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Assessment of Sustained Health-Related Quality of Life in Phase 3 Vivacity-MG3 Trial of Nipocalimab Versus Placebo in Generalized Myasthenia Gravis

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Introduction

- Generalized myasthenia gravis (gMG), a rare autoimmune disorder of the neuromuscular junction, is characterized by fluctuating muscle weakness and fatigability.¹
- Patients with gMG experience various symptoms including chronic fatigue which has a negative impact on activities of daily living and health-related quality of life (HRQoL). Patients with gMG have substantially reduced HRQoL.^{2,3}
- Nipocalimab is the first approved FcRn blocker for the treatment of anti-acetylcholine receptor (anti-AChR) or anti-muscle-specific tyrosine kinase (anti-MuSK) antibody positive gMG in adult and adolescent (≥ 12 years of age) patients.^{4,5}
- In the Vivacity-MG3 (NCT04951622) study, nipocalimab added to standard-of-care (SOC) demonstrated rapid and sustained disease control versus placebo+SOC over the 24-week double-blind phase in autoantibody-positive patients with gMG.⁶

Objective

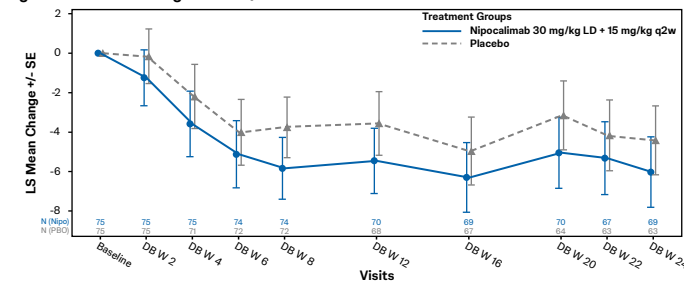
- To assess HRQoL over the 24-week double-blind phase of Vivacity-MG3, measured by the Myasthenia Gravis Quality of Life 15-item revised scale (MGQoL-15r) and the EuroQoL 5-Dimension Visual Analogue Scale (EQ-5D-VAS).

Results

LS mean change on MGQoL-15r and EQ-5D-VAS

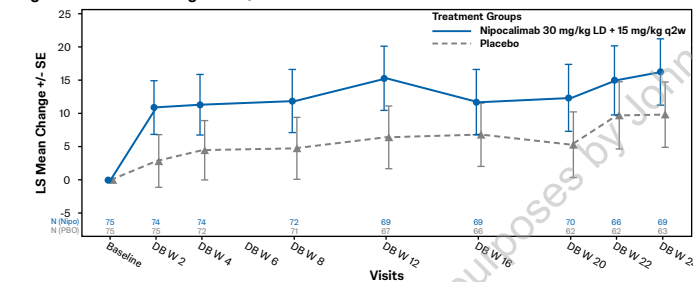
- LS-mean (95% CI) difference in change-from-baseline on MGQoL-15r was numerically greater with nipocalimab+SOC versus placebo+SOC (-1.38 [-3.14, 0.37]) at Week 4 and sustained (-1.61 [-3.55, 0.33]) at Week 24 (Figure 1).
- LS-mean (95% CI) difference in change-from-baseline on EQ-5D-VAS was greater with nipocalimab+SOC versus placebo+SOC (6.86 [2.07, 11.66], $p < 0.05$) at Week 4 and sustained (6.47 [1.05, 11.88], $p < 0.05$) at Week 24 (Figure 2).

Figure 1. LS Mean change on MGQoL-15r from baseline over time



MGQoL-15r was used to measure HRQoL, range 0-30; higher scores indicate worse quality of life.
DB=double-blind; LD=loading dose; LS=least square; MGQoL-15r=Myasthenia Gravis Quality of Life 15-item revised scale; PBO=placebo; q2w=every 2 weeks.
SE=standard error; W=week.

Figure 2. LS Mean change on EQ-5D-VAS from baseline over time

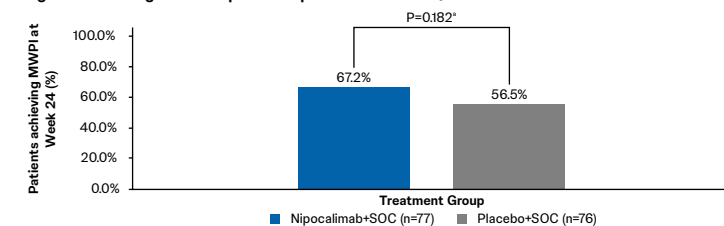


EQ-5D-VAS was used to assess HRQoL, range 0-100; higher scores indicate better health.
DB=double-blind; EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; LD=loading dose; LS=least square; PBO=placebo; q2w=every 2 weeks.
SE=standard error; W=week.

MWPI in MGQoL-15r and EQ-5D-VAS

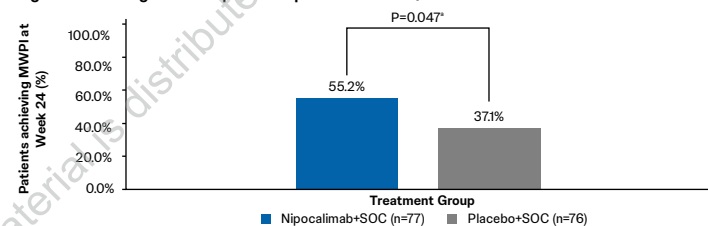
- At 24 weeks, 67.2% (45/67) versus 56.5% (35/62) patients achieved MWPI on MGQoL-15r (absolute difference=10.7%; not significant [ns]) in nipocalimab+SOC versus placebo+SOC (Figure 3).
- At 24 weeks, 55.2% (37/67) versus 37.1% (23/62) patients achieved MWPI on EQ-5D-VAS (absolute difference=18.1% [$p < 0.05$]) in nipocalimab+SOC versus placebo+SOC (Figure 4).
- For both measures, nipocalimab-treated patients were twice more likely to achieve MWPI over 24 weeks with median time-to-response of approximately 4 weeks with nipocalimab+SOC versus 8 weeks with placebo+SOC ($p < 0.05$).

Figure 3. Meaningful within-person improvement on MGQoL-15r at 24 weeks



MGQoL-15r was used to measure HRQoL, range 0-30; higher scores indicate worse quality of life.
*Based on CMH test adjusting for autoantibody status.
MGQoL-15r=Myasthenia Gravis Quality of Life 15-item revised scale; MWPI=Meaningful-within-person-improvement; SOC=standard-of-care.

Figure 4. Meaningful within-person improvement on EQ-5D-VAS at 24 weeks



EQ-5D-VAS was used to assess HRQoL, range 0-100; higher scores indicate better health.
*Based on CMH test adjusting for autoantibody status.
EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; MWPI=Meaningful-within-person-improvement; SOC=standard-of-care.

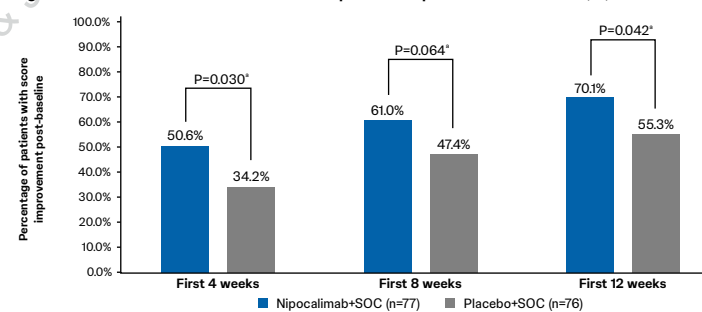
Methods

- All HRQoL data were analyzed in the efficacy analysis population that included all patients who received ≥ 1 dose (partial or complete) of any study intervention in the double-blind phase and were antibody positive for a gMG-related pathogenic antibody (anti-AChR, anti-MuSK, or anti-LRP4).
- Mean change-from-baseline (CFB) between groups in MGQoL-15r and EQ-5D-VAS over 24 weeks were compared using ANCOVA models.
- Meaningful within-person improvement (MWPI) was defined as a change of ≥ 4 -points⁸ on the MGQoL-15r scale and 10-point change in the EQ-5D-VAS.⁹
- Proportion of patients achieving MWPI and time-to-MWPI over 24 weeks were examined using Chi-square test and Kaplan-Meier analyses.
- Logistic regression was used to evaluate the likelihood of achieving MWPI over 24 weeks and sustaining MWPI for $\geq 8, 12, 16,$ and 20 weeks between groups.

Score improvement over time

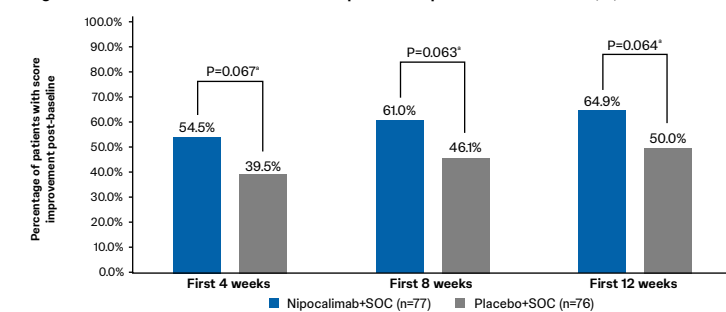
- Across time points, a significantly greater proportion of nipocalimab-treated patients (vs placebo-treated) achieved MWPI on MG-QoL-15r scale in the first 4 and 12 weeks of treatment (Figure 5).
- Across time points, a numerically greater proportion of nipocalimab-treated patients (vs placebo-treated) achieved MWPI on EQ-5D-VAS scale in the first 4, 8, and 12 weeks of treatment (Figure 6).

Figure 5. Patients with MG-QoL-15r score improvement post-baseline in first 4, 8, 12 weeks



MG-QoL-15r was used to measure HRQoL.
*Based on CMH test adjusting for autoantibody status.
MGQoL-15r=Myasthenia Gravis Quality of Life 15-item revised scale; SOC=standard-of-care.

Figure 6. Patients with EQ-5D-VAS score improvement post-baseline in first 4, 8, 12 weeks

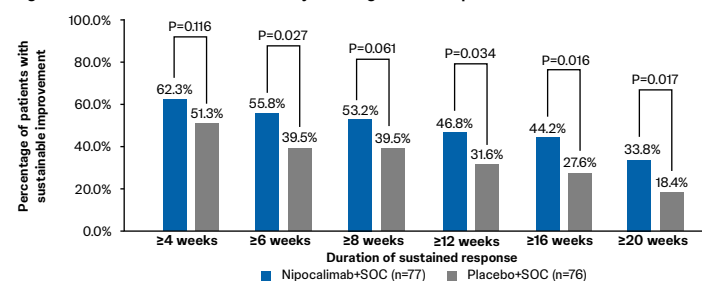


EQ-5D-VAS was used to assess HRQoL.
*Based on CMH test adjusting for autoantibody status.
EQ-5D-VAS=EuroQoL 5-Dimension questionnaire visual analogue scale; SOC=standard-of-care.

Sustained response on MG-QoL-15r and EQ-5D-VAS

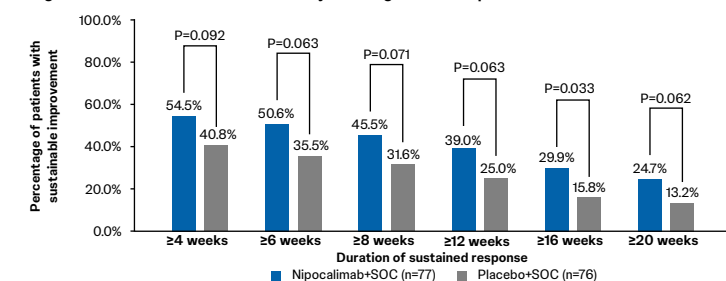
- Across time points, greater proportion of nipocalimab treated patients achieved and sustained MWPI on MG-QoL-15r versus patients treated with placebo+SOC, $\geq 6, 12, 16, 20$ weeks; $p < 0.05$ (Figure 7).
- Across time points, a numerically greater proportion of nipocalimab treated patients achieved and sustained MWPI on EQ-5D-VAS versus patients treated with placebo+SOC, $\geq 4, 6, 8, 12, 20$ weeks (Figure 8).

Figure 7. Sustained MG-QoL-15r clinically meaningful score improvement over time



MG-QoL-15r was used to measure HRQoL.
*Based on CMH test adjusting for autoantibody status.
MWPI=Meaningful-within-person-improvement; SOC=standard-of-care.

Figure 8. Sustained EQ-5D-VAS clinically meaningful score improvement over time



EQ-5D-VAS was used to assess HRQoL.
*Based on CMH test adjusting for autoantibody status.
MWPI=Meaningful-within-person-improvement; SOC=standard-of-care.