



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 standard deviation | 53.1 ± 15.4 | 59.9 ± 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 (\pm 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 (\geq) 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 (\geq) 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 |
| \geq 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 \geq 8-point Improvement in Total QMG Score at Day 57

| | |
|-----------------|--|
| End point title | Number of Subjects With a 3-, 4-, 5-, 6-, 7-, or \geq 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 |
| \geq 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 | | | |
| \geq 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: | |
| <p>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.</p> | |
| 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

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 occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Vessel Puncture Site Swelling subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Catarrh subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 1 / 13 (7.69%) 1 |
| Oropharyngeal Pain subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Investigations Alanine Aminotransferase Increased subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 1 / 14 (7.14%) 1 | 0 / 13 (0.00%) 0 |
| Aspartate Aminotransferase Increased subjects affected / exposed occurrences (all) | 1 / 14 (7.14%) 1 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 0 |
| Bacterial Test subjects affected / exposed occurrences (all) | 0 / 14 (0.00%) 0 | 1 / 14 (7.14%) 1 | 0 / 13 (0.00%) 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 occurrences (all) | 0 / 14 (0.00%) 0 | 0 / 14 (0.00%) 0 | 0 / 13 (0.00%) 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 occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Oedema Peripheral subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | 2 / 14 (14.29%) 2 | |
| Peripheral Swelling subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Vessel Puncture Site Pruritus subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Vessel Puncture Site Swelling subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | 0 / 14 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Catarrh subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 14 (0.00%) 0 | |
| Cough subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Dyspnoea subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 14 (0.00%) 0 | |
| Oropharyngeal Pain subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | 0 / 14 (0.00%) 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 occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 14 (0.00%) 0 | |
| Toothache subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | 0 / 14 (0.00%) 0 | |
| Vomiting subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Allergic subjects affected / exposed occurrences (all) | 1 / 13 (7.69%) 1 | 0 / 14 (0.00%) 0 | |
| Erythema subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Pruritus subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Rash subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 3 / 14 (21.43%) 3 | |
| Rash Erythematous subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Skin Swelling subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Swelling Face subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 14 (0.00%) 0 | |
| Endocrine disorders | | | |
| Hypothyroidism subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 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 | | | |

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|-----------------------------------|-----------------|-----------------|
| 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 occurrences (all) | 0 / 13 (0.00%) 0 | 2 / 14 (14.29%) 2 | |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 14 (0.00%) 0 | |
| Metabolism and nutrition disorders | | | |
| Glucose Tolerance Impaired | | | |
| subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 1 | |
| Hyperglycaemia | | | |
| subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 0 / 14 (0.00%) 0 | |
| Hypophosphataemia | | | |
| subjects affected / exposed occurrences (all) | 0 / 13 (0.00%) 0 | 1 / 14 (7.14%) 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 $\geq 2 \times$ upper limit of normal (ULN) and $< 5 \times$ 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: