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Effect of Nipocalimab on Sustained Myasthenia Gravis Control During Infections: Post-hoc Analysis of the Vivacity-MG3 Study

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Key Takeaways

- **Incidence of infections and infestations in the nipocalimab+SOC arm were comparable to that in the placebo+SOC arm**
- **MG-ADL and QMG scores remained stable during infections, demonstrating sustained improvement in gMG symptoms and maintenance of disease control with nipocalimab+SOC treatment**
- **Comparable results were seen in the primary efficacy and safety analysis sets for infection duration (overall, moderate, and severe) and for MG-ADL and QMG scores**

Introduction

- Generalized myasthenia gravis (gMG) is an autoantibody-driven disorder characterized by disruption of neurotransmission that severely affects daily functioning and quality of life in patients[1,2]
- Nipocalimab is the first and the only FcRn blocker approved for the treatment of gMG in anti-acetylcholine receptor (AChR) or anti-muscle-specific kinase (MuSK) antibody-positive adult and adolescent (≥12 years of age) patients[3,4]
- In the phase 3 Vivacity-MG3 study, nipocalimab+SOC demonstrated substantial reduction of IgG levels, including pathogenic IgG, when compared to placebo+SOC. Nipocalimab also demonstrated sustained improvements in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) total scores during the 24-week study[5]
  - Patients treated with nipocalimab+SOC experienced adverse events of infections and infestations, with incidences that were comparable with placebo+SOC arm, 42/98 [43%], in each arm[5]
- Infections can contribute to symptom exacerbations in gMG; therefore, monitoring MG-ADL and QMG total scores would help assess the symptom control and therapeutic adequacy during episodes of infections[6]

Objective

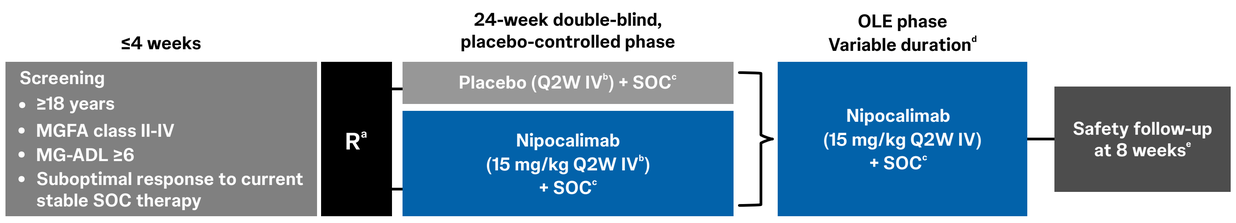
To evaluate the efficacy of nipocalimab treatment during/shortly after infection episodes in the double-blind phase of Vivacity-MG3 by measuring changes in MG-ADL and QMG scores

Methods

Study Design

- Vivacity-MG3 was a multicenter, randomized, double-blind, placebo-controlled study evaluating efficacy, safety, pharmacokinetics, and pharmacodynamics of nipocalimab in adults with gMG[5]

Figure 1. Study design[5]



[a]Randomization was stratified by autoantibody status (anti-AChR positive or anti-MuSK positive or anti-AChR negative and anti-MuSK negative), Day 1 MG-ADL total score (≤9 >9), and region (East Asia, US, rest of world). The analysis plan, however, grouped all seropositives together (AChR+, MuSK+ or LRP4+) vs triple seronegatives. [b]All patients received the loading dose of placebo or nipocalimab 30 mg/kg at Week 0 and then started placebo or nipocalimab 15 mg/kg Q2W IV from Week 2 to Week 24; [c]SOC includes acetylcholinesterase inhibitor, glucocorticosteroid, and/or immunosuppressant. [d]In the EU, the OLE phase will be up to 240 weeks. [e]Participants who withdraw or discontinue after receiving any amount of study intervention are required to complete a safety follow-up visit 8 weeks after their last dose.

***AChR**=acetylcholine receptor antibody, **EU**=European Union, **gMG**=generalized myasthenia gravis, **IV**=intravenous, **LRP4**=low-density lipoprotein-related protein receptor 4, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **MuSK**=muscle-specific tyrosine kinase antibody, **OLE**=open-label extension, **Q2W**=every 2 weeks, **R**=randomized, **SOC**=standard-of-care.*

Post-hoc Analysis

Analysis Sets

- Patients with infections/infestations/serious infections at any timepoint in the double-blind phase were analyzed
- All analyses were done on the safety analysis set and the primary efficacy analysis sets
- Safety analysis set: Included both seropositive and seronegative patients randomized to receive ≥1 dose (partial or complete) of any study intervention in the double-blind phase
- Primary efficacy set: Included all patients who received ≥1 dose (partial or complete) of study drug in the double-blind phase and were antibody-positive (anti-AChR, anti-MuSK, or anti-low-density lipoprotein-related protein receptor 4 (LRP4), confirmed before randomization

Assessments

- Pre-infection and post-infection MG-ADL and QMG scores were compared
- Pre-infection MG-ADL/QMG score was the most recent observation recorded within 16-days[a] immediately preceding infection start-date
- Post-infection MG-ADL/QMG score was the worst observation recorded from the infection start-date through 16-days[a] after the infection end-date

[a]Time frame where we expected to find at least one MG-ADL/QMG assessment corresponding to an infection event.

Results

Baseline demographics

- The safety analysis set included 196 patients: n=98, nipocalimab+SOC; n=98, placebo+SOC (**Table 1**)
- The primary efficacy analysis set included 153 antibody-positive patients: n=77, nipocalimab+SOC; n=76, placebo+SOC (**Table 1**)

Table 1. Patient demographics and baseline characteristics[5]

	Baseline MG-ADL total score 6–9	
	Nipocalimab+SOC	Placebo+SOC
Safety analysis set	**(n=98)**	**(n=98)**
Age, mean (SD), years	52.9 (15.49)	52.7 (15.60)
Female, n (%)	66 (67.30)	56 (57.10)
Duration of myasthenia gravis, mean (SD), years	6.8 (7.03)	8.9 (8.03)
Baseline MG-ADL total score, mean (SD)	9.5 (2.69)	9.3 (2.01)
Baseline QMG total score, mean (SD)	15.0 (4.80)	15.6 (4.71)
Antibody-positive at screening, n (%)		
Anti-AChR+	63 (64.30)	71 (72.4)
Anti-MuSK+	12 (12.20)	4 (4.10)
Anti-LRP4+	2 (2.00)	1 (1.00)
Primary efficacy analysis set	**(n=77)**	**(n=76)**
Age, mean (SD), years	52.5 (15.66)	52.3 (16.37)
Female, n (%)	50 (64.90)	42 (55.30)
Duration of myasthenia gravis, mean (SD), years	6.9 (7.44)	8.9 (8.13)
Baseline MG-ADL total score, mean (SD)	9.4 (2.73)	9.0 (1.97)
Baseline QMG total score, mean (SD)	15.1 (4.78)	15.7 (4.92)
Antibody-positive at screening, n (%)		
Anti-AChR+	63 (81.80)	71 (93.40)
Anti-MuSK+	12 (15.60)	4 (5.30)
Anti-LRP4+	2 (2.60)	1 (1.30)

***AChR**=acetylcholine receptor, **LRP4**=low-density lipoprotein-related protein receptor 4, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **MuSK**=muscle-specific tyrosine kinase, **QMG**=Quantitative Myasthenia Gravis, **SOC**=standard of care.*

Treatment-emergent adverse events - Infections and infestations

- Infection/infestations were reported in 42.9% patients in nipocalimab+SOC group in safety as well as the primary efficacy analysis set (**Figure 2**)
- COVID-19, nasopharyngitis, and upper respiratory tract infection were the most common events across the groups in both safety as well as primary efficacy analysis sets (**Table 2**)

Figure 2. Summary of treatment-emergent adverse events of infections and infestations in (A) Safety analysis set and (B) Primary efficacy analysis set

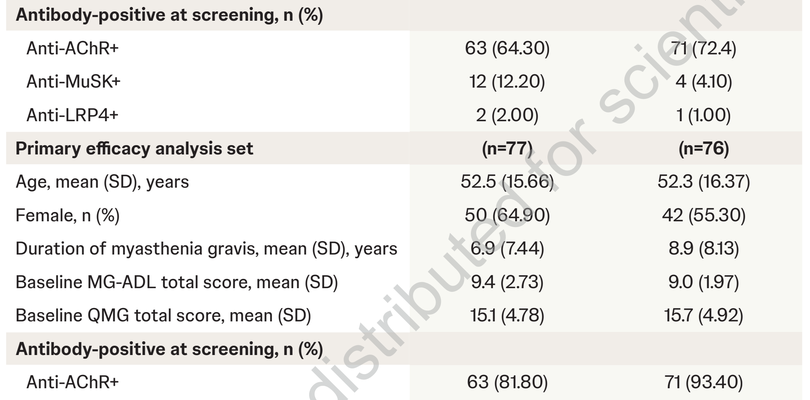


Table 2. Most frequent treatment-emergent adverse events - infections and infestations[a]

	Nipocalimab+SOC		Placebo+SOC	
	n (%)	Events, n	n (%)	Events, n
Safety Analysis Set				
COVID-19	11 (11.2%)	11	10 (10.2%)	11
Nasopharyngitis	9 (9.2%)	9	10 (10.2%)	11
Upper respiratory tract infection	6 (6.1%)	6	8 (8.2%)	8
Urinary tract infection	5 (5.1%)	5	0	0
Pneumonia	3 (3.1%)	4	1 (1.0%)	1
Primary Efficacy Analysis Set				
COVID-19	9 (11.7%)	9	5 (6.6%)	6
Nasopharyngitis	6 (7.8%)	6	8 (10.5%)	9
Upper respiratory tract infection	4 (5.2%)	4	6 (7.9%)	6
Urinary tract infection	3 (3.9%)	3	0	0
Pneumonia	3 (3.9%)	4	1 (1.3%)	1

Overall infection duration

- The median (IQR) duration of overall infections was comparable between nipocalimab+SOC and placebo+SOC groups in both safety as well as primary efficacy analysis sets (**Figure 3** and **Figure 4**)

Figure 3. Duration of infections[b,c,d] (safety analysis set)

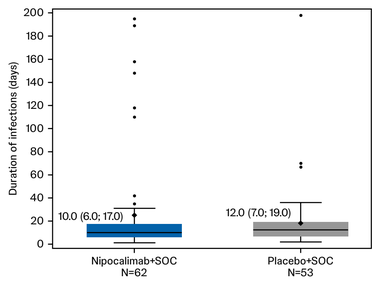
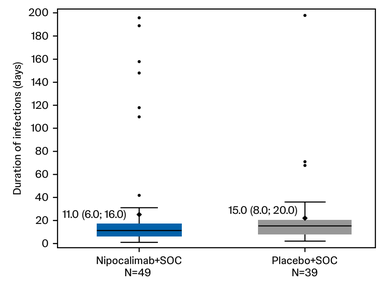


Figure 4. Duration of infections[b,c,d] (primary efficacy analysis set)



Moderate to severe infections duration

- The median (IQR) duration of moderate to severe infections was comparable between nipocalimab+SOC and placebo+SOC groups in both safety as well as primary efficacy analysis sets (**Figure 5** and **Figure 6**)

Figure 5. Duration of moderate to severe infections[b,c,d] (safety analysis set)

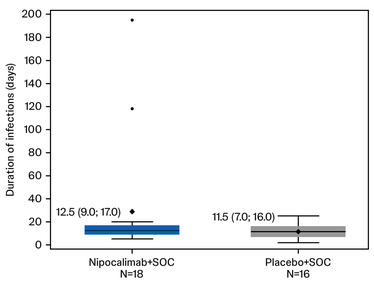
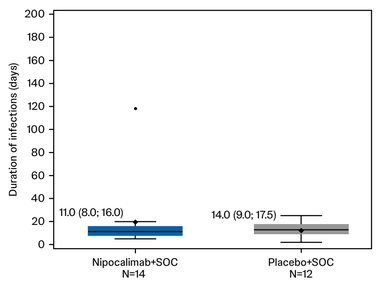


Figure 6. Duration of moderate to severe infections[b,c,d] (primary efficacy analysis set)



[a]Includes all adverse events coded to the system organ class "Infections and infestations". Preferred terms listed are those reported in >3% of patients in either treatment group. Events [n] represents the total number of treatment-emergent infection events. [b]Duration calculated as infection end date minus infection start date + 1 day. If infection end date is missing, it is imputed with the double-blind phase end date for patient [c]A patient could contribute more than one infection if the infections are mutually exclusive in time. A patient with temporal overlapping infections had the infections combined as one infection using the earliest start date and the latest end date. [d]A patient with temporal overlapping infections had the infections combined as one infection using the earliest start date and the latest end date.

*All Whisker plots' data are presented as median (IQR) and the bars represent the range. **ICE**=intercurrent event, **IQR**=interquartile range, **QMG**=Qualitative Myasthenia Gravis, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SOC**=standard-of-care.*

MG-ADL score changes during/after infections

- MG-ADL total scores remained generally stable during infections in nipocalimab+SOC treated patients (**Figure 7** and **Figure 8**)

Figure 7. MG-ADL scores (safety analysis set)

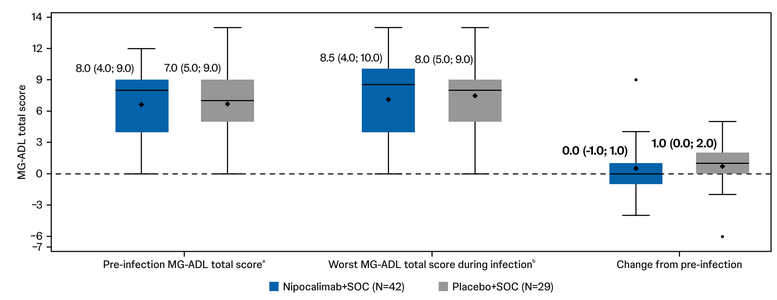
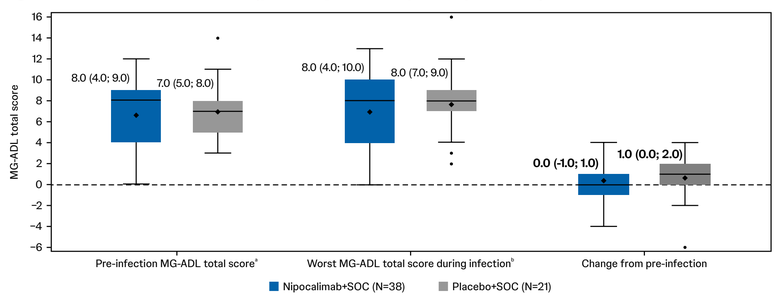


Figure 8. MG-ADL scores (primary efficacy analysis set)



*Data are presented as median (IQR) and the bars represent the range. [a]Latest total score within the 16 days before (and including) the infection start date; and not occurring after an ICE. [b]Worst total score occurring after the start date and up to (and including) 16 days after the end date; and not occurring after an ICE. **ICE**=intercurrent event, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SOC**=standard-of-care.*

QMG score changes during/after infections

- QMG total scores remained generally stable during infections in nipocalimab+SOC treated patients (**Figure 9** and **Figure 10**)

Figure 9. QMG scores (safety analysis set)

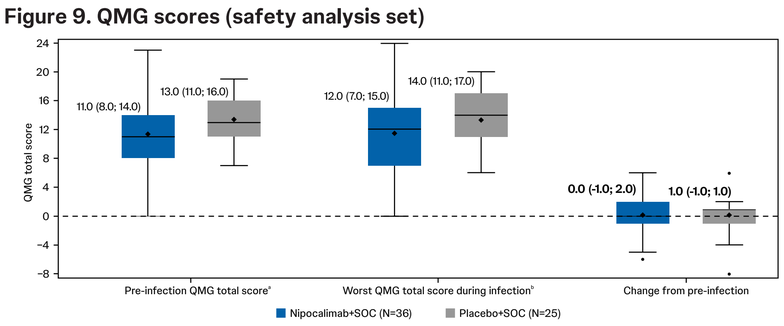
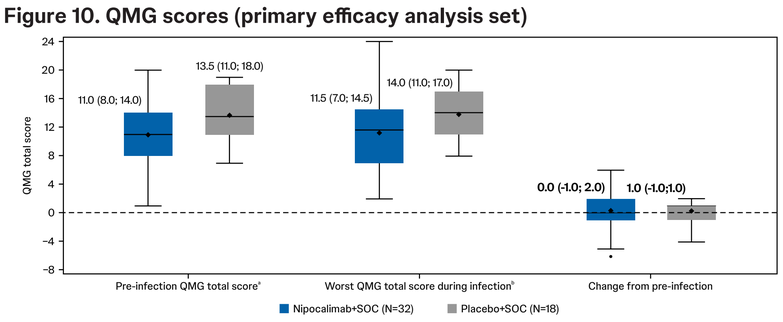


Figure 10. QMG scores (primary efficacy analysis set)



[a]Latest total score within the 16 days before (and including) the infection start date; and not occurring after an ICE. [b]Worst total score occurring after the start date and up to (and including) 16 days after the end date; and not occurring after an ICE.

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