Efficacy of Nipocalimab in Patients With Myasthenia Gravis and Lower Baseline Activity of Daily Living

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Key Takeaways

- **Nipocalimab demonstrated sustained disease control in patients with gMG and lower baseline MG-ADL scores (6–9)**
- **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 with lower disease burden**

Introduction

- Generalized myasthenia gravis (gMG) is a chronic autoimmune disease characterized by fluctuating muscle weakness and fatigability, which may worsen without effective treatment[1]
- Nipocalimab is the first approved neonatal Fc receptor (FcRn) blocker for the treatment of gMG in adult and adolescent (≥12 years of age) patients who are anti-acetylcholine receptor positive (AChR) or anti-muscle-specific kinase positive (MuSK) antibody positive[2,3]
- Nipocalimab + standard-of-care (SOC) vs placebo+SOC has demonstrated sustained disease control based on Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores in the 24-week phase 3, double-blind (DB) Vivacity-MG3 study in seropositive patients with gMG[4,5]

  Least square (LS) mean (standard error [SE]) change over weeks 22, 23, and 24 in
  - MG-ADL total score: −4.7 (0.33) vs −3.3 (0.34); difference: −1.45 (0.47); p=0.002
  - QMG total score: −4.9 (0.50) vs −2.1 (0.50); difference: −2.81 (0.71); p<0.001
- However, it is unclear whether patients with lower baseline MG-ADL scores, who may have less severe symptoms, derive similar benefit

Objective

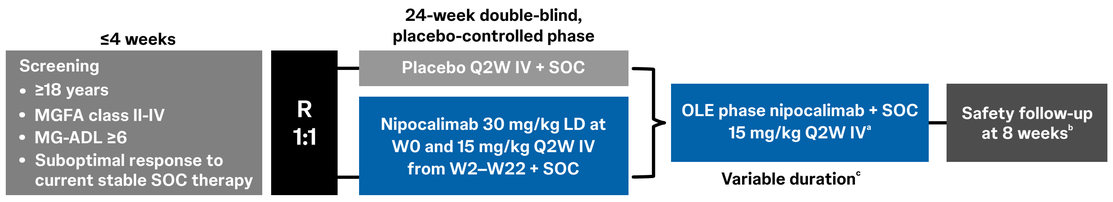
To assess the efficacy of nipocalimab+SOC in a subset of patients with gMG with lower baseline symptom burden (MG-ADL scores: 6–9) in Vivacity-MG3

Methods

Analysis population

- Patients with gMG and lower baseline symptom burden from efficacy analysis set of Vivacity-MG3 study (**Figure 1**)
  - 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) with baseline MG-ADL score below cohort median score of 9 (total score 6–9)

Figure 1. Study design[4]



[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, **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. Baseline characteristics

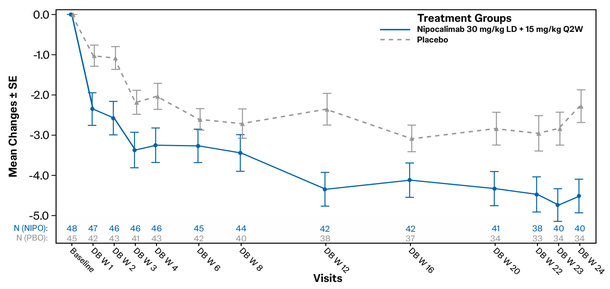
	Baseline MG-ADL total score 6–9	
	Nipocalimab+SOC (n=48)	Placebo+SOC (n=45)
Age, median (range), years	51.0 (20; 81)	47.0 (20; 81)
Female, n (%)	31 (64.6)	26 (57.8)
Race, n (%)		
Asian	18 (37.5)	19 (42.2)
Black or African American	0	1 (2.2)
White	28 (58.3)	24 (53.3)
Not reported	2 (4.2)	1 (2.2)
BMI, median (range), kg/m^2	26.1 (16; 40)	26.3 (16; 41)
Duration of MG, median (range), years	3.0 (0; 25)	7.0 (0; 37)
Age at onset, median (range), years	43.5 (4; 78)	38.0 (7; 78)
Baseline MG-ADL total score, mean (SD)	7.6 (0.87)	7.6 (1.02)
Baseline QMG total score, mean (SD)	13.6 (4.27)	14.9 (5.60)
Antibody-positive at screening, n (%)	48 (100.0)	45 (100.0)
Anti-AChR+	42 (87.5)	43 (95.6)
Anti-MuSK+	6 (12.5)	2 (4.4)
Anti-LRP4+	0	0
MGFA Class, n (%)		
I	1 (2.1)[a]	0
IIa	5 (10.4)	8 (17.8)
IIb	8 (16.7)	8 (17.8)
IIIa	24 (50.0)	17 (37.8)
IIIb	9 (18.8)	8 (17.8)
IVa	1 (2.1)	4 (8.9)
IVb	0	0

[a]Patient had MGFA class IIa at screening and MG-ADL of 8 at both screening and baseline.
***AChR**=acetylcholine receptor, **BMI**=body mass index, **LRP4**=low-density lipoprotein receptor-related protein 4, **MG**=myasthenia gravis, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **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: 3.2 (2.56); placebo+SOC: 5.3 (2.42)
- 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 baseline MG-ADL total score over time

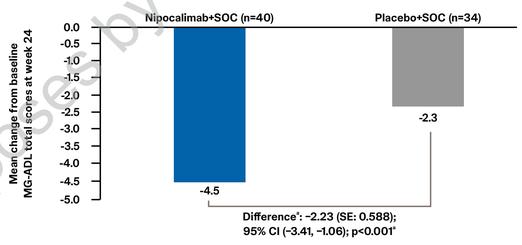


***DB**=double-blind, **LD**=loading dose, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **NIPO**=nipocalimab, **PBO**=placebo, **Q2W**=every 2 weeks, **SE**=standard error, **W**=week.*

MG-ADL Total Score: Mean change from baseline

- At week 24, mean (SD) change in baseline total score were, nipocalimab+SOC: −4.5 (2.64) versus placebo+SOC: −2.3 (2.37)
- Difference: −2.23 (SE: 0.588); 95% CI (−3.41, −1.06); p<0.001 (**Figure 3**)

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

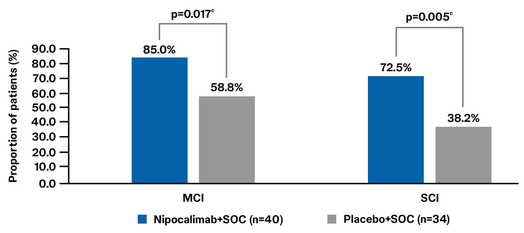


[a]Calculated from two-sample t-test comparing MG-ADL total score change from baseline between treatments.
***CI**=confidence interval, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SE**=standard error, **SOC**=standard of care.*

MG-ADL: MCI and SCI

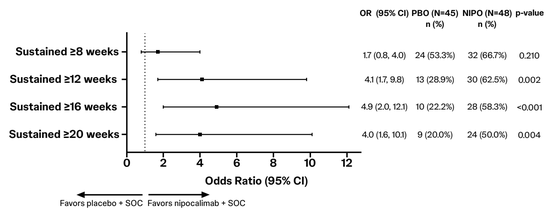
- At week 24, a greater proportion of nipocalimab+SOC patients met MCI and SCI criteria for MG-ADL total scores versus placebo+SOC (**Figure 4**)
- Patients treated with nipocalimab+SOC had 4 times greater odds of achieving MCI compared with patients treated with placebo+SOC over 24 weeks
  - Unstratified OR ratio (95% CI): 4.0 (1.3, 12.0); p=0.017
- Significantly greater proportion of nipocalimab+SOC patients sustained MCI for ≥12, 16, and 20 weeks compared with patients treated with placebo+SOC (**Figure 5**)
- Patients treated with nipocalimab+SOC had 4.3 times greater odds of achieving SCI compared with patients treated with placebo+SOC over 24 weeks
  - Unstratified OR ratio (95% CI): 4.3 (1.6, 11.3); p=0.005

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 improvements from baseline to week 24

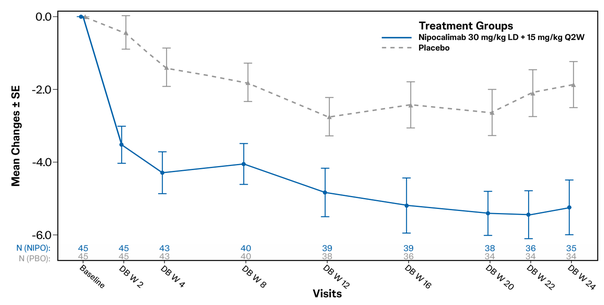


[a]Longest uninterrupted duration of improvement.
***CI**=confidence interval, **MCI**=meaningful clinical improvement, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **NIPO**=Nipocalimab, **OR**=odds ratio, **PBO**=placebo, **SOC**=standard-of-care.*

QMG Total Score: Change from baseline over time

- At week 24, mean (SD) total scores were: nipocalimab+SOC: 9.1 (5.65); placebo+SOC: 12.9 (6.55)
- 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 baseline QMG score over time during DB phase

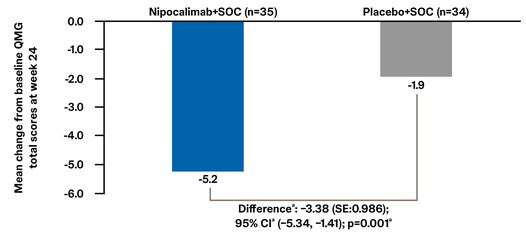


***DB**=double-blind, **LD**=loading dose, **NIPO**=Nipocalimab, **PBO**=placebo, **Q2W**=every 2 weeks, **QMG**=Quantitative Myasthenia Gravis, **SE**=standard error, **W**=week.*

QMG Total Score: Mean change from baseline

- At week 24, Mean (SD) change from baseline score were nipocalimab+SOC: −5.2 (4.45); placebo+SOC: −1.9 (3.69)
  - Difference: −3.38 (SE: 0.986); 95% CI (−5.34; −1.41); p=0.001 (**Figure 7**)

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

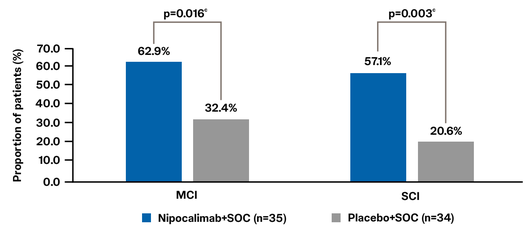


[a]Calculated from two-sample t-test comparing QMG total score change from baseline between treatments.
***CI**=confidence interval, **QMG**=Quantitative Myasthenia Gravis, **SE**=standard error, **SOC**=standard-of-care.*

QMG: MCI and SCI

- At week 24, a greater proportion of nipocalimab+SOC patients met MCI and SCI criteria for QMG total scores versus placebo+SOC (**Figure 8**)
- Patients treated with nipocalimab+SOC had 3.5 times greater odds of achieving MCI compared with patients treated with placebo+SOC over 24 weeks
  - Unstratified OR ratio (95% CI): 3.5 (1.3, 9.6), p=0.016
- Patients treated with nipocalimab+SOC had 5.1 times greater odds of achieving SCI compared with patients treated with placebo+SOC over 24 weeks
  - Unstratified OR ratio (95% CI): 5.1 (1.8, 15.0), p=0.003

Figure 8. Proportion of patients achieving QMG MCI-3[a] and SCI-4[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.*

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