	20 (± 3 d)	24 (± 3 d)	28 ± 3 days after last dose
HBV, HCV, HIV, VZV serology [s]	X															
PRO questionnaires [t]		X								X		X	X	X	X	X [d]
[redacted]																
PK blood sample collection [v,w]			X	X	X	X	X	X	X	X	X	X	X	X	X	
PD blood sample collection [x]	X	X	X	X		X				X		X	X	X	X	X
PK urine sample collection [y,z]			X	X	X	X	X	X	X	X	X	X	X	X	X	
Interactive Response Technology (IRT)	X	X				X				X		X	X	X	X	
BCX9930 dispensing		X				X				X		X	X	X	X	
BCX9930 accountability			X	X		X				X		X	X	X	X	X
BCX9930 dosing			←	—	—	—	—	—	—	—	—	—	—	—	→	
Record AEs [aa]	←	—	—	—	—	—	—	—	—	—	—	—	—	—	→	X
Prior/concomitant medications [bb]	←	—	—	—	—	—	—	—	—	—	—	—	—	—	→	X
Assessment of the clinical benefit of BCX9930 [cc]															X	
Optional entry/exit interview by phone [dd]	X															X
Pharmacogenomics sample [ee]			←	—	—	—	—	—	—	—	—	—	—	—	—	→

Abbreviations: AE = adverse event; AP = alternative pathway; BMI = body mass index; C3G = complement 3 glomerulopathy; d = day(s); ECG = electrocardiogram; eCRF = electronic case report form; eGFR = estimated glomerular filtration rate; EM = electron microscopy; FU = follow-up; FSH = follicle-stimulating hormone; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; IgAN = immunoglobulin A nephropathy; [redacted] PMN = primary membranous nephropathy; PRO = patient-reported outcome; SAE = serious adverse event; uACR = [redacted]

[a] All screening procedures do not need to be completed on the same day and the screening period can be extended up to 28 additional days with approval by the medical monitor on a case-by-case basis.

[b] All baseline/Day 1 study procedures should be evaluated or obtained prior to first dose of BCX9930.

[c] Additional safety assessments visits at Weeks 3, 5, 6, 7, and 10 can be conducted either at the investigative site, or at a local laboratory more convenient for the subject or via a home health service (where permitted and available); Results from local laboratory testing must be provided to the investigative site.

[d] All subjects including who discontinues the study prior to Week 52 will be asked to complete the safety FU Visit approximately 4 weeks (28 ± 3 days) after their last dose of BCX9930. Assessments indicated "X[d]" will be completed for subjects who discontinue prior to the Week 52 Visit only.

[e] Signing of informed consent may occur in advance of the Screening Visit and must be obtained from the subject as required by national or local law and institutional practice, prior to conducting any study-related assessments/procedures.

[f] Disease specific medical history form which will include baseline C3G, IgAN, or PMN clinical characteristics and disease.

[g] Height and weight will be measured, and BMI calculated at screening only; at all other indicated visits, only weight will be measured and used with the height measurement from screening for subsequent BMI calculations.

[h] Screening and Day 1 pre-dose physical examinations will be full physical examinations. All post-Day 1 physical examinations will be abbreviated (ie, symptom driven) examinations, targeted to new signs and symptoms.

[i] Bedside 12-lead ECGs will be conducted in triplicate at the baseline (Day 1) visit; all other ECGs may be single assessments. Subjects should rest quietly for 5 minutes in a supine position prior to the ECGs being performed. Any blood draws scheduled at the same time should occur after obtaining the ECG.

[j] Vital signs (to include blood pressure, pulse rate, and temperature) after ECGs will be performed at investigative site visits only (ie, excluding non-investigative site visits) and the subject has rested in a supine position.

[k] Urine microscopy will be performed on urine collected at investigative site visits (and, where possible, at remote visits where the laboratory has appropriate on-site testing capability). Urine microscopy should be performed using the site's local laboratory in lieu of the central laboratory.

[l] Subjects will receive instructions and a collection container for the intended 24-hour urine sample collection. During screening, subjects will be provided the urine collection containers at the screening visit and will return the collection container with the 24-hour urine specimen to the clinic as specified in a separate document for screening and, if applicable, at the Day 1 Visit. At all other clinic visits, subjects will be provided collection containers at the previous visit and will return the collection container with the 24-hour urine specimen as specified in a separate document within 3 days of the next scheduled visit. An aliquot from these collections may be reserved for analysis of the concentration and urinary excretion of BCX9930 and metabolites.

[m] Calculated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.

[n] Digital images of screening renal biopsy samples and local pathology report will be reviewed by the central pathologist to confirm biopsy criteria prior to scheduling Day 1 Visit. If a subject underwent renal biopsy procedure within 3 months of initiating screening with C3G, or within 6 months of initiating screening with IgAN or PMN, and digital images, and a pathology report are available that meet study requirements, then the screening biopsy requirement may be waived by the medical monitor and central pathologist on a case-by-case basis. An EM grid may be provided to the central pathologist for review if available.

[o] For subjects with C3G only, the biopsy may be performed within 7 days after completion of the Week 24 Visit but may not be performed prior to the Week 24 Visit. Protocol-specified, on-treatment biopsies will not be required for subjects with C3G who are discontinued from BCX9930 treatment prior to or at the Week 24 Visit.

[p] Single void urine sample will be analyzed for uPCR, uACR, [redacted] ingle void urine samples from Day 1 (pre-dose) and Week 24 may be processed for LC-MS/MS to evaluate changes from baseline. Additional exploratory assays may be evaluated.

[q] A serum pregnancy test will be administered to women of childbearing potential or who are postmenopausal for ≤ 2 years at screening. All other pregnancy tests performed during the study may be urine pregnancy tests (for women of childbearing potential only). The subject's continued use of contraception should be reviewed throughout the study.

[r] FSH will be measured at screening to confirm postmenopausal state in women who report no menses for ≥ 12 months and ≤ 2 years. FSH measurement is not needed at screening to confirm postmenopausal state in women who report no menses for > 2 years.

[s] Tests for HIV serology and active HBV and HCV infection – to include hepatitis B surface antigen, hepatitis B core antibody, hepatitis C antibody, HIV antibody, and VZV immunoglobulin G titer (Immunity Assessment).

[t] [redacted] questionnaires will be administered in the clinic.

[u] [redacted] Only the [redacted] will be administered at the Day 1 Visit for all 3 treatment cohorts. At the Week 24 Visit, the [redacted] will be administered to subjects with C3G only.

[v] A single venous blood sample for measurement of plasma concentration of BCX9930 and metabolites will be collected at each study visit, beginning at the Week 1 Visit (except if subject is participating in the PK/PD substudy procedures, in which case PK/PD substudy procedures will apply at the specified visits per Table 5). The time of sample collection, food status, and the time of the last 2 doses will be recorded for all PK samples.

[w] At study centers with appropriate facilities for the collection and processing of serial plasma samples, an optional PK/PD substudy will be performed per Table 5.

[x] [redacted] Additional exploratory assays may be evaluated. PD samples should be collected as close as possible to the same time as PK samples, where applicable.

[y] For subjects not enrolled in the optional PK/PD substudy, a single urine void for analysis of urine concentration of BCX9930 and metabolites will be collected at each investigative site visit from Week 1. PK samples and PD samples should be collected from the same single urine void, where applicable.

[z] For subjects enrolled in the optional PK/PD substudy, urine will be collected per Table 5.

[aa] AEs will be assessed and recorded from the time of signing of the informed consent through the appropriate follow-up period.

[bb] All medications during the study will be captured and concomitant medications will be captured on the prior/concomitant eCRF page(s) during the study.

[cc] The clinical benefit of BCX9930 treatment will be assessed by the investigator to determine continued BCX9930 dosing up to Week 52.

[dd] An optional semi-structured entry interview will be completed by phone during the screening period and an exit interview after either the safety FU Visit or Week 52 Visit (per Table 4) to capture patient experience and symptoms for subjects who agree to participate as captured in each subject's informed consent.

[ee] All subjects who sign a separate informed consent will participate in exploratory pharmacogenomics testing at a single visit from Day 1 up to the Week 24 Visit (including the safety FU Visit, if applicable).

Table 4: Schedule of Assessments (Week 28-Week 52)

Assessment/Procedure	Dosing Phase (Study Week)							Safety FU Visit [a]
	28 (± 3 d)	32 (± 3 d)	36 (± 3 d)	40 (± 3 d)	44 (± 3 d)	48 (± 3 d)	52 (± 3 d)	28 ± 3 days after last dose
Height, body weight, and BMI [b]	X	X	X	X	X	X	X	X
Physical examination [c]	X	X	X	X	X	X	X	X
12-lead ECG [d]	X	X	X	X	X	X	X	X
Vital signs [e]	X	X	X	X	X	X	X	X
Hematology and coagulation	X	X	X	X	X	X	X	X
Chemistry	X	X	X	X	X	X	X	X
Urinalysis including microscopy [f]	X	X	X	X	X	X	X	X
Intended 24-hour urine collection [g]	X	X	X	X	X	X	X	X
eGFR [h]	X	X	X	X	X	X	X	X
Percutaneous renal biopsy [i,j]			X			X	X	
Urine for biomarker testing [k]	X	X	X	X	X	X	X	X
Pregnancy test [l]	X	X	X	X	X	X	X	X
PRO questionnaires [m]			X				X	X [a]
[redacted]								
PK blood sample collection [o]	X	X	X	X	X	X	X	
PD blood sample collection [p]	X	X	X	X	X	X	X	X
PK urine sample collection [q]	X	X	X	X	X	X	X	

Assessment/Procedure	Dosing Phase (Study Week)							Safety FU Visit [a]
	28 (± 3 d)	32 (± 3 d)	36 (± 3 d)	40 (± 3 d)	44 (± 3 d)	48 (± 3 d)	52 (± 3 d)	28 ± 3 days after last dose
Interactive Response Technology (IRT)	X	X	X	X	X	X		
BCX9930 dispensing	X	X	X	X	X	X	X	
BCX9930 accountability	X	X	X	X	X	X	X	X
BCX9930 dosing	←	—	—	—	—	—	→	
Record AEs [r]	←	—	—	—	—	—	→	X
Prior/concomitant medications [s]	←	—	—	—	—	—	→	X
Optional entry/exit interview by phone [t]							X	X

Abbreviations: AE = adverse event; AP = alternative pathway; BMI = body mass index; C3G = complement 3 glomerulopathy; d = day(s); ECG = electrocardiogram; eCRF = electronic case report form; eGFR = estimated glomerular filtration rate; EM = electron microscopy; FU = follow-up; IgAN = immunoglobulin A nephropathy; IRT = Interactive Response Technology; LC-MS/MS = liquid chromatography-assisted tandem mass spectrometry; [redacted] PD = pharmacodynamic(s); [redacted]; [redacted]; PK = pharmacokinetic(s); PMN = primary membranous nephropathy; PRO = patient-reported outcome; SAE = serious adverse event; uACR = urine albumin-to-creatinine ratio; uPCR- = urine protein-to-creatinine ratio

[a] All subjects will be asked to complete the safety FU Visit approximately 4 weeks (28 ± 3 days) after their last dose of BCX9930. Assessments indicated "X[a]" will be completed for subjects who discontinue the study prior to the Week 52 Visit only.

[b] Height and weight will be measured, and BMI calculated at screening only; at all other indicated visits, only weight will be measured and used with the height measurement from screening for subsequent BMI calculations.

[c] All post-Day 1 physical examinations will be abbreviated (ie, symptom driven) examinations, targeted to new signs and symptoms.

[d] Subjects should rest quietly for 5 minutes in a supine position prior to the single assessment ECGs being performed. Any blood draws scheduled at the same time should occur after obtaining the ECG.

[e] Vital signs to include blood pressure, pulse rate, and temperature after ECGs will be performed at investigative site visits only (ie, excluding remote visits) and the subject has rested in a supine position.

[f] Urine microscopy will be performed on urine collected at investigative site visits (and, where possible, at remote visits where the laboratory has appropriate on-site testing capability). Urine microscopy should be performed using the site's local laboratory in lieu of the central laboratory.

[g] Subjects will receive instructions and a collection container for the intended 24-hour urine sample collection. Subjects will be provided collection containers at the previous visit and will return the collection container with the 24-hour urine specimen as specified in a separate document within 3 days of the next scheduled visit. An aliquot from these collections may be reserved for analysis of the concentration and urinary excretion of BCX9930 and metabolites.

[h] Calculated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.

[i] IgAN Cohort: The Week 36 on-treatment biopsy is optional. For patients who agree to have on-treatment biopsy, the biopsy will be performed after completion of all other assessments at the visit or within 7 days after completion of the Week 36 Visit but may not be performed prior to the Week 36 Visit.

[j] PMN Cohort: the Week 48-52 on-treatment biopsy is optional. For patients who agree to have on-treatment biopsy, the biopsy will be performed at the Week 48 up to within 3 days after the Week 52 Visit. If the biopsy is scheduled during the Week 48 or Week 52 Visit, the procedure will be after completion of all other assessment at the visit. If the biopsy procedure is performed after the Week 52 Visit, the subject will continue dosing until the day of the biopsy procedure and study drug (BCX9930) return and accountability will occur on the date of the procedure.

[k] Single void urine sample will be analyzed for uPCR, uACR, [redacted] Single void urine samples from Day 1 (pre-dose) and Week 36 or Week 52 may be processed for LC-MS/MS to evaluate changes from baseline. Additional exploratory assays may be evaluated.

[l] Administer a urine pregnancy test (for women of childbearing potential only)..

[m] [redacted]

[n] [redacted] will be administered in the clinic. Only the [redacted] will be administered at the Day 1 Visit for all 3 treatment cohorts. After the Day-1 Visit, the [redacted] will be administered once at the following specified visits by treatment cohort: Week 36 for IgAN only and Week 52 for PMN only (or at the safety FU visit, if not previously administered as described).

[o] A single venous blood sample for measurement of plasma concentration of BCX9930 and metabolites will be collected at each study visit. The time of sample collection, food status, and the time of the last 2 doses will be recorded for all PK samples.

[p] [redacted] Additional exploratory assays may be evaluated. PD samples should be collected as close as possible to the same time as PK samples, where applicable.

[q] Spot urine samples will be collected for analysis of the concentration of BCX9930 and metabolites at each investigative site visit until Week 52. PK samples and PD samples should be collected from the same single urine void, where applicable.

[r] AEs will be assessed and recorded from the time of signing of the informed consent through the appropriate follow-up period.

[s] All medications during the study will be captured and concomitant medications will be captured on the prior/concomitant eCRF page(s) during the study.

[t] An optional semi-structured entry interview will be completed by phone during the screening period and an exit interview after either the safety FU Visit or Week 52 Visit to capture patient experience and symptoms for subjects who agree to participate as captured in each subject's informed consent.

Table 5: Timing of Blood Sample and Urine Collection for PK/PD Substudy at Baseline (Day 1 Visit) and a Visit prior to Week 24

Collection		Required Post Dose			
	Pre-dose	[redacted]	[redacted]	[redacted]	[redacted]
PK Blood Sample [a]	X [b]	X	X	X	X
PD Blood Sample [c]	X		X	X	X
Urine Collection [d]	X	←	—	—	→

Abbreviations: PD = pharmacodynamics; PK = pharmacokinetics

Note: Subjects who do not participate at the Day 1 serial collection through 6 hours post dose are eligible to participate at another clinic visit prior to the Week 24 Visit.

[b] The actual date and time of each blood sample collection, the observed BCX9930 dose time, and whether the subject had eaten recently prior to dosing will be recorded in the eCRF. For the second (steady-state) PK/PD substudy visit, the date and time of the last 2 doses taken prior to the pre-dose blood collection, and whether these were taken with or without food, will also be recorded in the eCRF.

[b] A pre-dose PK sample is not required at the Day 1 Visit but is required at the second (steady-state) PK/PD substudy visit. At this visit, the PK sample should be collected immediately prior to dosing and as close as possible to 12 hours following the previous dose.

[c] PD samples should be taken at the same time as the associated PK samples, where applicable

[d] A single void urine sample will be collected pre-dose and up to two single void urine samples can be collected after dosing. If fewer than 2 voids are collected during the post-dose period, then subjects will be asked to provide a single void urine sample at the 6-hour post-dose timepoint.

5. PLANNED ANALYSES

5.1. Interim Analyses

The protocol states that interim analyses may be conducted for each study cohort based on ongoing review of individual subject safety and preliminary efficacy data.

At the time of study discontinuation, an interim analysis plan and shells were under development. No formal interim analyses were conducted prior to the study discontinuation.

5.2. Final Analyses

The final analyses will be conducted to support the CSR. The final analyses will be conducted after the clinical database has been cleaned, quality checked, and locked.

At the time of BCX9930 program discontinuation, there were only three screened subjects with one screen failure and two treated subjects in this study. The focus of the CSR will be on collected safety data. Summary tables will be presented for key safety variables. As this study had only a total of 2 treated subjects, only key efficacy endpoints described in the study protocol will be summarized using descriptive statistics. All data collected in this study including safety, efficacy and exploratory endpoints will be presented in data listings.

6. GENERAL CONSIDERATIONS FOR DATA HANDLING AND ANALYSIS POPULATIONS

Derived datasets are created using SAS® software. Data analyses and summary tables are generated using SAS version 9.4 or higher.

6.1. General Summary Table and Individual Subject Data Listing Considerations

Summary tables and listings will include "footers" providing:

1. Date of data extraction.
2. Date of output generation.
3. SAS program name, including the path that generates the output.
4. Any other output specific details that require further elaboration.

Medications will be coded using the World Health Organization (WHO) drug dictionary version B3 March 2021. AEs will be mapped to MedDRA version 24 preferred term (PT) and system organ class (SOC). AEs will be graded according to the CTCAE scales (Version 5.0, 27 November 2017).

6.2. General Post Text Summary Table and Individual Subject Data Listing Format Considerations

Tables, listings, and figures will be numbered using a decimal system to indicate the main levels of unique displays and sub-levels of replicate displays. The first level represents the appendix within which the tables, figures, and listings will appear. This will be 14 for tables and figures and 16.2.x for listings.

Listings will include all the key variables collected on the corresponding CRF page(s) and will present the data as it appears in the database. For example, the start date and time and end date and time of an AE will be displayed as reported on the eCRF (ie, any imputed values will not be listed).

All tables and listings must have explanatory notes that give the definition of all derived variables and decodes for coded data.

6.3. Data Management

The standard operating procedures (SOPs) of Rho, the selected data management and statistical and programming vendor for this study, are used. A data management plan has been developed and approved prior to commencement of data entry. Data were captured using the Medidata electronic data capture system. Electronic validation steps (edit checks) were used, and data cleaning occurred in conjunction with each site. Prior to transfer of data provided by vendors (eg, laboratory data), a data transfer agreement including specifications for the type of file, definitions of variables, and contact information for the sending and receiving parties was developed and finalized.

Data are mapped to Study Data Tabulation Model (SDTM)-compliant datasets prior to creation of Analysis Data Model (ADaM)-compliant derived datasets for use in the creation of summary tables.

6.4. Data Presentation Conventions

A table of contents, at the end of this SAP, provides the expected titles and numbers of the tables, listings, and figures of the final report. Changes to titles or numbering in the final report will not necessitate a revision to the SAP, nor will it be considered a deviation from planned analyses. Additional data listings supporting the tables will not be considered a deviation from the planned analyses.

6.5. Analysis Populations

The populations used for data analysis of this study are defined below.

6.5.1. Screened Subjects

Screened subjects are those subjects who are screened for this study and are either screen failures or treated.

6.5.2. Screen Failures

Subjects who provide informed written consent but do not receive study treatment are considered screen failures.

6.5.3. Safety Population

The Safety population is defined as all subjects who receive at least one dose of study medication. This population will be used in the assessment and reporting of safety data. In addition, efficacy summaries will be based on this population.

6.6. Baseline Definition

For a given subject and assessment, baseline will generally be defined as the latest non missing result prior to administration of the first dose of study drug. If a subject is enrolled, but fails to receive study drug, baseline will be the last non-missing result.

The baseline ECG values will be the average of the triplicate ECG readings obtained on Day 1 (or screening if the Day 1 average is missing).

6.7. Derived and Transformed Data

6.7.1. Baseline Age

The subject’s baseline age in years will be the age provided in the eCRF as collected at the time of informed consent.

6.7.2. Study Day

If the date of interest occurs on or after the date of the first dose, then study day will be calculated as (date of interest – date of first dose) + 1. If the date of interest occurs prior to the

first dose date, then study day will be calculated as (date of interest – date of first dose). There is no study day 0.

6.7.3. Change from Baseline, Percent Change from Baseline and Ratio to Baseline

The following changes from baseline will be derived:

- Change from baseline will be calculated as (post-baseline result – baseline result)
- Percent change from baseline will be calculated as (change from baseline/baseline result * 100)
- Ratio to baseline will be calculated as post-baseline result divided by baseline result

If either the baseline or the post-baseline result is missing, then the changes from baseline described above will be missing. If the baseline value is 0, the percent change from baseline or ratio to baseline will be missing.

Note: The CKD-EPI formula will use the serum creatinine in the computation of eGFR included in the efficacy summary table.

6.7.4. Fold Change

Fold change from the ULN will be calculated as (result/ULN), and fold change from the LLN will be defined similarly as (result/LLN).

6.7.5. Questionnaire Assessments

Scale scores and total scores resulting from questionnaire assessments will be calculated per the official assessment guidelines. Details are provided in Section 14.3.

6.7.6. Visit Windows

Visit windows will not be applied.

6.7.7. Multiple Assessments in a Visit Window

Visit windows will not be applied.

For lab parameters where a central lab and local lab were collected at the same scheduled visit, the central lab value will be used. Local lab will be used if central lab data are not available.

6.8. Handling of Missing Data

6.8.1. Missing Efficacy Endpoints

Not applicable.

6.8.2. Missing Start and Stop Dates for Prior and Concomitant Medication

An incomplete time has either the hours or minutes missing, but not both; or a time may have hours and minutes but be recorded on a 12-hour clock and AM/PM cannot be determined from other information. For calculation purposes, incomplete times will be treated as completely missing.

If the medication start date is completely missing and the medication stop date is after the start date of the first dose of study drug (or the medication is ongoing) then the medication will be considered concomitant. If both dates being compared are present and either or both times are missing, then dates alone will be compared.

An incomplete date has at least one of the day, month, or year unknown, but at least one is present. For analysis of medications, a complete date should be established to identify medication as occurring during treatment or not. For the purposes of handling partially reported start and stop dates for medication, the following algorithm will be applied:

- Missing start day, but month and year present:

  If study medication had been taken in the same month and year as the occurrence of the medication, then the start day of the medication will be assigned to the day of first dose of study medication.

  Otherwise, the start day will be set to the first day of the month.

- Missing start day and month, but year present:

  If study medication had been taken in the same year as the occurrence of the medication, then the start date of the medication will be assigned to the date of first application of study medication.

  Otherwise, the start day and month will be set to 01 January.

- Missing end day, but month and year present:

  The day will be set to the last day of the month.

- Missing end day and month, but year present:

  The end day and month will be set to the date of trial termination for the subject.

If after following the steps above, an imputed start date comes after an end date (either actual or imputed), the start date will be imputed to be equal to the end date.

In subject data listings, start and stop date of medication will be displayed as reported on the eCRF.

6.8.3. Missing Start and Stop Dates for Adverse Events

The same conventions to address incomplete dates for prior and concomitant medications (see Section 6.8.2 above) will also be used for AEs.

7. GENERAL CONSIDERATIONS FOR DATA ANALYSES

Continuous variables (eg, age) are summarized using descriptive statistics (the number of subjects with available data, the mean, standard deviation (SD), median and minimum and maximum). Categorical variables (eg, race) are summarized using counts and percentages.

The following conventions are applied to all data presentations and summaries.

- For continuous variables, all mean and median values are formatted to one more decimal place than the measured value. Standard deviation values are formatted to two more decimal places than the measured value. Minimum and maximum values are presented with the same number of decimal places as the measured value.
- For categorical variables, the number and percentage of responses are presented in the form XX (XX.X%) where the percentage is in the parentheses.
- Date variables are formatted as DDMMMYYYY for presentation. Time is formatted to 24-hour format as HH:MM for presentation, if applicable.
- Wherever possible, data will be decimal aligned.
- Any row with all zeros will not appear except with reasons for not completing the study. Summary tables will clearly indicate the number of subjects to which the data apply. If a table, listing, or figure has no available data, then the body should read ‘No data to report.’

7.1. Treatment group Descriptors

There were only 3 screened subjects who had historical C3G in this study. Two of them had confirmed C3G per central pathologist and started BCX9930 under 500 mg BID. The unconfirmed C3G subject was a screen failure. No subjects were enrolled under the other two cohorts (IgAN and PMN).

Disposition summaries will be presented by the ‘C3G’ cohort and all screened subjects.

Demographics and baseline characteristics summaries will be presented by the ‘C3G’ cohort. All other summaries will be presented by the following dosing groups:

- C3G 500 mg BID
- C3G 500 mg Total Daily Dose
- Total All Doses (Efficacy summaries will not have this column).

8. DATA DISPLAYS RELATED TO THE STUDY POPULATION

8.1. Subjects Disposition

Subject disposition will be summarized by C3G cohort and all screened subjects. The number of subjects who screened, had historical C3G, had confirmed C3G and among them, the number and percentage who were screening failures (along with the reasons) will be summarized. The number of subjects in safety population (treated), and among them, the number and percentage of subjects who discontinued from the study (along with the reasons) and those who completed the study will be presented. These data will also be listed.

A consort diagram will also be provided to display a graphical view of the study status.

8.2. Screen Failures

Screening failure information will be summarized in the subject disposition table (see Section 8.1 above) and listed.

8.3. Protocol Deviations

Protocol deviations will be identified by major or minor status, category, and importance per the protocol deviations plan. Protocol deviations will be listed.

8.4. Demographic and Baseline Characteristics

Demographic data and baseline characteristics including age at time of consent, age category at time of consent (< 18, $18 – 64$, ≥ 65 with subcategories $65 – 74$ and ≥ 75), sex at birth, childbearing potential (females only), ethnicity, race, height, weight, and BMI will be summarized by the C3G cohort.

Demographic data and baseline characteristics data will be listed.

8.5. Listing of Subject Inclusion and Exclusion Criteria

Inclusion/exclusion criterion not met will be listed.

8.6. Medical History and Medical Conditions Present at Entry

Medical history, including disease specific medical history, will be coded using the Medical Dictionary for Regulatory Affairs (MedDRA) version 24 and listed.

8.7. Prior Medication History and Medications Present at Entry

Any medication that was received and stopped prior to the date of first dose will be considered prior medications. Prior medications will be listed.

8.8. Baseline Physical Examination

Baseline physical examination data will be listed.

8.9. Baseline Vital Signs

Baseline vital sign data will be listed.

8.10. Baseline Laboratory Data

Baseline laboratory data will be listed.

8.11. Baseline Primary and Secondary Efficacy Evaluations

See Section 9.

9. EFFICACY

Due to the study discontinuation at a total of 2 treated subjects, efficacy analysis will be limited to descriptive statistics for the following key efficacy endpoints: 24-hour uPCR, 24-hour urine protein excretion and eGFR.

Descriptive statistics will be presented on observed values, change from baseline, percent change form baseline and ratio to baseline by scheduled visit using nominal visits. Source data of these key efficacy endpoints will be listed.

Source data collected for all other efficacy endpoints will be listed.

9.1. General Considerations

Not applicable.

9.2. Testing Statistical Assumptions Including Comparability at Baseline

Not applicable.

9.3. Statement of the Null and Alternate Hypotheses

Not applicable.

9.4. Subgroup Analyses

Not applicable.

9.5. Multiple Comparisons and Multiplicity

Not applicable.

9.6. Analysis of the Primary Efficacy Endpoint

See introduction to Section 9 above.

9.6.1. Primary Efficacy Analysis

See introduction to Section 9 above.

9.6.2. Sensitivity Analyses of the Primary Efficacy Results

Not applicable.

9.7. Analysis of the Secondary Efficacy Endpoints

See introduction to Section 9 above.

9.8. Summary of Reasons for Exclusion from the Per Protocol Efficacy Analyses

Not applicable.

10. SAFETY AND TOLERABILITY

All AEs and SAEs, regardless of investigator attribution, will be collected from the time of signing of the informed consent through to the last study visit (ie, through the post treatment follow-up visit[s]). TEAEs are defined, within a dosing group, as AEs that started on or after the first dose of study treatment through 30 days after the last dose of study drug.

An overall summary of TEAEs will be presented by dosing group for the followings:

- Number and proportion of subjects with a treatment-emergent adverse event (TEAE)
- Number and proportion of subjects with an investigator rated TEAE of mild, moderate, or severe.
- Number and proportion of subjects with a TEAE related to study drug
- Number and proportion of subjects with a TEAE leading to treatment interruption
- Number and proportion of subjects with a TEAE leading to treatment discontinuation
- Number and proportion of subjects with a TEAE leading to study discontinuation
- Number and proportion of subjects who experience a Common Terminology Criteria for Adverse Events (CTCAE) Grade 3 or 4 TEAE
- Number and proportion of subjects who experience a treatment-emergent serious adverse event (TESAE)
- Number and proportion of subjects with a TEAE leading to death

With respect to severity, if a subject has the same event more than once, the event with the highest severity will be counted. Likewise, if a subject has the same event more than once, the event with the highest relationship to investigational product will be counted. If the relationship between the AE or SAE and the study drug is determined to be possibly, probably, or definitely related, the event will be considered related to the study drug. If an adverse event has a missing severity or relationship, it will be classified as having the highest severity and/or strongest relationship to study treatment.

All AEs will be listed.

10.1. Adverse Event Preferred Term and Body/Organ System Summary Tables

TEAEs will be summarized by SOC and PT by dosing group. For a given event, a subject will be counted once for the subject count, if the subject reported one or more of the same events. Each event will be counted separately for the number of events.

10.1.1. Summaries of Adverse Event Incidence Rates for All Subjects

Not applicable.

10.1.2. Missing and Partial AE Onset Dates

See Section 6.8.3

10.1.3. Summaries of Adverse Incidence Rates for Serious Adverse Events (SAE), Adverse Event Dropouts, and Death

SAEs will be listed.

10.2. Total Duration of Therapy, Average Daily Dose, Maximum Daily Dose, Final Daily Dose of Study Medication, and Compliance

The duration of exposure (Days), within a dosing group, is calculated as follows:

- Duration of Exposure (Days) = the later of (the last date returned or final treatment end date) minus the treatment start date+1.

The Total duration of exposure (Days) is computed as the sum of the individual study drug durations across dosing groups.

Descriptive statistics will be presented for the duration of exposure (in days) by dosing group. The following duration of exposure categories will also be summarized by dosing group: at least 1 day, at least 7 days, at least 14 days, at least 28 days, at least 56 days, at least 84 days, at least 112 days, and at least 140 days.

Drug compliance for each study visit is captured in eCRF.

Study treatment exposure and drug compliance data will be listed.

10.3. Concomitant and Other Medications

Any medication that was ongoing, started, or ended on or after the initiation of study drug will be considered concomitant. Concomitant medications will be summarized by dosing groups.

For the subject who received study drug under two different dosing groups, medications taken on or after the initiation of study drug in the first dosing group through one day before the start of the second dosing group will be considered concomitant medications for the first dosing group. Medications taken on or after the start of the second dosing group will be considered concomitant medications for the second dosing group.

Concomitant medications will be listed.

10.4. Routine Laboratory Data

An assessment of drug induced liver injury (DILI) for elevations in liver function tests will be performed. For ALT, AST, total bilirubin and international normalized ratio (INR) within a dosing group, the maximum post-baseline value across a subject's visits (scheduled and unscheduled, out to 30 days post dose) will be determined for each test. The maximum value for each parameter will then be summarized per the categories given below:

ALT/ AST/ ALT and AST/ ALT or AST	**Total Bilirubin**	**INR**	**ALT or AST and Total Bilirubin**
> 1.5X ULN > 3X ULN > 5X ULN > 10X ULN > 20X ULN	> ULN > 1.5X ULN > 2X ULN	> 1.5	ALT > 3X ULN and Total Bilirubin > 1.5X ULN ALT > 3X ULN and Total Bilirubin > 2X ULN AST > 3X ULN and Total Bilirubin > 1.5X ULN AST > 3X ULN and Total Bilirubin > 2X ULN (ALT > 3X ULN or AST > 3X ULN) and Total Bilirubin > 1.5X ULN (ALT > 3X ULN or AST > 3X ULN) and Total Bilirubin > 2X ULN

Within a specific outcome (eg, ALT, AST, etc.), the categories are descending cumulative and not mutually exclusive.

In addition, for serum creatinine, within a dosing group, the maximum post-baseline value across a subject's visits (scheduled and unscheduled, out to 30 days post dose) will be determined. The maximum value will then be summarized by dosing group for the categories given below:

- > ULN but ≤ 1.5 × ULN
- > 1.5 × ULN but < 3 × ULN
- ≥ 3 × ULN
- ≥ 0.3 mg/dL increase from baseline.

Laboratory abnormalities will be graded according to CTCAE (Version 5.0, 27 November 2017). Any graded abnormality that occurs following the initiation of study drug (within 30 days post last dose) and represents at least 1-grade increase from the baseline assessment is defined as treatment emergent. A listing of all liver function test results for subjects experiencing a treatment-emergent Grade 3 or 4 liver function test will be provided.

All laboratory data will be listed.

10.5. Vital Signs

Vital sign data will be listed.

10.6. Electrocardiograms

ECG values and findings will be listed.

10.7. Physical Examination

Physical examination data will be listed.

10.8. Pregnancy

Pregnancy test results will be listed.

10.9. Study Termination Status

Study termination status will be summarized on the subject disposition table.

11. HEALTH OUTCOMES

[redacted]

12. PHARMACOKINETIC/ PHARMACODYNAMIC ANALYSIS

12.1. Pharmacokinetics

PK concentration and PK parameters will be listed.

12.2. Pharmacodynamics and [redacted]

PD and [redacted] will be listed.

13. REFERENCES

ICH E3 (1996). "Structure and Content of Clinical Study Reports."

14. APPENDIX

14.1. Table of Contents for Data Display Specifications

Title		Population
Tables		
14.1.1.1	Subject Disposition	All Subjects
14.1.2	Demographics and Baseline Characteristics	Safety
14.1.3	Concomitant Medications	Safety
14.1.4.1	Exposure to Study Medication	Safety
14.2.1	Summary of Key Efficacy Endpoints	Safety
14.3.1.1	Overall Summary of Treatment-emergent Adverse Events	Safety
14.3.1.2	Treatment-emergent Adverse Events by MedDRA System Organ Class and Preferred Term	Safety
14.3.2.1	Maximum Elevations in Post-baseline Liver Function Tests	Safety
14.3.2.2	Maximum Elevations in Post-baseline Serum Creatinine	Safety
Figures		
14.1.1.2	Consort Diagram	All Subjects

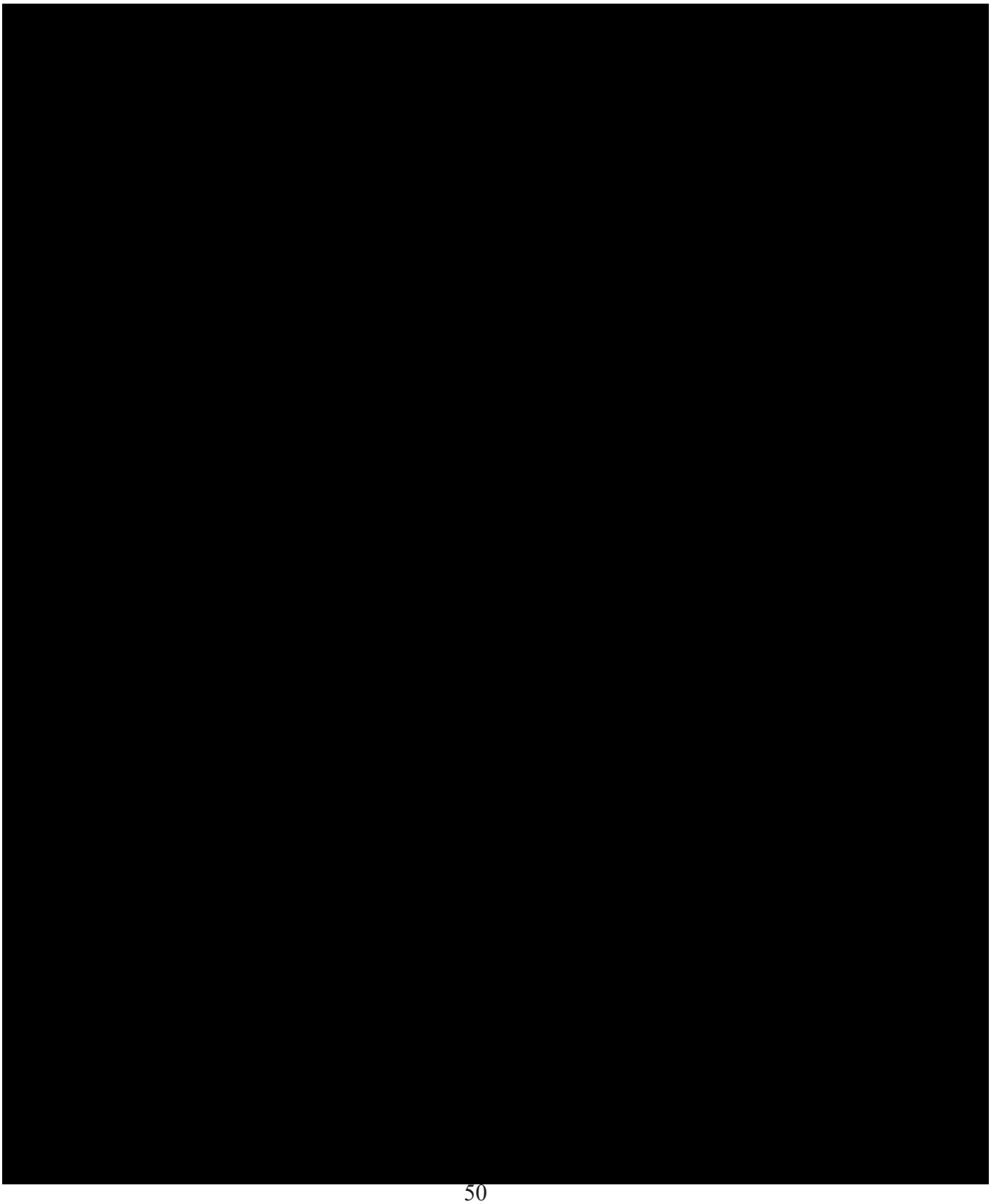
Listings

Listing Number	Title	Population
16.2.1.1	Informed Consent and Screen Failures	All Subjects
16.2.1.2	Subject Disposition	All Subjects
16.2.2.1	Inclusion/Exclusion Criteria Not Met	All Subjects
16.2.2.2	Protocol Deviations	All Subjects
16.2.3	Analysis Populations	All Subjects
16.2.4.1	Demographic and Baseline Characteristics	All Subjects
16.2.4.2	Medical History	All Subjects
16.2.4.3	Disease Specific Medical History	All Subjects
16.2.4.4	Prior and Concomitant Medications	All Subjects
16.2.4.5	C3G/IgAN/PMN (Medication) History	All Subjects
16.2.5.1	Treatment Administration	All Subjects

16.2.5.2	Treatment Compliance	All Subjects
16.2.6.1	24-Hour Urine	All Subjects
16.2.6.2	Pathology Scoring	All Subjects
16.2.6.3	Constitutive Blood Levels of Complement Biomarkers	All Subjects
16.2.6.4	Single Void Urine Levels of Complement Biomarkers	All Subjects
16.2.6.5	Complement Biomarker Measurements of Ex Vivo Stimulation Assays	All Subjects
16.2.6.6.1	[redacted]	All Subjects
16.2.6.7.1	[redacted]	All Subjects
16.2.6.7.2	[redacted]	All Subjects
16.2.6.8	[redacted]	All Subjects
16.2.7.1	Adverse Events	All Subjects
16.2.7.2	Serious Adverse Events	All Subjects
16.2.7.3	Adverse Events Leading to Study Discontinuation	All Subjects
16.2.7.4	Adverse Events Related to Study Treatment	All Subjects
16.2.7.5	Adverse Events with CTCAE Grade 3 or Grade 4 Severity	All Subjects
16.2.7.6	Rashes	All Subjects
16.2.8.1	Laboratory Results – Clinical Chemistry	All Subjects
16.2.8.2	Laboratory Results – Hematology	All Subjects
16.2.8.3	Laboratory Results – Urinalysis	All Subjects
16.2.8.4	Laboratory Results – Coagulation	All Subjects
16.2.8.5	Single Void Urine Test Results	All Subjects
16.2.8.6	Liver Function Test Results for Subjects Experiencing a Treatment-emergent Grade 3 or 4 Liver Function Test	All Subjects
16.2.9	Vital Signs	All Subjects
16.2.10	12-Lead ECG	All Subjects
16.2.11	Physical Examinations	All Subjects
16.2.12.1	Pregnancy Test	All Women
16.2.12.2	Drug Screen	All Subjects
16.2.12.3	Other Laboratory Results	All Subjects
16.2.13.1	Individual Plasma and Urine BCX9930 Pharmacokinetic Concentration-Time Data	All Subjects
16.2.13.2	Individual PK Parameters in plasma and urine	All Subjects

14.2. Data Display Specifications

Specifications for data displays will be provided in a separate document.



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