

Efficacy and Safety of Nipocalimab: Switch From 15 mg/kg Every 2 Weeks to 30 mg/kg Every 4 Weeks (Vivacity-MG3 Open-Label Extension)

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Introduction

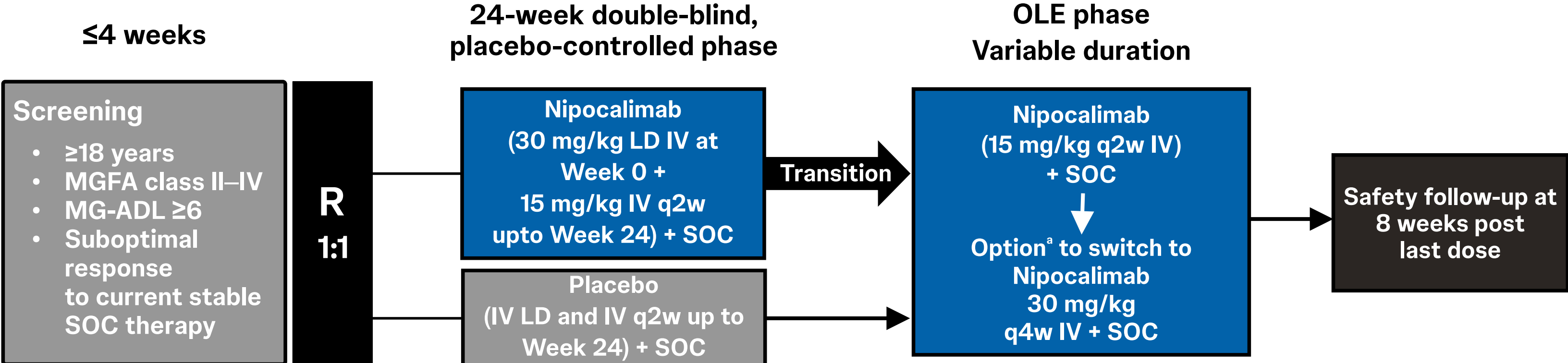
- Generalized myasthenia gravis (gMG) is a chronic autoimmune neuromuscular disorder characterised by fluctuating skeletal muscle weakness and fatigability¹
- Nipocalimab is the first approved neonatal Fc receptor (FcRn) blocker for the treatment of gMG in anti-acetylcholine receptor (AChR) or anti-muscle-specific kinase (MuSK) antibody-positive adult and adolescent (≥12 years of age) patients^{2,3}
 - Approved dosing regimen (intravenous [IV]): loading dose of 30 mg/kg followed by a maintenance dose of 15 mg/kg every 2 weeks (q2w)
- In the randomized, double-blind (DB), placebo-controlled treatment phase of the Vivacity-MG3 study, nipocalimab+SOC demonstrated rapid and sustained disease control based on changes in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores in adult patients with gMG.⁴ Symptom improvements were maintained through the 96-week extension (120 weeks total)⁵
- During the open-label extension phase (OLE), patients from the double-blind phase were transitioned to 15 mg/kg IV q2w dosing and had the option to switch to 30 mg/kg IV every 4 week (q4w) dosing⁴

Objectives

To assess the efficacy and safety of nipocalimab in participants who switched from 15 mg/kg q2w to 30 mg/kg q4w in the OLE of the VIVACITY-MG3 study

Methods

Study design



Efficacy endpoints

- MG-ADL and QMG scores were assessed at OLE baseline, pre-switch (average of 3 visit values before initiation of q4w administration) and post-switch (average of all visit values after initiation of q4w administration but prior to the start of subsequent 15 mg/kg q2w).

Safety endpoints

- Treatment-emergent adverse events (TEAEs) were compared between q2w and q4w dosing periods.

Statistical Analysis

- Statistical analyses were descriptive, with mean, standard deviation, median, range reported for efficacy and safety endpoints
- The efficacy analysis set included all seropositive participants (n=21); the safety analysis included all seropositive and seronegative participants who switched to 30 mg/kg q4w dosing during the OLE (n=25)

Results

Baseline Demographics

- A total of 153 participants entered the OLE
- During the OLE, 25 participants switched to 30 mg/kg q4w dosing, 21 were seropositive
- Of the 21 participants who were seropositive:
 - The median age was 48.0 years (range: 26–83), and 61.9% were female (Table 1)
 - Mean (SD) duration of q4w dosing was 17.7 (15.78) weeks
 - Mean (SD) baseline MG-ADL and QMG total scores were 8.3 (3.50) and 14.8 (6.08), respectively

Table 1. Demographics and OLE baseline characteristics in seropositive patients who switched to nipocalimab 30 mg/kg q4w in OLE

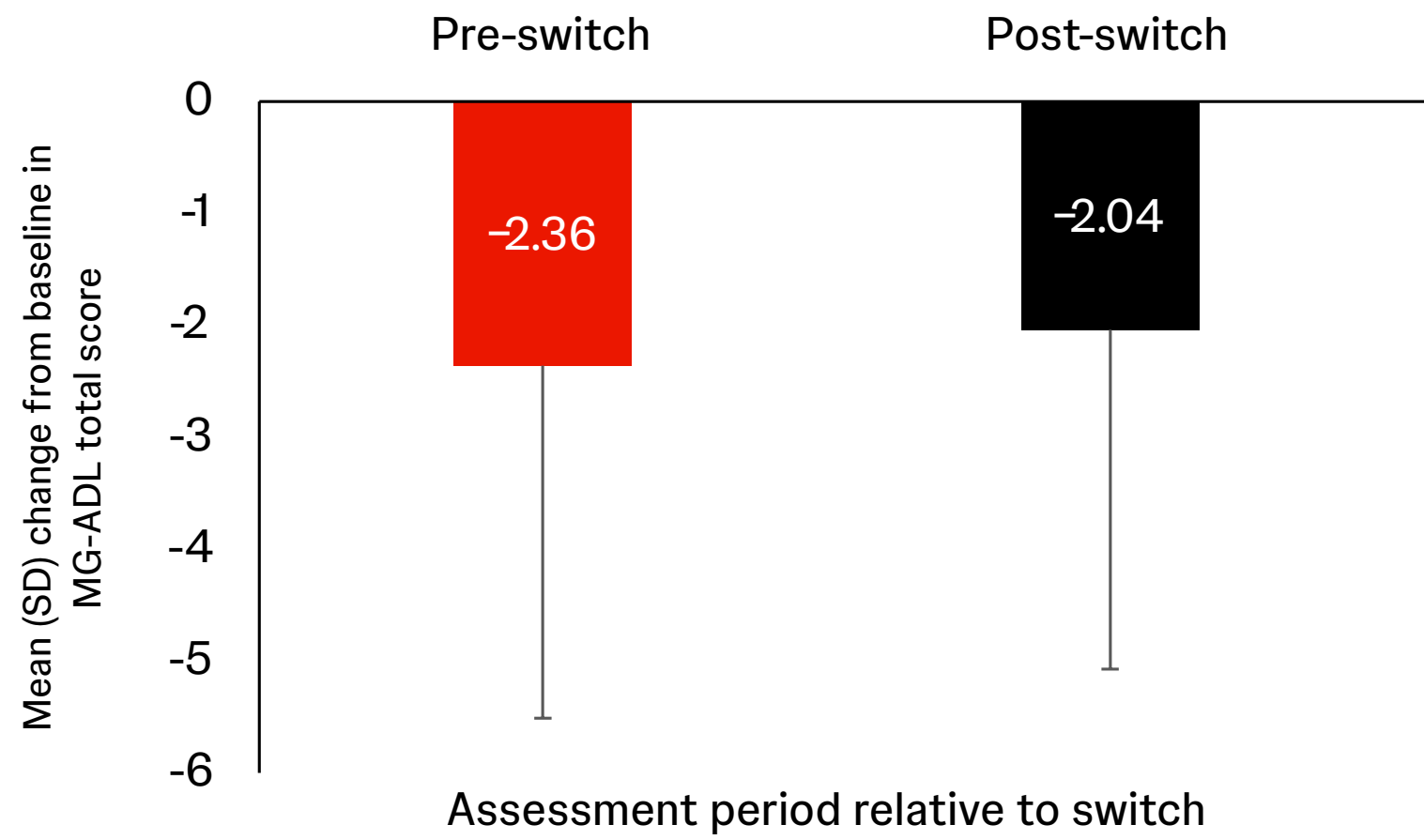
Characteristic	Nipocalimab 30 mg/kg q4w (N=21)
Age, median (range)	48 (26–83)
Female, n (%)	13 (61.9)
BMI, kg/m ² , mean (SD)	30.1 (8.12)
Total duration of treatment (weeks), mean (SD)*	17.7 (15.78)
Total number of administrations received, mean (SD)	5.0 (1–13)
MG-ADL total score, n	16
Baseline, mean (SD)	8.3 (3.50)
QMG total score, n	15
Baseline, mean (SD)	14.8 (6.08)
Autoantibody status at screening, n (%)	21
Anti-AChR+	18 (85.7)
Anti-MuSK+	2 (9.5)
Anti-LRP4+	1 (4.8)
MGFA classes, n (%)	21
I	0 (0.0)
IIa	7 (33.3)
IIb	7 (33.3)
IIIa	9 (42.9)
IIIb	1 (4.8)
IVa	2 (9.5)
IVb	0 (0.0)

**The total duration of treatment is defined as (date of last dose of study intervention – date of first dose of study intervention) + 1. AChR=Acetylcholine receptor, BMI=Body mass index, LRP4=Low-density lipoprotein receptor-related protein 4, MG-ADL=Myasthenia Gravis Activities of Daily Living, MGFA=Myasthenia Gravis Foundation of America, MuSK=Muscle-specific kinase, OLE=open-label extension, q4w=Every 4 weeks, QMG=Quantitative Myasthenia Gravis, SD=Standard deviation.*

MG-ADL: Mean Change From Baseline

- In seropositive participants who switched to 30 mg/kg q4w the baseline mean (SD) MG-ADL total score was 8.3 (3.50)
- There was no significant difference in MG-ADL total scores before vs after switch to 30 mg/kg q4w; mean (SD) change from baseline was –2.36 (3.15) pre-switch and –2.04 (3.03) post-switch (Figure 1)

Figure 1. Mean (SD) change from baseline^a in MG-ADL total score before vs after switch to 30 mg/kg q4w

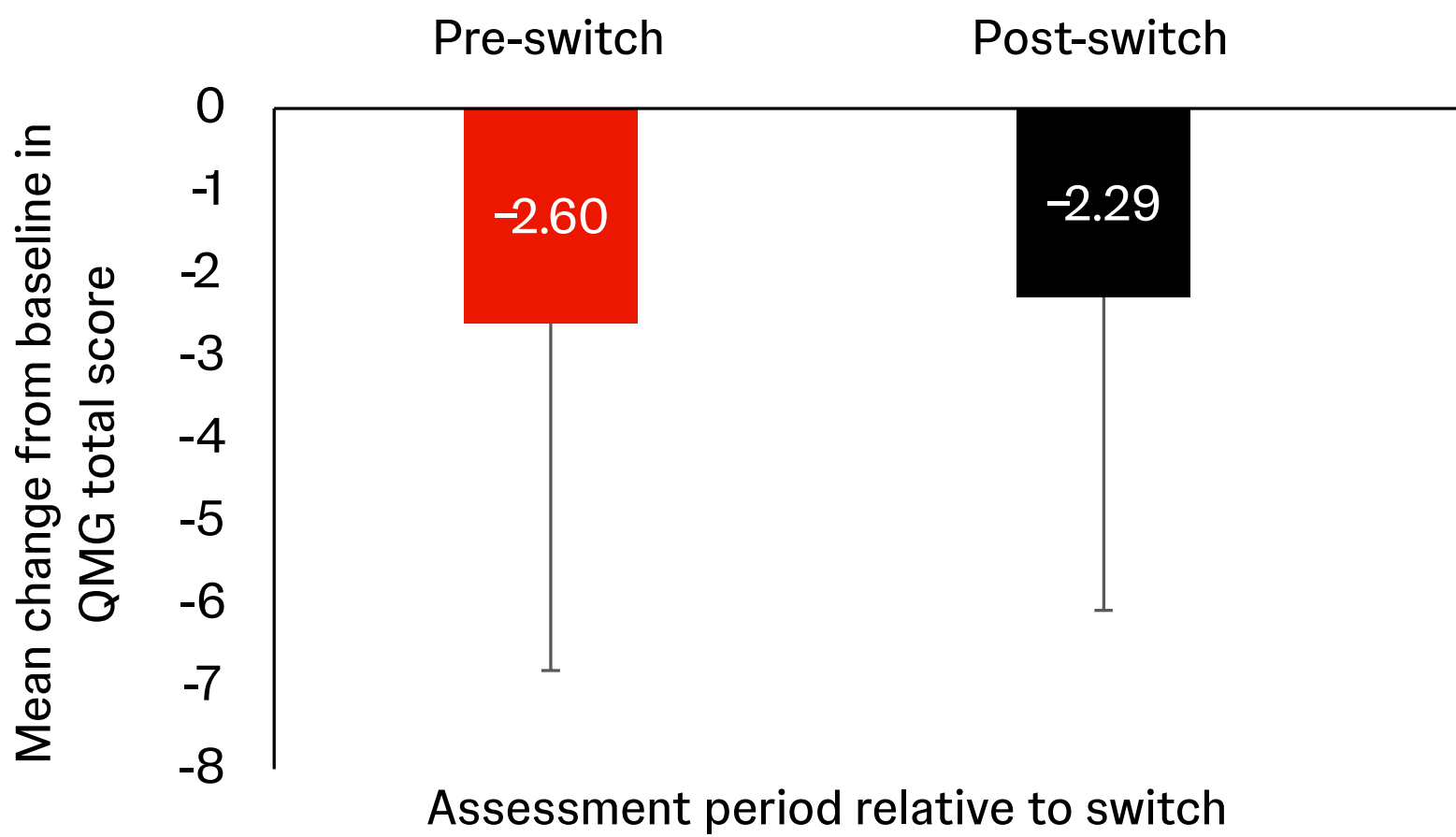


^aBaseline values for 5 patients were obtained from DB baseline; baseline data for remaining patients were taken from OLE baseline. Note: Negative values indicate improvement. Pre q4 was based on the average of 3 visits before initiation of q4w administration. Post 30 mg/kg q4w is based on the average of all visits after initiation of q4w administration prior to the start of subsequent 15 mg/kg q2w. MG-ADL=Myasthenia Gravis-Activities of Daily Living, q2w=Every 2 weeks, q4w=Every 4 weeks, SD=standard deviation.

QMG: Mean Change From Baseline

- For the seropositive q4w QMG analysis set, the baseline mean (SD) QMG total score was 14.8 (6.08)
- Mean (SD) change from baseline was –2.60 (4.21) pre-switch and –2.29 (3.79) post-switch (Figure 2)

Figure 2. Mean (SD) change from baseline^a in QMG total score before vs after switch to 30 mg/kg q4w



^aBaseline values for 5 patients were obtained from DB baseline; baseline data for remaining patients were taken from OLE baseline. Note: Pre q4w is based on the average of 3 visits before initiation of q4w administration. Post 30mg/kg q4w is based on the average of all visits after initiation of q4w administration prior to the start of subsequent 15 mg/kg q2w. Negative values indicate improvement. DB=Double-Blind, OLE=open-label extension, SD=standard deviation, QMG=Quantitative Myasthenia Gravis, q2w=Every 2 Weeks, q4w=Every 4 weeks.



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Key Takeaways

Temporary switch of nipocalimab dosing from 15 mg/kg q2w to 30 mg/kg q4w dosing in the Vivacity-MG3 OLE phase maintained clinical efficacy and a safety profile consistent with 15 mg/kg q2w dosing

However, the small sample size and short duration of follow-up limit the interpretation of results in the 30 mg/kg q4w dosing group.

Safety Outcomes

- Safety outcomes were comparable between q2w and q4w dosing groups (Table 2)
- Infections and infestations were the most commonly reported TEAEs (44.0% vs 48.0% for q2w and q4w dosing groups)
- The most commonly occurring TEAEs by preferred terms included sinusitis, and nasopharyngitis; and myasthenia gravis (Table 3)
- There were no serious related TEAEs or TEAEs leading to permanent treatment discontinuation or fatal TEAEs

Table 2. Overall summary of TEAEs by dosing group

	Nipocalimab	
Characteristic, n (%)	15 mg/kg q2w (N=25)	30 mg/kg q4w (N=25)
Average duration of follow-up (weeks)	18.07	21.01
≥1 TEAEs	24 (96.0)	19 (76.0)
≥1 related TEAEs	12 (48.0)	5 (20.0)
≥1 serious TEAEs	3 (12.0)	1 (4.0)
≥1 related serious TEAEs	0	0
TEAEs leading to death	0	0
TEAEs leading to temporary discontinuation	5 (20.0)	1 (4.0)
TEAEs leading to permanent discontinuation	0	0
TEAEs leading to termination of study participation	0	0
COVID-19 associated TEAEs	3 (12.0)	3 (12.0)
COVID-19 associated serious TEAEs	0	0

Related TEAEs are those examined by the investigator as related to the study agent. COVID-19=Coronavirus disease 2019, q2w=Every 2 weeks, q4w=Every 4 weeks, TEAE=Treatment-emergent adverse event.

Table 3. TEAEs reported in >10% participants

System Organ Class / Preferred Term	Nipocalimab	
Characteristic, n (%)	15 mg/kg q2w (N=25)	30 mg/kg q4w (N=25)
Infections and infestations	11 (44.0)	12 (48.0)
Sinusitis	0	3 (12.0)
Nasopharyngitis	3 (12.0)	2 (8.0)
Nervous system disorders	3 (12.0)	4 (16.0)
Myasthenia gravis	2 (8.0)	4 (16.0)

q2w=Every 2 weeks, q4w=Every 4 weeks, TEAE=Treatment-emergent adverse events.