

Two-Year Follow-Up Results of Nipocalimab in Adolescents With Generalized Myasthenia Gravis During Active-Treatment and Long-Term Extension Phases: vibrance-mg Phase 2/3 Study

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Introduction

- Nipocalimab is a fully human monoclonal antibody that binds to the neonatal Fc receptor (FcRn) with high affinity and specificity, reducing circulating levels of IgG, including pathogenic IgG-based autoantibodies^{1,2}
- Nipocalimab is approved for the treatment of generalized MG (gMG) in adult and adolescent (≥ 12 years of age) patients who are anti-acetylcholine receptor (AChR) positive or anti-muscle-specific tyrosine kinase (MuSK) antibody positive^{3,4}
 - This approval was supported by the pivotal phase 3 Vivacity-MG3 study involving adults with gMG⁵
 - In Vivacity-MG3, nipocalimab added to standard of care (SOC) lowered levels of circulating IgG and pathogenic IgG autoantibodies, and led to symptom improvement sustained over 24 weeks, and up to 60 weeks in the open-label extension^{5,6}
- In the phase 2/3 vibrance-mg study, nipocalimab added to SOC demonstrated rapid and substantial reductions in total serum IgG, and sustained disease control over 24 weeks in adolescents (12 to <18 years of age) with gMG⁵

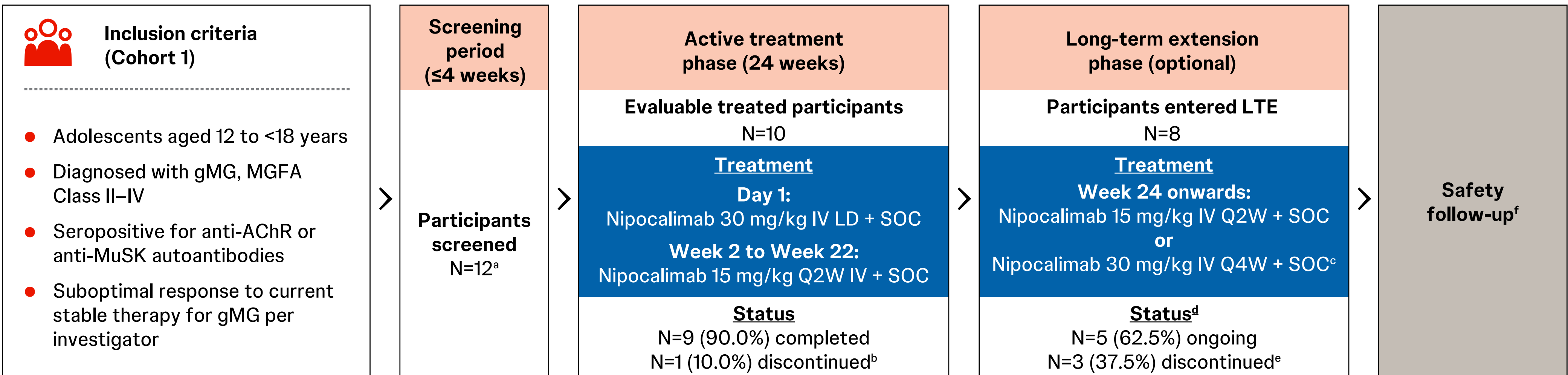
Objective

To analyze long-term efficacy and safety of nipocalimab added to SOC therapy in adolescent patients with gMG in the vibrance-mg study through 2 years of treatment

Methods

- Vibrance-mg (NCT05265273) is a global, multicenter, open-label phase 2/3 study evaluating nipocalimab + SOC in adolescents (Cohort 1; **Figure 1**) and children (Cohort 2; enrollment ongoing) with suboptimally controlled gMG on stable SOC therapy^{5,7}
- At the end of the 24-week active treatment (AT) phase, participants had the option to enroll in the long-term extension (LTE) phase
- Cohort 1 participants received an initial loading dose of nipocalimab 30 mg/kg IV, followed by 15 mg/kg every 2 weeks (Q2W). During the LTE, dosing could be adjusted at the investigator's discretion to either 15 mg/kg Q2W or 30 mg/kg every 4 weeks (Q4W)

Figure 1. Study design (Cohort 1)



¹Two participants failed during the screening phase. ²Due to lack of efficacy. ³Five participants switched from Q2W to Q4W at various times. ⁴As of data cutoff, January 26, 2026. ⁵Withdrawal by participant due to lack of improvement in MG disease status. (n=2); withdrawal by participant to pursue alternative treatment (n=1). ⁶Participants who withdraw or discontinue after receiving any amount of study intervention will be required to complete a safety follow-up visit 8 weeks after their last dose. ⁷AChR=acetylcholine receptor, AT=active treatment, gMG=generalized myasthenia gravis, IV=intravenous, LD=loading dose, LTE=long-term extension. ⁸MGFA=Myasthenia Gravis Foundation of America, MuSK=muscle-specific kinase, Q2W=every 2 weeks, Q4W=every 4 weeks, SOC=standard of care. This figure has been adapted from the figure previously presented at the MGFA Scientific Session of the AANEM Annual Meeting and AANEM Annual Meeting, Savannah, Georgia, USA; October 15–18, 2024.

✓

Nipocalimab showed rapid and substantial reductions in serum total IgG, and sustained disease control up to 2 years of treatment in adolescents with gMG

✓

The majority of patients on corticosteroids reduced their dose or discontinued corticosteroids during nipocalimab treatment

✓

The safety profile of nipocalimab was similar to that reported in adult patients, and no new safety signals were identified

Results

Participant disposition and baseline characteristics

- Among 10 evaluable adolescents in Cohort 1, median age is 13.5 years, and 8 (80%) are female (**Table 1**)
 - Race: 6 (60%) Asian, 1 (10%) Black or African American, 1 (10%) White, 2 (20%) unknown
- A total of 9 adolescents completed the AT phase; among these, 8 entered the LTE
 - 5 participants are continuing treatment as of data cutoff; 3 participants discontinued (all withdrawal by participant, due to lack of improvement in MG disease status [n=2] or to pursue alternative treatment [n=1])
- Median duration of follow-up was 102.6 (range: 18–152) weeks

Table 1. Demographics and AT baseline characteristics of adolescent participants in cohort 1

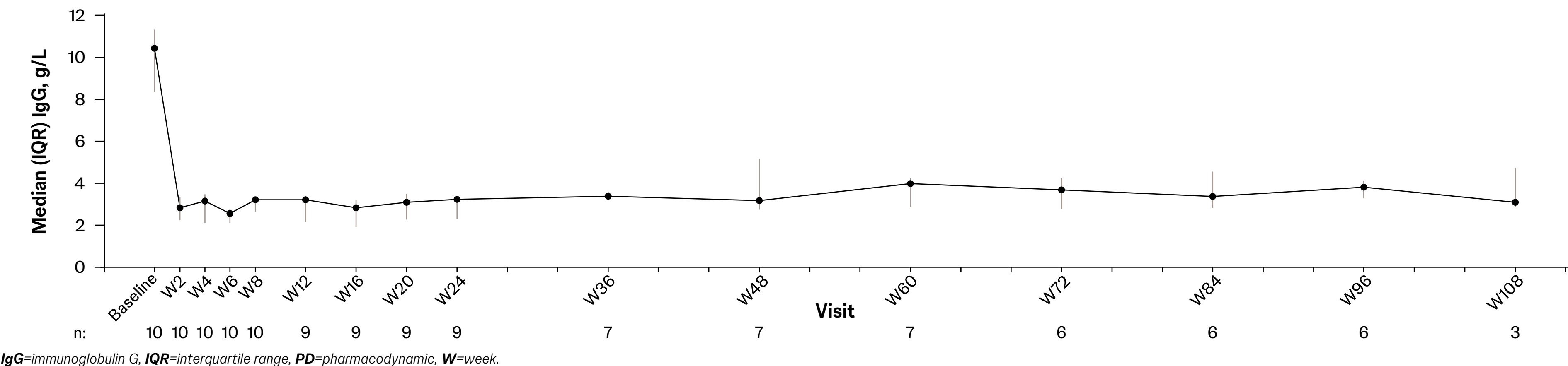
Characteristics	Cohort 1 (N=10)
Age, years	13.5 (12–16)
Sex, female, n (%)	8 (80.0)
Weight, kg	52.2 (30.9–95.5)
Duration of MG, years	3.6 (0.3–11.5)
Baseline MG-ADL total score	3.5 (2.0–9.5)
Autoantibody type, anti-AChR+, n (%)	10 (100.0)
Baseline QMG total score	13.3 (6.5–19.0)
Age at onset of MG, years	10.5 (0.5–15.7)
Participants with ≥ 1 concomitant MG medications, n (%) ^a	10 (100.0)
Immunosuppressants	8 (80.0)
Corticosteroids for systemic use	7 (70.0)

Data shown are median (range) unless otherwise indicated. ^aAlso included other nervous system drugs (acetylcholinesterase inhibitors pyridostigmine and pyridostigmine bromide), and drugs for acid related disorders. AChR=acetylcholine receptor, AT=active treatment, MG=myasthenia gravis, MG-ADL=Myasthenia Gravis-Activities of Daily Living, QMG=Quantitative Myasthenia Gravis.

Effect of nipocalimab on total serum IgG

- Nipocalimab treatment led to rapid and sustained reductions in total serum IgG (**Figure 2**)
- Median (IQR) % change from baseline in total IgG was –73.34% (–77.92, –70.16) at Week 2 and was –73.30% (–78.69, –68.93) at Week 24
- Effect on total IgG lowering was generally sustained in the LTE, to –50.21% (–74.21, –43.09) at Week 108
- In the subgroup of participants receiving Q2W (n=2) at Week 108, mean % change from baseline in total IgG was –62.21%

Figure 2. Median (IQR) total serum IgG levels over time

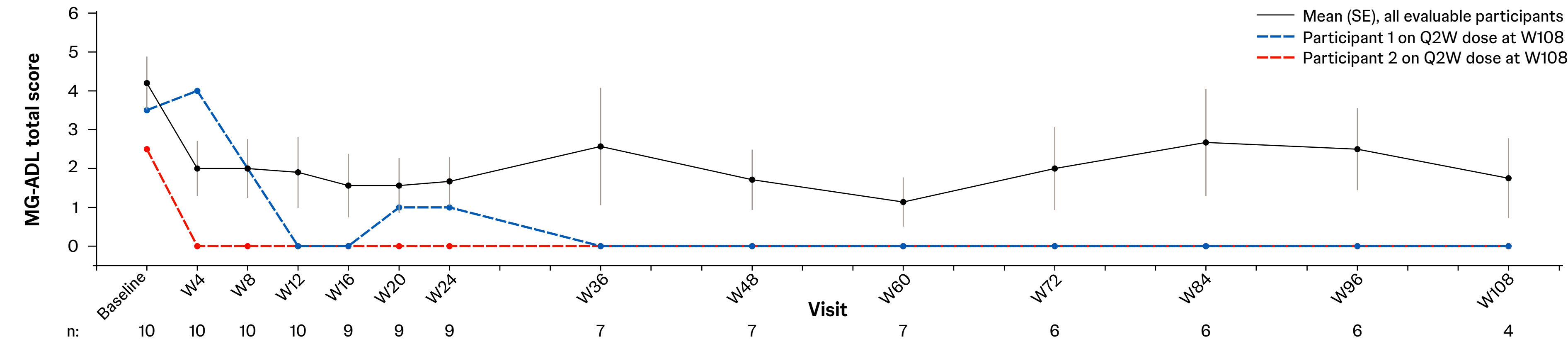


IgG=immunoglobulin G, IQR=interquartile range, PD=pharmacodynamic, W=week.

Effect of nipocalimab on MG-ADL total score

- A clinically meaningful reduction in MG-ADL score was observed by Week 4, and was maintained through the AT phase (**Figure 3**)
 - Mean (SE) change from baseline in MG-ADL was –2.20 (0.490) at Week 4 and was –2.44 (0.242) at Week 24
- Effect on MG-ADL reduction was generally sustained in the LTE, to –2.88 (1.143) at Week 108
- 6 of 9 participants (66.7%) with available MG-ADL assessment showed minimal symptom expression (MSE; MG-ADL of 0 or 1) at Week 24
- At Week 108, 2 of 4 (50.0%) participants showed MSE; both were on Q2W dose (**dotted lines in Figure 3**)
- In the subgroup of participants receiving Q2W (n=2) at Week 108, mean change from baseline in MG-ADL total score was –3 (**Figure 3**)

Figure 3. MG-ADL total scores over time

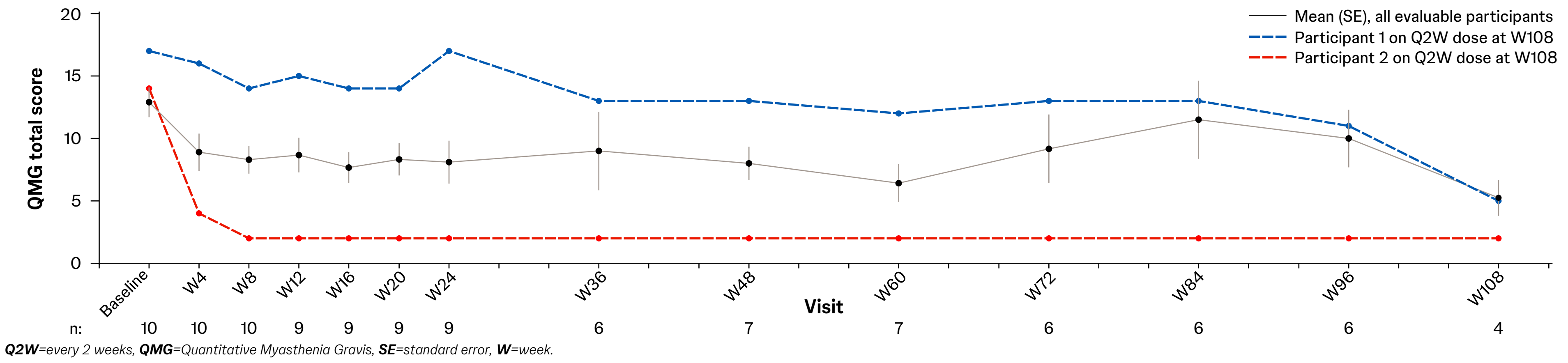


MG-ADL=Myasthenia Gravis-Activities of Daily Living, Q2W=every 2 weeks, SE=standard error, W=week.

Effect of nipocalimab on QMG total score

- A clinically meaningful reduction in QMG total score was observed at Week 4 and maintained through the AT phase (**Figure 4**)
 - Mean (SE) change from baseline in QMG was –4.00 (1.133) at Week 4 and was –4.83 (1.106) at Week 24
- Effect on QMG reduction was generally sustained in the LTE, to –8.25 (2.203) at Week 108
- In the subgroup of participants receiving Q2W (n=2) at Week 108, mean change from baseline in QMG total score was –12 (**Figure 4**)

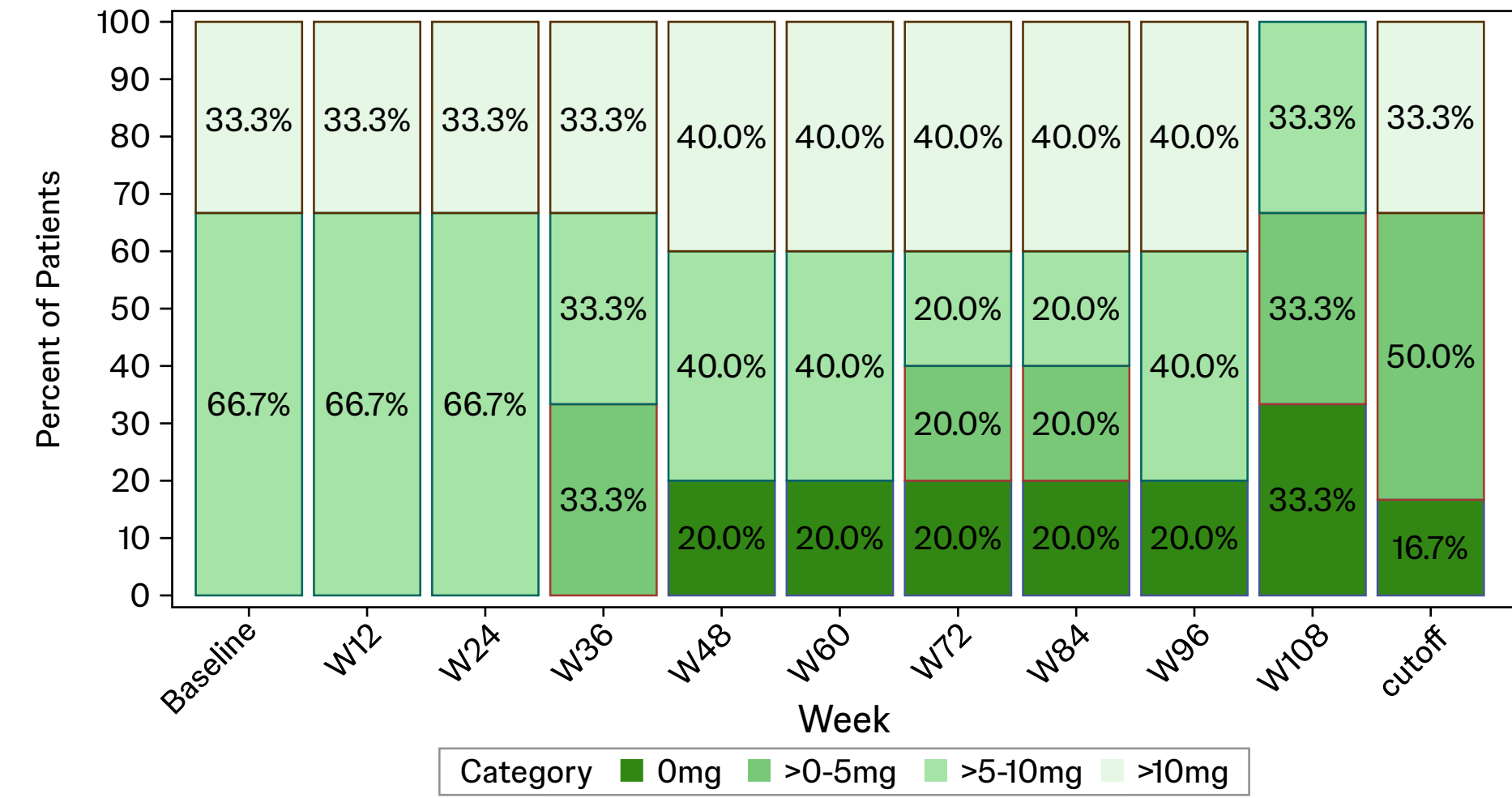
Figure 4. QMG total score over time



Corticosteroid use

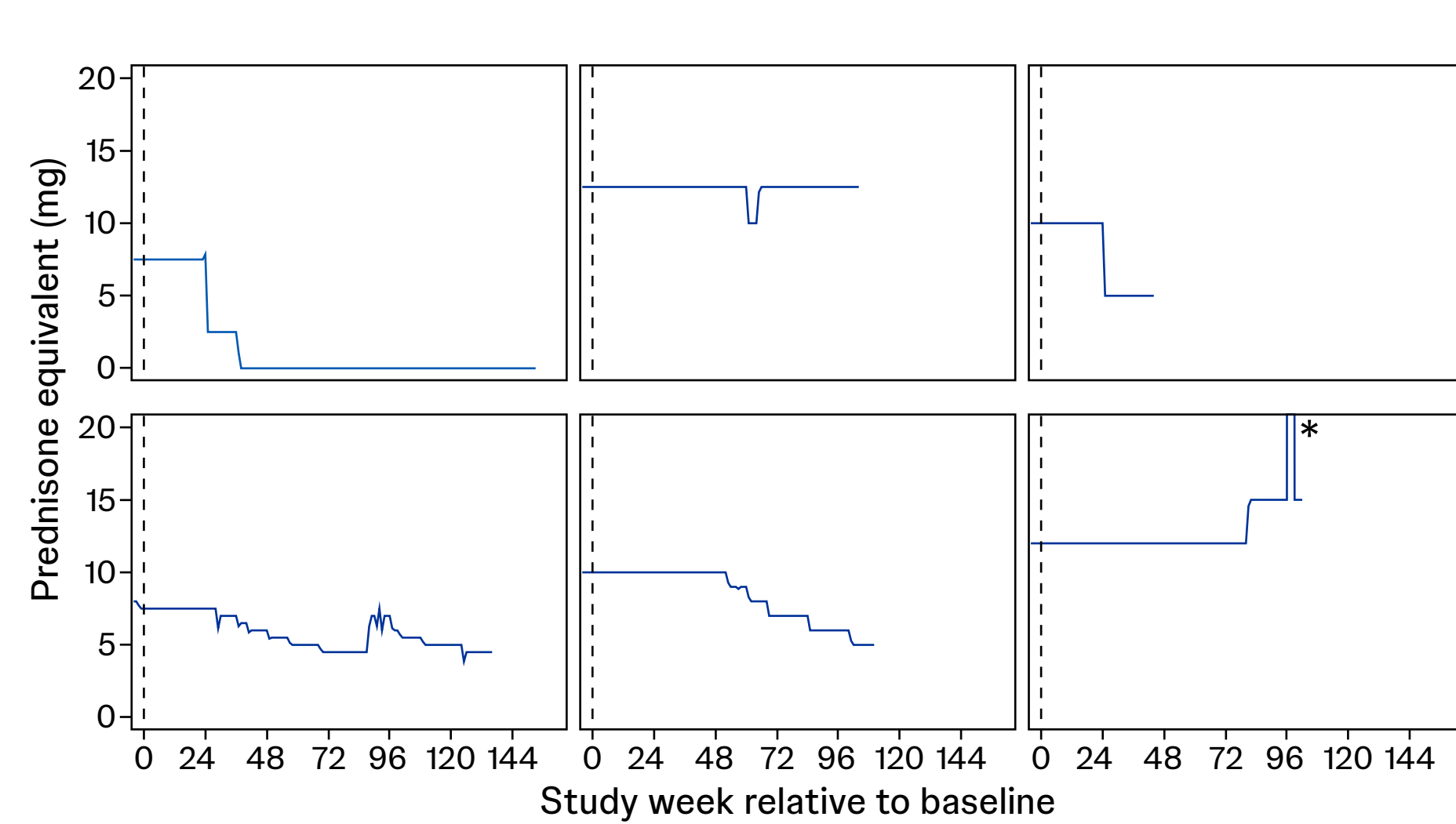
- Steroid usage and doses decreased over the study period (**Figure 5**)
 - Corticosteroid tapering was allowed only during the LTE and was at the investigator's discretion
- During the LTE and up to data cutoff, 4 of 6 participants receiving corticosteroids at LTE entry reduced or discontinued corticosteroid therapy (3 reduced dosage, 1 discontinued corticosteroids), while 1 maintained a stable dose and 1 increased the dose (**Figure 6**)

Figure 5. Percentage of patients in each steroid dose category over the study period (AT and LTE)



Prednisone (mg) dose at each timepoint equals the mean daily prednisone dose for the 28 days prior to and including that timepoint. Cutoff date is the analysis reference end date for patient or discontinuation date for patients that discontinued study treatment. AT=active treatment, LTE=long-term extension, W=week.

Figure 6. Steroid doses over time in individual participants



Prednisone (mg) dose at each timepoint equals the mean daily prednisone dose for the 7 days prior to and including that timepoint. *Participant received prednisone equivalence (mg) of 1,250 for 3 days in response to an adverse event (worsening of MG).

Safety

- Nipocalimab was generally well tolerated across both the AT and LTE phases (**Table 2**)
- The most common treatment-emergent adverse events (TEAEs) were nasopharyngitis (n=4 [40%]), COVID-19 (n=2 [20%]), and diarrhea (n=2 [20%]) in the AT phase, and nasopharyngitis (n=5 [62.5%]), influenza (n=3 [37.5%]), diarrhea (n=2 [25%]), upper respiratory tract infection (n=2 [25%]), fatigue (n=2 [25%]), rhinitis (n=2 [25%]) and myasthenia gravis (n=3 [37.5%]) in the LTE phase
- No AEs of special interest (AESI) were reported during the study

Table 2. Summary of TEAEs in AT and LTE phases

	AT phase (n=10)		LTE phase (n=8)	
	Pts, n	EAIR ^a	Pts, n	EAIR ^a
Average duration of follow-up, in weeks	24.11		80.04	
Participant-Years ^a	5.65		33.32	
Patients with ≥ 1 TEAEs	10	1.77	8	0.24
Related TEAEs	3	0.53	3	0.09
Patients with TEAEs leading to death	0	0	0	0
Patients with SAEs	0	0	2 ^c	0.06
TEAEs leading to temporary discontinuation of study treatment ^d	0	0	2 ^c	0.06
AEs leading to termination of study participation	0	0	0	0
COVID-19 associated TEAEs ^e	2	0.35	0	0
AESIs ^f	0	0	0	0

^aSum of all exposure including follow-up time. ^bEAIR per participant year of exposure. ^cWorsened myasthenia gravis in both participants. ^dNo TEAEs led to permanent discontinuation of study treatment during the AT and LTE phase. ^eInfluenza (n=1) and injection site pain (n=1). ^fNo SAEs related to COVID-19 were reported during the AT and LTE phase. ^gDefined as severe infections requiring systemic treatment or intervention, hypobunimemia (albumin <20 g/L), opportunistic infections, and serious and non-serious deep vein thrombosis and/or pulmonary embolism. ^hAE=adverse event, AESI=adverse event of special interest, AT=active treatment, COVID-19=coronavirus disease 2019, EAIR=exposure-adjusted incidence rate, gMG=generalized myasthenia gravis, LTE=long-term extension, SAE=serious adverse event, SD=standard deviation, TEAE=treatment-emergent adverse event.

PRESENTED AT: Myasthenia Gravis Foundation of America (MGFA) Scientific Session at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting, September 29, 2026, Orlando, FL, USA. **REFERENCES:** 1. Liu JH, et al. *Front Neurosci*. 2024;18:1302714. 2. Ling LH, et al. *Clin Pharmacol Ther*. 2019;105(4):1031–1039. 3. IMaVY™ (nipocalimab-ahm) injection for intravenous use [Package Insert] Horsham, PA: Janssen Pharmaceutical Companies, August, 2026. 4. European Medicines Agency. Imavvy™. European Medicines Agency; 2026 June 1. https://www.ema.europa.eu/en/medicines/human/EPAR/imavvy. 5. Antozzi C, et al. *Lancet Neurol*. 2025;24(10):116. 6. Antozzi C, et al. Presented at: American Academy of Neurology (AAN) Annual Meeting, April 5–9, 2025; San Diego, CA, USA. 7. Antozzi C, et al. *Neurology*. 2023;102(2):e207937. **ACKNOWLEDGMENTS:** The authors thank the study patients and investigators for their participation. Medical writing support was provided by Naniko Abe, PhD, of Johnson & Johnson and Rajani Thakur, PhD, of SIRO Medical Writing Pvt. Ltd., India. Layout design support was provided by Ankit Kaul of SIRO Medical Writing Pvt. Ltd., India (funded by Johnson & Johnson). **DISCLOSURES:** Jonathan Strober: Consultant fees from Pfizer; advisory data monitoring board fees from Scholar Rock; argenx speaker bureau fees from Biogen; research support from Anymon; PTC; Fibrogen; Johnson & Johnson; Biowave; paid editor, associate editor, or editorial advisory board member for Pediatric Neurology; Expert Witness fees from many law firms. **Saunder Bernes:** Declares no conflicts of interest. **Akiyuki Uzawa:** Received honoraria from Alexion Pharmaceuticals, argenx, and UCB. **Yasuhiro Kimoto:** Declares no conflicts of interest. **Keiko Ishigaki:** Consultant fees from ChUGA, Nippon Shinyaku, Amgen, Therapeutics and UCB; advisory board fees from Pfizer, Kenes and Novartis, Japan; speaker bureau fees from Biogen, Sanofi, and Alexion Pharma. **Tuan Vu:** MG-related research or grant support. **Alexion:** AstraZeneca, Rare Disease, Amgen, argenx, Cellcris, CCR, Dianthus, Johnson & Johnson, Immunovant, IVD Pharma, Regeneron, and UCB, consultant &/or speaker bureau; Alexion, argenx, CSL Behring, Amgen, Johnson & Johnson, ImmunAvs, and Dianthus. **Erin Neil Knierbein:** Declares no conflicts of interest. **Erik Niks:** Myasthenia gravis-related clinical trials; argenx and Alexion. **Maria Mazurkiewicz-Beldzinska:** Myasthenia gravis-related clinical trials; argenx. **Hideki Shimomura:** Declares no conflicts of interest. **Sindhu Ramchandren, Dan Huang, Jelena Dukovski, Amita Singh, and Yaowei Zhu:** are employees of Johnson & Johnson and may hold stock or stock options in Johnson & Johnson. **FUNDING:** This work was funded by Johnson & Johnson.