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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Key Takeaways

- **Temparory 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.**

Introduction

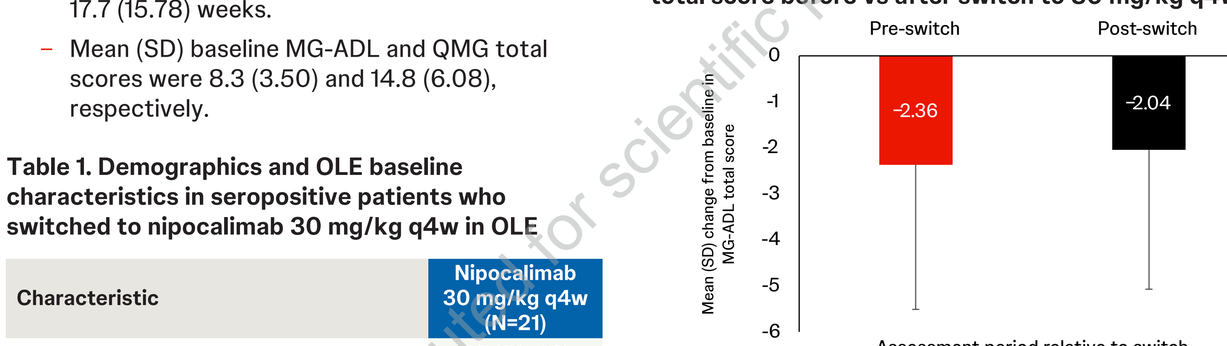
- Generalized myasthenia gravis (gMG) is a chronic autoimmune neuromuscular disorder characterised by fluctuating skeletal muscle weakness and fatigability.[1]
- Nipocalimab is the first approved FcRn blocker for the treatment of gMG in anti-AChR or anti-MuSK antibody-positive adult and adolescent (≥12 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) dosing.[4]

Objectives

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

Methods

Study design



[a]*This option was available for a limited period and was subsequently removed following a protocol amendment[4].*
***DB**=Double-blind, **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.*

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 siropositive.
- 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)[a]	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)

[a]*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, **LRP4**=Low-density Lipoprotein Receptor-related Protein 4, **MG-ADL**=Myasthenia Gravis-Actvities of Daily Living, **MuSK**=Muscle-Specific Kinase, **QMG**=Quantitative Myasthenia Gravis, **q4w**=Every 4 weeks.*

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**).

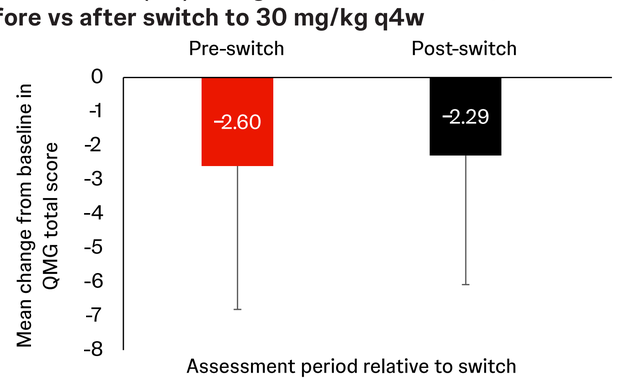
Figure 1. Mean (SD) change from baseline[a] in MG-ADL total score before vs after switch to 30 mg/kg q4w

[a]*Baseline 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 q4wis 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



[a]*Baseline 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,*
***QMG**=Quantitative Myasthenia Gravis, **q2w**=Every 2 Weeks, **q4w**=Every 4 weeks, **SD**=Standard deviation.*

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

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.*

PRESENTED AT: International Congress on Neuromuscular Diseases (ICNMD); July 7–11, 2026; Florence, Italy. **REFERENCES: 1.** Gilhus NE, et al. *Nat Rev Dis Primers.* 2019;5:30. **2.** IMAAVY™ (nipocalimab-aahu) injection for intravenous use [Package Insert] Horsham, PA; Janssen Pharmaceutical Companies, 2025. **3.** European Medicines Agency. ImaavyTM. European Medicines Agency; 2025 Sep 22. https://www.ema.europa.eu/en/medicines/human/ EPAR/imaavy. **4.** Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105–116. **5.** Tuan Vu. 2026. Efficacy and Safety of Nipocalimab: Switch From 15-mg/kg Every-2-Week to 30-mg/kg Every-4-Week (VIVACITY-MG3 Open-Label Extension). 2026 AAN Annual Meeting. **DISCLOSURES: Tuan Vu:** USF Site Principal Investigator for MG clinical trials sponsored by Alexion/AstraZeneca Rare Disease, Amgen, argenx, Cartesian Therapeutics, COUR Pharma, Dianthus Therapeutics, EMD Serono, Immunovant, Johnson & Johnson, NMD Pharma, Regeneron, and UCB. Speaker for Alexion/AstraZeneca Rare Disease CSL Behring, and argenx and participated on advisory boards for Alexion/AstraZeneca Rare Disease, argenx, Amgen, Dianthus Therapeutics, Johnson & Johnson, ImmunAbs, and NMD Pharma. **Marie Fitzgibbon, Kavita Gandhi, Yaowei Zhu, Jocelyn H. Leu, Ibrahim Turkoz, Sindhu Ramchandren:** Employees of Johnson & Johnson and may hold stock or stock options in Johnson & Johnson. **Nolan Campbell** was an employee of Johnson & Johnson and presently is an employee of Vor Bio. Nolan owns stock in Johnson & Johnson and Vor Bio. **ACKNOWLEDGEMENT:** The authors thank the study patients and investigators for their participation. Himabindu Gutha, PhD CMPP (SIRO Medical Writing Pvt. Ltd., India) provided medical writing assistance and Doyel Mitra, PhD CMPP (Johnson & Johnson) provided additional editorial support. Sandeep Chavan (SIRO Medical Writing Pvt. Ltd., India) provided graphic designing support. An internal enterprise GenAI assistant (Evidence CoPilot) was used to support the development of a preliminary draft of this presentation; all outputs were independently reviewed, verified, and edited by the medical writer and authors, who take full responsibility for the content. **FUNDING:** This work was funded by Johnson & Johnson.