Clinical trial results:
An Open-label Extension Study of MOM-M281-004 to Evaluate the Safety, Tolerability, and Efficacy of M281 Administered to Patients with Generalized Myasthenia Gravis

Summary

EudraCT number	2018-003618-41
Trial protocol	GB DE BE ES PL IT
Global end of trial date	22 June 2020

Results information

Result version number	v1
This version publication date	23 December 2021
First version publication date	23 December 2021

Trial information

Trial identification

Sponsor protocol code	MOM-M281-005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03896295
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Momenta Pharmaceuticals, Inc.
Sponsor organisation address	301 Binney Street, Cambridge, United States, MA02142
Public contact	Clinical Registry group, Momenta Pharmaceuticals, Inc., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Momenta Pharmaceuticals, Inc., ClinicalTrialsEU@its.jnj.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	22 June 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 June 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to evaluate the long-term safety and tolerability of nipocalimab in subjects with generalized myasthenia gravis (gMG).

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice (GCP) and applicable regulatory requirements. Safety assessments included collection of adverse events (AEs) and serious AEs (SAEs), adverse events of special interests (AESIs), clinical laboratory testing (including chemistry, hematology, coagulation, and urinalysis), vital signs, physical examinations, electrocardiogram (ECG) findings, and the Columbia-Suicide Severity Rating Scale (C-SSRS).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 February 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Poland: 7
Country: Number of subjects enrolled	United States: 15
Worldwide total number of subjects	37
EEA total number of subjects	22

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)	25
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects from study MOM-M281-004 (NCT03772587) who completed the Day 113 visit of that study were eligible to enroll in this open-label extension study (MOM-M281-005). The Day 113 visit of MOM-M281-004 occurred approximately 8 weeks after the last dose in that study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo-Nipocalimab

Arm description:

Subjects who received placebo in MOM-M281-004 study (NCT03772587) rolled-over and received intravenous (IV) infusion of nipocalimab 30 milligrams per kilogram (mg/kg) every 4 weeks (Q4W) starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Nipocalimab 30 mg/kg was administered once Q4W as IV infusion starting Day 1 up to 8 weeks. The dose and/or dosing frequency could be individually adjusted per investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding Q2W after 8 weeks of treatment.

Arm title	Nipocalimab-Nipocalimab

Arm description:

Subjects who received nipocalimab in MOM-M281-004 study (NCT03772587) rolled-over and received IV infusion of nipocalimab 30 mg/kg Q4W starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Nipocalimab 30 mg/kg was administered once Q4W as IV infusion starting Day 1 up to 8 weeks. The dose and/or dosing frequency could be individually adjusted per investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding Q2W after 8 weeks of treatment.

Number of subjects in period 1	Placebo-Nipocalimab	Nipocalimab-Nipocalimab
Started	7	30
Completed	0	0
Not completed	7	30
Adverse event, serious fatal	-	1
Covid-19	7	29

Baseline characteristics

Reporting groups	
Reporting group title	Placebo-Nipocalimab
Reporting group description:	
Subjects who received placebo in MOM-M281-004 study (NCT03772587) rolled-over and received intravenous (IV) infusion of nipocalimab 30 milligrams per kilogram (mg/kg) every 4 weeks (Q4W) starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).	
Reporting group title	Nipocalimab-Nipocalimab
Reporting group description:	
Subjects who received nipocalimab in MOM-M281-004 study (NCT03772587) rolled-over and received IV infusion of nipocalimab 30 mg/kg Q4W starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).	

Reporting group values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Total
Number of subjects	7	30	37
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	20	25
From 65 to 84 years	2	10	12
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	53.7	53	
standard deviation	± 20.39	± 16.93	-
Title for Gender Units: subjects			
Female	4	18	22
Male	3	12	15

End points

End points reporting groups

Reporting group title	Placebo-Nipocalimab

Reporting group description:

Subjects who received placebo in MOM-M281-004 study (NCT03772587) rolled-over and received intravenous (IV) infusion of nipocalimab 30 milligrams per kilogram (mg/kg) every 4 weeks (Q4W) starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).

Reporting group title	Nipocalimab-Nipocalimab

Reporting group description:

Subjects who received nipocalimab in MOM-M281-004 study (NCT03772587) rolled-over and received IV infusion of nipocalimab 30 mg/kg Q4W starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).

Subject analysis set title	Nipocalimab (All Subjects)
Subject analysis set type	Full analysis

Subject analysis set description:

All subjects who received placebo or nipocalimab in MOM-M281-004 study rolled-over and received IV infusion of nipocalimab 30 mg/kg Q4W starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding Q2W.

Primary: Number of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Subjects with Treatment-emergent Adverse Events (TEAEs)[1]

End point description:

Number of subjects with TEAEs were reported. An adverse event (AE) is any untoward medical event that occurs in a subject administered an investigational product and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. TEAEs are defined as any AE occurring during or after the initiation of the first infusion of study drug in this study. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Up to 257 days post-baseline (Baseline is Day 1)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	30	37	
Units: subjects	4	18	22	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Treatment-emergent Serious Adverse Events (SAEs)

End point title	Number of Subjects with Treatment-emergent Serious Adverse Events (SAEs)[2]

End point description:

An adverse event (AE) is any untoward medical event that occurs in a subject administered an investigational product and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. An SAE is defined as any AE occurring at any dose that results in any of the following outcomes: death, life-threatening AE, hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Up to 257 days post-baseline

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	30	37	
Units: subjects	1	4	5	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Treatment-emergent Adverse Events of Special Interest (AESIs)

End point title	Number of Subjects with Treatment-emergent Adverse Events of Special Interest (AESIs)[3]

End point description:

Number of subjects with treatment-emergent AESIs were reported. Severe infections and hypoalbuminemia (Grade 3 or higher according to the Common Terminology Criteria for Adverse Events [CTCAE] v5.0) were considered as AESIs. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Up to 257 days post-baseline

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	30	37	
Units: subjects	1	1	2	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Treatment-emergent Abnormal Vital Signs

End point title	Number of Subjects with Treatment-emergent Abnormal Vital Signs[4]

End point description:

Number of subjects with treatment-emergent abnormal vital signs including pulse rate (less than or equal to [<=] 50 beats per minutes [bpm] with greater than or equal to [>=] 15 bpm decrease from baseline, >= 120 bpm with >=15 bpm increase from baseline), systolic blood pressure (SBP) (<= 90 millimeters of mercury [mmHg] with >= 20 mmHg decrease from baseline, >= 160 mmHg with >= 20 mmHg increase from baseline) and diastolic blood pressure (DBP) (<= 50 mmHg with >=15 mmHg decrease from baseline, >=100 mmHg with >=15 mmHg decrease from baseline) were reported. Safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Up to 257 days post-baseline

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	30	37	
Units: subjects				
PR<=50 with >=15 bpm decrease from baseline	0	0	0	
PR>= 120 with >=15 bpm increase from baseline	0	0	0	
SBP<=90 with >=20 mmHg decrease from baseline	0	1	1	
SBP>=160 with >=20 mmHg increase from baseline	0	1	1	
DBP<=50 with >=15 mmHg decrease from baseline	0	2	2	
DBP>=100 with >=15 mmHg decrease from baseline	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Abnormalities in Physical Examinations

End point title	Number of Subjects with Abnormalities in Physical Examinations[5]

End point description:

Number of subjects with abnormalities in physical examinations (abdomen, head, ears, eyes, nose, throat, and sinuses, lungs, neurological, skin, blood and lymphatic system, cardiovascular, chest, gastrointestinal, general appearance and musculoskeletal) were reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. Here, 'n' specifies the number of subjects evaluated for specific categories. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Week 12

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	17	21	
Units: subjects				
Abdomen (n=4,17,21)	1	0	1	
Head, Ears, Eyes, Nose, Throat, Sinuses(n=4,17,21)	0	0	0	
Lungs (n=4,17,21)	0	0	0	
Neurological (n=4,16,20)	0	1	1	
Skin (n=4,17,21)	1	4	5	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Chemistry Laboratory Parameters: Albumin and Protein

End point title	Change from Baseline in Chemistry Laboratory Parameters: Albumin and Protein[6]

End point description:

Change from baseline in chemistry laboratory parameters: albumin and protein were reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	17	21	
Units: grams per liter (g/L)				
arithmetic mean (standard deviation)				
Albumin	-1.5 (± 2.89)	-1.2 (± 3.21)	-1.3 (± 3.08)	
Protein	-3.5 (± 2.08)	-3.8 (± 4.99)	-3.7 (± 4.54)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Chemistry Laboratory Parameters: Bicarbonate, Calcium, Chloride, Cholesterol, Glucose, Phosphate, Potassium, Sodium, Triglycerides, Urate and Urea Nitrogen

End point title	Change from Baseline in Chemistry Laboratory Parameters: Bicarbonate, Calcium, Chloride, Cholesterol, Glucose, Phosphate, Potassium, Sodium, Triglycerides, Urate and Urea Nitrogen[7]

End point description:

Change from baseline in chemistry laboratory parameters: bicarbonate, calcium, chloride, cholesterol, glucose, phosphate, potassium, sodium, triglycerides, urate and urea nitrogen were reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	17	21	
Units: millimoles per liter (mmol/L)				
arithmetic mean (standard deviation)				
Bicarbonate	-2.0 (± 2.45)	1.6 (± 2.91)	1.0 (± 3.14)	
Calcium	0.010 (± 0.0627)	-0.018 (± 0.1005)	-0.013 (± 0.0938)	
Chloride	0.5 (± 1.91)	0.6 (± 2.85)	0.6 (± 2.66)	
Cholesterol	0.480 (± 1.0100)	0.261 (± 0.5732)	0.303 (± 0.6509)	
Glucose	0.280 (± 0.5054)	-0.258 (± 1.1401)	-0.155 (± 1.0607)	
Phosphate	-0.018 (± 0.0971)	-0.002 (± 0.1903)	-0.005 (± 0.1744)	
Potassium	0.05 (± 0.173)	0.05 (± 0.583)	0.05 (± 0.526)	
Sodium	0.8 (± 0.96)	1.4 (± 2.18)	1.2 (± 2.00)	
Triglycerides	0.223 (± 0.5799)	0.081 (± 0.3223)	0.108 (± 0.3699)	

Urate	-0.0090 (± 0.04285)	0.0174 (± 0.04790)	0.124 (± 0.04716)	
Urea Nitrogen	-0.270 (± 1.7830)	-0.105 (± 1.7292)	-0.136 (± 1.6951)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Chemistry Laboratory Parameters: Alanine Aminotransferase, Alkaline Phosphatase, Aspartate Aminotransferase, Creatine Kinase, Gamma Glutamyl Transferase, Lactate Dehydrogenase

End point title	Change from Baseline in Chemistry Laboratory Parameters: Alanine Aminotransferase, Alkaline Phosphatase, Aspartate Aminotransferase, Creatine Kinase, Gamma Glutamyl Transferase, Lactate Dehydrogenase[8]

End point description:

Change from baseline in chemistry laboratory parameters: alanine aminotransferase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatine kinase, gamma glutamyl transferase, lactate dehydrogenase were reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. Here, 'n' specifies the number of subjects evaluated for specific categories. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	17	21	
Units: units per liter (U/L)				
arithmetic mean (standard deviation)				
ALT (n=4,17, 21)	17.0 (± 28.76)	2.6 (± 5.33)	5.3 (± 13.43)	
Alkaline Phosphatase (n=4,16, 20)	6.3 (± 2.06)	5.2 (± 11.46)	5.4 (± 10.23)	
AST (n=4,17, 21)	23.5 (± 47.67)	0.9 (± 3.42)	5.2 (± 20.80)	
Creatine Kinase (n=4,17, 21)	-17.8 (± 33.13)	13.6 (± 38.34)	7.7 (± 38.73)	
Gamma Glutamyl Transferase (n=4,17, 21)	4.3 (± 11.95)	1.5 (± 13.21)	2.0 (± 12.74)	
Lactate Dehydrogenase (n=4,16, 20)	30.0 (± 15.68)	30.9 (± 58.10)	30.7 (± 52.0)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Chemistry Laboratory Parameters: Bilirubin,

Creatinine and Direct Bilirubin

End point title	Change from Baseline in Chemistry Laboratory Parameters: Bilirubin, Creatinine and Direct Bilirubin[9]

End point description:

Change from baseline in chemistry laboratory parameters: bilirubin, creatinine and direct bilirubin were reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. Here, 'n' specifies the number of subjects evaluated for specific categories. Here, "99999" indicates that standard deviation can not be calculated for 1 subject. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	17	21	
Units: micromoles per liter (micromol/L)				
arithmetic mean (standard deviation)				
Bilirubin (n=4,17, 21)	0.13 (± 2.616)	-0.59 (± 2.403)	-0.46 (± 2.393)	
Creatinine (n=4,17, 21)	-9.0 (± 7.35)	-2.6 (± 13.20)	-3.9 (± 12.41)	
Direct Bilirubin (n=1,2, 3)	-1.20 (± 99999)	-0.70 (± 0.283)	-0.87 (± 0.359)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Laboratory Parameter: Erythrocytes (Red Blood Cell)

End point title	Change from Baseline in Hematology Laboratory Parameter: Erythrocytes (Red Blood Cell)[10]

End point description:

Change from baseline in erythrocytes (red blood cell (hematology laboratory test parameter) were reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	16	20	
Units: 10^12 per Liter				
arithmetic mean (standard deviation)	0.188 (± 0.0822)	0.121 (± 0.2702)	0.135 (± 0.2438)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Laboratory Parameter: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Platelets and Leukocytes

End point title	Change from Baseline in Hematology Laboratory Parameter: Basophils, Eosinophils, Lymphocytes, Monocytes, Neutrophils, Platelets and Leukocytes[11]

End point description:

Change from baseline in hematology laboratory parameters: basophils, eosinophils, lymphocytes, monocytes, neutrophils, platelets and leukocytes were reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. Here 'n' specifies the number of subjects evaluated for specific categories. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	16	20	
Units: 10^9 per Liter				
arithmetic mean (standard deviation)				
Basophils (n=4,8,12)	-0.003 (± 0.0150)	0.010 (± 0.0200)	0.006 (± 0.0188)	
Eosinophils (n=4,13, 17)	0.015 (± 0.0465)	0.013 (± 0.0776)	0.014 (± 0.0702)	
Lymphocytes (n=4,16, 20)	-0.045 (± 0.4498)	0.063 (± 0.4715)	0.041 (± 0.4576)	
Monocytes (n=4,16, 20)	-0.105 (± 0.1964)	0.059 (± 0.2008)	0.027 (± 0.2061)	
Neutrophils (n=4,16, 20)	-0.433 (± 0.5744)	0.411 (± 1.8622)	0.243 (± 1.7058)	
Platelets (n=4,16, 20)	27.8 (± 11.81)	12.3 (± 53.20)	15.4 (± 47.93)	
Leukocytes (n=4,16, 20)	-0.568 (± 0.9214)	0.567 (± 1.9956)	0.340 (± 1.8694)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration

End point title	Change from Baseline in Hematology Parameter: Erythrocytes Mean Corpuscular Hemoglobin (HGB) Concentration[12]

End point description:

Change from baseline in erythrocytes mean corpuscular HGB concentration (hematology parameter) was reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	16	20	
Units: grams per Liter (g/L)				
arithmetic mean (standard deviation)	-6.5 (± 25.70)	-2.1 (± 7.61)	-3.0 (± 12.38)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline inHematology Laboratory Parameter: Erythrocytes Mean Corpuscular Hemoglobin (HGB)

End point title	Change from Baseline inHematology Laboratory Parameter: Erythrocytes Mean Corpuscular Hemoglobin (HGB)[13]

End point description:

Change from baseline in erythrocytes mean corpuscular HGB (hematology laboratory parameter) were reported. The safety analysis set included all subjects who received at least 1 dose of study drug (nipocalimab). Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	16	20	
Units: picograms (pg)				
arithmetic mean (standard deviation)	0.03 (± 0.873)	-0.61 (± 0.813)	-0.48 (± 0.842)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Laboratory Parameter: Erythrocytes Mean Corpuscular Volume

End point title	Change from Baseline in Hematology Laboratory Parameter: Erythrocytes Mean Corpuscular Volume[14]

End point description:

Change from baseline in erythrocytes mean corpuscular volume (hematology laboratory parameter) was reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	16	20	
Units: femtoliters (fL)				
arithmetic mean (standard deviation)	2.45 (± 6.174)	-1.41 (± 3.406)	-0.64 (± 4.206)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Laboratory Parameter: Hematocrit

End point title	Change from Baseline in Hematology Laboratory Parameter: Hematocrit[15]

End point description:

Change from baseline in hematocrit values (hematology laboratory parameter) was reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	16	20	
Units: liter of cells per liter of blood (L/L)				
arithmetic mean (standard deviation)	0.0278 (± 0.03542)	0.0048 (± 0.02401)	0.0094 (± 0.02725)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Hematology Laboratory Parameter: Hemoglobin

End point title	Change from Baseline in Hematology Laboratory Parameter: Hemoglobin[16]

End point description:

Change from baseline in hemoglobin values (hematology laboratory parameter) was reported. The safety analysis set included all subjects who received at least 1 dose of study drug (nipocalimab). Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	16	20	
Units: g/L				
arithmetic mean (standard deviation)	5.8 (± 4.65)	0.6 (± 7.29)	1.7 (± 7.06)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Urinalysis Laboratory Parameter: pH

End point title	Change from Baseline in Urinalysis Laboratory Parameter:

End point description:

Change from baseline in pH (urinalysis laboratory parameter) was reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	17	21	
Units: pH				
arithmetic mean (standard deviation)	-0.8 (± 0.96)	0.0 (± 1.06)	-0.1 (± 1.06)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline in Urinalysis Laboratory Parameter: Specific Gravity

End point title	Change from Baseline in Urinalysis Laboratory Parameter: Specific Gravity[18]

End point description:

Change from baseline in specific gravity (urinalysis laboratory parameter) was reported. The safety analysis set included all subjects who received at least 1 dose of study drug (nipocalimab). Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Baseline up to Week 12

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	17	21	
Units: ratio				
arithmetic mean (standard deviation)	-0.0003 (± 0.00660)	-0.0030 (± 0.00973)	-0.0025 (± 0.00914)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Treatment-emergent Abnormal Electrocardiograms (ECG) Values

End point title	Number of Subjects with Treatment-emergent Abnormal Electrocardiograms (ECG) Values[19]

End point description:

Number of subjects with treatment-emergent abnormal ECG values for variables including mean heart rate (abnormally low refers to less than or equal to [<=] 50 beats per minute [bpm], abnormally high refers greater than or equal to [>=] 120 bpm), PR interval (abnormally low refers to < 120 and abnormally high refers to >200 milliseconds [msec]), RR interval (abnormally low refers to <600 msec and abnormally high refers to >1200 msec) and QRS duration (abnormally > 120) were reported. Safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Up to 257 days post-baseline

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	29	36	
Units: subjects				
ECG Mean Heart Rate (<= 50)	0	5	5	
ECG Mean Heart Rate (>=120)	0	0	0	
PR Interval (<120)	0	0	0	
PR Interval (> 200)	0	5	5	
RR Interval (<600)	0	0	0	
RR Interval (>=1200)	0	4	4	
QRS Duration (>120)	1	3	4	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Columbia Suicide Severity Rating Scale (C-SSRS) Scores

End point title	Number of Subjects with Columbia Suicide Severity Rating Scale (C-SSRS) Scores[20]

End point description:

C-SSRS is a questionnaire designed to solicit occurrence, severity, frequency of suicide-related ideation and behaviors. Total score ranges from 1 to 10. Higher total scores indicate greater severity. Maximum score assigned for each subject summarized into one of 3 broad categories: no suicidal ideation or behavior (0), suicidal ideation (1 to 5), suicidal behavior (6 to 10). Higher score indicates more suicidal behavior/ideation. Suicidal ideation includes subjects who did not have suicidal ideation or behavior at baseline and had suicidal ideation without behavior, Suicidal behavior includes subjects who did not have suicidal ideation or behavior at baseline and had suicidal behavior at some time point post-baseline. Safety analysis set included all subjects who received at least 1 dose of nipocalimab. Number of subjects analyzed specifies all subjects who were evaluated for this endpoint. Per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Up to 257 days post-baseline

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	6	30	36	
Units: subjects				
No Suicidal Ideation/Behavior	5	30	35	
Suicidal Ideation	1	0	1	
Suicidal Behavior	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Below/Above Normal Coagulation Laboratory Values

End point title	Number of Subjects with Below/Above Normal Coagulation Laboratory Values[21]

End point description:

Number of subjects with at least one value above upper limit of normal (> ULN) or below the lower limit of normal (< LLN) value of coagulation parameters (activated partial thromboplastin time [APTT] and prothrombin time [PT]) were reported. The lab reference range for APTT is 25.1 to 36.5 seconds. The lab reference range for PT is 9.4 to 12.5 seconds. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Primary

End point timeframe:

Up to 257 days post-baseline

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistical analysis was planned for the Primary Endpoint.

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	28	35	
Units: subjects				
APTT (>ULN)	2	15	17	
APTT (<LLN)	0	3	3	
PT (>ULN)	1	8	9	
PT (<ULN)	0	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total Myasthenia Gravis – Activities of Daily Living (MG-ADL) Score Over Time

End point title	Change from Baseline in Total Myasthenia Gravis – Activities of Daily Living (MG-ADL) Score Over Time

End point description:

MG-ADL assessed subject's MG symptom severity and 8 functions (talking, chewing, swallowing, breathing, impairment of ability to brush teeth or comb hair, impairment of ability to arise from a chair, double vision, and eyelid droop), rated on a 4-point scale: 0 (no impairment) to 3 (severe impairment). Total score is sum of 8 function scores, ranges from 0 to 24. Higher scores indicated greater symptom severity in performing daily living activities. Full analysis set included all subjects who received at least 1 dose of nipocalimab. Here, number of subjects analyzed specifies all subjects evaluated for this endpoint, 'n' specifies number of subjects evaluated for specific timepoints,"99999" for Week 24 timepoint category indicates that standard deviation could not be calculated for 1 subject and for EoT category indicates that no/0 subjects in Placebo-Nipocalimab arm were analysed at EoT. Per planned analysis, data is reported both for individual arms and all (total) subjects.

End point type	Secondary

End point timeframe:

Baseline up to Weeks 4, 8, 12, 24, End of Treatment (EoT) (up to 253 days post-baseline), Follow-up (up to 257 days post-baseline)

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	26	31	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=5,26,31)	0.6 (± 1.34)	-0.6 (± 2.42)	-0.4 (± 2.30)	
Week 8 (n=5,19,24)	-0.8 (± 3.70)	-0.9 (± 2.63)	-0.9 (± 2.80)	
Week 12 (n=4,17,21)	-0.3 (± 4.35)	-1.2 (± 2.49)	-1.0 (± 2.82)	
Week 24 (n=1,5,6)	-1.0 (± 99999)	-1.2 (± 1.92)	-1.2 (± 1.72)	
EoT (n=0,16,16)	99999 (± 99999)	-2.4 (± 2.55)	-2.4 (± 2.55)	
Follow-up (n=5,24,29)	-0.6 (± 1.14)	1.2 (± 3.08)	0.9 (± 2.91)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With a 2-, 3-, 4-, 5-, 6-, 7-, or greater than or equal to (>=) 8-point Improvement in Total MG-ADL Score Over Time

End point title	Number of Subjects With a 2-, 3-, 4-, 5-, 6-, 7-, or greater than or equal to (>=) 8-point Improvement in Total MG-ADL Score Over Time

End point description:

Number of subjects with 2-, 3-, 4-, 5-, 6-, 7-, or >= 8-point improvement in total MG-ADL score over time were reported. MG-ADL assess subject's MG symptom severity and 8 functions (talking, chewing, swallowing, breathing, impairment of ability to brush teeth or comb hair, impairment of ability to arise from a chair, double vision, and eyelid droop) rated on 4-point scale:0 (no impairment) to 3 (severe impairment). Total score is sum of 8 function scores ranging from 0 to 24. Higher scores indicated greater symptom severity in performing daily living activities. FAS included all subjects who received at least 1 dose of nipocalimab. Here, 'n' (number analyzed) specifies the number of subjects evaluated for specific timepoints,99999 indicates that no/0 subjects were analysed in Placebo-Nipocalimab arm. Per planned analysis, data is reported both for individual arms and all(total) subjects.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, 24, End of Treatment (EoT) (up to 253 days post-baseline), Follow-up (up to 257 days post-baseline)

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	30	37	
Units: subjects				
Week 4 (2 Point Improvement) (n=0,6,6)	99999	2	2	
Week 4 (3 Point Improvement) (n=0,6,6)	99999	1	1	
Week 4 (4 Point Improvement) (n=0,6,6)	99999	0	0	
Week 4 (5 Point Improvement) (n=0,6,6)	99999	1	1	
Week 4 (6 Point Improvement) (n=0,6,6)	99999	2	2	
Week 4 (7 Point Improvement) (n=0,6,6)	99999	0	0	
Week 4 (>= 8 Point Improvement) (n=0,6,6)	99999	0	0	
Week 8 (2 Point Improvement) (n=2,7,9)	1	2	3	
Week 8 (3 Point Improvement) (n=2,7,9)	0	4	4	
Week 8 (4 Point Improvement) (n=2,7,9)	0	0	0	
Week 8 (5 Point Improvement) (n=2,7,9)	0	0	0	
Week 8 (6 Point Improvement) (n=2,7,9)	1	0	1	
Week 8 (7 Point Improvement) (n=2,7,9)	0	0	0	
Week 8 (>= 8 Point Improvement) (n=2,7,9)	0	1	1	
Week 12 (2 Point Improvement) (n=1,5,6)	0	2	2	
Week 12 (3 Point Improvement) (n=1,5,6)	0	0	0	
Week 12 (4 Point Improvement) (n=1,5,6)	0	0	0	

Week 12 (5 Point Improvement) (n=1,5,6)	0	0	0	
Week 12 (6 Point Improvement) (n=1,5,6)	1	3	4	
Week 12 (7 Point Improvement) (n=1,5,6)	0	0	0	
Week 12 (>= 8 Point Improvement) (n=1,5,6)	0	0	0	
Week 24 (2 Point Improvement) (n=0,2,2)	99999	1	1	
Week 24 (3 Point Improvement) (n=0,2,2)	99999	0	0	
Week 24 (4 Point Improvement) (n=0,2,2)	99999	1	1	
Week 24 (5 Point Improvement) (n=0,2,2)	99999	0	0	
Week 24 (6 Point Improvement) (n=0,2,2)	99999	0	0	
Week 24 (7 Point Improvement) (n=0,2,2)	99999	0	0	
Week 24 (>= 8 Point Improvement) (n=0,2,2)	99999	0	0	
EoT (2 Point Improvement)(n=0,8,8)	99999	2	2	
EoT (3 Point Improvement)(n=0,8,8)	99999	2	2	
EoT (4 Point Improvement) (n=0,8,8)	99999	0	0	
EoT (5 Point Improvement) (n=0,8,8)	99999	1	1	
EoT (6 Point Improvement) (n=0,8,8)	99999	1	1	
EoT (7 Point Improvement) (n=0,8,8)	99999	2	2	
EoT (>=8 Point Improvement)(n=0,8,8)	99999	0	0	
Follow-up (2 Point Improvement)(n=1,4,5)	1	3	4	
Follow-up (3 Point Improvement)(n=1,4,5)	0	1	1	
Follow-up (4 Point Improvement)(n=1,4,5)	0	0	0	
Follow-up (5 Point Improvement)(n=1,4,5)	0	0	0	
Follow-up (6 Point Improvement)(n=1,4,5)	0	0	0	
Follow-up (7 Point Improvement)(n=1,4,5)	0	0	0	
Follow-up (>=8 Point Improvement)(n=1,4,5)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total Quantitative Myasthenia Gravis (QMG) Score Over Time

End point title	Change from Baseline in Total Quantitative Myasthenia Gravis (QMG) Score Over Time

End point description:

The QMG test was used to assess the subject’s strength. The quantitative results of each of the 13 strength components were mapped to a 4-point scale where 0 equals to (=) none, 1= mild, 2= moderate and 3= severe. The total score is the sum of the 13 scale scores and ranges from 0 to 39.

Higher scores indicated more severe impairment. The full analysis set (FAS) included all subjects who received at least 1 dose of study drug nipocalimab. Here 'n' specifies the number of subjects evaluated for specific timepoints. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. Here "99999" for follow-up timepoint category indicates that standard deviation could not be calculated for 1 subject and for Week 24 and EoT category indicates that no/ 0 subjects in the Placebo-Nipocalimab group were analysed at Weeks 24 and EoT. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Secondary

End point timeframe:

Baseline up to Weeks 4, 8, 12, 24, End of Treatment (EoT) (up to 253 days post-baseline), follow-up (up to 257 days post-baseline)

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2	9	11	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=2,9, 11)	1.5 (± 6.36)	-1.3 (± 2.60)	-0.8 (± 3.28)	
Week 8 (n=2,7,9)	-3.0 (± 5.66)	1.0 (± 1.53)	0.1 (± 2.98)	
Week 12 (n=2,6,8)	-0.5 (± 3.54)	-1.2 (± 2.23)	-1.0 (± 2.33)	
Week 24 (n=0,3,3)	99999 (± 99999)	-2.7 (± 1.53)	-2.7 (± 1.53)	
EoT (n=0,7,7)	99999 (± 99999)	-2.4 (± 4.12)	-2.4 (± 4.12)	
Follow-up (n=1,7,8)	-3.0 (± 99999)	-1.6 (± 2.07)	-1.8 (± 1.98)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total Revised Myasthenia Gravis Quality of Life – 15 Scale (MG-QoL15r) Score Over Time

End point title	Change from Baseline in Total Revised Myasthenia Gravis Quality of Life – 15 Scale (MG-QoL15r) Score Over Time

End point description:

MG-QoL15r was used to assess subject’s limitations related to living with MG. Each of 15 questions were rated by subject on a 3-point scale (0= Not at all, 1= somewhat, 2=very much) based on a recall period of “over past few weeks”. Total score is the sum of 15 question scores and ranges from 0 to 30. Higher scores indicated more limitation. FAS included all subject who received at least 1 dose of study drug nipocalimab. Here 'n' specifies the number of subjects evaluated for specific timepoints. Here "99999" for Week 24 timepoint category indicates that standard deviation could not be calculated for 1 subject and for EoT category indicates that no/ 0 subjects in the Placebo-Nipocalimab arm were analysed. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Secondary

End point timeframe:

Baseline up to Weeks 4, 8, 12, 24, End of Treatment (EoT) (up to 253 days post-baseline), Follow-up (up to 257 days post-baseline)

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	7	30	37	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=5,26,31)	1.4 (± 3.85)	-2.2 (± 4.53)	-1.6 (± 4.57)	
Week 8 (n=5,19,24)	-0.4 (± 3.97)	-1.9 (± 4.34)	-1.6 (± 4.23)	
Week 12 (n= 4,17,21)	-1.0 (± 6.27)	-3.4 (± 4.70)	-2.9 (± 4.95)	
Week 24 (1, 5,6)	-3.0 (± 99999)	-1.4 (± 1.52)	-1.7 (± 1.51)	
EoT (n=0,16,16)	99999 (± 99999)	-3.7 (± 5.28)	-3.7 (± 5.28)	
Follow-up (n=6, 24,30)	-1.3 (± 5.72)	0.1 (± 3.11)	-0.2 (± 3.69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Global Impression of Severity (CGI-S) Scores Over Time

End point title	Change from Baseline in Clinical Global Impression of Severity (CGI-S) Scores Over Time

End point description:

CCGI-S scale is clinician’s global assessment of illness severity of MG and rated by answering on 8-point scale. Subject is assessed on severity of illness according to: 0=not performed; 1=normal, not at all ill; 2=borderline illness; 3=mildly ill; 4=moderately ill; 5=markedly ill; 6=severely ill; 7=among most extremely ill patients. Higher scores indicated more severity of illness. Values of 0 (not assessed) were excluded from analysis. FAS included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint, 'n' specifies number of subjects evaluated for specific timepoints, "99999" for Week 24 timepoint category indicates that standard deviation could be calculated for 1 subject and for EoT category indicates that no/ 0 subjects in Placebo-Nipocalimab group analysed. Per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Secondary

End point timeframe:

Baseline up to Weeks 4, 8, 12, 24, End of Treatment (EoT) (up to 253 days post-baseline), Follow-up (up to 257 days post-baseline)

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	26	31	
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=5, 26,31)	-0.2 (± 0.84)	-0.3 (± 0.60)	-0.3 (± 0.63)	
Week 8 (n=5,19,24)	-1.0 (± 0.71)	-0.6 (± 0.90)	-0.7 (± 0.86)	
Week 12 (n=4,17,21)	-0.5 (± 1.00)	-0.5 (± 0.80)	-0.5 (± 0.81)	
Week 24 (n=1,5,6)	0.0 (± 99999)	-0.6 (± 0.89)	-0.5 (± 0.84)	
EoT (n=0,16,16)	99999 (± 99999)	-0.7 (± 0.95)	-0.7 (± 0.95)	
Follow-up (n=5,21,26)	-1.0 (± 1.22)	-0.1 (± 0.73)	-0.3 (± 0.88)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Improvement of Illness Over Time based on Clinical Global Impression of Improvement (CGI-I) Scale Score

End point title	Number of Subjects with Improvement of Illness Over Time based on Clinical Global Impression of Improvement (CGI-I) Scale Score

End point description:

Number of subjects with improvement of illness based on CGI-I scale score over time were reported. The CGI-I scale is the clinician/physician's global assessment of the change in severity of the patient's gMG since starting this study. The rating is given on a 7-point scale with lower scores indicating greater improvement (1= Very much improved; 2 = Much improved; 3 = Minimally improved; 4 = No change; 5 =Minimally worse; 6 = Much worse; 7 = Very much worse. Values of 0 (not assessed) were excluded from analysis. Higher score indicates more severity. The FAS included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'n' specifies the number of subjects evaluated for specific timepoints. Per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12, 24, End of Treatment (EoT) (up to 253 days post-baseline), Follow-up (up to 257 days post-baseline)

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	26	31	
Units: subjects				
Week 4 (Very much worse) (n=5,26, 31)	0	0	0	
Week 4 (Much worse) (n=5,26,31)	0	0	0	
Week 4 (Minimally worse) (n=5,26,31)	1	2	3	
Week 4 (No change) (n=5,26,31)	1	7	8	
Week 4 (Minimally improved) (n=5,26,31)	2	12	14	
Week 4 (Much improved) (n=5,26,31)	0	5	5	
Week 4 (Very much improved) (n=5,26,31)	1	0	1	
Week 8 (Very much worse) (n=5,19,24)	0	0	0	
Week 8 (Much worse) (n=5,19,24)	0	0	0	
Week 8 (Minimally worse) (n=5,19,24)	0	2	2	
Week 8 (No change) (n=5,19,24)	0	3	3	
Week 8 (Minimally improved) (n=5,19,24)	2	6	8	
Week 8 (Much improved) (n=5,19,24)	2	8	10	
Week 8 (Very much improved) (n=5,19,24)	1	0	1	

Week 12 (Very much worse) (n=4,17,21)	0	0	0	
Week 12 (Much worse) (n=4,17,21)	0	0	0	
Week 12 (Minimally worse) (n=4,17,21)	0	2	2	
Week 12 (No change) (n=4,17,21)	2	1	3	
Week 12 (Minimally improved) (n=4,17,21)	1	3	4	
Week 12 (Much improved) (n=4,17,21)	1	10	11	
Week 12 (Very much improved) (n=4,17,21)	0	1	1	
Week 24 (Very Much worse) (n=1,5,6)	0	0	0	
Week 24 (Much worse) (n=1,5,6)	0	0	0	
Week 24 (Minimally worse) (n=1,5,6)	0	0	0	
Week 24 (No change) (n=1,5,6)	1	0	1	
Week 24 (Minimally improved) (n=1,5,6)	0	1	1	
Week 24 (Much improved) (n=1,5,6)	0	4	4	
Week 24 (Very Much improved) (n=1,5,6)	0	0	0	
EoT (Very Much worse) (n=0,16,16)	99999	0	0	
EoT (Much worse) (n=0,16,16)	99999	0	0	
EoT (Minimally worse) (n=0,16,16)	99999	0	0	
EoT (No change) (n=0,16,16)	99999	1	1	
EoT (Minimally improved) (n=0,16,16)	99999	7	7	
EoT (Much improved) (n=0,16,16)	99999	7	7	
EoT (Very much improved) (n=0,16,16)	99999	1	1	
Follow-up (Very Much worse) (n=5,21, 26)	0	0	0	
Follow-up (Much worse) (n=5,21, 26)	1	2	3	
Follow-up (Minimally worse)(n=5,21,26)	0	3	3	
Follow-up (No change) (n=5,21,26)	0	5	5	
Follow-up (Minimally improved) (n=5,21,26)	0	8	8	
Follow-up (Much improved) (n=5,21,26)	3	2	5	
Follow-up (Very much improved) (n=5,21,26)	1	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Change from Baseline in Myasthenia Gravis Foundation of America (MGFA) Classification Score Over Time

End point title	Number of Subjects with Change from Baseline in Myasthenia Gravis Foundation of America (MGFA) Classification Score Over Time

End point description:

MGFA assessed subject's MG severity, identifies subgroup subject with MG sharing distinct clinical features or severity of disease: Class I (ocular MG), classes II, III and IV generalized MG with mild, moderate, severe disease, respectively; Class V MG crisis. Separate subclasses under classes II, III, IV designed: 'a' if predominant weakness affecting limb/axial weakness or both; 'b' if predominant weakness affecting oropharyngeal or respiratory muscles or both. Lower roman numerals mean less severity. Changes in MGFA classification (regardless of subclass) categorized as 'Improved', 'Same', or 'Worsened'. FAS included all subjects who received at least 1 dose of nipocalimab. Number of subjects

analyzed specifies subjects evaluated for this endpoint, 'n' specifies number of subjects evaluated for specific timepoint category, '99999' indicates 0/no subjects analysed in respective arm for EoT. As planned, data is reported both for individual arms and all (total) subjects.

End point type	Secondary

End point timeframe:

Weeks 8, 24 and End of Treatment (EoT) (up to 253 days post-baseline)

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	4	9	13	
Units: subjects				
Week 8 (Improved) (n=4,9,13)	1	5	6	
Week 8 (Same) (n=4,9,13)	3	3	6	
Week 8 (Worsened) (n=4,9,13)	0	1	1	
Week 24 (Improved) (n=1,1, 2)	0	0	0	
Week 24 (Same) (n=1,1, 2)	1	1	2	
Week 24 (Worsened) (n=1,1, 2)	0	0	0	
EoT (Improved) (n=0,8, 8)	99999	4	4	
EoT (Same) (n=0,8,8)	99999	3	3	
EoT (Worsened) (n=0,8,8)	99999	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Anti-drug Antibodies (ADA) to Nipocalimab

End point title	Number of Subjects with Anti-drug Antibodies (ADA) to Nipocalimab

End point description:

Number of subjects with ADA to nipocalimab were reported. The FAS included all subjects who received at least 1 dose of study drug nipocalimab. Here 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As planned, data is reported both for individual arms and all (total) subjects.

End point type	Secondary

End point timeframe:

Up to 257 days post-baseline

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	6	29	35	
Units: subjects	0	3	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Neutralizing Antibodies (NAbs) to Nipocalimab

End point title	Number of Subjects with Neutralizing Antibodies (NAbs) to Nipocalimab

End point description:

Number of subjects with NAbs were reported. Samples positive for ADA in this study were not further analyzed for neutralizing antibodies (NAbs) to nipocalimab due to limited number of subjects developed ADA. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Secondary

End point timeframe:

Up to 257 days post-baseline

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	0[22]	0[23]	0[24]	
Units: subjects				

Notes:

[22] - ADA positive samples not analyzed for NAbs as limited number of subjects developed ADA.

[23] - ADA positive samples not analyzed for NAbs as limited number of subjects developed ADA.

[24] - ADA positive samples not analyzed for NAbs as limited number of subjects developed ADA.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Serum Immunoglobulin (Ig)G Concentration Over Time

End point title	Change from Baseline in Serum Immunoglobulin (Ig)G Concentration Over Time

End point description:

Change from baseline in serum immunoglobulin (Ig)G concentration over time was reported. The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab. Here, 'N' (number of subjects analyzed) specifies all subjects who were evaluated for this endpoint. Here 'n' specifies the number of subjects evaluated for specific timepoints. Here, '99999' indicates that no/0 subjects in the Placebo-Nipocalimab group were analysed at Week 36 and '99999' for Week 24 category indicates standard deviation can not be calculated for 1 subject. As per planned analysis, data is reported for individual arms and for all (total) subjects both.

End point type	Secondary

End point timeframe:

Baseline to Weeks 2, 4, 8, 12, 24, up to 253 days post-baseline, up to 257 days post-baseline

End point values	Placebo-Nipocalimab	Nipocalimab-Nipocalimab	Nipocalimab (All Subjects)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	27	32	
Units: g/L				
arithmetic mean (standard deviation)				
Week 2 (n=5,27,32)	-6.888 (± 0.6104)	-5.457 (± 1.2510)	-5.681 (± 1.2804)	
Week 4 (n=5,26, 31)	-3.234 (± 1.1858)	-2.796 (± 0.9728)	-2.866 (± 1.0014)	
Week 8 (n=5,19, 24)	-2.996 (± 1.3773)	-3.122 (± 1.3466)	-3.095 (± 1.3235)	
Week 12 (n=4,17, 21)	-3.243 (± 1.6378)	-3.639 (± 2.2627)	-3.563 (± 2.1269)	
Week 24 (n=1,5, 6)	-3.870 (± 99999)	-4.072 (± 1.2826)	-4.038 (± 1.1502)	
253 days post-baseline (n=0,14,14)	99999 (± 99999)	-3.494 (± 1.208)	-3.494 (± 1.9208)	
257 days post-baseline (n=5,16, 21)	-1.150 (± 0.5687)	-0.020 (± 1.6162)	-0.289 (± 1.5056)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 257 days post-baseline	
Adverse event reporting additional description:	
The safety analysis set included all subjects who received at least 1 dose of study drug nipocalimab.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups	
Reporting group title	Nipocalimab-Nipocalimab
Reporting group description:	
Subjects who received nipocalimab in MOM-M281-004 study (NCT03772587) rolled-over and received IV infusion of nipocalimab 30 mg/kg Q4W starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).	
Reporting group title	Placebo-Nipocalimab
Reporting group description:	
Subjects who received placebo in MOM-M281-004 study rolled-over and received intravenous (IV) infusion of nipocalimab 30 milligrams per kilogram (mg/kg) every 4 weeks (Q4W) starting Day 1 up to 8 weeks. After 8 weeks of treatment on a stable dose of nipocalimab, the dose and/or dosing frequency could be individually adjusted, at the investigator's discretion to receive maximum dose of 60 mg/kg at a frequency of not exceeding every 2 weeks (Q2W).	

Serious adverse events	Nipocalimab-Nipocalimab	Placebo-Nipocalimab	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 30 (13.33%)	1 / 7 (14.29%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gliosarcoma			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Nervous system disorders			
Myasthenia Gravis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			

Coronavirus Infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Covid-19 Pneumonia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Nipocalimab-Nipocalimab	Placebo-Nipocalimab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 30 (56.67%)	4 / 7 (57.14%)	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Feeling Hot			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Oedema Peripheral			
subjects affected / exposed	3 / 30 (10.00%)	1 / 7 (14.29%)	
occurrences (all)	4	1	
Peripheral Swelling			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Menorrhagia			

subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Increased Viscosity of Upper Respiratory Secretion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Dyspnoea			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal Pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Depressed Mood			
subjects affected / exposed	0 / 30 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Investigations			
Blood Immunoglobulin G Decreased			
subjects affected / exposed	4 / 30 (13.33%)	1 / 7 (14.29%)	
occurrences (all)	4	1	
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	3	0	
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Blood Potassium Decreased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	2	0	

Lymphocyte Count Decreased			
subjects affected / exposed	2 / 30 (6.67%)	0 / 7 (0.00%)	
occurrences (all)	3	0	
Platelet Count Decreased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Neutrophil Count Increased			
subjects affected / exposed	2 / 30 (6.67%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
White Blood Cell Count Increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Foot Fracture			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Foreign Body			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Ligament Sprain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Skin Laceration			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Wound			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 30 (6.67%)	0 / 7 (0.00%)	
occurrences (all)	5	0	
Myasthenia Gravis			

subjects affected / exposed	0 / 30 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Neuropathy Peripheral			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Vertigo Positional			
subjects affected / exposed	0 / 30 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Eye disorders			
Conjunctival Haemorrhage			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Conjunctival Hyperaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 30 (6.67%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Dyspepsia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	2 / 30 (6.67%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Toothache			
subjects affected / exposed	0 / 30 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Vomiting			

subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			
Rash Maculo-Papular			
subjects affected / exposed	0 / 30 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Osteoporosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Pain in Extremity			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Herpes Zoster			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Oral Herpes			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Otitis Media			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Pharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Viral Upper Respiratory Tract Infection			

subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 30 (6.67%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Metabolism and nutrition disorders			
Vitamin B6 Deficiency			
subjects affected / exposed	1 / 30 (3.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 December 2018	The first amendment dated: 03-dec-20218 included following changes: added a medical monitor review of any patient who received rescue therapy during the proof-of-concept (POC) study, before enrollment in this study; deleted text that implied last infusion is given at early termination; added potential risks and plans for mitigation section; added/revised to include a medical monitor review of any patient who received rescue therapy during the POC study, clarification of abstinence, length of abstinence following last statement, acceptable methods of contraception, clarification regarding infection, and clarification of diagnosed Gilbert's disease; revised patient position when measuring blood pressure and window of time when assessments are to be started; added event of pregnancy to individual patient's study drug stopping rules; added a required approval by regulatory authority(ies) before resuming drug.
01 August 2019	The second amendment, dated 01 August 2019, included the following changes: The Clinical Global Impression of Change (CGI-C) is now referred to as the Clinical Global Impression of Improvement (CGI-I); removed all references to the infusion duration. A post infusion safety observation period will only be required for a minimum of the first 2 infusions. Home infusions may be allowed for every other infusion. Deleted Table 2. Section 6 Study Assessments and Procedures, Table 2 Schedule of Assessments Before and After Study Drug Infusion; Added hypoalbuminemia as an AE of special interest; Modified the criterion for exclusionary elevated creatine kinase (CK); Modified exclusion #2 for clarity. Modified exclusion #3 for consistency with the text in Section 6.1.7, C-SSRS and to provide greater clarity to study sites regarding assessment of suicidal ideation/behavior. Modified exclusion #14 to permit patients who have moderate increases in CK at screen, the opportunity to repeat the assessment and potentially qualify for the study if the Investigator believes the elevation is not of pathological origin; added new text regarding the Infusion Manual; added text about allowed nipocalimab dose adjustments. Removed all references to the infusion duration. A post infusion safety observation period will only be required for a minimum of the first 2 infusions; added text regarding the option for home infusions; added text about labeling of nipocalimab supplies; added a Week 10 visit for subjects on a every 2 weeks (Q2W) regimen (with the same assessments as for a regular Q2W or every 4 weeks [Q4W] visit), and clarified that visits every 12 weeks (Q12W) applies to both regimens; added the time frame for reporting a pregnancy in the female partner of a male patient; Converted the CGI-S and CGI-I to 8-point scales (formerly 7-point scales).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
	Study was originally halted due to the COVID-19 pandemic. The study was later terminated prematurely due to the continuing COVID-19 pandemic, and because as the subjects will have the option to enter into an open-label extension portion of a planned future study. It was not due to safety concerns.	-

Notes:

Limitations and caveats

None reported