Efficacy of Nipocalimab in Adult Patients with None-to-Mild Ocular Manifestations and Generalized Myasthenia Gravis in Phase 3 VIVACITY-MG3

Kristl G. Claeys[1*], Kavita Gandhi[2], Ibrahim Turkoz[3], Michael Kutch[4], Marie Fitzgibbon[5], Sindhu Ramchandren[3]

[1]Department of Neurology, University Hospitals Leuven, and Laboratory for Muscle Diseases and Neuropathies, KU Leuven, Leuven, Belgium; [2]Johnson & Johnson, Horsham, PA, USA; [3]Johnson & Johnson, Titusville, NJ, USA; [4]Cytel, Inc, Cambridge, MA, USA; [5]Johnson & Johnson, Raritan, NJ, USA

*Presenting author

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Key Takeaways

- **In this post-hoc analysis of patients with gMG and none-to-mild ocular manifestations, nipocalimab + SOC treatment showed meaningful and substantial clinical improvements in MG-ADL total and QMG total scores versus placebo + SOC, consistent with findings in the overall population**
  - **Despite only ~20% of patients meeting subgroup criteria for none-to-mild ocular manifestations, statistically significant differences were observed, although results should be interpreted with caution given the small subgroup sizes**
- **These findings are suggestive that nipocalimab provides rapid and sustained disease control in a broad population of patients with gMG, including those with none-to-mild ocular symptoms**

Introduction

- Ocular manifestations are the most common presenting symptom in patients with generalized myasthenia gravis (gMG); however, 15–50% of patients do not experience ocular symptoms[1,2]
- Nipocalimab is a fully human monoclonal antibody that binds the neonatal Fc receptor (FcRn) with high affinity and specificity, inhibiting IgG recycling and thereby reducing circulating total IgG, including pathogenic IgG autoantibodies[3,4]
- Nipocalimab is approved by the US Food and Drug Administration and European Medicines Agency for the treatment of gMG in adult and adolescent patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) positive[5,6]
- In phase 3 VIVACITY-MG3 study, nipocalimab + standard-of-care (SOC) demonstrated sustained disease control vs placebo + SOC through Myasthenia Gravis-Activities of Daily Living (MG-ADL) total scores in the overall population and in a subgroup with moderate-to-severe ocular manifestations[7]

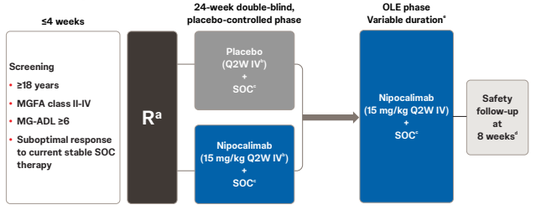
Objective

- **The aim of this post-hoc analysis was to evaluate the effect of nipocalimab on MG-ADL and Quantitative Myasthenia Gravis (QMG) scores in a subgroup of patients with none-to-mild ocular manifestations**

Methods

- Vivacity-MG3 (NCT04951622) was a double-blind, randomized, placebo-controlled, multicenter, phase 3 study evaluating efficacy and safety of nipocalimab in adults with gMG[6]

Figure 1: Study Design[3]



*Randomization was stratified by autoantibody status (anti-AChR+ and/or anti-MuSK+, 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. †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. ‡SOC includes acetylcholinesterase inhibitor, glucocorticosteroid, and/or immunosuppressant. §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. ¶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, **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, **Q2W**=every 2 weeks, **R**=randomized, **SOC**=standard-of-care.

- The primary efficacy analysis dataset included all randomized patients who received at least one dose of study drug in the double-blind phase and were seropositive (anti-AChR positive, anti-MuSK positive or anti-lipoprotein-related protein receptor 4 [LRP4] positive)
- Post hoc analyses were conducted in the subgroup of patients with none-to-mild ocular manifestations at baseline (double-blind phase), among the primary efficacy analysis dataset
  - None-to-mild ocular manifestations was defined as ≤1 score on diplopia and ptosis items of the MG-ADL scale
- Assessments:
  - MG-ADL total score
    - Change from baseline to Week 24 (double-blind phase)
    - Achievement of meaningful clinical improvement (MCI; ≥2-point improvement from baseline) at Week 24
    - Achievement of substantial clinical improvement (SCI; ≥3-point improvement from baseline) at Week 24
  - QMG total score
    - Change from baseline to Week 24 (double-blind phase)
    - Achievement of MCI (≥3-point improvement from baseline) at Week 24
    - Achievement of SCI (≥4-point improvement from baseline) at Week 24

Results

Baseline characteristics

- Subgroup criteria for none-to-mild ocular manifestations were met by 17 of 77 patients in the nipocalimab + SOC group and 14 of 76 patients in the placebo + SOC group
- Among patients with none-to-mild ocular manifestations, baseline characteristics were generally balanced between nipocalimab + SOC vs placebo + SOC, and were similar to those of the overall efficacy population (**Table 1**)

Table 1. Patient demographics and baseline characteristics

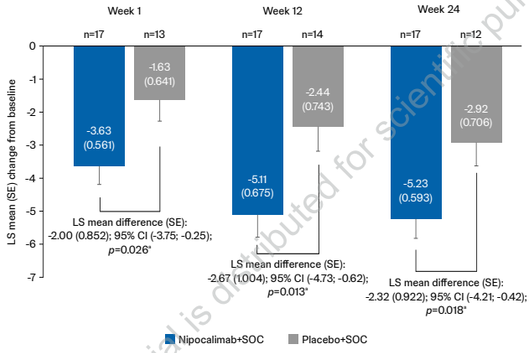
	Nipocalimab+SOC (n=17)	Placebo+SOC (n=14)
Age, median (range), years	50.0 (20–79)	50.5 (20–77)
Female, n (%)	12 (70.6)	7 (50.0)
Duration of MG, median (range), years	4.5 (0–21)	8 (0–18)
Age at onset, median (range), years	43 (4–66)	41 (20–73)
Baseline MG-ADL total score, mean (SD)	7.6 (0.89)	7.5 (1.56)
Baseline QMG total score		
Baseline, n	15	14
Mean (SD)	12.4 (2.83)	13.9 (5.37)
Antibody-positive at screening, n (%)	17 (100.0)	14 (100.0)
Anti-AChR+	14 (82.4)	14 (100.0)
Anti-MuSK+	3 (17.6)	0
Anti-LRP4+	0	0

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

MG-ADL score—Mean change from baseline to Week 24

- Patients with none-to mild ocular symptoms in the nipocalimab + SOC group showed rapid and sustained improvement from baseline in MG-ADL total score versus those in the placebo + SOC group (**Figure 2**)
  - Significant differences in LS mean change from baseline were observed as early as Week 1 (the first assessment timepoint)

Figure 2. LS mean (SE) change from baseline in total MG-ADL score



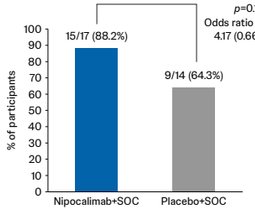
*Based on ANCOVA model with treatment group and autoantibody status as factors and baseline total score as the covariate. ***ANCOVA***=analysis of covariance, ***CI***=confidence interval, ***LS***=least squares, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***SE***=standard error, ***SOC***=standard-of-care.

MG-ADL score—Proportion of patients who achieved MCI or SCI at Week 24

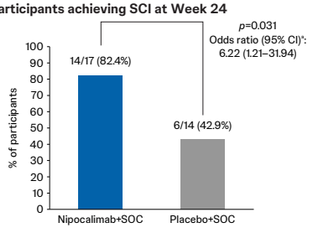
- The proportion of patients with none-to-mild ocular symptoms achieving MCI was numerically greater, and those achieving SCI was significantly greater in the nipocalimab + SOC group versus the placebo + SOC group (**Figure 3**)

Figure 3. Proportion of participants who achieved (A) MCI or (B) SCI in MG-ADL at Week 24

A. Participants achieving MCI at Week 24



B. Participants achieving SCI at Week 24

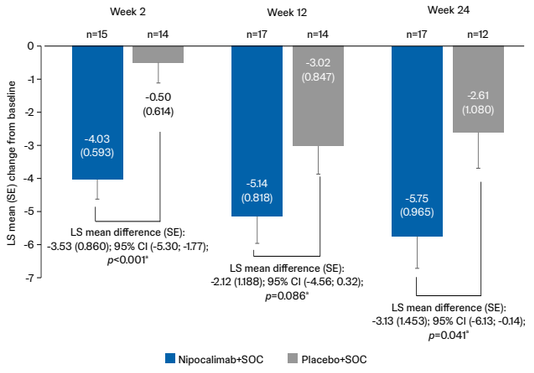


*Unstratified. ***MCI***=meaningful clinical improvement, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***SCI***=substantial clinical improvement, ***SOC***=standard-of-care.

QMG score—Mean change from baseline to Week 24

- Nipocalimab + SOC treatment in the none-to-mild ocular symptoms group led to rapid and sustained improvement from baseline in QMG total score versus placebo + SOC (**Figure 4**); significant differences in LS mean change from baseline were observed as early as Week 2 (the first assessment timepoint)

Figure 4. LS mean (SE) change from baseline to Week 24 in total QMG Score



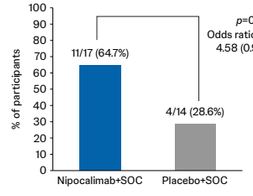
*Based on ANCOVA model with treatment group and autoantibody status as factors and baseline total score as the covariate. ***ANCOVA***=analysis of covariance, ***CI***=confidence interval, ***LS***=least squares, ***QMG***=Quantitative Myasthenia Gravis, ***SD***=standard deviation, ***SE***=standard error, ***SOC***=standard-of-care.

QMG score—Proportion of patients who achieved MCI or SCI at Week 24

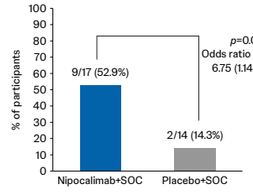
- The proportion of patients achieving MCI or SCI in QMG total score was greater in the nipocalimab + SOC group compared with placebo +SOC (**Figure 5**)

Figure 5. Proportion of patients who achieved (A) MCI or (B) SCI in QMG at Week 24

A. Participants achieving MCI at Week 24



B. Participants achieving SCI at Week 24



*Unstratified. ***MCI***=meaningful clinical improvement, ***QMG***=Quantitative Myasthenia Gravis, ***SCI***=substantial clinical improvement, ***SOC***=standard-of-care.

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