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

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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]

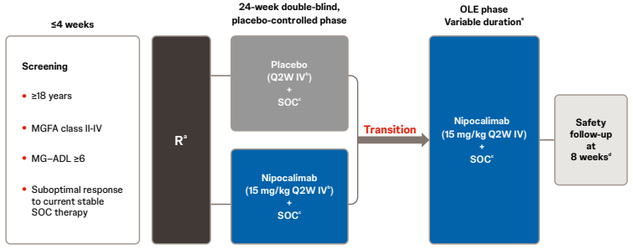
Objective

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

Methods

- Vivacity-MG3 (NCT04951622) was a multicenter, randomized, double-blind, placebo-controlled study evaluating efficacy, safety, pharmacokinetics, and pharmacodynamics of nipocalimab in adults with gMG (**Figure 1**).[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]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; [e]In the EU, the OLE phase will be up to 240 weeks.
AChR+=anti-acetylcholine receptor antibody-positive, **EU**=European Union, **gMG**=generalized myasthenia gravis, **IV**=intravenous, **LRP4**=lipoprotein-related protein receptor 4, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **MuSK+**=anti-muscle-specific tyrosine kinase antibody-positive, **OLE**=open-label extension, **QMG**=Quantitative Myasthenia Gravis, **Q2W**=every 2 weeks, **R**=randomized, **SOC**=standard-of-care, **US**=United States.

Analysis sets

- Patients with infections/infestations/serious infections at any timepoint in the double-blind phase were examined.
- All analyses were done on the safety analysis set that included both seropositive and seronegative patients randomized to receive ≥1 dose (partial or complete) of any study intervention in the double-blind phase.
- In addition, a further analysis was done in the primary efficacy set that 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-LRP4), confirmed before randomization.

Assessments

- Pre-infection and post-infection MG-ADL and QMG total 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.

Key Takeaways

- **Incidence of Infections and infestations in the nipocalimab+SOC arm was comparable to that in the placebo+SOC arm.**
- **MG-ADL and QMG total scores did not differ before and after periods of infection demonstrating maintenance of gMG symptom improvement and sustained disease control with nipocalimab+SOC treatment during periods of infections.**

Results

Baseline demographics

- The safety analysis set included 196 patients: n=98, nipocalimab+SOC; n=98, placebo+SOC (**Table 1**).

Table 1. Patient demographics and baseline characteristics

	Nipocalimab+SOC (N=98)	Placebo+SOC (N=98)
Age, mean (SD), years	52.9 (15.49)	52.7 (15.60)
Female, n (%)	66 (67.3)	56 (57.1)
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(%)		
Seronegative	21 (21.4)	22 (22.4)
Seropositive	77 (78.6)	76 (77.6)
Anti-AChR+	63 (64.3)	71 (72.4)
Anti-MuSK+	12 (12.2)	4 (4.1)
Anti-LRP4+	2 (2.0)	1 (1.0)

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

Treatment-emergent adverse events of infections and infestations

- Infection and infestations were reported in 42 (42.9%) patients in the nipocalimab+SOC group (vs 41 [41.8%] in placebo+SOC), with COVID-19, nasopharyngitis, and upper respiratory tract infection being the most common events (**Figure 2, Table 2**).

Figure 2. Summary of treatment-emergent adverse events of infections and infestations (safety analysis set)

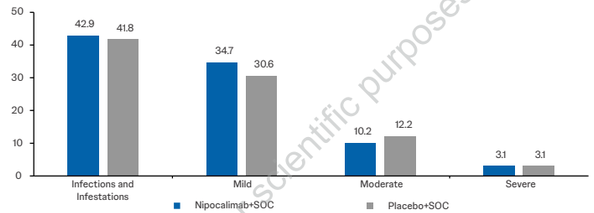


Table 2. Most frequent treatment-emergent adverse events of infections and infestations (safety analysis set)

	Nipocalimab+SOC		Placebo+SOC	
	n (%)	Events, n	n (%)	Events, n
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

Includes all adverse events coded to the system organ class "Infections and infestations". Preferred terms listed are those reported in >2% of patients in either treatment group. Events (n) represents the total number of treatment-emergent infection events.
COVID-19=coronavirus disease 2019, ***SOC***=standard-of-care.

Duration of infections and moderate to severe infections

- The median (IQR) duration of overall infections and moderate to severe infections was comparable between the treatment groups (**Figure 3 and Figure 4**).

Figure 3. Duration of Infections[a,b,c] (safety analysis set)

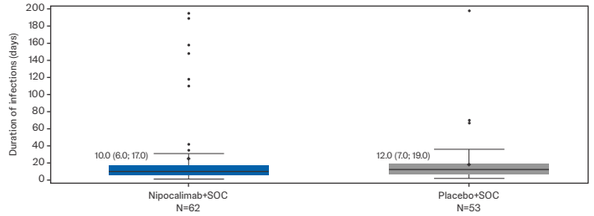
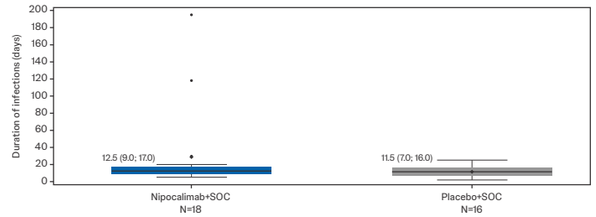


Figure 4. Duration of moderate to severe infections[a,b,c] (safety analysis set)



Data are presented as median (IQR) and the bars represent the range. [a]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; [b]A patient could have more than one infection if the infections were mutually exclusive in time; [c]A patient with temporal overlapping infections had the infections combined as one infection using the earliest start date and the latest end date.
IQR=interquartile range, ***SOC***=standard-of-care.

MG-ADL and QMG Scores

- MG-ADL and QMG total scores remained generally stable during infections in both treatment groups, with only minimal change from pre-infection values (**Figure 5 and Figure 6**).

Figure 5. MG-ADL total scores (safety analysis set)

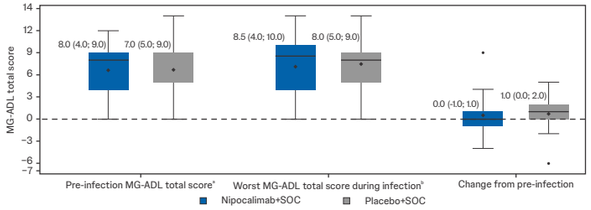
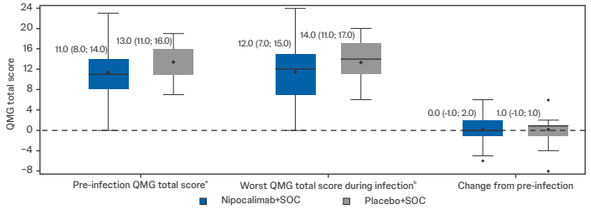


Figure 6. QMG total scores (safety analysis set)



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 events, ***IQR***=interquartile range, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***QMG***=Qualitative Myasthenia Gravis, ***SOC***=standard-of-care.

- When analyzed in the efficacy population, similar results were observed with respect to duration of overall/moderate and severe infections as well as the MG-ADL and QMG total scores.

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