Clinical trial results:
A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacokinetics, and Pharmacodynamics of Nipocalimab Administered to Adults with Generalized Myasthenia Gravis

Summary

EudraCT number	2018-002247-28
Trial protocol	GB BE PL ES IT
Global end of trial date	25 June 2020

Results information

Result version number	v1
This version publication date	07 July 2021
First version publication date	07 July 2021

Trial information

Trial identification

Sponsor protocol code	MOM-M281-004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03772587
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	25 June 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 June 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this trial was to evaluate the efficacy of nipocalimab for generalized myasthenia gravis (gMG) as measured by the change in Myasthenia Gravis – Activities of Daily Living (MG-ADL) score and to evaluate the safety and tolerability of treatment with nipocalimab in subjects with gMG who have an insufficient clinical response to ongoing, stable standard of care therapy.

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), 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	18 December 2018
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	Belgium: 1
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	United States: 25
Worldwide total number of subjects	68
EEA total number of subjects	34

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)	43
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 68 subjects were randomized and treated with study drug, with 65 subjects completing the study.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received intravenous (IV) infusion of placebo matching to nipocalimab once every 2 weeks (Q2W) starting Day 1 up to Day 57.

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

Dosage and administration details:

Matching placebo was administered as IV infusion once Q2W starting Day 1 up to Day 57.

Arm title	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)

Arm description:

Subjects received IV infusion of 5 mg/kg nipocalimab once every 4 weeks (Q4W) starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.

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

Dosage and administration details:

Matching placebo was administered as IV infusion on Days 15 and 43 to maintain the blinding.

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

Dosage and administration details:

Nipocalimab 5 mg/kg was administered once Q4W as IV infusion starting Day 1 up to Day 57.

Arm title	Nipocalimab 30 mg/kg

Arm description:

Subjects received IV infusion of 30 mg/kg nipocalimab once Q4W starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.

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

Dosage and administration details:

Matching placebo was administered as IV infusion on Days 15 and 43 to maintain the blinding.

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 Day 57.

Arm title	Nipocalimab 60 mg/kg

Arm description:

Subjects received IV infusion of 60 mg/kg nipocalimab single dose on Day 1. To maintain blinding, subjects received matching placebo on Days 15, 29, 43 and 57.

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 60 mg/kg single dose was administered as IV infusion on Day 1.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Matching placebo was administered as IV infusion on Days 15, 29, 43 and 57 to maintain the blind.

Arm title	Nipocalimab 60 mg/kg (Q2W)

Arm description:

Subjects received IV infusion of 60 mg/kg nipocalimab once Q2W starting Day 1 up to Day 57.

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 60 mg/kg was administered once Q2W as IV infusion starting Day 1 up to Day 57.

Number of subjects in period 1	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg
Started	14	14	13
Completed	13	14	12
Not completed	1	0	1
Consent withdrawn by subject	1	-	-
Covid-19	-	-	1

Number of subjects in period 1	Nipocalimab 60 mg/kg	Nipocalimab 60 mg/kg (Q2W)
Started	13	14
Completed	12	14
Not completed	1	0
Consent withdrawn by subject	-	-
Covid-19	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received intravenous (IV) infusion of placebo matching to nipocalimab once every 2 weeks (Q2W) starting Day 1 up to Day 57.	
Reporting group title	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)
Reporting group description:	
Subjects received IV infusion of 5 mg/kg nipocalimab once every 4 weeks (Q4W) starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.	
Reporting group title	Nipocalimab 30 mg/kg
Reporting group description:	
Subjects received IV infusion of 30 mg/kg nipocalimab once Q4W starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.	
Reporting group title	Nipocalimab 60 mg/kg
Reporting group description:	
Subjects received IV infusion of 60 mg/kg nipocalimab single dose on Day 1. To maintain blinding, subjects received matching placebo on Days 15, 29, 43 and 57.	
Reporting group title	Nipocalimab 60 mg/kg (Q2W)
Reporting group description:	
Subjects received IV infusion of 60 mg/kg nipocalimab once Q2W starting Day 1 up to Day 57.	

Reporting group values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg
Number of subjects	14	14	13
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	8	9	9
From 65 to 84 years	6	5	4
85 years and over	0	0	0
Title for AgeContinuous			
Units: years			
arithmetic mean	57.7	54.8	49
standard deviation	± 17.85	± 17.64	± 19.54
Title for Gender			
Units: subjects			
Female	8	6	9
Male	6	8	4

Reporting group values	Nipocalimab 60 mg/kg	Nipocalimab 60 mg/kg (Q2W)	Total
Number of subjects	13	14	68
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	9	8	43

From 65 to 84 years	4	6	25
85 years and over	0	0	0

Title for AgeContinuous Units: years			
arithmetic mean	53.1	59.9	
standard deviation	± 15.4	± 15.03	-
Title for Gender Units: subjects			
Female	9	5	37
Male	4	9	31

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received intravenous (IV) infusion of placebo matching to nipocalimab once every 2 weeks (Q2W) starting Day 1 up to Day 57.	
Reporting group title	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)
Reporting group description:	
Subjects received IV infusion of 5 mg/kg nipocalimab once every 4 weeks (Q4W) starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.	
Reporting group title	Nipocalimab 30 mg/kg
Reporting group description:	
Subjects received IV infusion of 30 mg/kg nipocalimab once Q4W starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.	
Reporting group title	Nipocalimab 60 mg/kg
Reporting group description:	
Subjects received IV infusion of 60 mg/kg nipocalimab single dose on Day 1. To maintain blinding, subjects received matching placebo on Days 15, 29, 43 and 57.	
Reporting group title	Nipocalimab 60 mg/kg (Q2W)
Reporting group description:	
Subjects received IV infusion of 60 mg/kg nipocalimab once Q2W starting Day 1 up to Day 57.	

Primary: Number of Subjects with Treatment-emergent Adverse Event (TEAEs) as a Measure of Safety and Tolerability

End point title	Number of Subjects with Treatment-emergent Adverse Event (TEAEs) as a Measure of Safety and Tolerability[1]
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. TEAEs are defined as any AE occurring during or after the initiation of the first infusion of study drug. The Safety Population included all subjects who received any amount of nipocalimab or placebo.	
End point type	Primary
End point timeframe:	
Up to Day 113	

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 (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	13	13
Units: subjects	11	12	9	12

End point values	Nipocalimab 60			

	mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: subjects	12			

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 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. 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 population included all subjects who received any amount of nipocalimab or placebo.

End point type	Primary

End point timeframe:

Up to Day 113

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 (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	13	13
Units: subjects	2	0	1	0

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: subjects	0			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An 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. For this study, any common terminology criteria for adverse events (CTCAE) Grade 3 or higher event of severe infection or hypoalbuminemia was considered as AESI. The safety population included all subjects who received any amount of nipocalimab or placebo.

End point type	Primary

End point timeframe:

Up to Day 113

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 (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	13	13
Units: subjects	0	0	0	0

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: subjects	0			

Statistical analyses

No statistical analyses for this end point

Primary: Change from Baseline to Day 57 in the Myasthenia Gravis – Activities of Daily Living (MG-ADL) Total Score

End point title	Change from Baseline to Day 57 in the Myasthenia Gravis – Activities of Daily Living (MG-ADL) Total Score[4]

End point description:

MG-ADL assesses the subject's MG symptom severity. It assesses eight 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) on a 4-point rating scale: 0 (no impairment) to 3 (severe impairment). The total score is the sum of the eight function scores ranging from 0 to 24. Higher scores indicated greater symptom severity/difficulty in performing daily living activities. Intent-to-treat (ITT) population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint.

End point type	Primary

End point timeframe:

Baseline to Day 57

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 (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	12	13
Units: score on a scale				
arithmetic mean (standard deviation)	-1.8 (± 3.22)	-2.5 (± 2.41)	-3.9 (± 3.00)	-1.5 (± 2.82)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: score on a scale				
arithmetic mean (standard deviation)	-3.9 (± 3.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Model Predicated Change From Baseline in Total MG-ADL Score as a Function of Total Serum Immunoglobulin G (IgG) at Day 57

End point title	Model Predicated Change From Baseline in Total MG-ADL Score as a Function of Total Serum Immunoglobulin G (IgG) at Day 57

End point description:

MG-ADL assesses subject's MG symptom severity. It assesses eight 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) on a 4-point scale rating scale: 0 (no impairment) to 3 (severe impairment). Total score is sum of eight function scores ranging from 0 to 24. Higher scores indicated greater symptom severity/difficulty in performing daily living activities. Higher IgG lowering indicated higher MG-ADL score reductions. Analysis for this endpoint was performed via Pharmacokinetic/Pharmacodynamic (PK/PD) modelling as planned. ITT population included all randomized subjects. Here '99999' indicates that data for this endpoint was analyzed graphically based on Model prediction for evaluating relationship between MG-ADL and IgG; no descriptive statistics was performed.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	13	13
Units: score on a scale				
arithmetic mean (standard deviation)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: score on a scale				
arithmetic mean (standard deviation)	9999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total MG-ADL Score as a Response to Percent Change in Total Serum IgG, for Subjects Positive for Anti-acetylcholine Receptor (Anti-AChR) Antibodies, at Day 57

End point title	Change From Baseline in Total MG-ADL Score as a Response to Percent Change in Total Serum IgG, for Subjects Positive for Anti-acetylcholine Receptor (Anti-AChR) Antibodies, at Day 57

End point description:

MG-ADL assesses subject’s MG symptom severity. It assesses eight 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) on a 4-point scale rating : 0 (no impairment) to 3 (severe impairment). Total score is sum of eight function scores ranging from 0 to 24. Higher scores indicated greater symptom severity/difficulty in performing daily living activities. Higher IgG lowering indicated higher MG-ADL score reductions. ITT population included all randomized subjects. Here '99999' indicates that 90 percent (%) of subjects were positive for Anti-AChR antibodies. In that case, data of anti-AChR positive subgroup must be same as of total population, so analyses for subgroup was not performed. Data for total population was analyzed graphically based on Model prediction for evaluating the relationship between MG-ADL and IgG; no descriptive statistics was performed.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	13	13
Units: score on a scale				
arithmetic mean (standard deviation)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: score on a scale				
arithmetic mean (standard deviation)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Model Predicted Change From Baseline in Total Quantitative Myasthenia Gravis (QMG) Score as a Function of Total Serum IgG at Day 57

End point title	Model Predicted Change From Baseline in Total Quantitative Myasthenia Gravis (QMG) Score as a Function of Total Serum IgG at Day 57

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. Subjects with higher IgG lowering tended to have higher QMG score reductions. Analysis for this endpoint was performed via Pharmacokinetic/Pharmacodynamic (PK/PD) modelling as planned. ITT population included all randomized subjects. Here '99999' indicates that data for this endpoint was captured graphically based on Model prediction for evaluating relationship between QMG and IgG; no descriptive statistics was performed.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	13	13
Units: score on a scale				
arithmetic mean (standard deviation)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: score on a scale				
arithmetic mean (standard deviation)	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total QMG Score as a Response to Percent Change in Total Serum IgG, for Subjects Positive for Anti-acetylcholine Receptor (Anti-AChR) Antibodies, at Day 57

End point title	Change From Baseline in Total QMG Score as a Response to Percent Change in Total Serum IgG, for Subjects Positive for Anti-acetylcholine Receptor (Anti-AChR) Antibodies, at Day 57

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. Subjects with higher IgG lowering tended to have higher QMG score reductions. ITT population included all randomized subjects. Here '99999' indicates that 90 % of the subjects were positive for Anti-AChR antibodies. In that case, data of the anti-AChR positive subgroup must be same as of total population, so analyses for the subgroup was not performed. Data for total population was analyzed graphically based on Model prediction for evaluating the relationship between QMG and IgG; no descriptive statistics was performed.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	14	13	13
Units: score on a scale				
arithmetic mean (standard deviation)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Nipocalimab 60 mg/kg (Q2W)			

Subject group type	Reporting group			
Number of subjects analysed	14			
Units: score on a scale				
arithmetic mean (standard deviation)	99999 (± 99999)			

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 at Day 57

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 at Day 57

End point description:

MG-ADL assesses the subject's MG symptom severity. It assesses eight 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) on a 4-point scale rating scale: 0 (no impairment) to 3 (severe impairment). The total score is the sum of the eight function scores ranging from 0 to 24. Higher scores indicated greater symptom severity/difficulty in performing daily living activities. Population analyzed included ITT subjects for whom data was available at Day 57.

End point type	Secondary

End point timeframe:

Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	12	13
Units: subjects				
2-point Improved	7	9	10	7
3-point Improved	5	9	8	5
4-point Improved	1	5	5	3
5-point Improved	1	2	5	2
6-point Improved	1	1	3	1
7-point Improved	1	1	3	0
>= 8-point Improved	1	0	1	0

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: subjects				
2-point Improved	12			

3-point Improved	11			
4-point Improved	7			
5-point Improved	6			
6-point Improved	3			
7-point Improved	2			
>= 8-point Improved	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total QMG Score at Day 57

End point title	Change From Baseline in Total QMG Score at Day 57

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. ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	13	10	11
Units: score on a scale				
arithmetic mean (standard deviation)	-3.7 (± 2.94)	-3.5 (± 4.10)	-4.1 (± 3.45)	-1.5 (± 2.54)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: score on a scale				
arithmetic mean (standard deviation)	-5.9 (± 5.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With a 3-, 4-, 5-, 6-, 7-, or >= 8-point Improvement in Total QMG Score at Day 57

End point title	Number of Subjects With a 3-, 4-, 5-, 6-, 7-, or >= 8-point Improvement in Total QMG Score at Day 57

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. Population analyzed included ITT subjects for whom data was available at Day 57.

End point type	Secondary

End point timeframe:

Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	13	10	11
Units: subjects				
3-point Improved	8	6	6	4
4-point Improved	5	5	6	3
5-point Improved	5	5	5	1
6-point Improved	2	5	4	1
7-point Improved	2	5	1	0
>= 8-point Improved	2	3	1	0

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: subjects				
3-point Improved	10			
4-point Improved	10			
5-point Improved	8			
6-point Improved	5			
7-point Improved	3			
>= 8-point Improved	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Revised Myasthenia Gravis Quality of Life - 15 (MG-QoL-15r) Scale Score at Day 57

End point title	Change From Baseline in Total Revised Myasthenia Gravis Quality of Life - 15 (MG-QoL-15r) Scale Score at Day 57

End point description:

The MG-QoL15r was used to assess the subject's limitations related to living with MG. Each of the 15 questions were rated by the subject on a 3-point scale (0= Not at all, 1= somewhat, 2=very much) based on a recall period of "over the past few weeks". The total score is the sum of the 15 question scores and ranges from 0 to 30. Higher scores indicated more limitation. ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	12	13
Units: score on a scale				
arithmetic mean (standard deviation)	-2.0 (± 4.58)	-1.7 (± 4.16)	-6.8 (± 5.73)	-1.2 (± 1.91)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: score on a scale				
arithmetic mean (standard deviation)	-3.7 (± 5.37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Serum IgG at Day 57

End point title	Change From Baseline in Total Serum IgG at Day 57

End point description:

Change from baseline in total serum IgG was reported. Blood samples were collected for analysis of total serum IgG. ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	13	10	11
Units: gram/liter (g/L)				
arithmetic mean (standard deviation)	-0.3 (± 1.82)	-1.5 (± 1.01)	-3.4 (± 1.01)	-1.7 (± 1.23)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: gram/liter (g/L)				
arithmetic mean (standard deviation)	-7.6 (± 2.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total MG-ADL Score at Day 85 and 113

End point title	Change from Baseline in Total MG-ADL Score at Day 85 and 113

End point description:

MG-ADL assesses the subject’s MG symptom severity. It assesses eight 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) on a 4-point rating scale: 0 (no impairment) to 3 (severe impairment). The total score is the sum of the eight function scores ranging from 0 to 24. Higher scores indicated greater symptom severity/difficulty in performing daily living activities. ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint and 'n' (number analyzed) included the number of subjects evaluated for specific timepoints.

End point type	Secondary

End point timeframe:

Baseline, Day 85 and Day 113

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	12	13
Units: score on a scale				
arithmetic mean (standard deviation)				
Day 85 (n=11, 14, 11, 13, 14)	-2.2 (± 2.64)	-2.1 (± 2.40)	-3.7 (± 2.69)	-1.9 (± 2.29)
Day 113 (n=12, 14, 12, 12, 14)	-2.6 (± 3.09)	-1.0 (± 2.25)	-2.8 (± 2.33)	-2.4 (± 2.78)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: score on a scale				
arithmetic mean (standard deviation)				
Day 85 (n=11, 14, 11, 13, 14)	-3.6 (± 2.79)			
Day 113 (n=12, 14, 12, 12, 14)	-2.6 (± 3.30)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total QMG Score at Day 85 and 113

End point title	Change from Baseline in Total QMG Score at Day 85 and 113

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. ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint and 'n' (number analyzed) included the number of subjects evaluated for specific timepoints.

End point type	Secondary

End point timeframe:

Baseline, Day 85 and Day 113

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	14	10	9
Units: score on a scale				
arithmetic mean (standard deviation)				
Day 85 (n=10, 13, 9, 9, 13)	-4.0 (± 2.62)	-3.6 (± 3.23)	-4.8 (± 2.49)	-2.0 (± 2.60)
Day 113 (n=9, 14, 10, 9 12)	-4.7 (± 3.04)	-2.1 (± 2.40)	-4.2 (± 3.08)	-3.2 (± 2.28)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: score on a scale				
arithmetic mean (standard deviation)				

Day 85 (n=10, 13, 9, 9, 13)	-5.1 (± 3.52)			
Day 113 (n=9, 14, 10, 9 12)	-3.3 (± 5.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Total MG-QoL15r Score at Day 85 and 113

End point title	Change from Baseline in Total MG-QoL15r Score at Day 85 and 113

End point description:

The MG-QoL15r was used to assess the subject's limitations related to living with MG. Each of the 15 questions were rated by the subject on a 3-point scale (0= Not at all, 1= somewhat, 2=very much) based on a recall period of "over the past few weeks". The total score is the sum of the 15 question scores and ranges from 0 to 30. Higher scores indicated more limitation. ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint and 'n' (number analyzed) included the number of subjects evaluated for specific timepoints.

End point type	Secondary

End point timeframe:

Baseline, Day 85 and Day 113

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	12	13
Units: score on a scale				
arithmetic mean (standard deviation)				
Day 85 (n=11, 14, 11, 13, 13)	-2.5 (± 2.84)	-2.9 (± 3.74)	-6.5 (± 5.66)	-0.7 (± 4.25)
Day 113 (n= 12, 14, 12, 12, 13)	-3.2 (± 3.90)	-1.6 (± 4.20)	-4.2 (± 4.32)	-1.0 (± 2.92)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: score on a scale				
arithmetic mean (standard deviation)				
Day 85 (n=11, 14, 11, 13, 13)	-3.5 (± 5.61)			
Day 113 (n= 12, 14, 12, 12, 13)	-2.5 (± 6.09)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Shift From Baseline in Myasthenia Gravis Foundation of America (MGFA) Classification at Day 57

End point title	Number of Subjects with Shift From Baseline in Myasthenia Gravis Foundation of America (MGFA) Classification at Day 57

End point description:

MGFA classification identifies subgroup subjects with MG who share distinct clinical features/severity of disease: Class I (ocular MG), classes II, III and IV generalized MG with mild, moderate and severe disease, respectively; Class V MG crisis. Separate subclasses under classes II, III and IV designed as: "a" if predominant weakness is affecting limb/axial weakness or both; subclass "b" if predominant weakness is affecting oropharyngeal or respiratory muscles or both. Lower roman numerals mean less severity. Changes in MGFA classification (regardless of subclass) are categorized as "Improved" (example, III to II), "Same" (example, II to II), or "Worsened" (example, II to III). ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline and Day 57

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	11	12
Units: subjects				
Improved	6	3	7	4
Same	6	9	3	8
Worsened	0	0	1	0

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: subjects				
Improved	7			
Same	4			
Worsened	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Shift From Baseline in MGFA Classification to Day 113

End point title	Number of Subjects with Shift From Baseline in MGFA Classification to Day 113

End point description:

MGFA classification identifies subgroup subjects with MG who share distinct clinical features/severity of disease: Class I (ocular MG), classes II, III and IV generalized MG with mild, moderate and severe disease, respectively; Class V MG crisis. Separate subclasses under classes II, III and IV designed as: “a” if predominant weakness is affecting limb/axial weakness or both; subclass “b” if predominant weakness is affecting oropharyngeal or respiratory muscles or both. Lower roman numerals mean less severity. Changes in MGFA classification (regardless of subclass) are categorized as "Improved" (example, III to II), "Same" (example, II to II), or "Worsened" (example, II to III). ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint.

End point type	Secondary

End point timeframe:

Baseline to Day 113

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	8	7
Units: subjects				
Improved	3	2	3	2
Same	6	5	4	5
Worsened	0	2	1	0

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: subjects				
Improved	3			
Same	5			
Worsened	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Serum IgG at Day 85 and 113

End point title	Change From Baseline in Total Serum IgG at Day 85 and 113

End point description:

Change from baseline in total serum IgG at Day 85 and Day 113 was reported. Blood samples were collected for analysis of total serum IgG. ITT population included all randomized subjects. Here 'N' (number of subjects analyzed) included all subjects who were evaluated for this endpoint and 'n' (number analyzed) included the number of subjects evaluated for specific timepoints.

End point type	Secondary

End point timeframe:

Baseline, Day 85 and Day 113

End point values	Placebo	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	14	11	9
Units: g/L				
arithmetic mean (standard deviation)				
Day 85 (n=11, 13, 10, 9, 13)	-0.5 (± 1.02)	-1.4 (± 1.93)	-3.8 (± 1.28)	-1.2 (± 1.02)
Day 113 (n= 10,14, 11, 9, 12)	-0.6 (± 1.19)	-0.7 (± 1.48)	-1.2 (± 0.78)	-0.7 (± 1.09)

End point values	Nipocalimab 60 mg/kg (Q2W)			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: g/L				
arithmetic mean (standard deviation)				
Day 85 (n=11, 13, 10, 9, 13)	-5.7 (± 2.30)			
Day 113 (n= 10,14, 11, 9, 12)	-2.2 (± 1.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentrations of Nipocalimab

End point title	Serum Concentrations of Nipocalimab[5]

End point description:

Serum concentrations of nipocalimab were reported. Concentrations below the lowest quantifiable concentration (less than [<] LLOQ) that is < 0.15 microgram/milliliter (mcg/mL) was treated as zero in calculating the summary statistics. The safety population included all subjects who received any amount of nipocalimab or placebo. Here 'n' (number analyzed) included the number of subjects evaluated for specific timepoints.

End point type	Secondary

End point timeframe:

Baseline (Pre Infusion and Post Infusion), Day 15 (Pre Infusion), Day 29 (Pre Infusion), Day 43 (Pre Infusion), Day 57 (Pre Infusion and Post Infusion) and Day 85

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: Statistical Analysis was not planned for all the arms of Baseline period.

End point values	Nipocalimab (M281) 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg	Nipocalimab 60 mg/kg	Nipocalimab 60 mg/kg (Q2W)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	13	13	14
Units: micrograms/milliliter (mcg/mL)				
arithmetic mean (standard deviation)				
Baseline (Pre Infusion) (n=14,12, 13,14)	0.0 (± 0.0)	0.02 (± 0.066)	0.0 (± 0.0)	0.0 (± 0.0)
Baseline (Post Infusion) (n=13, 12, 13, 14)	107.35 (± 39.826)	708.07 (± 95.185)	1739.93 (± 287.127)	1794.93 (± 1308.695)
Day 15 (Pre Infusion) (n=13,13, 13,14)	0.0 (± 0.0)	0.0 (± 0.0)	22.56 (± 36.198)	25.38 (± 33.402)
Day 29 (Pre Infusion) (n=14,10, 11,14)	0.0 (± 0.0)	0.02 (± 0.052)	0.0 (± 0.0)	58.34 (± 113.158)
Day 43 (Pre Infusion) (n=14,12, 11,14)	0.0 (± 0.0)	0.0 (± 0.0)	0.0 (± 0.0)	61.28 (± 80.513)
Day 57 (Pre Infusion) (n=13,10, 11,13)	0.0 (± 0.0)	0.02 (± 0.071)	0.0 (± 0.0)	35.95 (± 54.440)
Day 57 (Post Infusion) (n=12,9,11, 13)	105.65 (± 43.331)	752.47 (± 154.608)	0.0 (± 0.0)	1568.92 (± 288.500)
Day 85 (n=13, 10, 9, 13)	0.0 (± 0.0)	0.03 (± 0.08)	0.0 (± 0.0)	0.0 (± 0.0)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to Day 113	
Adverse event reporting additional description:	
The safety population included all subjects who received any amount of nipocalimab or placebo.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received intravenous (IV) infusion of placebo matching to nipocalimab once every 2 weeks (Q2W) starting Day 1 up to Day 57.	
Reporting group title	Nipocalimab 5 milligrams/kilogram (mg/kg)
Reporting group description:	
Subjects received IV infusion of 5 mg/kg nipocalimab once every 4 weeks (Q4W) starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.	
Reporting group title	Nipocalimab 30 mg/kg
Reporting group description:	
Subjects received IV infusion of 30 mg/kg nipocalimab once Q4W starting Day 1 up to Day 57. To maintain blinding, subjects received matching placebo on Days 15 and 43.	
Reporting group title	Nipocalimab 60 mg/kg
Reporting group description:	
Subjects received IV infusion of 60 mg/kg nipocalimab single dose on Day 1. To maintain blinding, subjects received matching placebo on Days 15, 29, 43 and 57.	
Reporting group title	Nipocalimab 60 mg/kg (Q2W)
Reporting group description:	
Subjects received IV infusion of 60 mg/kg nipocalimab once Q2W starting Day 1 up to Day 57.	

Serious adverse events	Placebo	Nipocalimab 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 14 (14.29%)	0 / 14 (0.00%)	1 / 13 (7.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Ischaemic Stroke			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (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
Myasthenia Gravis			

subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (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
Musculoskeletal and connective tissue disorders			
Musculoskeletal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Nipocalimab 60 mg/kg	Nipocalimab 60 mg/kg (Q2W)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Nervous system disorders			
Ischaemic Stroke			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia Gravis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (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: 5 %

Non-serious adverse events	Placebo	Nipocalimab 5 milligrams/kilogram (mg/kg)	Nipocalimab 30 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 14 (71.43%)	12 / 14 (85.71%)	8 / 13 (61.54%)

Vascular disorders			
Brachiocephalic Vein Thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	2 / 14 (14.29%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Hypotension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Feeling Cold			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Feeling Hot			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infusion Site Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vessel Puncture Site Pruritus			

subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vessel Puncture Site Swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oropharyngeal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Bacterial Test			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Blood Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood Pressure Increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Carbohydrate Antigen 19-9 Increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Helicobacter Test Positive			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Liver Function Test Increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Lymphocyte Count Decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Neutrophil Count Increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Neutrophil Percentage Increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urine Analysis Abnormal			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Weight Decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Fall			

subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Limb Injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Muscle Rupture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Muscle Strain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Palate Injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin Laceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Spinal Compression Fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	4
Dysgeusia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 14 (7.14%)	2 / 14 (14.29%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Hypoaesthesia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mononeuropathy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Myasthenia Gravis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Presyncope			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tension Headache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	3
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Eye Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eyelid Ptosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			

subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 14 (7.14%)	1 / 14 (7.14%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gastric Ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
Salivary Hypersecretion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	5	0
Skin and subcutaneous tissue disorders			
Dermatitis Allergic			

subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rash Erythematous			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin Swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Swelling Face			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Muscle Spasms			

subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Muscle Twitching			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neck Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Spinal Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Hordeolum			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 14 (7.14%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Urinary Tract Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Glucose Tolerance Impaired			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 14 (7.14%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 14 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Nipocalimab 60 mg/kg	Nipocalimab 60 mg/kg (Q2W)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 13 (92.31%)	12 / 14 (85.71%)	
Vascular disorders			
Brachiocephalic Vein Thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Feeling Cold			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Feeling Hot			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Hernia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Infusion Site Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Malaise			

subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Oedema Peripheral			
subjects affected / exposed	1 / 13 (7.69%)	2 / 14 (14.29%)	
occurrences (all)	1	2	
Peripheral Swelling			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Vessel Puncture Site Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Vessel Puncture Site Swelling			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Catarrh			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Dysphonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Investigations			

Alanine Aminotransferase Increased				
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)		
occurrences (all)	1	0		
Aspartate Aminotransferase Increased				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Bacterial Test				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood Creatine Phosphokinase Increased				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood Pressure Increased				
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)		
occurrences (all)	0	1		
Carbohydrate Antigen 19-9 Increased				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Helicobacter Test Positive				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Liver Function Test Increased				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Lymphocyte Count Decreased				
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)		
occurrences (all)	0	2		
Neutrophil Count Increased				
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Neutrophil Percentage Increased				
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)		
occurrences (all)	0	1		
Urine Analysis Abnormal				

subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Weight Decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Limb Injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Muscle Rupture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Muscle Strain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Palate Injury			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Skin Laceration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Spinal Compression Fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			

Dizziness			
subjects affected / exposed	2 / 13 (15.38%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Dysgeusia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	2 / 13 (15.38%)	1 / 14 (7.14%)	
occurrences (all)	7	1	
Hypoaesthesia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Mononeuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Myasthenia Gravis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Tension Headache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Eye disorders			

Blepharitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Eye Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Eyelid Ptosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Vision Blurred			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal Pain Upper			
subjects affected / exposed	1 / 13 (7.69%)	1 / 14 (7.14%)	
occurrences (all)	1	1	
Constipation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	2 / 13 (15.38%)	2 / 14 (14.29%)	
occurrences (all)	3	2	
Dysphagia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Gastric Ulcer			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Salivary Hypersecretion			

subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Dermatitis Allergic			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Erythema			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	0 / 13 (0.00%)	3 / 14 (21.43%)	
occurrences (all)	0	3	
Rash Erythematous			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Skin Swelling			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Swelling Face			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Arthritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Back Pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 14 (7.14%)	
occurrences (all)	1	1	
Muscle Spasms			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Muscle Twitching			
subjects affected / exposed	1 / 13 (7.69%)	1 / 14 (7.14%)	
occurrences (all)	1	1	
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Musculoskeletal Pain			
subjects affected / exposed	2 / 13 (15.38%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Neck Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Spinal Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Bronchitis			

subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Herpes Zoster			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Hordeolum			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Nasopharyngitis			
subjects affected / exposed	2 / 13 (15.38%)	2 / 14 (14.29%)	
occurrences (all)	2	3	
Pharyngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Urinary Tract Infection			

subjects affected / exposed	0 / 13 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Glucose Tolerance Impaired			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 October 2018	Provided information on potential risks and plans for mitigation to enhance patient safety; Revised inclusion criteria to clarify definition of abstinence, duration of contraception/avoidance of pregnancy following last study treatment for males, and acceptable methods of contraception; Added pregnancy as a drug stopping rule for an individual subject; Added a requirement for approval by regulatory authority(ies) before resuming drug, if study treatment had been temporarily held because of meeting a stopping rule.
11 December 2018	Added MGFA Clinical Classification as an efficacy assessment, to be done at screening, baseline, Day 57, and Day 113; Expanded the number of study centers from 45 to 60; Added provisions for specific circumstances under which subjects who had an equivocal QuantiFERON®-TB Gold retest, and for subjects who had been treated for hepatitis C virus (HCV) could be enrolled; Added a time window for post-infusion vital sign assessments, and changed positioning of subject for vital sign measurements from supine to recumbent; Added more information about pregnancy reporting procedures (including SAEs associated with a pregnancy after the subject has completed the study and considered possibly related to the study agent), and added a provision for collecting information on pregnancy outcomes; Added a test for urine myoglobin, only to be done if serum creatine kinase was elevated; Clarified the assessments to be completed for subjects who discontinued from study treatment.
04 June 2019	Changed from plasma to serum for the pharmacokinetic (PK) blood samples; Removed the Day 8 study visit and associated assessments; The infusion duration was reduced and requirements for post-infusion safety procedure/observation were relaxed based on data obtained from a study of nipocalimab infusion rates in healthy adults (MOM-M281-007). Details were provided in the Infusion Manual; Added Grade 3 or higher hypoalbuminemia as an adverse event of special interest; Added a provision to the inclusion criterion to allow enrollment of subjects on immunomodulatory agents whose IgG level is not lower than 75% of the lower limit of normal; Added an inclusion criterion that, under certain conditions, allowed enrollment of subjects who had undergone splenectomy (formerly, splenectomy was exclusionary); Specified that a suicidal ideation score of 4 or 5 on the C-SSRS was exclusionary (Exclusion number 9); Allowed enrollment of subjects with a family history of congenital or hereditary immunodeficiency if the condition was confirmed absent in the subject; Allowed enrollment of subjects with spontaneous resolution of HCV if the serum HCV ribonucleic acid level was negative; Under certain conditions, allowed enrollment of subjects with creatine kinase >= 2*upper limit of normal (ULN) and <5*ULN; Allowed the option for the study center to source the supplies used for placebo and to store the placebo according to the package insert; For subjects not entering the open-label extension study, added a requirement for follow-up of subjects with total serum IgG of <600 milligram/deciliter (mg/dL) at Day 113 until the IgG is >= 600 mg/dL; Relaxed the requirement for administration of the MG-ADL and QMG by a clinician/physician to administration by any trained qualified healthcare professional; Post-infusion samples were no longer required after every infusion, only as specified in the Infusion Manual (after the first infusion and after the Day 57 infusion).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Limitations to this study include the small sample sizes of each treatment arm and the study activity disruption due to the COVID-19 pandemic, especially the missed QMG assessments which hampered the analysis of the endpoint.

Notes: