Clinical trial results:
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

Summary

EudraCT number	2020-005054-19
Trial protocol	CZ BG DE BE ES
Global end of trial date	06 May 2024

Results information

Result version number	v1
This version publication date	22 May 2025
First version publication date	22 May 2025

Trial information

Trial identification

Sponsor protocol code	MOR202C206

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05065970
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Biogen
Sponsor organisation address	225 Binney Street, Cambridge, Massachusetts, United States, 02142
Public contact	Biogen Study Medical Director, Biogen, clinicaltrials@biogen.com
Scientific contact	Biogen Study Medical Director, Biogen, clinicaltrials@biogen.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 May 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to assess the efficacy of Felzartamab compared to placebo in participants with IgAN based on the change in urine protein to creatinine ratio (UPCR) at 9 months.

Protection of trial subjects:

Written informed consent was obtained from each subject’s parent or legal guardian prior to evaluations being performed for eligibility. Adequate time to review the information in the informed consent and ask questions concerning all portions of the conduct of the study was provided. Through the informed consent process, awareness of the purpose of the study, the procedures, the benefits and risks of the study, the discomforts and the precautions taken was made. Any side effects or other health issues occurring during the study were followed up by the study doctor. Subjects were able to stop taking part in the study at any time without giving any reason.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 August 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Bulgaria: 3
Country: Number of subjects enrolled	Czechia: 8
Country: Number of subjects enrolled	Georgia: 3
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Japan: 8
Country: Number of subjects enrolled	Korea, Republic of: 6
Country: Number of subjects enrolled	Malaysia: 1
Country: Number of subjects enrolled	Philippines: 2
Country: Number of subjects enrolled	Serbia: 4
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	Taiwan: 1
Country: Number of subjects enrolled	Ukraine: 3
Country: Number of subjects enrolled	United States: 2
Worldwide total number of subjects	54
EEA total number of subjects	24

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	52
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at the investigative sites in Belgium, Bulgaria, Czechia, Georgia, Germany, Japan, Republic of Korea, Malaysia, Philippines, Serbia, Spain, Taiwan, Ukraine, and the United States from 31 August 2021 to 06 May 2024.

Pre-assignment

Screening details:

A total of 54 participants diagnosed with Immunoglobulin A Nephropathy (IgAN) were enrolled in the study, of which 48 participants completed the study. The study had 2 parts - Part 1 (Global Cohort) and Part 2 (Japanese Cohort).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

The Global Study (Part I) was double-blind and the Japanese Cohort (Part II) was open-label.

Arms

Are arms mutually exclusive?	No
Arm title	Part 1: Placebo

Arm description:

Participants were administered felzartamab matching placebo as an intravenous (IV) infusion on Days 1, 8, 15, 22, 29, 57, 85, 113 and 141.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: Felzartamab Dosing Arm M1

Arm description:

Participants were administered felzartamab as an IV infusion based on their body weight on Days 1 and 15, and felzartamab matching placebo on Days 8, 22, 29, 57, 85, 113 and 141.

Arm type	Experimental
Investigational medicinal product name	Felzartamab
Investigational medicinal product code	MOR202
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: Felzartamab Dosing Arm M2

Arm description:

Participants were administered felzartamab as an IV infusion based on their body weight on Days 1, 8,15, 29, and 57, and felzartamab matching placebo on Days 22, 85, 113 and 141.

Arm type	Experimental
Investigational medicinal product name	Felzartamab
Investigational medicinal product code	MOR202
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 1: Felzartamab Dosing Arm M3

Arm description:

Participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.

Arm type	Experimental
Investigational medicinal product name	Felzartamab
Investigational medicinal product code	MOR202
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Arm title	Part 2: Japan Cohort

Arm description:

Japanese participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.

Arm type	Experimental
Investigational medicinal product name	Felzartamab
Investigational medicinal product code	MOR202
Other name	
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered as specified in the treatment arm.

Number of subjects in period 1	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2
Started	12	12	11
Completed	10	11	9
Not completed	2	1	2
Withdrawal of Consent	1	1	1
Requires Prohibited Medication	-	-	1
Investigator Decision	1	-	-

Number of subjects in period 1	Part 1: Felzartamab Dosing Arm M3	Part 2: Japan Cohort
Started	13	6
Completed	12	6
Not completed	1	0
Withdrawal of Consent	-	-

Requires Prohibited Medication	1	-
Investigator Decision	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Part 1: Placebo
Reporting group description:	
Participants were administered felzartamab matching placebo as an intravenous (IV) infusion on Days 1, 8, 15, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M1
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1 and 15, and felzartamab matching placebo on Days 8, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M2
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1, 8,15, 29, and 57, and felzartamab matching placebo on Days 22, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M3
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 2: Japan Cohort
Reporting group description:	
Japanese participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.	

Reporting group values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2
Number of subjects	12	12	11
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	39.6	47.4	35.1
standard deviation	± 11.84	± 10.41	± 14.31
Gender categorical Units: Subjects			
Male	9	6	8
Female	3	6	3
Race Units: Subjects			
White	9	6	9
American Indian or Alaska Native	0	1	0
Asian	3	5	2
Ethnicity Units: Subjects			
Hispanic or Latino	1	1	0
Not Hispanic or Latino	11	8	8
Not Reported	0	2	3
Unknown	0	1	0

Urine Protein to Creatinine Ratio (UPCR) Units: gram per gram (g/g)			
arithmetic mean	2.04	1.57	1.76
standard deviation	± 1.158	± 0.742	± 0.828

Reporting group values	Part 1: Felzartamab Dosing Arm M3	Part 2: Japan Cohort	Total
Number of subjects	13	6	54
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	39.2	51.7	
standard deviation	± 7.20	± 14.19	-
Gender categorical Units: Subjects			
Male	10	3	36
Female	3	3	18
Race Units: Subjects			
White	9	0	33
American Indian or Alaska Native	0	0	1
Asian	4	6	20
Ethnicity Units: Subjects			
Hispanic or Latino	2	0	4
Not Hispanic or Latino	8	6	41
Not Reported	3	0	8
Unknown	0	0	1
Urine Protein to Creatinine Ratio (UPCR) Units: gram per gram (g/g)			
arithmetic mean	1.69	1.02	
standard deviation	± 1.301	± 0.324	-

Subject analysis sets

Subject analysis set title	All Felzartamab and Placebo-Treated Participants
Subject analysis set type	Full analysis

Subject analysis set description:

All participants who received felzartamab or placebo during the study with evaluable IgA data and evaluable felzartamab serum concentrations (in felzartamab-treated participants only) divided into exposure quartiles.

Subject analysis set title	All Felzartamab-Treated Participants
Subject analysis set type	Full analysis

Subject analysis set description:

All participants who received felzartamab during the study and had evaluable maximum felzartamab serum concentrations after the first dose.

Reporting group values	All Felzartamab and Placebo-Treated Participants	All Felzartamab-Treated Participants	
Number of subjects	45	39	

Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	0	0	
standard deviation	± 0	± 0	
Gender categorical Units: Subjects			
Male	0	0	
Female	0	0	
Race Units: Subjects			
White	0	0	
American Indian or Alaska Native	0	0	
Asian	0	0	
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	0	0	
Not Reported	0	0	
Unknown	0	0	
Urine Protein to Creatinine Ratio (UPCR) Units: gram per gram (g/g)			
arithmetic mean	0		
standard deviation	± 0	±	

End points

End points reporting groups

Reporting group title	Part 1: Placebo
Reporting group description:	
Participants were administered felzartamab matching placebo as an intravenous (IV) infusion on Days 1, 8, 15, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M1
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1 and 15, and felzartamab matching placebo on Days 8, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M2
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1, 8,15, 29, and 57, and felzartamab matching placebo on Days 22, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M3
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 2: Japan Cohort
Reporting group description:	
Japanese participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.	
Subject analysis set title	All Felzartamab and Placebo-Treated Participants
Subject analysis set type	Full analysis
Subject analysis set description:	
All participants who received felzartamab or placebo during the study with evaluable IgA data and evaluable felzartamab serum concentrations (in felzartamab-treated participants only) divided into exposure quartiles.	
Subject analysis set title	All Felzartamab-Treated Participants
Subject analysis set type	Full analysis
Subject analysis set description:	
All participants who received felzartamab during the study and had evaluable maximum felzartamab serum concentrations after the first dose.	

Primary: Relative Change From Baseline in Urine Protein to Creatinine Ratio (UPCR) in 24-hour Urine at Month 9

End point title	Relative Change From Baseline in Urine Protein to Creatinine Ratio (UPCR) in 24-hour Urine at Month 9[1]
End point description:	
Proteinuria is high levels of protein in the urine and is measured by UPCR. Relative change in UPCR was estimated based on a mixed effects model for repeated measure (MMRM) model. Least squares (LS) mean and standard error (SE) were reported. 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). Negative change from baseline indicates less proteinuria. The full analysis set (FAS) included all participants randomized to Part 1 of the study. 'Overall number of participants analyzed' signifies number of participants with data available for outcome measure analysis.	
End point type	Primary
End point timeframe:	
Baseline, Month 9	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo and Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	9	12
Units: gram per gram (g/g)				
least squares mean (standard error)	-24.7 (± 19.43)	-16.5 (± 19.41)	-30.6 (± 21.72)	-38.5 (± 16.60)

Statistical analyses

Statistical analysis title	Part 1: Placebo, Part 1: Felzartamab M2

Statistical analysis description:

In the MMRM model, the ratio of post baseline UPCR over baseline UPCR at month 9 in log scale was response variable, while baseline UPCR in log scale, treatment, visit, treatment by visit interaction were fixed effect covariates.

Comparison groups	Part 1: Placebo v Part 1: Felzartamab Dosing Arm M2
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7599 [2]
Method	MMRM
Parameter estimate	Geometric LS Mean Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.57

Notes:

[2] - Geometric mean ratio of UPCR at post baseline over baseline between Part 1: Felzartamab M2 to Part 1: Placebo.

Statistical analysis title	Part 1: Placebo, Part 1: Felzartamab M1

Statistical analysis description:

In the MMRM model, the ratio of post baseline UPCR over baseline UPCR at month 9 in log scale was response variable, while baseline UPCR in log scale, treatment, visit, treatment by visit interaction were fixed effect covariates.

Comparison groups	Part 1: Placebo v Part 1: Felzartamab Dosing Arm M1
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6837 [3]
Method	MMRM
Parameter estimate	Geometric LS Mean Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.84

Notes:

[3] - Geometric mean ratio of UPCR at post baseline over baseline between Part 1: Felzartamab M1 to Part 1: Placebo.

Statistical analysis title	Part 1: Placebo, Part 1: Felzartamab M3

Statistical analysis description:

In the MMRM model, the ratio of post baseline UPCR over baseline UPCR at month 9 in log scale was response variable, while baseline UPCR in log scale, treatment, visit, treatment by visit interaction were fixed effect covariates.

Comparison groups	Part 1: Placebo v Part 1: Felzartamab Dosing Arm M3
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4165
Method	MMRM
Parameter estimate	Geometric LS Mean Ratio
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	1.35

Secondary: Integrative Analysis of Several Endpoints: Percent Change From Baseline in Immunoglobulin A (IgA) Concentration by Predose Serum Concentration (Ctrough) Group

End point title	Integrative Analysis of Several Endpoints: Percent Change From Baseline in Immunoglobulin A (IgA) Concentration by Predose Serum Concentration (Ctrough) Group

End point description:

All felzartamab and placebo-treated participants with evaluable IgA data and felzartamab serum concentrations (in felzartamab-treated participants only) were divided into exposure quartiles using the sum of measurable felzartamab Ctrough values up to 9 months after the first dose. Percent change from baseline in IgA concentration in these participants was summarized as per each serum concentration quartile. ll participants who received felzartamab or placebo during the study with evaluable IgA data and evaluable felzartamab serum concentrations (in felzartamab-treated participants only). 'Overall number of participants analyzed’ signifies the number of participants with evaluable IgA data and felzartamab serum concentrations (in felzartamab-treated participants only).

End point type	Secondary

End point timeframe:

Up to 9 months

End point values	All Felzartamab and Placebo-Treated Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: percent change				
arithmetic mean (standard deviation)				
Serum Concentration 0-180 µg/mL	-6.12 (± 15.0)			

Serum Concentration 180-370 µg/mL	-14.1 (± 15.6)			
Serum Concentration 370-850 µg/mL	-19.7 (± 22.7)			
Serum Concentration >850 µg/mL	-26.1 (± 10.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Integrative Analysis of Several Endpoints: Maximum Serum Concentrations (Cmax) as per the Infusion-Related Reactions (IRRs) After the First Dose

End point title	Integrative Analysis of Several Endpoints: Maximum Serum Concentrations (Cmax) as per the Infusion-Related Reactions (IRRs) After the First Dose

End point description:

All participants with evaluable maximum felzartamab concentrations after the first dose were included in the analysis. Cmax values were assessed by infusion-related reaction status after the first dose. PK analysis set included all participants with any available quantifiable felzartamab serum concentration data. Overall number of participants analyzed' signifies the number of participants with data available for outcome measure analysis.

End point type	Secondary

End point timeframe:

Up to 1 week

End point values	All Felzartamab-Treated Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: µg/mL				
arithmetic mean (standard deviation)				
Cmax in Participants With IRR	445 (± 198)			
Cmax in Participants Without IRR	367 (± 131)			

Statistical analyses

No statistical analyses for this end point

Secondary: Relative Change From Baseline in UPCR in 24-hour Urine at Months 3, 6, 12, 18 and 24

End point title	Relative Change From Baseline in UPCR in 24-hour Urine at Months 3, 6, 12, 18 and 24 [4]

End point description:

Proteinuria is high levels of protein in the urine and is measured by UPCR. Relative change in UPCR will be estimated based on an MMRM model. 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). Negative change from baseline indicates less proteinuria. The FAS included all

participants randomized to Part 1 of the study. Number analysed (n) signifies number of participants analysed for the specified measurement.

End point type	Secondary

End point timeframe:

Baseline, Months 3,6,12,18 and 24

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo and Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	13
Units: g/g				
least squares mean (standard error)				
Change at Month 3 (n=12,11,6,9)	-18.0 (± 13.09)	-7.5 (± 13.47)	-35.1 (± 17.06)	-35.5 (± 14.57)
Change at Month 6 (n=10,11,8,9)	-12.8 (± 20.85)	-29.3 (± 20.07)	-44.5 (± 23.32)	-43.9 (± 21.29)
Change at Month 12 (n=11,11,9,11)	-3.9 (± 19.52)	1.1 (± 19.49)	-44.4 (± 21.81)	-38.2 (± 19.02)
Change at Month 18 (n=10,10,9,12)	-11.0 (± 23.40)	-24.9 (± 23.03)	-39.3 (± 25.54)	-48.3 (± 21.81)
Change at Month 24 (n=10,9,8,10)	-38.1 (± 33.67)	-15.3 (± 34.24)	-30.9 (± 38.03)	-48.6 (± 32.19)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Complete Response (CR) at Months 3, 6, 9, 12, 18 and 24

End point title	Number of Participants With Complete Response (CR) at Months 3, 6, 9, 12, 18 and 24 [5]

End point description:

CR was defined as the reduction of proteinuria to less than 0.3 g/g UPCR, serum albumin within the reference range of the central laboratory and stable estimated glomerular filtration rate (eGFR) (at least 80% of value at baseline visit). The FAS included all participants randomized to Part 1 of the study. Number analysed (n) signifies number of participants analysed for the specified measurement.

End point type	Secondary

End point timeframe:

Months 3,6,9,12,18 and 24

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo and Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	13
Units: participants				
Month 3 (n=12,11,6,9)	0	0	0	1
Month 6 (n=10,11,8,9)	0	1	0	1
Month 9 (n=11,11,9,12)	0	0	0	4
Month 12 (n=11,11,9,11)	0	0	0	3
Month 18 (n=10,10,9,12)	0	0	0	4
Month 24 (n=10,9,8,10)	1	0	0	4

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Response at Months 3, 6, 9, 12, 18 and 24

End point title	Percentage of Participants With Response at Months 3, 6, 9, 12, 18 and 24 [6]

End point description:

Response was defined as reduction of proteinuria to below 0.6 g/g (UPCR) and stable eGFR (at least 80% of value at baseline visit), but not CR. The FAS included all participants randomized to Part 1 of the study. Number analysed (n) signifies number of participants analysed for the specified measurement.

End point type	Secondary

End point timeframe:

Months 3,6,9,12,18 and 24

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo and Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	13
Units: percentage of participants				
number (not applicable)				
Month 3 (n=12,11,6,9)	8.3	9.1	0	44.4
Month 6 (n=10,11,8,9)	0	9.1	0	55.6
Month 9 (n=11,11,9,12)	9.1	0	11.1	8.3
Month 12 (n=11,11,9,11)	9.1	0	22.2	27.3
Month 18 (n=10,10,9,12)	0	0	22.2	16.7
Month 24 (n=10,9,8,10)	0	11.1	12.5	20.0

Statistical analyses

No statistical analyses for this end point

Secondary: Albumin-Creatinine Ratio (ACR) at Months 6, 9, 12, 18 and 24

End point title	Albumin-Creatinine Ratio (ACR) at Months 6, 9, 12, 18 and 24[7]

End point description:

The FAS included all participants randomized to Part 1 of the study. Number analysed (n) signifies number of participants analysed for the specified measurement.

End point type	Secondary

End point timeframe:

Months 6, 9,12,18 and 24

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo and Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	13
Units: milligrams per gram (mg/g)				
arithmetic mean (standard deviation)				
Month 6 (n=10,11,8,9)	1.278 (± 0.8101)	0.802 (± 0.4633)	0.841 (± 0.7925)	0.723 (± 1.0052)
Month 9 (n=11,11,9,12)	1.053 (± 0.717)	0.830 (± 0.3378)	0.834 (± 0.4391)	0.948 (± 1.1494)
Month 12 (n=11,11,9,11)	1.324 (± 0.7726)	1.062 (± 0.5072)	0.702 (± 0.4307)	1.013 (± 1.5322)
Month 18 (n=10,10,9,12)	1.305 (± 0.9155)	0.729 (± 0.3501)	0.822 (± 0.6515)	0.827 (± 0.9789)
Month 24 (n=10,9,8,10)	1.102 (± 0.8979)	0.903 (± 0.5079)	0.913 (± 0.6047)	0.622 (± 0.9405)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response[8]

End point description:

Duration of response was defined as date of 1st observation of progressive disease minus date of 1st observation of response+1 day. The FAS included all participants randomized to Part 1 of the study. 'Overall number of participants analysed' signifies number of participants evaluable for this outcome measure. '99.999, 999, and 99999' signifies confidence interval was not estimable due to low number of participants.

End point type	Secondary

End point timeframe:

Up to 2 years

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo and Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	1	7
Units: days				
median (confidence interval 95%)	250 (78 to 99999)	140 (92 to 99999)	451 (99.999 to 999)	188 (83 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response

End point title	Time to Response[9]

End point description:

Time to response was defined as date of 1st observation of response minus date of randomization+1 day. The FAS included all participants randomized to Part 1 of the study. 'Overall number of participants analysed' signifies number of participants evaluable for this outcome measure. '99.999, 999, and 99999' signifies that median and confidence interval were not estimable due to low number of participants.

End point type	Secondary

End point timeframe:

Up to 2 years

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Placebo and Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	0[10]	6
Units: days				
median (confidence interval 95%)	767 (99.999 to 999)	99999 (99999 to 99999)	(to)	720 (260.0 to 99999)

Notes:

[10] - None of the participants had a response.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in eGFR Over Time

End point title	Change From Baseline in eGFR Over Time

End point description:

eGFR was calculated as per the chronic kidney disease epidemiology collaboration (CKD-EPI) equation. eGFR =141×min(Scr/κ, 1)α×max(Scr κ,1)-1.209×0.993Age ×1.018[if female]×1.159 [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 eGFR as a measure of kidney function. eGFR was calculated in terms of milliliter per minute per 1.73 meter square (mL/min/1.73 m^2). A numerically smaller negative change in eGFR indicates a slowing in kidney disease progression. All enrolled participants

included all randomized participants from the FAS plus all Japanese participants who were enrolled in Part 2. Number analysed (n) signifies number of participants analysed for the specified measurement. '99999' mean and standard deviation were not estimable due to low number of participants.

End point type	Secondary

End point timeframe:

Baseline, Months 3,6,9,12,15,18, and 24

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	13
Units: mL/min/1.73 m^2				
arithmetic mean (standard deviation)				
Change at Month 3 (n=12,11,6,9,6)	-1.985 (± 7.5920)	2.058 (± 4.9858)	8.100 (± 18.1222)	4.224 (± 8.3131)
Change at Month 6 (n=11,11,7,10,6)	-8.163 (± 12.4166)	-2.560 (± 6.6112)	3.914 (± 12.4652)	0.033 (± 12.7546)
Change at Month 9 (n=10,10,9,12,6)	-10.006 (± 9.3866)	-5.792 (± 7.3286)	3.619 (± 11.2770)	-4.199 (± 15.8864)
Change at Month 12 (n=10,11,9,11,6)	-8.299 (± 11.1636)	-4.618 (± 7.9684)	-0.747 (± 15.3308)	-4.198 (± 9.1530)
Change at Month 18 (n=9,10,9,12,0)	-11.131 (± 9.7842)	-6.707 (± 8.4971)	2.167 (± 11.0455)	-4.778 (± 11.7583)
Change at Month 24 (n=10,10,8,10,0)	-9.550 (± 18.1470)	-7.394 (± 6.0913)	-3.342 (± 17.0161)	-6.210 (± 9.9485)

End point values	Part 2: Japan Cohort			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: mL/min/1.73 m^2				
arithmetic mean (standard deviation)				
Change at Month 3 (n=12,11,6,9,6)	1.011 (± 6.3803)			
Change at Month 6 (n=11,11,7,10,6)	0.296 (± 7.1089)			
Change at Month 9 (n=10,10,9,12,6)	-1.890 (± 2.9519)			
Change at Month 12 (n=10,11,9,11,6)	-8.959 (± 5.6681)			
Change at Month 18 (n=9,10,9,12,0)	99999 (± 99999)			
Change at Month 24 (n=10,10,8,10,0)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment Emergent Adverse Event (TEAE) and Treatment Emergent Serious Adverse Event (TESAE)

End point title	Number of Participants With Treatment Emergent Adverse Event (TEAE) and Treatment Emergent Serious Adverse Event (TESAE)

End point description:

TEAEs were defined as any AEs reported after the start of trial treatment until 28 days after the last trial treatment, defined as the treatment-emergent period. TESAEs were TEAEs that met the following criteria: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, or an important medical event that jeopardized participant and required medical intervention to prevent 1 of the outcomes listed in this definition.

End point type	Secondary

End point timeframe:

From the first dose until 28 days after last dose of study drug (up to 191 days)

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	13
Units: participants				
TEAE	6	10	9	11
TESAE	0	1	1	0

End point values	Part 2: Japan Cohort			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: participants				
TEAE	3			
TESAE	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentrations of Felzartamab Over Time

End point title	Serum Concentrations of Felzartamab Over Time [11]

End point description:

Pharmacokinetic (PK) analysis set included all participants with any available quantifiable felzartamab serum concentration data. Number analysed (n) signifies number of participants analysed for the specified measurement.

End point type	Secondary

End point timeframe:

Predose and 30 minutes post-dose on Days 1, 15, 29; predose on Days 8, 57, 85, 113, 141; Post Treatment Days 169 and 267

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Felzartamab dosing arms were planned to be analysed for this end point.

End point values	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3	Part 2: Japan Cohort
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	13	6
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Day 1: Predose (n=12,10,13,6)	67.9 (± 143.5)	54.6 (± 28.2)	50.0 (± 0.0)	50.0 (± 0.0)
Day 1: 30 mins postdose (n=12,9,11,6)	204326.5 (± 3176.6)	320616.0 (± 56.2)	424347.7 (± 42.9)	355517.2 (± 21.9)
Day 8: Predose (n=12,11,11,6)	123890.6 (± 34.3)	111734.3 (± 17.7)	119475.8 (± 29.9)	119280.5 (± 35.6)
Day 15: Predose (n=12,8,9,6)	58680.3 (± 39.6)	73299.3 (± 136.9)	242622.8 (± 14.9)	217362.3 (± 21.7)
Day 15: 30 mins postdose (n=11,7,9,6)	479855.1 (± 27.8)	564030.0 (± 14.5)	726082.1 (± 18.0)	579946.2 (± 19.9)
Day 29: Predose (n=10,7,10,6)	93782.5 (± 40.0)	142190.5 (± 28.3)	156053.1 (± 777.0)	339770.3 (± 39.1)
Day 29: 30 mins postdose (n=10,8,10,6)	94110.3 (± 42.2)	471802.8 (± 29.7)	868596.5 (± 30.2)	696420.5 (± 22.7)
Day 57: Predose (n=11,6,10,6)	5243.4 (± 1663.5)	70569.7 (± 68.4)	126530.5 (± 40.1)	132181.4 (± 69.6)
Day 85: Predose (n=11,7,9,6)	69.6 (± 153.0)	21010.4 (± 3668.4)	55920.7 (± 89.4)	69524.7 (± 96.5)
Day 113: Predose (n=10,8,10,6)	74.6 (± 199.2)	849.3 (± 2399.8)	28697.5 (± 209.5)	63543.2 (± 95.0)
Day 141: Predose (n=10,8,10,6)	74.6 (± 194.4)	50.0 (± 0.0)	59744.8 (± 50.9)	18172.1 (± 9900.0)
Post Treatment Day 169 (n=11,8,10,6)	64.8 (± 104.8)	50.0 (± 0.0)	48355.6 (± 109.3)	35243.0 (± 194.3)
Post Treatment Day 267 (n=10,8,10,6)	72.8 (± 176.5)	50.0 (± 0.0)	50.0 (± 0.0)	50.0 (± 0.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Anti- Felzartamab Antibodies

End point title	Percentage of Participants With Anti- Felzartamab Antibodies

End point description:

Blood samples were collected for measurement of anti-felzartamab antibodies in the serum. Number of participants with Anti-drug antibody (ADA) status positive/negative was summarized. The Immunogenicity analysis set included all participants with at least one ADA sample. Number analysed (n) signifies number of participants analysed for the specified measurement.

End point type	Secondary

End point timeframe:

From the first dose up to the end of the study (up to 2 years)

End point values	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 1: Felzartamab Dosing Arm M2	Part 1: Felzartamab Dosing Arm M3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	13
Units: percentage of participants				
number (not applicable)				
Positive (Any Postbaseline Visit) n=12,12,10,13,6	1	6	3	3
Negative (All Postbaseline Visit) n=12,12,10,13,6	11	6	7	10

End point values	Part 2: Japan Cohort			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: percentage of participants				
number (not applicable)				
Positive (Any Postbaseline Visit) n=12,12,10,13,6	1			
Negative (All Postbaseline Visit) n=12,12,10,13,6	5			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From signing of informed consent up to the end of the study (up to 24 months)	
Adverse event reporting additional description:	
Safety analysis set included all participants who received at least one dose of trial treatment.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27

Reporting groups	
Reporting group title	Part 1: Placebo
Reporting group description:	
Participants were administered felzartamab matching placebo as an IV infusion on Days 1, 8, 15, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M1
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1 and 15, and felzartamab matching placebo on Days 8, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 2: Japan Cohort
Reporting group description:	
Japanese participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M3
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1,8,15, 22, 29, 57, 85, 113 and 141.	
Reporting group title	Part 1: Felzartamab Dosing Arm M2
Reporting group description:	
Participants were administered felzartamab as an IV infusion based on their body weight on Days 1, 8,15, 29, and 57, and felzartamab matching placebo on Days 22, 85, 113 and 141.	

Serious adverse events	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 2: Japan Cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Dedifferentiated liposarcoma			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1: Felzartamab Dosing Arm M3	Part 1: Felzartamab Dosing Arm M2	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Dedifferentiated liposarcoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Part 1: Placebo	Part 1: Felzartamab Dosing Arm M1	Part 2: Japan Cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 12 (50.00%)	10 / 12 (83.33%)	3 / 6 (50.00%)

Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	2	11	0
Oedema peripheral			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Drug hypersensitivity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypogammaglobulinaemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device allergy			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Penile pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Erectile dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	7	0
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Hyperventilation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis chronic			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthma			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchial disorder			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with anxiety			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Digestive enzyme abnormal			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Lipase abnormal			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram T wave abnormal			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			

alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Eye injury			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hand fracture			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle contusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin laceration			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sinus arrhythmia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Angina pectoris			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Coronary artery occlusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Palpitations			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	3	6	0
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Migraine			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Anaemia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Polycythaemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	9	0
Vision blurred			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Presbyopia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Nausea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Nail ridging			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neurodermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Haematuria			

subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Nocturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Glycosuria			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Azotaemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Muscle twitching			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Articular calcification			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rheumatic disorder			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Muscle tightness			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc protrusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			

COVID-19			
subjects affected / exposed	3 / 12 (25.00%)	4 / 12 (33.33%)	2 / 6 (33.33%)
occurrences (all)	3	4	2
Nasopharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 6 (16.67%)
occurrences (all)	1	4	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	4	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Diarrhoea infectious			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urethritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hordeolum			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Laryngitis			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Candida infection			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal bacterial infection			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Keratitis bacterial			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Otitis externa			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Paronychia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: Felzartamab Dosing Arm M3	Part 1: Felzartamab Dosing Arm M2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 13 (84.62%)	8 / 11 (72.73%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Hypotension			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	2	0	
Fatigue			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	
occurrences (all)	9	9	
Oedema peripheral			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Vessel puncture site haematoma			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Non-cardiac chest pain			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Drug hypersensitivity			

subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	
occurrences (all)	1	1	
Hypogammaglobulinaemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Device allergy			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Penile pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Erectile dysfunction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Hyperventilation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Wheezing			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal discomfort			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Bronchitis chronic			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Asthma			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Rhinitis allergic			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	2 / 13 (15.38%)	1 / 11 (9.09%)	
occurrences (all)	3	1	
Bronchial disorder			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	
occurrences (all)	1	1	
Anxiety			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Adjustment disorder with anxiety			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Depression			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Amylase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	5	0	
Blood bicarbonate decreased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Digestive enzyme abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Lipase abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	4	0	
Liver function test increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Blood bilirubin increased			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Blood creatine phosphokinase increased			

alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
SARS-CoV-2 test positive			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 13 (15.38%)	2 / 11 (18.18%)	
occurrences (all)	2	3	
Eye injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Hand fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Joint injury			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Contusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Muscle contusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			

Coronary artery stenosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Sinus arrhythmia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Angina pectoris			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Coronary artery occlusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Palpitations			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	
occurrences (all)	1	4	
Somnolence			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Dizziness			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	
occurrences (all)	0	3	
Migraine			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			

Neutropenia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	
occurrences (all)	1	1	
Eosinophilia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	2	0	
Lymphopenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Polycythaemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Motion sickness			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Presbyopia			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	
occurrences (all)	3	0	
Nausea			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	
occurrences (all)	1	1	
Toothache			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	
occurrences (all)	0	3	
Abdominal discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Haemorrhoids			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Abdominal pain upper			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Gastritis			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Nail ridging			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Neurodermatitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Night sweats			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Dermatitis atopic			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Dermal cyst			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	2 / 13 (15.38%)	1 / 11 (9.09%)	
occurrences (all)	2	1	
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Nocturia			

subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Urine flow decreased			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Renal impairment			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Glycosuria			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Azotaemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Muscle twitching			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Arthralgia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	
occurrences (all)	3	0	
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Rhabdomyolysis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Articular calcification			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Rheumatic disorder			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Muscle tightness			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Muscle spasms			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Joint stiffness			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Intervertebral disc protrusion			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
COVID-19			
subjects affected / exposed	6 / 13 (46.15%)	2 / 11 (18.18%)	
occurrences (all)	7	3	
Nasopharyngitis			
subjects affected / exposed	2 / 13 (15.38%)	3 / 11 (27.27%)	
occurrences (all)	3	5	
Upper respiratory tract infection			

subjects affected / exposed	1 / 13 (7.69%)	2 / 11 (18.18%)	
occurrences (all)	1	2	
Bronchitis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	
occurrences (all)	1	1	
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Diarrhoea infectious			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Urethritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Viral infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Laryngitis			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	
occurrences (all)	2	0	
Bacterial infection			

alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Candida infection			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis bacterial			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal bacterial infection			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Influenza			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Keratitis bacterial			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Otitis externa			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Paronychia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
alternative dictionary used: MedDRA 27			

subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	
Subcutaneous abscess			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Respiratory tract infection			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Hyperphosphataemia			
alternative dictionary used: MedDRA 27			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 September 2021	- Trial design section updated to include country specific (Japanese) open-label cohort to enroll 4 additional participants in M3 dosing arm (part II). - Revised exclusion criterion no. 9 (i.e. minimum hemoglobin limit at screening changed from 80 to 90 gram per liter (g/L)). - Implemented post infusion monitoring requirements, added additional pre-medication for prevention of IRRs, and recommendation of post infusion medication for participants with a history of asthma and chronic obstructive pulmonary disease. - Revised the total volume to 250 milliliter (ml) in the table providing an example of infusion speeds - Added stratification information for the 4 Japanese participants enrolling in global study (part I). - Revised treatment discontinuation criterion to ensure that participants with grade 3 infusion related reaction (IRR)/allergic reaction or grade 2 cytokine release syndrome (CRS) cannot continue receiving felzartamab. - Added criteria of grade 4 hematological abnormalities related to investigational medicinal product (IMP) and clinically significant elevated liver enzymes to the list of reasons for discontinuation from treatment. - Removed criteria of "use of prohibited treatment" to clarify that participants using prohibited treatment will be discontinued from the trial - Clarified that a participants can be withdrawn from the study due to lack of efficacy. - Clarified timing of analysis; primary analysis will be conducted after all participants in global study (part I) complete their 9-month visit or discontinued early. Final analysis will be conducted after all randomized participants in global Study (part I) and Japanese cohort (part II) have completed their last visit, or discontinued the trial earlier. - Added Japan population to facilitate further analysis on Japanese participants safety and PK profile. - Updated analysis method for primary endpoint. - Added description of eGFR under the statistical consideration section.
01 December 2021	- An overview of procedures related to interim analysis (IA) including unblinding procedures was included. - Timing of the 3-months pharmacokinetic (PK) IA was included. - IA section was added to describe timing, scope, and procedures related to 3-months PK biomarkers IA with no changes to the planned study design or conduct. - A summary of statistical analysis and protocol title was added to section 1. - Reporting of treatment error, misuse or abuse section was added. - Council for International Organizations of Medical Sciences (CIOMS) international ethical guidelines was added under regulatory and ethical consideration. - Text on quality tolerance limits (QTLs) was added.
17 February 2022	- Section 1.1 and 5 trial design, section 1.3 dosing, section 1.4 trial population were updated to enable flexible enrollment in Japan across part I and part II. - Treatment assignment section was updated to clarify stratification in Part I based on country (Japan vs ex-Japan). - Section 10.1 Sample size determination and section 10.2 integrative analysis of dose and dosing regimens were updated to include the number of participants in Japan. - Section 7.1 Treatments administered were updated to recommend the Investigator to consult medical monitor and sponsor for an alternative premedication(s) in case of unavailability of any of the prespecified premedication.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported