COVER PAGE

Official Title:	A Double Blind, Randomized, Placebo-Controlled, Multicenter Phase IIa, Clinical Trial to Assess Efficacy and Safety of the Human Anti-CD38 Antibody Felzartamab in IgA Nephropathy - IGNAZ
NCT Number:	NCT05065970
Document Date:	12 September 2024

STATISTICAL ANALYSIS PLAN

Version 3.2

A Double Blind, Randomized, Placebo-Controlled, Multicenter Phase IIa, Clinical Trial to Assess Efficacy and Safety of the Human Anti-CD38 Antibody Felzartamab in IgA Nephropathy - IGNAZ

Protocol No: MOR202C206

IND Number:	142840
EudraCT Number:	2020-005054-19
Sponsor:	Human Immunology Biosciences, Inc (HI-Bio)
Author:	[redacted]
SAP Version:	Version 3.2 (12-Sep-2024)
Supersedes SAP Version:	Version 3.1 (8 Aug 2024)

STATISTICAL ANALYSIS PLAN

SIGNATURE PAGE

Protocol No: MOR202C206 – Version 4.1 and local PA CTP V4.1 JP 3.1

A Double Blind, Randomized, Placebo-Controlled, Multicenter Phase IIa, Clinical Trial to Assess Efficacy and Safety of the Human Anti-CD38 Antibody Felzartamab in IgA Nephropathy – IGNAZ

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Signing Time: 19-Sep-2024 | 12:25:45 PM PDT
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Signer Name: [redacted]
Signing Reason: I approve this document
Signing Time: 19-Sep-2024 | 12:46:27 PM PDT
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TABLES/FIGURES

DOCUMENT HISTORY

Document History – Changes compared to the previous finalized version

Version	Date	Changes	Rationale for Change
1.0	27-10-2021	Initial Version	N/A
2.0	24-03-2023	Update based on global CTP V 4 and local PA CTP V4.0 JP 3.0, as well as sponsor information	To accommodate global PA to V4.0 and local PA to V4.0 JP 3.0 and sponsor information
3.0	29-07-2023	Details in below	To accommodate global PA to V4.1 and additional analysis requirements from sponsor to support the interim analysis and final analysis
3.1	08-08-2024	Details in below	To add more details to handle visits for early discontinuation from treatment or study
3.2	12-09-2024	Details in below	To add imputation rules when lab result is LLQ

Summary of Changes from Version 1.0 to Version 2.0

Section	Change(s)	Rationale
Section 4	Update protocol version	SAP version 2 is based on global CTP V 4 and local PA CTP V4.0 JP 3.0.
[redacted]		
Section 6.1	Update study design related information	To be consistent with protocol version 4 and local PA V4.0 JP 3.0
Section 6.2	Add schedule of assessments for open-label Part II and update footnote 5.	To be consistent with local PA V4.0 JP 3.0
Section 6.3	Update language on Japanese cohort	To be consistent with protocol version 4.
Section 6.5	Update sample size related language on open label part II of the trial for Japanese patients	To be consistent with protocol version 4.
Section 7.7	Remove the visit mapping language and stick with the visit number in the eCRF	To be consistent with decisions made from other Felza studies

Section 7.8	1.Remove the pre/post dose criteria when getting unscheduled visits into analysis window 2.Remove the language regarding assessment window.	For [redacted] and PK, this was taken care of in the visit information. For all other parameters, only pre-dose is collected. Assessment window does not apply anymore given the update of section 7.7.
Section 7.11	Update definition for complete response and response	To be consistent with local PA V4.0 JP 3.0
Section 10	Add clarification language on analysis time point for Global part I and open-label part II	To be consistent with local PA V4.0 JP 3.0
Section 10.2	Update language for complete response and response	To be consistent with local PA V4.0 JP 3.0
Section 10.5	Updated to “section 7.11” since section 7.12 doesn’t exist in the SAP.	Correct typo
[redacted]	[redacted]	[redacted]

Summary of Changes from Version 2.0 to Version 3.0

Section	Change(s)	Rationale
Section 7.4	Add MMRM model for eGFR change from baseline	eGFR is a key secondary endpoint akin to ACR and should have an MMRM output in addition to summary stats. eGFR is not a ratio, like ACR and UPCR, so a log transform is not needed for the MMRM model.
Section 7.1 and 7.4	Add MMRM sensitivity analyses directly modeling % change from baseline as dependent variable	Other companies have reported results for eGFR and UPCR in terms of % change from BL.
Section 7.1 and 7.4	Expand MMRM analyses to include data out to Month 15	While primary endpoint is Month 9, subsequent visits are also of interest.
Section 4.9	Modify Table 4-3 to include Japanese subjects from Part 2 (N = 6) in certain efficacy summary tables as a separate cohort.	While Part 2 is non-randomized, demographically distinct, and has a different SoA, summary measures of efficacy are still of interest.
Section 4.9	Add EAP population to table Part 2 Japanese subjects into certain TFLs along with the FAS.	Want to add in high-level assessment of summary stats from Part 2 Japanese subjects without generating lots of additional unique tables. Also allows for easy cross-referencing of Part 1 vs Part 2.

Section 3.6	Add detailed description of interim analysis	Give more details on the scope of interim analysis and the cutoff of timepoint for ongoing data.

Summary of Changes from Version 3.0 to Version 3.1

Section	Change(s)	Rationale
Section 1	Update protocol version	This Statistical Analysis Plan (SAP) describes the planned analysis and reporting of data collected from Human Immunology Biosciences protocol MOR202C206, Version 4.1, dated 10-Oct-2022 and local PA CTP V4.1 JP 3.1, dated 14-Oct-2022.
Section 4.7	Add more details for early EOS visit	Additionally, if a patient completes treatment, but discontinues study early, their early EOS visit will be mapped to the nearest analysis visit based on Study Day.

Summary of Changes from Version 3.1 to Version 3.2

Section	Change(s)	Rationale
Section 11	Add imputation rules when [redacted] lab result is LLOQ	In addition, certain [redacted], in particular [redacted], that are reported as being below the LLOQ will be analyzed using the LLOQ value for the purpose of numerical analysis and reporting, for example, to determine change or (percent) change from baseline.

LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

ACR	Albumin Creatinine Ratio
ADA	Anti-drug antibody
ADaM	Analysis Data Model
AE	Adverse event
AESI	Adverse Event of Special Interest
ATC	Anatomical Therapeutic Chemical Classification
BMI	Body Mass Index
BLOQ	Below Limit of Quantification
CDISC	Clinical Data Interchange Standards Consortium
COVID-19	Official name for disease caused by the SARS-CoV-2 (coronavirus)
CR	Complete response
CRF	Case Report Form
CSR	Clinical study report
CV	Coefficient of variation
EAP	All enrolled patients analysis set
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
eGFR	estimated glomerular filtration rate
EOS	End of study
EOT	End of treatment
EudraCT	European Union Drug Regulating Authorities Clinical Trials
FAS	Full analysis set
[redacted]	[redacted]
IAS	Immunological analysis set
IgA	Immunoglobulin A
IgAN	IgA Nephropathy
IRR	infusion related reaction
IST	Immunosuppressive therapy
JPS	Japan analysis set
LLOQ	Lower Limit of Quantification
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligram
mL	Milliliter
Max	maximum
Min	minimum
PD	Protocol deviation
PE	Physical examination
PK	Pharmacokinetics
PKAS	Pharmacokinetic Analysis Set
PK/[redacted]	pharmacokinetic/[redacted]
PPS	Per protocol set
PT	Preferred term
QTcB	QT interval corrected for heart rate according to Bazett
QTcF	QT interval corrected for heart rate according to Fridericia
Q1	25th Percentile
Q3	75th Percentile
SAE	Serious adverse event
SAF	Safety analysis set

SAP	Statistical analysis plan
SCA	Screening analysis set
SDTM	Study data tabulation model
SOC	System organ class
SOP	Standard Operating Procedure
SD	Standard deviation
TEAE	Treatment emergent adverse event
UPCR	Urine protein to creatinine ratio
WHO	World Health Organization

1. INTRODUCTION

This Statistical Analysis Plan (SAP) describes the planned analysis and reporting of data collected from Human Immunology Biosciences protocol MOR202C206, Version 4.1, dated 10-Oct-2022 and local PA CTP V4.1 JP 3.1, dated 14-Oct-2022. Any amendments to the protocol, which do not affect the statistical aspects of the trial, will not necessitate a SAP update.

This study is a randomized, placebo-controlled, multi-center, double-blind, proof of concept phase IIa and dose evaluation trial of Felzartamab in IgAN. The planned analyses identified in this SAP may be included in clinical study report (CSRs) and/or in relevant summary report documents (e.g. regulatory submissions, or future manuscripts). Also, post hoc [redacted] not necessarily identified in this SAP may be performed to further examine study data and will not require updating the final SAP. Any post-hoc, or unplanned, [redacted] analysis performed will be clearly identified as such and described in the final CSR.

The reader of this SAP is encouraged to also read the clinical protocol, and other identified documents, for details on the planned conduct of this study. Operational aspects related to collection and timing of planned clinical assessments are not repeated in this SAP unless relevant to the planned analysis.

2. STUDY OBJECTIVES AND ENDPOINTS

An overview of the study objectives and endpoints is depicted in Table 2-1.

*Patients enrolled in open-label Part II of the study will undergo secondary and [redacted] endpoint assessments up to 12 months (Visit 13, EOS timepoint).

Table 2-1: Study objectives and endpoints

Study objective	Endpoint	SAP section
Primary objective:	**Primary endpoint:**	
To assess the efficacy of Felzartamab compared to placebo in patients with IgAN based on the change in urine protein to creatinine ratio (UPCR) at 9 months.	Relative change in UPCR in 24h urine at 9 months compared to the reference proteinuria value in the Felzartamab dose groups vs. placebo.	7.1
Secondary objectives*:	**Secondary endpoints:**	
To assess the relationship between exposure, safety, and efficacy in each of the three dose groups vs. placebo to support a decision for a dose in further trials	Integrative analysis of several endpoints	Not applicable in this SAP
To assess the efficacy of Felzartamab compared to placebo in patients with IgAN based on the following:		
• Change in UPCR at 3, 6, 12, 18 and 24 months.	Relative change in UPCR in 24h urine at 3, 6, 12, 18 and 24 months compared to the reference proteinuria value in each Felzartamab dose group vs. placebo.	7.1
• Complete response (CR) at 3, 6, 9, 12, 18 and 24	CR at 3, 6, 9, 12, 18 and 24 months in each Felzartamab dose group vs. placebo.	7.2

Study objective	Endpoint	SAP section
months.		
• Proportion of patients with response at 3, 6, 9, 12, 18 and 24 months.	Proportion of patients with response at 3, 6, 9, 12, 18 and 24 months in each Felzartamab dose group vs. placebo.	7.2
• Albumin-creatinine ratio (ACR) at 3, 6, 9, 12, 18 and 24 months.	ACR from 24 h urine at 3, 6, 9, 12, 18 and 24 months in each Felzartamab dose group vs. placebo.	7.3
• Duration of response.	Duration of response in each Felzartamab dose group vs. placebo.	7.5
• Time to response.	Time to response in each Felzartamab dose group vs. placebo.	7.5
To assess the renal function of Felzartamab compared to placebo in patients with IgAN.	Renal function (determined by estimated glomerular filtration rate [eGFR] over time) in each Felzartamab dose group vs. placebo.	7.4
To assess the safety of Felzartamab in patients with IgAN.	Frequency, incidence, seriousness, relatedness, and severity of treatment emergent- adverse events (TEAEs) across all treatment groups.	8.1
To assess the pharmacokinetic (PK) profile of Felzartamab in patients with IgAN.	Serum concentrations of Felzartamab over time in each Felzartamab dose group.	9
To investigate the potential immunogenicity of Felzartamab in patients with IgAN	Formation of anti-drug antibodies (ADAs) over time in all groups	10

[redacted]

3. STUDY DESIGN

3.1 General study design

This randomized, placebo-controlled, multi-center, double-blind parallel-group phase IIa trial assesses the efficacy, safety and pharmacokinetic (PK)/[redacted] relationship of the human anti-CD38 antibody Felzartamab in patients with IgA Nephropathy (IgAN). It serves as a proof of concept and dose evaluation trial for Felzartamab in patients with IgAN. The trial has 2 parts i.e. Part I (applicable to all countries including Japan) and Part II (Japanese Cohort – applicable to Japan). A total of 8 Japanese patients will be enrolled in Part I and/or Part II of the study.

Global Study Part I:

All patients will receive angiotensin-converting enzyme inhibitors (ACEi) and/or angiotensin receptor blockers (ARB) – the supportive standard of care therapy throughout the trial. Patients will be randomized to receive one of 3 different dosing schedules of Felzartamab (dosing arms M1, M2 or M3) or placebo. Overall, approximately 44 patients will be randomized in this trial with 11 patients per dosing arm (including placebo). Up to four patients from Japan can be enrolled during the double-blind part of the trial (Part I) and receive felzartamab (dosing arms M1, M2 or M3) or placebo.

All patients in study Part I will follow the clinical trial schedule (Table 3-1) consisting of a:

- Screening Phase (up to 6 weeks)
- Treatment Phase (6 months)
- Follow-up Phase (18 months)

Japanese Cohort Part II (applicable to Japan only):

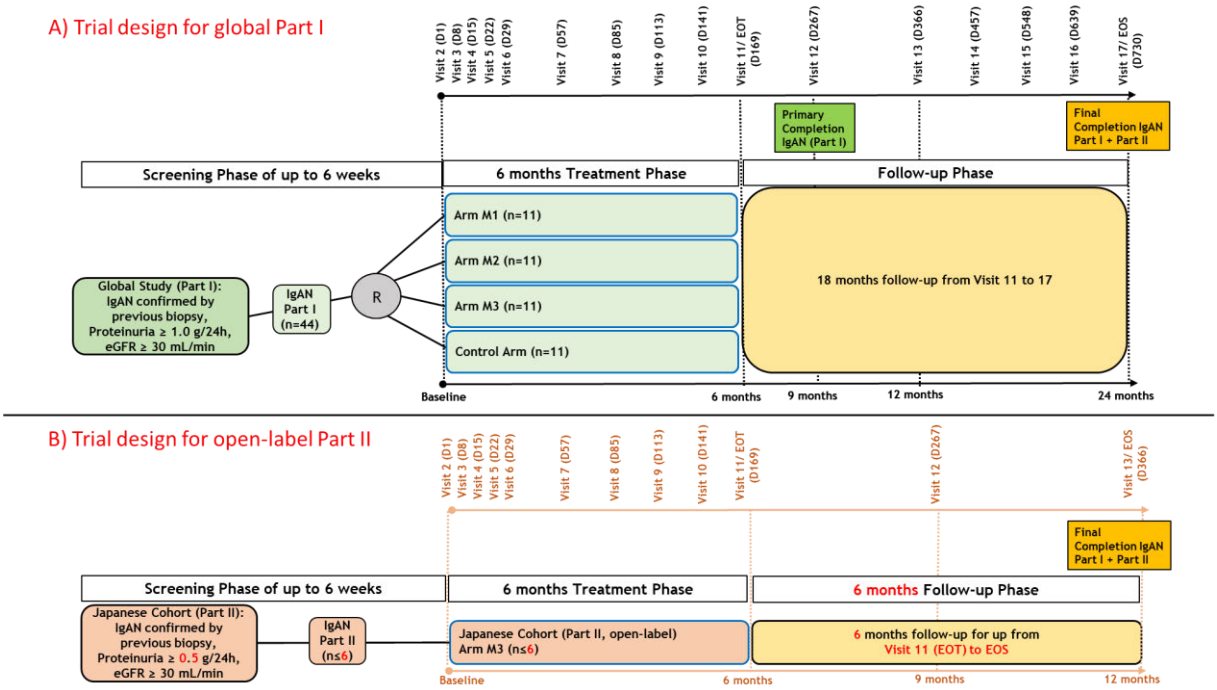
After the enrollment of patients is completed in the global Part I, the remaining Japanese patients will be enrolled in the open-label part II of the trial to achieve the target number of 8 Japanese patients in the trial in total. Patients in this open label part II will receive 9 doses of felzartamab according to M3 dosing schedule.

All patients in study Part II will follow the clinical trial schedule (Table 3-2) consisting of a:

- Screening Phase (up to 6 weeks)
- Treatment Phase (6 months)
- Follow-up Phase (6 months)

Excluding the screening visit, patients in Part I will attend 16 trial visits, whereas patients in Part II will attend 12 trial visits. A patient is considered to have completed the trial if s/he has completed all applicable phases of the trial.

Figure 3-1 Trial design MOR202C206 IGNAZ



3.2 Schedule of assessments

Table 3-1 Schedule of Assessments for global Part I

Study Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11/ EOT**	**12**	**13**	**14**	**15**	**16**	**17/ EOS**
Study Day	**-42 to 0**	**1**	**8**	**15**	**22**	**29**	**57**	**85**	**113**	**141**	**169**	**267**	**366**	**457**	**548**	**639**	**730**
Window (days)			**±2**	**±3**	**±3**	**±7**	**±7**	**±7**	**±14**	**±14**	**±14**	**±14**	**±14**	**±14**	**±14**	**±14**	**±14**
EVENT	**SCR**	**BL**						**3m visit**			**6m visit**	**9m visit**	**12m visit**	**15m visit**	**18m visit**	**21m visit**	**24m visit**
Informed consent	X																
Medical history (IgAN history)/demography/ disease therapy history/ allergies	X																
Prior medication	X																
Concomitant medication		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height	X																
Body weight	X	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X		X				X
Kidney biopsy[1]	X[1]																
Randomization		X															
Blood typing and screening for irregular antibodies		X															
Serum pregnancy (in FCBP)	X										X	X					
Urine pregnancy stick test (in FCBP)		X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]							

Study Visit	1	2	3	4	5	6	7	8	9	10	11/ EOT	12	13	14	15	16	17/ EOS
Study Day	-42 to 0	1	8	15	22	29	57	85	113	141	169	267	366	457	548	639	730
Window (days)			±2	±3	±3	±7	±7	±7	±14	±14	±14	±14	±14	±14	±14	±14	±14
EVENT	SCR	BL						3m visit			6m visit	9m visit	12m visit	15m visit	18m visit	21m visit	24m visit
Serum tests for hepatitis, HIV	X	X[6,7]				X[6]	X[6]	X[6]	X[6]	X[6]	X[6,7]	X[6]	X[6]				X[6]
HbA1c in patients with diabetes mellitus II	X																
Dosing Felzartamab /Placebo		X	X	X	X	X	X	X	X	X							
Adverse event recording	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
12-lead ECG (in triplicate)	X	X[3]	X[3]					X[3]			X		X				X
Physical examination	X	X						X			X		X				X
Vital signs	X	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X	X	X	X	X	X	X
Urine analysis	X	X[2]				X[2]		X[2]		X[2]	X		X		X		X
Blood count	X	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X	X	X	X	X	X	X
Serum biochemistry and [redacted]	X	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X	X	X	X	X	X	X
Lipid panel		X									X		X				X
Anti-drug antibodies (ADA) sampling		X[2]				X[2]	X[2]	X[2]			X	X	X	X	X		X
24 h urine collection for proteinuria, UPCR and ACR ratio, Na^+	X	X[4]						X[2]			X	X	X	X	X	X	X

Study Visit	1	2	3	4	5	6	7	8	9	10	11/ EOT	12	13	14	15	16	17/ EOS
Study Day	-42 to 0	1	8	15	22	29	57	85	113	141	169	267	366	457	548	639	730
Window (days)			±2	±3	±3	±7	±7	±7	±14	±14	±14	±14	±14	±14	±14	±14	±14
EVENT	SCR	BL						3m visit			6m visit	9m visit	12m visit	15m visit	18m visit	21m visit	24m visit
PK sampling Felzartamab (serum)		X[3]	X[2]	X[3]		X[3]	X[2]	X[2]	X[2]	X[2]	X	X					X[5]
[redacted]																	

ACR: albumin to creatinine ratio; BL: baseline; ECG: electrocardiogram; EOS: end of study; EOT: end of treatment; FCBP = female of childbearing potential; HIV: human immunodeficiency virus; PK: pharmacokinetics; SCR: screening; UPCR: urine protein to creatinine ratio.

1: Mandatory for all patients if not done within the last 8 years prior to signing ICF, mandatory for patients with diabetes mellitus type II if not done within the last 6 months before start of screening. The results of all kidney biopsies performed (taken as routine clinical care or stipulated by this trial protocol) will be recorded in the eCRF.

2: Predose if Felzartamab/Placebo dosing occurs on the same day.

3: Predose and 30 min after end of infusion. ECG should be performed in triplicate.

4: 24 h urine collection at baseline to be completed before Felzartamab/Placebo infusion.

5: For end of study visit only

6: Only hepatitis B virus (HBV) DNA test by PCR for patients with positive hepatitis B core antibody [anti-HBc] at screening.

7: Only HCV RNA PCR for patients with positive anti hepatitis C virus [anti-HCV] antibody at screening.

The minimum interval between Visit 10 and Visit 11 is 28 days.
Patients missing a treatment visit within the specified visit window for reasons other than toxicity will get the next dose at the next scheduled visit and thus receive less than the planned 9 IMP applications.
Parameters in italics are measured in a central laboratory.

Table 3-2 Schedule of activities for open-label Part II (Japanese cohort)

Study Visit	1	2	3	4	5	6	7	8	9	10	11/ EOT	12	13/ EOS
Study Day	**-42 to 0**	**1**	**8**	**15**	**22**	**29**	**57**	**85**	**113**	**141**	**169**	**267**	**366**
Window (days)			**±2**	**±3**	**±3**	**±7**	**±7**	**±7**	**±14**	**±14**	**±14**	**±14**	**±14**
EVENT	**SCR**	**BL**						**3m visit**			**6m visit**	**9m visit**	**12m visit**
Informed consent	X												
Medical history (IgAN history)/demography/ disease therapy history/ allergies	X												
Prior medication	X												
Concomitant medication		X	X	X	X	X	X	X	X	X	X	X	X
Height	X												
Body weight	X	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X		X
Kidney biopsy[1]	X[1]												
Randomization		X											
Blood typing and screening for irregular antibodies		X											
Serum pregnancy (in FCBP)	X										X	X	
Urine pregnancy stick test (in FCBP)		X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]			

Study Visit	1	2	3	4	5	6	7	8	9	10	11/ EOT	12	13/ EOS
Study Day	**-42 to 0**	**1**	**8**	**15**	**22**	**29**	**57**	**85**	**113**	**141**	**169**	**267**	**366**
Window (days)			**±2**	**±3**	**±3**	**±7**	**±7**	**±7**	**±14**	**±14**	**±14**	**±14**	**±14**
EVENT	**SCR**	**BL**						**3m visit**			**6m visit**	**9m visit**	**12m visit**
Serum tests for hepatitis, HIV	X	X[6,7]				X[6]	X[6]	X[6]	X[6]	X[6]	X[6,7]	X[6]	X[6]
HbA1c in patients with diabetes mellitus II	X												
Dosing felzartamab/ Placebo		X	X	X	X	X	X	X	X	X			
Adverse event recording	X	X	X	X	X	X	X	X	X	X	X	X	X
12-lead ECG (in triplicate)	X	X[3]	X[3]					X[3]			X		X
Physical examination	X	X						X			X		X
Vital signs	X	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]	X	X	X
Urine analysis	X	X[2]				X[2]		X[2]		X[2]	X		X
Blood count	X	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X	X	X
Serum biochemistry and [redacted]	X	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X[2]	X	X	X
Lipid panel		X									X		X
Anti-drug antibodies (ADA) sampling		X[2]				X[2]	X[2]	X[2]			X	X	X
24 h urine collection for proteinuria, UPCR and ACR ratio, Na^+	X	X[4]						X[2]			X	X	X

Study Visit	1	2	3	4	5	6	7	8	9	10	11/ EOT	12	13/ EOS
Study Day	**-42 to 0**	**1**	**8**	**15**	**22**	**29**	**57**	**85**	**113**	**141**	**169**	**267**	**366**
Window (days)			**±2**	**±3**	**±3**	**±7**	**±7**	**±7**	**±14**	**±14**	**±14**	**±14**	**±14**
EVENT	**SCR**	**BL**						**3m visit**			**6m visit**	**9m visit**	**12m visit**
PK sampling felzartamab (serum)		X[3]	X[2]	X[3]		X[3]	X[2]	X[2]	X[2]	X[2]	X	X	X[5]
[redacted]													

ACR: albumin to creatinine ratio; BL: baseline; ECG: electrocardiogram; EOS: end of study; EOT: end of treatment; FCBP = female of childbearing potential; HIV: human immunodeficiency virus; PK: pharmacokinetics; SCR: screening; UPCR: urine protein to creatinine ratio.

1: Mandatory for all patients if not done within the last 8 years prior to signing ICF, mandatory for patients with diabetes mellitus type II if not done within the last 6 months before start of screening. The results of all kidney biopsies performed (taken as routine clinical care or stipulated by this trial protocol) will be recorded in the eCRF.

2: Predose if felzartamab/Placebo dosing occurs on the same day.

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6: Only hepatitis B virus (HBV) DNA test by PCR for patients with positive hepatitis B core antibody [anti-HBc] at screening.

7: Only HCV RNA PCR for patients with positive anti hepatitis C virus [anti-HCV] antibody at screening.

The minimum interval between Visit 10 and Visit 11 is 28 days.
Patients missing a treatment visit within the specified visit window for reasons other than toxicity will get the next dose at the next scheduled visit and thus receive less than the planned 9 IMP applications.
Parameters in italics are measured in a central laboratory.

3.3 Dosing

Patients in the Global Cohort (Part I) will receive 9 infusions of either Felzartamab or Placebo on Day 1, 8, 15, 22, 29, 57, 85, 113 and 141 according to Table 3-1.

All patients enrolling in the Japanese Cohort (Part II) will receive Felzartamab treatment as per the dosing arm M3 and will receive 9 infusions of Felzartamab on Day 1, 8, 15, 22, 29, 57, 85, 113 and 141.

Table 3-3 Dosing Arms

Dosing arm	Felzartamab	Placebo
M1	**2 Doses:** Day 1 and 15	Day 8, 22, 29, 57, 85, 113 and 141
M2	**5 Doses:** Day 1, 8, 15, 29 and 57	Day 22, 85, 113 and 141
M3	**9 Doses:** Day 1, 8, 15, 22, 29, 57, 85, 113 and 141	none
Control arm	none	Day 1, 8, 15, 22, 29, 57, 85, 113 and 141

[redacted]

3.4 Inclusion and exclusion criteria

Please refer to section 1.4 of the clinical trial protocol for the detailed inclusion/exclusion criteria.

3.5 Determination of Sample Size

Approximately 11 patients will be enrolled in each arm of the Global Study (Part I). With an assumed drop-out rate of [redacted] approximately 10 patients per arm will be evaluable for the primary endpoint analysis.

A separate open-label cohort of patients in Japan (Part II) is planned to ensure that in total approximately 8 Japanese patients are enrolled in this trial. This will enable a meaningful evaluation of PK and safety in comparison to non-Japanese patients.

For details, please refer to Section 10.1 of the clinical trial protocol.

3.6 Timing of analyses

The primary analysis will be performed after all randomized patients in the Global study (Part I) have completed their 9 month-visit or discontinued the trial earlier. The final analysis of all endpoints will be performed after all patients (both, Part I and Part II) have completed their last visit, or discontinued the trial earlier.

For primary analysis, all efficacy data up to 9 months and all safety data as well as all PK (serum and urine), ADA and [redacted] results will be included and analysed. [redacted] For final analysis, all data will be included.

An interim analysis before the primary analysis timepoint may be performed, if needed. Additional follow-up analyses for safety or efficacy endpoints may be performed between the primary and final analysis if needed or requested.

The interim analysis will include efficacy data [redacted], safety data, PK data (serum and urine), and ADA data collected up to date. When performing MMRM model, only data at month 3, 6, 9, 12, and 15 will be used.

4. DEFINITIONS AND GENERAL METHODOLOGY

4.1 Study drug administration

4.1.1 Date of first administration of study drug

The date of first administration of study drug for a subject is the first date when a study drug is administered and is referred to as “start date of study drug” or “first dose date”.

4.1.2 Date of last administration of study drug

The date of last administration of study drug for a subject is the last date when a study drug is administered and is referred to as “end date of study drug” or “last dose date”.

4.2 Reference start date and study day

The reference start date will be defined as the start date of study drug.

The study day describes the day of the event or assessment, relative to the reference start date. The reference start date is designated as Study Day 1. Study Day -1 is the day that precedes Study Day 1. Study Day 0 is not defined.

The study day will be calculated as:

- The date of the event (visit date, assessment date, etc.) – reference start date + 1 day, if the event is on or after the reference start date
- The date of the event (visit date, assessment date, etc.) – reference start date, if the event precedes the reference start date

4.3 Screening failure

Screening failures are subjects who have signed informed consent but are not subsequently randomized. Subjects who were randomized but have never received treatment are not considered as screening failures. These subjects are referred to as “Not treated subjects”.

4.4 Time unit

A month-length is 30.4375 days (365.25/12). If duration is to be reported in months, duration in days is divided by 30.4375. If duration is to be reported in years, duration in days will be divided by 365.25.

4.5 Baseline

Baseline is the result of an investigation describing the "true" uninfluenced state of the subject, defined as the period from the date of signing any informed consent document to the start date of study drug.

Unless otherwise stated in the respective sections, the last non-missing assessment, including unscheduled assessments, on or before the start date of study drug prior to the first dosing of the study drug will be used as "baseline" value or "baseline" assessment. Assessments collected post-dose on the first date of treatment are not considered as baseline values.

If a subject has no value as defined above, the baseline value will be considered as missing.

Change from baseline calculation

Absolute change from baseline will be calculated as

[visit value – baseline value]

Percentage change from baseline will be calculated as

$$\left[\frac{\text{visit value} - \text{baseline value}}{\text{baseline value}} \times 100\right].$$

4.6 End of treatment

End of treatment (EOT) is defined as the assessment obtained on the EOT visit date.

4.7 Assessment windows and analysis visits

Table 4-1 Assessment windows

Scheduled Visit Number	Visit (label)	Time Interval (day)	Target Time Point (day)
1	Screening	-28 to -1	-28 to -1
2	Visit 2 (Baseline)	1	1
3	Visit 3 (Day 8)	2 to 12	8
4	Visit 4 (Day 15)	13 to 17	15
5	Visit 5 (Day 22)	18 to 25	22
6	Visit 6 (Day 29)	26 to 31	29
7	Visit 7 (Day 57)	44 to 70	57
8	Visit 8 (Month 3)	71 to 99	85
9	Visit 9 (Day 113)	100 to 126	113

10	Visit 10 (Day 141)	127 to 155	141
11	Visit 11 (Month 6)	156 to 182	169
12	Visit 12 (Month 9)	237 to 297	267
13	Visit 13 (Month 12)	336 to 396	366
14	Visit 14 (Month 15)	417 to 487	457
15	Visit 15 (Month 18)	518 to 578	548
16	Visit 16 (Month 21)	609 to 669	639
17	Visit 17 (Month 24)	700 to 760	730

Analysis visits

All assessments collected at scheduled and unscheduled visits will be included in the listings. For parameters that will be summarized by visit, the nominal visit as recorded in the eCRF will be used. When the data from a scheduled visit is not available, unscheduled visit within the assessment window may be used to replace the scheduled visit. If a patient discontinues treatment early, their EOT visit and all subsequent visits will be mapped to the next sequential visits and will be used in all visit-based analysis. Additionally, if a patient completes treatment, but discontinues study early, their early EOS visit will be mapped to the nearest analysis visit based on Study Day.

In the case of multiple records for one visit, selection rules are described below.

4.8 Selection of data in the event of multiple records

Depending on the statistical analysis method, single values may be required for each visit. For example, change from baseline by visit usually requires a single value per visit, whereas a time-to-event analysis would not require one value per visit but rather one value for the study.

Unless otherwise noted in the respective sections, when a single value is needed, the following rules will be used.

- Scheduled visits will be used regardless of the assessment window.
- If more than one assessment falls in the same assessment window, the non-missing assessment closest target study day will be selected for analysis.
- If more than one assessment is the same number of days away from the target study day or from the same day, the latter value will be used.

4.9 Analysis populations

Table 4-2 Analysis Populations

Analysis population	Description	Primary purpose
Screening analysis set (SCA)	All patients who are screened for this trial	Disposition
Full analysis set (FAS)	All patients who are randomized to the trial. Analyses using FAS will be based on the treatment to which each patient is randomized. For clarity, the FAS refers to subjects randomized to Part I of the study.	Analysis of efficacy endpoints Demographics, baseline, medical history
Per-protocol analysis set (PPS)	All patients who received at least one dose of trial treatment who do not have any relevant major protocol deviations (PDs). Major PDs that will lead to an exclusion of the PPS will be decided on prior to database lock. All PDs or conditions leading to exclusion from the PPS will be documented prior to any data base lock.	Sensitivity analysis of selected efficacy endpoints
Safety analysis set (SAF)	All patients who received at least one dose of trial treatment. Analyses using the SAF will be based on the actual treatment received.	Analysis of safety endpoints
PK analysis set (PKAS)	All patients with any available quantifiable Felzartamab serum concentration data.	Analysis of PK endpoints
Immunogenicity analysis set (IAS)	All patients with at least one ADA sample.	Analysis of immunogenicity endpoints
Japan analysis set (JPS)	All Japanese patients who were enrolled under global cohort (Part I) and Japan-only cohort (Part II)	Evaluate Japanese patients' safety and PK profile.
All Enrolled Patients (AEP)	All randomized patients from the FAS plus all Japanese patients who were enrolled in Part 2.	Report summary stats on demographics and select efficacy endpoints. Update FAS listings to be EAP.

[redacted]

Table 4-3 gives an overview of the assessments performed on the different analysis populations.

Table 4-3 Planned analyses for different populations

Analysis	SCA	FAS	SAF	PPS	PKAS	IAS	JPS	AEP
Subject disposition	X	X					X	
Baseline and demographic characteristics		X					X	X
Medical history		X						
Study treatment		X						

Analysis	SCA	FAS	SAF	PPS	PKAS	IAS	JPS	AEP
Prior and concomitant medications		X						
Efficacy analysis		X		X*				X**
Safety analysis			X				X	
PK profile of MOR202					X		X	
Immunogenicity of MOR202						X		
[redacted]								

*: Sensitivity analysis of selected efficacy endpoints as well as [redacted] will be performed on PPS as needed. **: Select efficacy summary tables will be created for the EAP. In general, listings will be generated for the EAP instead of the FAS since FAS is a subset of EAP.

4.10 Withdrawal of informed consent

The date on which a subject signs the main informed consent, or additional informed consent for future research is recorded in the eCRF.

Any data collected in the clinical database after a subject withdraws the main informed consent from further participation in the trial, will not be included in the analysis data sets.

Exceptions are the information entered to close a page after the date of withdrawal of consent, e.g. End of Treatment or End of Study information.

4.11 Implementation of efficacy assessments

Table 4-4 Definition of efficacy endpoints

<table>
<tr><th>Efficacy parameter</th><th>Definition</th></tr>
<tr><td>Proteinuria assessment</td><td>Proteinuria changes are reflected by the reduction of proteinuria as measured by UPCR. They will be evaluated as a continuous variable. The reference proteinuria value before start of treatment is defined as the mean of the values determined at screening and prior to baseline (visit 2) predose (UPCR from 24h urine).</td></tr>
<tr><td>Complete Response (CR) for global Part I</td><td>Reduction of proteinuria to less than 0.3 g/g UPCR, serum albumin within the reference range of the central laboratory and stable eGFR (at least 80% of value at baseline visit)</td></tr>
<tr><td>Complete Response (CR) for open-label Part II</td><td><table>
<tr><th>Baseline UPCR</th><th>Complete Response (CR)</th></tr>
<tr><td>≥1.0 g/g</td><td>Reduction of proteinuria to less than 0.3 g/g UPCR, serum albumin within the reference range of the central laboratory and stable eGFR (at least 80% of value at baseline visit)</td></tr>
<tr><td>≥0.75 to <1.0 g/g</td><td>Reduction of proteinuria to less than 0.2 g/g UPCR, serum albumin within the reference range of the central laboratory and stable eGFR (at least 80% of value at baseline visit)</td></tr>
<tr><td>≥0.5 to <0.75 g/g</td><td>Reduction of proteinuria to less than 0.15 g/g UPCR, serum albumin within the reference range of the central laboratory and stable eGFR (at least 80% of value at baseline visit)</td></tr>
</table></td></tr>
<tr><td>Response for global Part I</td><td>Reduction of proteinuria to below 0.6 g/g (UPCR) and stable eGFR (at least 80% of value at baseline visit), but not CR.</td></tr>
<tr><td>Response for open-label Part II</td><td><table>
<tr><th>Baseline UPCR</th><th>Response (but not CR)</th></tr>
<tr><td>≥1.0 g/g</td><td>Reduction of proteinuria to below 0.6 g/g and stable eGFR (at least 80% of value at baseline visit), but not CR.</td></tr>
<tr><td>≥0.75 to <1.0 g/g</td><td>Reduction of proteinuria to below 0.5 g/g and stable eGFR (at least 80% of value at baseline visit), but not CR</td></tr>
<tr><td>≥0.5 to <0.75 g/g</td><td>Reduction of proteinuria to below 0.3 g/g and stable eGFR (at least 80% of value at baseline visit), but not CR</td></tr>
</table></td></tr>
<tr><td>Duration of response</td><td>Date of 1st observation of progressive disease minus date of 1st observation of response+1 day</td></tr>
</table>

Progressive disease	Decrease of eGFR by more than 30% of baseline eGFR, or increase in urine protein: creatinine ratio (UPCR) by more than 50% from baseline value in non-responding patients or more than 25% over nadir in responding patients
Time to CR	Determined as date of 1st observation of CR minus date of randomization + 1 day
Time to Response	Determined as date of 1st observation of Response minus date of randomization +1 day
Estimated glomerular filtration rate (eGFR)	eGFR is calculated as per the chronic kidney disease epidemiology collaboration (CKD-EPI) equation (**Levey 2007**, **Levey 2009**): eGFR = $141 \times \min(Scr/\kappa, 1)^{\alpha} \times \max(Scr/\kappa,1)^{-1.209} \times 0.993^{Age} \times 1.018[\text{if female}] \times 1.159[\text{if black}]$ where: – Scr is serum creatinine in µmol/L, – κ is 61.9 for females and 79.6 for males, – α is -0.329 for females and -0.411 for males, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1 estimating glomerular filtration rate (eGFR) as a measure of kidney function

For the analysis of time to event and duration of response variables using the Kaplan-Meier method, the following censoring rules are defined.

Table 4-5 Censoring rules

Situation	Time to event variable	Date of event or censoring	Outcome	Censoring Reason
Ongoing and no event until data cut-off	Time to CR, Time to Response, Duration of response	Date of cut-off	Censored	Ongoing
Discontinued the study with no event	Time to CR, Time to Response, Duration of response	Date of study discontinuation	Censored	Discontinued without event
No baseline assessment for the time to event variable	Time to CR, Time to Response, Duration of response	Date of first dose	Censored	No baseline assessment
Subject received prohibited treatment before event	Time to CR, Time to Response, Duration of response	Date of initiation of prohibited treatment	Censored	Start of prohibited treatment

5. GENERAL STATISTICAL CONSIDERATION

5.1 General principles of statistical programming

The statistical analysis will be performed on the analysis study database with appropriate software, SAS Software version 9.4 or above (SAS Institute, Cary, N.C.).

5.2 Variable types and descriptive statistics

Descriptive statistics will be calculated using as reference to the number of subjects in the relevant analysis population (any exception will be specified) according to the nature of the data as follows:

Continuous variables: summary statistics, including number of observations, arithmetic mean, standard deviation (SD), Median, Q1(first quartile) and Q3(third quartile), Minimum and Maximum values will be displayed.

Descriptive statistics of serum concentrations and PK parameters will include number of observations, arithmetic mean, geometric mean, standard deviation (SD, Median, Coefficient of Variation CV (%), geometric CV (%), Minimum and Maximum. Geometric Mean and the Geometric CV (%) will be derived from non-zero values. For serum concentrations, the number of non-zero values (m) will also be reported.

Categorical variables: number of observations and the relevant percentage on the analysis population will be provided.

In case of subcategories, the relative frequencies will be calculated on the basis of the subjects in the respective category.

Time to event variables: (e.g. Time to Response) Unless otherwise stated, Kaplan Meier estimates of Q1, Median, and Q3 along with their 95% Confidence Intervals will be presented.

5.3 Convention on missing data

Unless otherwise specified, missing data will not be imputed. Details on missing data imputation are present in the respective sections.

5.4 Data included in the analysis and cut-off date

All the analyses will be performed using data collected in the database up to the data cut-off date. A cut-off date will be defined for each of these analyses and will be specified in the outputs.

If it is required to impute an end date to be able to perform a specific analysis, the cut-off date needs to be imputed as an end date.

Any data collected beyond a subject's withdrawal of consent will not be included in the analysis.

5.5 Specifications and analysis database

Based on dataset in SDTM format, analysis datasets adhering to CDISC ADaM standard will be generated with SAS software, version 9.4 or above, after the soft lock of data for the primary completion analysis or hard lock of complete study database for the final analysis and according to agreed Analysis Dataset specifications.

5.6 Subject grouping for summary tables

Analyses in the FAS population will be grouped according to randomized treatment assignment. Certain analyses (demographics, efficacy summary statistics tables) will be performed in the EAP which includes the non-randomized Japanese subjects from Part 2 of the study (N=6). These subjects, although having received 9 doses of Felzartamab, will be tabled separately in an additional distinct column from the randomized patients. Any Japanese patients who participated in Part 1 will be grouped according to their randomized treatment and will not be double counted in the additional column.

Analyses in the SAF population will be grouped according to treatment actually received with Part 2 Japanese subjects included as an extra distinct column as described in the previous paragraph. Similarly, Japanese patients who participated in Part 1 will be grouped according to their Part 1 treatment actually received and will not be double counted in the additional Part 2 cohort column.

Outputs in the JPS population including all Japanese patients across Parts 1 and 2 will be generated separately.

6. SUBJECT DISPOSITION, BACKGROUND AND BASELINE CHARACTERISTICS

6.1 Subject disposition

The following subject disposition summaries will be provided.

- The number and percentage of patients who were: screened, failed screening, randomized at baseline visit, completed treatment phase, completed follow-up phase. Summary will be provided by the initial randomized treatment group (analysis population: SCA).
- The number and percentage of patients who completed the study and the number and percentage of patients who discontinued the study at any time, by the initial randomized treatment group and primary reason for discontinuation (analysis population: FAS).
- The number and percentage of patients who completed the treatment phase and the number and percentage of patients who discontinued from treatment phase, by treatment group and primary reason for discontinuation (analysis population: FAS).
- The number and percentage of patients who completed follow-up phase and the number and percentage of patients who discontinued from follow-up phase, by treatment group and primary reason for discontinuation (analysis population: FAS).

6.2 Protocol deviations

The number (%) of subjects in the FAS with any significant protocol deviations as defined in the Deviation Management Plan and Study Deviation Rules will be tabulated by deviation category and deviation term and will be summarized by initial randomized group.

A by patient listing of important protocol deviations will be provided.

Only important protocol deviations that directly affect the subject's rights, safety and well-being will be reported in the Clinical Study Report. Protocol deviations pertaining to the study sites will not be considered.

In addition, a frequency table by visit will be produced for the number (%) of subjects with missed visits in the FAS with the reason for the missed visit (including missed visits in the context of COVID-19).

6.3 Demographic and Baseline characteristics

Patient demographic will be summarized by treatment group and overall for the FAS population. The continuous variables will be summarized using descriptive statistics and the categorical variables will be summarized using frequency counts and percentages. No formal statistical comparison will be made between treatment groups unless otherwise specified.

- Age (Year of screening – Year of birth, in years)
- Age group: 18 – 64 years, 65 – 84 years, ≥ 85 years
- Gender
- Race
- Ethnicity
- Country
- Weight at screening (kg)
- Height at screening (cm)
- Body Mass Index (BMI) ($kg/m2$) at screening, calculated as BMI = $Weigh\ t\ (kg)/Heigh\ t\ (m)$^2

Baseline characteristics consist of the following:

- Vital Signs (systolic blood pressure (mmHg), diastolic blood pressure(mmHg), heart rate (beats/min), respiratory (breaths/min), and body temperature (C))
- UPCR (g/g)
- UPCR group: < 0.5g/g, ≥ 0.5 to < 0.75 g/g, ≥ 0.75 to < 1.0 g/g, and ≥ 1.0 g/g
- ACR (g/g)
- eGFR (mL/min/1.73m^2)

A by patient baseline demographic listing will be provided.

6.4 Medical history

6.4.1 Coding

Medical history will be summarized using the current Medical Dictionary for Regulatory Activities (MedDRA) system organ class (SOC) and preferred term classifications. At the end of the trial, all MedDRA codes will be updated with the latest MedDRA versions.

6.4.2 Summary of medical history

The relevant medical history will be summarized by primary SOC, PT and toxicity grade for the FAS.

Data on kidney biopsies history will be summarized by MEST-C Score and Pathological variables MEST score on FAS.

6.5 Study treatment

6.5.1 Exposure

Duration of exposure to study drug

Exposure to study treatment will be summarized for the FAS population. The duration of exposure will be calculated as follows:

Duration of exposure (days) = [end date of study drug – start date of study drug + 1 day]

Cumulative Dose

The cumulative dose is defined as the sum of total doses that the subject received from the first study treatment administration until the last study treatment administration.

A summary table with the following information will be presented on FAS:

- Duration of exposure (days)
- Duration of exposure (categorized: >0 days, >=7 days, >=14 days, >=30 days, >=60 days, >=90 days, >=120 days, >=183 days)
- Duration of exposure (categorized: >0 to <7 days, >=7 to <14 days, >=14 to <30 days, >=30 to <60 days, >=60 to <90 days, >=90 to 120 days, >=120 days to < 183 days, >=183 days)
- Total number of MOR202 infusions per subject
- Cumulative Dose (mg) per subject

Individual study treatment administration data will be listed by subject and arm, including the study day, the volume of infusion bag used [redacted] or other, if other specify volume), actual total infusion volume administered, the information on start and end times of administration(s), infusion volume(s) and reason(s) for dose interruptions, if applicable, and volume used for the infusion line flushing.

Listings of the vial numbers for each subject per administration will be provided.

6.5.2 Dose interruption

The number (%) of subjects with at least one temporary interruption and the associated reasons will be summarized by study visit on FAS.

6.5.3 Compliance

Compliance for a study drug infusion at a certain visit will be calculated by dividing the actual infusion dose with the planned infusion dose (Table 3-4) and multiplied by 100. Overall compliance for study drug per subject will be calculated by dividing the sum of actual infusion doses with the sum of planned infusion doses and multiplied by 100. For subject early discontinued, the planned infusion doses are calculated up to the date of early discontinuation.

A subject is non-compliant for each infusion if the study drug dose administered is ≤ 70% or > 130% of the planned dose.

The following information will be displayed on FAS:

- Number (%) of subjects in the following compliance categories per single infusion:
  - ≤ 70%
  - > 70% - ≤ 130%
  - > 130%
- Summary statistics of compliance per infusion visit
- Number (%) of subjects in the following compliance categories for the overall compliance:
  - ≤ 70%
  - > 70% - ≤ 130%
  - > 130%
- Summary statistics of the overall compliance

6.6 Prior and concomitant medications and non-drug treatments/procedures

6.6.1 Coding

Concomitant medications/non-drug treatment will be recorded and coded using the WHO Drug Dictionary Enhanced and grouped by Anatomical Therapeutic Chemical (ATC) classes Level 4. Higher level (e.g. level 3) ATC classes may be used when Level 4 is not available. Tabulations with counts and percentages will show the number of medications/percentage used in each class and preferred drug name by treatment.

6.6.2 Definitions

Pre-medication: Medication given prior to MOR202 infusion to mitigate potential infusion-related reactions.

Prior medication/non-drug treatment: If the treatment starts before the first dose of the study drug, the medication/non-drug treatment will be classified as prior medication/non-drug treatment. Subjects will only be counted once for multiple drug use by preferred drug/ name.

Concomitant medication/non-drug treatment: If the medication start date is before, on or after start of study drug, but has a stop date on or after the first dose date, the medication will be considered as concomitant medication. Subjects will only be counted once for multiple drug use by preferred drug name. If the medication start and stop date are incomplete, the following algorithm will be applied to exclude the medication from the concomitant medication category. If the start date is missing and

- If stop day is missing but month is complete, medication will only be excluded from concomitant medication if stop month is before month of treatment start.
- If stop day and month are missing but year is complete, medication will only be excluded from concomitant medication if stop year is before year of treatment start.
- If stop date is completely missing, medication will not be excluded.

6.6.3 Data presentation

Summary tables will be presented by treatment for:

- Prior medications
- Concomitant medications
- Prior non-drug treatments/procedures
- Concomitant non-drug treatments/procedures

6.6.4 Prior immunosuppressive medications

A listing will be presented on prior immunosuppressive medications, including information on:

- Medication name
- Number of the particular IST therapy line
- Therapy start date
- Therapy end date
- Duration of the therapy (in months)
- Route and dosing regimen

Following calculation is defined:

Duration of prior IST (in months): [End date of last prior IST – Start date of last prior IST + 1 day]/30.4375

- If the end date or the start date is completely missing, the date will not be imputed
- If both the day and month, or year of the start or end date is missing, the date will not be imputed
- If only the day of the start date is missing, it will be replaced by the first day of the month
- If only the day of the end date is missing, it will be replaced by the last day of the month, or the date of screening, whichever is first

7. EFFICACY ANALYSIS

All efficacy endpoints will be analysed by treatment arm using the FAS. Sensitivity analysis of selected efficacy endpoints may be performed on PPS as needed.

Patients enrolled in double-blind Part I of the study will undergo secondary and [redacted] endpoint assessments up to 24 months while patients enrolled in open-label Part II of the study will undergo endpoint assessments up to 12 months (Visit 13, EOS).

7.1 Urine protein to creatinine ratio (UPCR)

The baseline of 24h UPCR is defined as the mean of the values determined at screening and prior to baseline (visit 2) predose (UPCR from 24h urine).

Assuming the ratio of post baseline UPCR over baseline UPCR follows a lognormal distribution, the primary endpoint of relative decrease in UPCR will be estimated based on an MMRM (mixed effects model for repeated measure) model. In this model, the ratio of post baseline UPCR over baseline UPCR at month 3, 6, 9, 12, 18, and 24 in log scale will be response variable, while baseline UPCR in log scale, treatment, visit, treatment by visit interaction will be fixed effect covariates. Within group treatment effect estimates and between group treatments comparisons will be based on this MMRM model. Unstructured covariance structure will be the default method, if model cannot converge, compound symmetry covariance structure will be used. For within group comparison, estimates on relative decrease from baseline and associated standard error will be displayed. For between groups, the geometric mean ratio of UPCR at post baseline over baseline between treatment group vs placebo group, its associated [redacted] and confidence intervals will be provided as well. [redacted]

If the MMRM model still run into convergence issues after changing covariance structure, we will impute missing values with the “last observation carried forward” method and use an ANCOVA model to perform related analysis by each post baseline visit. In this case, baseline log UPCR and treatment group will serve as covariates.

In addition, the raw UPCR values will be summarized descriptively by treatment and visit.

[redacted]

7.2 Response endpoints

Please refer to section 4.11 for definition of complete response, response and progressive disease.

The number and % of patients with complete response (CR) at 3, 6, 9, 12, 18 and 24 months will be reported by treatment arm.

The number and % of patients with response at 3, 6, 9, 12, 18 and 24 months will be reported by treatment arm.

The number and % of patients who met the progressive disease criterion at 3, 6, 9, 12, 18 and 24 months will be reported by treatment arm.

For the main analysis of these endpoints, patients with missing values will be treated as non-responders. As a sensitivity analysis, missing values will be imputed using the "last observation carried forward" method.

A fisher's exact test may be used to check potential difference between treatment arms. [redacted]

7.3 Albumin Creatinine Ratio (ACR)

ACR at 3, 6, 9, 12, 18 and 24 months will be summarized descriptively by treatment arm and visit. Similar with UPCR, an MMRM model may be used to compare treatment effect difference between each Felzartamab dose group vs. placebo for ratio of post baseline ACR over baseline ACR in log scale. An ANCOVA model may be used with LOCF as missing data imputation method if MMRM run into convergence issues.

[redacted]

7.4 Estimated glomerular filtration rate (eGFR)

The following information will be summarized by treatment group on FAS:

• Descriptive summary of absolute levels of eGFR by visit

• Number (%) of subjects who had >=30% decrease from baseline by visit. Fisher's exact test may be used to see the potential treatment difference. [redacted]

Change from baseline in eGFR will be estimated based on an MMRM (mixed effects model for repeated measure) model. In this model, eGFR change from baseline at month 3, 6, 9, 12, 18, and 24 will be the response variable, while baseline eGFR, treatment, visit, treatment by visit interaction will be fixed effect covariates. Within group treatment effect estimates and between group treatments comparisons will be based on this MMRM model. Unstructured covariance structure will be the default method, if model cannot converge, compound symmetry covariance structure will be used. For within group comparison, estimates on change from baseline and associated standard error will be displayed. For between groups, the mean change from baseline between treatment group vs placebo group, its associated [redacted] and confidence intervals will be provided as well. [redacted]

[redacted]

7.5 Time to response and duration of response

Summary tables and Kaplan-Meier plots will be presented by treatment group on FAS for the following:

- Time to first Complete Response
- Time to first Response
- Duration of Response

Definition for the above variables and censoring rules are defined in section 4.11 of the SAP.

The number (%) of subjects of responders (e.g. achieving a response) and censored subjects, including the reason for censoring (specified in Table 4-5) will also be presented.

[redacted]

8. SAFETY ANALYSES

All safety analyses will be based on the SAF. No formal statistical testing will be performed. The analysis of safety assessments in this trial will include the evaluation of:

- Adverse Events
- Vital signs
- Physical Examination
- Electrocardiogram
- Laboratory evaluations

8.1 Adverse events

Please refer to protocol section 10.6.4.1 for definition of pre-treatment adverse events, treatment-emergent adverse events, and post-treatment adverse events.

Serious Adverse Events (SAE) are defined in protocol section 12.4 appendix 4.

[redacted]

If the start date and time of an AE are partially or completely missing, the AE will be assumed to be a TEAE if it cannot be definitely shown that the AE did not occur during the treatment emergent period (worst case approach). Missing dates and times will not be replaced. The following approach will be followed:

- If the start time of an AE is missing but the start date is complete, an AE will only be excluded from TEAE if the start day is before the day of first study drug administration or the start date is after the end date of the treatment-emergent period
- If the start time and day are missing but the start month is complete, an AE will only be excluded from TEAE if the start month is before the month of first study drug administration

or the start month is after the end month of the treatment-emergent period or if the stop date and time is before the start of first study drug administration
- If the start day and months are missing but the start year is complete, an AE will only be excluded from TEAE if the start year is before the year of first study drug administration or if the start year is after the end year of the treatment-emergent period or if the stop date and time is before the start of first study drug administration
- If the start date is completely missing, an AE will not be excluded from TEAE unless the stop date and time is before the start of first study drug administration.

An AE present prior to first study drug administration but increased in severity after treatment start will also be included as TEAE.

8.1.1 Dictionary coding of adverse events

AEs will be coded according to the current Medical Dictionary for Regulatory Activities (MedDRA) version and will be reported by primary system organ class (SOC), preferred term (PT) and toxicity grade. At the end of the trial all MedDRA codes will be updated to the newest versions.

8.1.2 Grading of adverse events

Please refer to clinical trial protocol appendix 4 regarding AE grading criteria.

8.1.3 General Rules for AE reporting

AE tables

- AEs will be summarized by SOC, PT and toxicity grade, unless otherwise specified.
- AE frequency tables will display the number of events (incidence), the number of subjects experiencing an event and the percentage of subjects with the event by SOC, PT and toxicity grade, unless otherwise specified.
- If a subject experiences an adverse event where there is a change in severity throughout the duration of that one AE, only the worst severity will be counted in the summary tables
- If a subject reported more than one AE with the same PT, the AE with the maximum toxicity grade will be presented
- If a subject reported more than one AE within the same SOC, the subject will be counted only once with the maximum toxicity grade at the SOC level, where applicable
- The time to event onset and duration of selected AEs if applicable.

AE listings

- All AEs will be listed by subject and treatment group, along with information regarding onset, start and end date, relationship to study drug, intensity, toxicity grade, action taken with study drug, treatment of event, and outcomes.
- In the AE listings, AEs that started prior to the administration of study drug will be flagged as pre-treatment AEs. AEs that start 28 days after the last date of study drug administration will be flagged as post-treatment AEs. AEs that start between the first administration of study drug and within 28 days of the last date of study drug administration will be flagged as on-treatment AEs.

8.1.4 Adverse Event summaries and listings

The following summary tables will be presented by SOC, PT, and toxicity grade:

- Overall Summary of AEs
- TEAEs and post-treatment AEs
- Treatment-emergent and post-treatment SAEs (Including death)
- Treatment-emergent and post-treatment AESIs
- All AEs suspected to be related to study drug
- AE leading to drug interruption
- AE reported as reason for study treatment discontinuation

The following summary tables will be presented by PT:

- TEAEs and post-treatment AEs
- Treatment-emergent and post-treatment SAEs
- All AEs suspected to be related to study drug
- All AEs with Grade 3 or Higher

The following listings will be presented:

- Listing of all AEs
- Listing of SAEs (including death)
- Listing of AEs leading to drug interruption
- Listing of AEs reported as reason for study treatment discontinuation
- Listing of AESIs including COVID-19 related AEs

8.2 Vital signs

The following information will be summarized by treatment group:

- Absolute values and percentage changes from baseline for all time points available for below parameters: weight, systolic blood pressure, diastolic blood pressure, heart rate, respiratory, and body temperature
- Number (%) of subjects with at least one post-baseline abnormal value below or above the normal limit by vital signs variables

Normal limits are defined as follows:

- Systolic blood pressure: 90-120 mmHg
- Diastolic blood pressure: 60-80 mmHg
- Heart rate: 60-100 beats per minute
- Respiratory Rate: 10-24 breaths per minute
- Body temperature:
  - 35.9-37.1 °C axillary temperature
  - 35.9-37.5 °C oral, ear, forehead, rectal temperature

A Listing of subjects with vital sign values outside the reference ranges will be produced.

A listing on subjects' body weight at each visit will be provided to facilitate PK analysis.

8.3 Physical examination

The number (%) of subjects with a physical examination assessment by body system of the following categories will be displayed by visit:

- Normal
- Abnormal, clinically relevant
- Abnormal, not clinically relevant

8.4 Electrocardiogram (ECG)

The following information will be summarized by treatment group.

Triplicate 12-lead ECGs will be obtained at the scheduled visits and time points. The average of triplicate ECG measurements will be calculated and utilized for the summaries.

Summary statistics for all time points will be displayed for QT and the QTcF and QTcB.

The number and percentage of patients with QTc values above the normal limit (> 450 ms and ≤ 480 ms, > 480 ms and ≤ 500 ms, and > 500 ms) and the number and percentage of patients who experienced a change from baseline ≥ 30 ms and < 60 ms or a change from baseline ≥ 60 ms will be presented by time point.

The worst among triplicate interpretation of overall ECG assessments (categories: “Normal”, “Abnormal, not clinically significant”, “Abnormal, clinically significant”) will be tabulated by time point using frequency tables. ECG findings including any available cardiological evaluations will be listed by visit and treatment arm.

8.5 Laboratory data

Depending on the nature of the lab analyte, the following analysis (for selective lab analytes) may be presented by treatment group on SAF:

- Descriptive summaries of absolute values and absolute change from baseline values will be presented for SAF by treatment group and visit
- Shift tables in assessments from baseline (low, normal or high) to worst post baseline value (High, Low, High and Low) will be presented based on classifications relative to the laboratory reference ranges
- Number (%) of subjects at each time point having clinical relevant findings of laboratory parameters will be tabulated by visit for each clinical laboratory parameter

A Listing of subjects with laboratory values outside the reference ranges will be produced.

9. PHARMACOKINETIC (PK) ANALYSES

9.1 MOR202 in Serum

Analysis of MOR202 concentrations in serum (free drug levels) is one of the secondary objective in this study.

9.1.1 Derivation Rules

Time deviation:

The actual sampling time will be used for graphical presentation of individual data.

Handling of Below Lower Limit of Quantification (BLOQ) values:

- Concentration BLOQ will be imputed by 0 for the calculation of descriptive statistics, PK analyses and graphical presentation except for the geometric mean and the geometric CV, where it will be imputed as Lower Limit of Quantification (LLOQ)/2
- If the concentrations before the first quantifiable concentration time point is BLOQ, the concentration will be set to 0.
- If the concentrations after the last quantifiable concentration time point is BLOQ, the concentration will be set to missing.
- If there are embedded BLOQ values between quantifiable concentrations, these BLOQ values will be set to missing.
- If there is a quantifiable concentration after 2 consecutive BLOQ values at the end of the profile, this quantifiable concentration and any further quantifiable concentration will be set to missing.

9.1.2 Summary Statistics

Summary statistics include n, arithmetic mean, standard deviation (SD), geometric mean, coefficient of variation (CV), median, minimum and maximum. The CV will be expressed as a percentage and calculated as follows:

- CV of the arithmetic mean (%): $\frac{StD}{mean} \times 100$
- CV of the geometric mean (%): $\sqrt{\exp(variance\ for \log transformed\ data) - 1} \times 100$

A table with summaries by arm and overall, and by study visit will be presented with the following information:

- MOR202 serum concentrations, split by pre-dose and post-dose where applicable

Individual plots of MOR202 serum concentrations over actual sampling time with all subjects on the same plot will be generated using linear and semi-logarithmic scales (i.e. log y-axis) by arm.

Figures of mean (± standard error) serum concentrations of MOR202 versus nominal days by arm will be generated using both linear and semi-logarithmic scales (i.e. log y-axis) and split by pre-dose and 30 minutes post-dose.

MOR202 serum levels may be further analyzed performing population PK analyses, which will be reported separately.

Listings of individual serum concentrations and actual sampling times of MOR202 will be presented by arm on PKAS.

A listing of individual PK serum samples that were stored outside the validated temperature range for PK serum sample stability from storage at the sites until arrival at the bioanalytical laboratory will be presented on PKAS.

[redacted]

[redacted]

10. IMMUNOGENICITY ANALYSES

Analysis of potential immunogenicity of Felzartamab is one of the secondary objectives in this study.

ADA status (positive/negative), the ADA titre when ADA positive and potential drug interference in the assay when ADA negative (yes/no) will be summarized descriptively, by treatment group and time point. The analyses will be performed using the IAS population.

The following results will be tabulated for each treatment group by visit.

- Number (%) of subjects with ADA status positive/negative
- For ADA status positive subjects: summary (n, mean, SD) of ADA titre
- For ADA status negative subjects: number (%) of subjects with potential drug interference in the assay (yes/no)

Listings of individual ADA results including titre values when ADA positive and potential drug interference in the assay when ADA negative (yes/no) will be presented by treatment arm and on IAS.

[redacted]

[redacted]

12. STATISTICAL ANALYSIS ON JAPAN POPULATION

The Japanese analysis population includes all Japanese patients who were enrolled under the randomized global cohort (Part I) and the open-label Japan-only cohort (Part II). Analysis on Japan population, including patient demography, disposition, AE and PK will be performed. Additionally, summary table of TEAE/SAE for comparison between Japan population versus non-Japan population will be performed if applicable. Also figures of mean (± standard deviation) serum concentrations of Felzartamab versus study visits (by arm) will be generated using both linear and semi-logarithmic scales (i.e. log y-axis) and split by pre-dose and 30 minutes post-dose. These graphs will contain information of Japanese population versus non-Japanese population.

13. REFERENCES

Levey AS, Coresh J, Greene T, et al (2007) Expressing the Modification of Diet in Renal Disease Study equation for estimating glomerular filtration rate with standardized serum creatinine values. Clin Chem; 53(4):766–72.

Levey AS, Stevens LA, Schmid CH, et al (2009) A new equation to estimate glomerular filtration rate. Ann Intern Med; 150(9):604–12.

14. APPENDIX

SAS code for reference.

Statistical Inference	Table	SAS Code
Mixed model repeated measures (MMRM)	Efficacy endpoints	PROC MIXED; WHERE PARAMCD='xxx'; CLASS SUBJECT TRT VISIT; MODEL LOG(AVAL/BASE) = TRT VISIT

		TRT*VISIT LOG(BASE)/ SOLUTION DDFM=KR; REPEATED VISIT/ TYPE = UN (or CS) SUB=SUBJECT; LSMEANS TRT*VISIT/CL PDIFF ALPHA=0.05; RUN; AVAL is post-baseline value BASE is baseline value for the efficacy parameter of interest PARAMCD is efficacy parameter of interest

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Source Envelope:
Document Pages: 45
Signatures: 4
Envelope Originator:
Certificate Pages: 5
Initials: 0
[redacted]
AutoNav: Enabled
[redacted]
EnvelopeId Stamping: Enabled
IP Address: [redacted]
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Record Tracking

Status: Original
9/19/2024 12:21:49 PM
Holder: [redacted]
[redacted]
Location: DocuSign

Signer Events	Signature	Timestamp
[redacted] [redacted] Security Level: Email, Account Authentication (Required)	Signed by: [redacted] Signer Name: [redacted] Signing Reason: I approve this document Signing Time: 19-Sep-2024 | 12:36:07 PM PDT AD088F78B505423480E922E90A6DC6A6 Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 9/19/2024 12:24:46 PM Viewed: 9/19/2024 12:35:36 PM Signed: 9/19/2024 12:36:10 PM
Electronic Record and Signature Disclosure: Accepted: 9/19/2024 12:35:36 PM ID: a90e122b-b033-423f-ad9d-665eb4c57b60		
[redacted] [redacted] Security Level: Email, Account Authentication (Required)	Signed by: [redacted] Signer Name: [redacted] Signing Reason: I approve this document Signing Time: 19-Sep-2024 | 12:32:21 PM PDT 27F80F2B159640F39048B2B5EBD2FC33 Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 9/19/2024 12:24:46 PM Viewed: 9/19/2024 12:31:52 PM Signed: 9/19/2024 12:32:35 PM
Electronic Record and Signature Disclosure: Accepted: 9/19/2024 12:31:52 PM ID: 80c211e0-c5a4-479e-b497-a76c1e399b1b		

Signer Events	Signature	Timestamp
[redacted] [redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Drawn on Device Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 9/19/2024 12:24:47 PM Viewed: 9/19/2024 12:45:44 PM Signed: 9/19/2024 12:46:35 PM
Electronic Record and Signature Disclosure: Accepted: 2/21/2023 7:33:38 AM ID: 260a5f33-94c5-4900-85f5-ce42b7b214e5		
[redacted] [redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signature ID: [redacted] Using IP Address: [redacted] With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 9/19/2024 12:24:45 PM Viewed: 9/19/2024 12:25:27 PM Signed: 9/19/2024 12:25:50 PM
Electronic Record and Signature Disclosure: Accepted: 3/19/2024 3:48:05 PM ID: 0a6b719e-79a9-4096-b087-a92e0bc736e4		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	9/19/2024 12:24:47 PM
Certified Delivered	Security Checked	9/19/2024 12:25:27 PM
Signing Complete	Security Checked	9/19/2024 12:25:50 PM
Completed	Security Checked	9/19/2024 12:46:35 PM

Payment Events	Status	Timestamps

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