Efficacy of Nipocalimab in Patients Early in Their Disease Course of Generalized Myasthenia Gravis: Post Hoc Analysis of Vivacity-MG3

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Key Takeaways

- **Nipocalimab demonstrated sustained disease control in patients with gMG and recently diagnosed gMG (≤5 years before study initiation)**
- **At week 24, a greater proportion of patients treated with nipocalimab achieved meaningful and substantial clinical improvements in MG-ADL and QMG total scores compared to those treated with placebo**
- **Nipocalimab may provide meaningful and substantial clinical benefit, even in patients in early stages of gMG**

Introduction

- Generalized myasthenia gravis (gMG) is a chronic autoimmune disease characterized by fluctuating muscle weakness and fatigue caused by pathogenic immunoglobulin G (IgG) autoantibodies[1,2]
  - Symptoms of gMG often tend to be more severe and are poorly controlled during the first few years after diagnosis, before stabilizing over time[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]
- Nipocalimab + standard-of-care (SOC; vs placebo+SOC) has demonstrated rapid and sustained efficacy during the 24-week double-blind (DB) phase of the phase 3 Vivacity-MG3 study in seropositive gMG patients with a mean disease duration of 6.9 vs 8.9 years[6,7]
  Least-square mean (standard error [SE]) changes from baseline to weeks 22, 23, and 24
  - Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score: −4.7 (0.33) vs −3.3 (SE, 0.34); difference: −1.45 (0.47); p=0.002
  - Quantitative Myasthenia Gravis (QMG) total score: −4.9 (0.50) vs −2.1 (0.50); difference: −2.81 (0.71); p<0.001
- However, it is currently unclear whether patients with gMG who are early in their disease course would derive similar benefit from treatment with nipocalimab +SOC

Objective

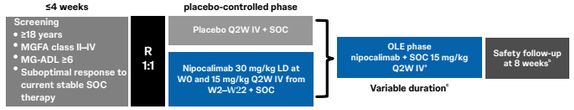
To evaluate if the efficacy of nipocalimab observed in the overall Vivavity-MG3 population was achievable in a subgroup of patients with recently diagnosed gMG (≤5 years before study initiation)

Methods

Analysis population

- Subset of patients recently diagnosed with gMG from efficacy analysis set of the Vivacity-MG3 study
  - All patients who received ≥1 dose of nipocalimab+SOC or placebo+SOC in the DB phase and were antibody positive for a gMG-related pathogenic antibody (anti-AChR, anti-MuSK, or anti-LRP4) and who had been diagnosed with gMG within ≤5 years (below the cohort median of 5 years)

Figure 1. Study design[6]



[a]Due to the COVID-19 pandemic, some participants from the Phase 2 study (NCT03772587) were unable to enter the Phase 2 OLE study (NCT03896295). These participants could directly enter the Phase 3 OLE and their data will be disclosed later. [b]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. [c]In the EU, the OLE phase will be up to 240 weeks.
COVID-19=coronavirus disease 2019; ***EU***=European Union; ***IV***=intravenous; ***LD***=loading dose; ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living; ***MGFA***=Myasthenia Gravis Foundation of America; ***OLE***=open-label extension; ***Q2W***=every 2 weeks, ***R***=randomized 1:1; ***SOC***=standard-of-care; ***W***=week.

Efficacy endpoints

- Mean change from baseline in MG-ADL and QMG total scores at week 24
- The proportion of patients achieving a meaningful within-patient change, defined as a ≥2-point improvement (meaningful clinical improvement [MCI]) and a ≥3-point improvement (substantial clinical improvement [SCI]) in MG-ADL total scores at week 24
- The proportion of patients achieving a MCI, defined as a ≥3-point improvement and SCI, defined as a ≥4-point improvement in QMG total scores at week 24

Statistical analysis

- Differences between treatment groups for mean changes from baseline were evaluated using two-sample t-tests
- Differences between treatment groups for proportions of MCI and SCI were examined using odds ratios (ORs) and 95% confidence intervals (CIs)

Results

Baseline demographics

- Baseline demographics were generally balanced between nipocalimab and placebo-treated patients (**Table 1**)

Table 1. Patient demographics and baseline characteristics

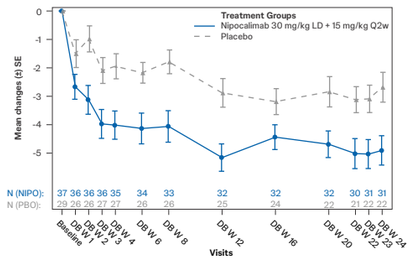
	Patients diagnosed with gMG within ≤5 years	
	Nipocalimab+SOC (n=37)	Placebo+SOC (n=29)
Age, median (range), years	48.0 (20–81)	57.0 (20–81)
Female, n (%)	21 (56.8)	15 (51.7)
Duration of MG, median (range), years	2 (0–5)	3 (0–5)
Age at onset, median (range), years	47 (19–78)	52 (18–80)
Baseline MG-ADL total score, mean (SD)	8.8 (2.28)	9.2 (1.64)
Baseline QMG total score		
Baseline, n	34	29
Mean (SD)	13.3 (3.49)	16.0 (4.51)
Antibody-positive at screening, n (%)	37 (100.0)	29 (100.0)
Anti-AChR+	31 (83.8)	27 (93.1)
Anti-MuSK+	6 (16.2)	1 (3.4)
Anti-LRP4+	0	1 (3.4)

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

MG-ADL Total Score: Change from baseline over time

- At week 24, **mean (standard deviation[SD]) total scores** were: nipocalimab+SOC: 3.8 (3.24); placebo+SOC: 6.3 (2.70)
- Across the 24-week treatment period, patients receiving nipocalimab+SOC demonstrated consistently greater reductions in MG-ADL total scores compared with placebo+SOC (**Figure 2**)

Figure 2. Mean (SE) change in MG-ADL total score over time during the DB phase

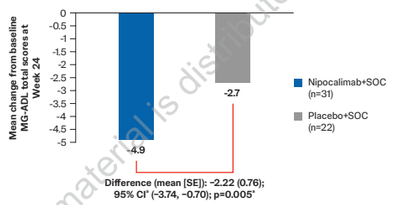


DB=double-blind, ***LD***=loading dose, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***NIPO***=nipocalimab, ***PBO***=placebo, ***Q2W***=every 2 weeks, ***SE***=standard error, ***W***=week.

MG-ADL Total Score: Mean change from baseline

- At week 24, mean (SD) change from baseline in total score: nipocalimab+SOC: −4.9 (2.88); placebo+SOC: −2.7 (2.46)
  - Difference: −2.22 (SE: 0.76); 95%CI (−3.74, −0.70); p=0.005 (**Figure 3**)

Figure 3. Mean change from baseline to week 24 in MG-ADL total score

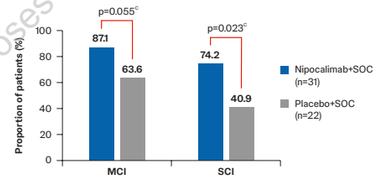


[a]Calculated from two-sample t-test comparing MG-ADL total score change from baseline between treatments.
CI=confidence interval, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***SE***=standard error.

MG-ADL: MCI and SCI

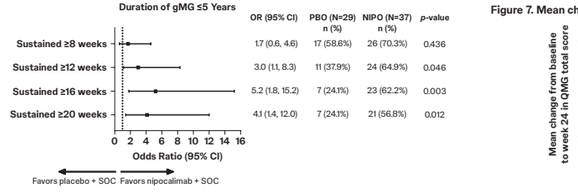
- At week 24, a greater proportion of patients receiving nipocalimab+SOC met MCI and SCI criteria for MG-ADL total scores versus placebo+SOC (**Figure 4**)
- Patients treated with nipocalimab+SOC had 3.9 times greater odds of achieving MCI compared with patients treated with placebo+SOC
  - OR (95% CI): 3.9 (1.0, 15.1); p=0.055
- Patients treated with nipocalimab+SOC had 4.2 times greater odds of achieving SCI compared with patients treated with placebo+SOC
  - OR (95% CI): 4.2 (1.3; 13.4); p=0.023
- Significantly greater proportion of nipocalimab+SOC patients sustained MCI for ≥12, 16, and 20 weeks compared with patients treated with placebo+SOC (**Figure 5**)

Figure 4. Proportion of patients achieving MG-ADL MCI[a] and SCI[b] from baseline to week 24



[a]Defined as MG-ADL total score improvement of ≥2 points from baseline. [b]Defined as MG-ADL total score improvement of ≥3 points from baseline. [c]Calculated from Fisher's exact test.
MCI=meaningful clinical improvement, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***SCI***=substantial clinical improvement, ***SOC***=standard-of-care.

Figure 5. Sustained[a] MG-ADL MCI[b] improvements from baseline to week 24

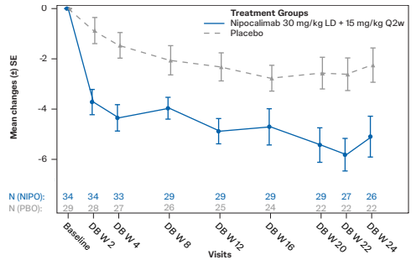


[a]Longest uninterrupted duration of improvement. [b]Defined as MG-ADL total score improvement of ≥2 points from baseline.
CI=confidence interval, ***gMG***=generalized myasthenia gravis, ***MCI***=meaningful clinical improvement, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***Nipo***=nipocalimab, ***PBO***=placebo, ***OR***=odds ratio, ***SOC***=standard-of-care.

QMG Total Score: Change from baseline over time

- At week 24, mean (SD) total scores were: nipocalimab+SOC: 8.7 (4.98); placebo+SOC: 13.9 (5.68)
- Across the 24-week treatment period, patients receiving nipocalimab+SOC demonstrated consistently greater reductions in QMG total scores compared with placebo+SOC (**Figure 6**)

Figure 6. Mean (SE) change in QMG score over time during DB phase

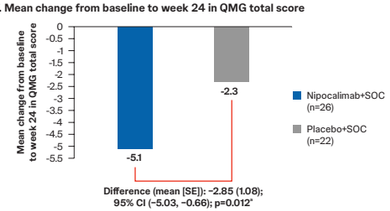


DB=double-blind, ***LD***=loading dose, ***NIPO***=nipocalimab, ***PBO***=placebo, ***Q2W***=every 2 weeks, ***QMG***=Quantitative Myasthenia Gravis, ***SE***=standard error, ***W***=week.

QMG: Mean change from baseline

- At week 24, mean (SD) change from baseline: nipocalimab+SOC: −5.1 (4.14), n=26; placebo+SOC: −2.3 (3.20), n=22
  - Difference: −2.85 (SE: 1.08); 95%CI (−5.03, −0.66); p=0.012 (**Figure 7**)

Figure 7. Mean change from baseline to week 24 in QMG total score

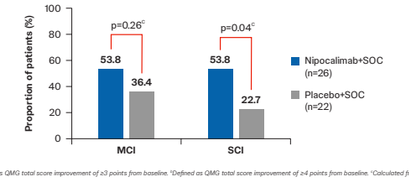


[a]Calculated from two-sample t-test comparing QMG total score change from baseline between treatments.
CI=confidence interval, ***QMG***=Quantitative Myasthenia Gravis, ***SE***=standard error, ***SOC***=standard-of-care.

QMG: MCI and SCI

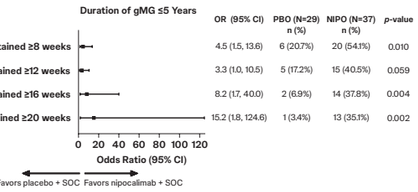
- At week 24, a greater proportion of patients receiving nipocalimab+SOC met the MCI and SCI criteria for QMG total scores vs placebo+SOC (**Figure 8**)
  - Patients treated with nipocalimab+SOC had 2 times greater odds of achieving MCI compared with patients treated with placebo+SOC, OR (95% CI): 2.0 (0.6; 6.5); p=0.259
  - Patients treated with nipocalimab+SOC had 4 times greater odds of achieving SCI compared with patients treated with placebo+SOC, OR (95% CI): 4.0 (1.1; 14.0); p=0.040
- Significantly greater proportion of nipocalimab+SOC patients sustained MCI for ≥8, 16, and 20 weeks (**Figure 9**)

Figure 8. Proportion of patients achieving QMG MCI[a] and SCI[b] from baseline to week 24



[a]Defined as QMG total score improvement of ≥3 points from baseline. [b]Defined as QMG total score improvement of ≥4 points from baseline. [c]Calculated from Fisher's exact test.
MCI=meaningful clinical improvement, ***QMG***=Quantitative Myasthenia Gravis, ***SCI***=substantial clinical improvement, ***SOC***=standard-of-care.

Figure 9. Sustained[a] QMG[b] MCI improvements from baseline to week 24



[a]Longest uninterrupted duration of improvement. [b]Defined as QMG total score improvement of ≥3 points from baseline.
CI=confidence interval, ***gMG***=generalized myasthenia gravis, ***MCI***=meaningful clinical improvement, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***Nipo***=nipocalimab, ***PBO***=placebo, ***QMG***=Quantitative Myasthenia Gravis, ***OR***=odds ratio, ***SOC***=standard-of-care.

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