

Effect of Nipocalimab on Sustained Disease Control in Patients who Responded After Week-2 of Treatment Initiation: Post-Hoc Analysis of the Vivacity-MG3 Study

Michael D. Weiss,^{1*} Carly J. Paoli,² Ibrahim Turkoz,³ Marie Fitzgibbon,⁴ Michael Kutch,⁵ Carlo Antozzi⁶
¹Department of Neurology, University of Washington, Seattle, WA, USA; ²Johnson & Johnson, Horsham, PA, USA; ³Johnson & Johnson, Titusville, NJ, USA;
⁴Johnson & Johnson, Raritan, NJ, USA; ⁵Cytel Inc., Cambridge, MA, USA; ⁶Immunotherapy and Apheresis Unit, Neuroimmunology and Muscle Pathology Unit, Fondazione IRCCS Istituto Neurologico C. Besta, Milan, Italy

*Presenting author

Introduction

- Generalized myasthenia gravis (gMG) is an autoantibody-driven disorder characterized by disruption of neurotransmission that severely affects daily functioning and quality of life in patients^{1,2}
- 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 (anti-AChR) or anti-muscle-specific tyrosine kinase (anti-MuSK) antibody positive^{3,4}
- Nipocalimab added to standard-of-care (SOC) demonstrated rapid and substantial IgG reduction and clinical improvement within 2-weeks of treatment and sustained disease control through 24-weeks in the majority of autoantibody-positive (anti-AChR+/anti-MuSK+/anti-low-density lipoprotein receptor-related protein 4 [anti-LRP4]+) patients with gMG in the Vivacity-MG3 (NCT04951622) study⁵
- However, the response characteristics among those who did not respond within the first 2 weeks has not been previously reported

Objective

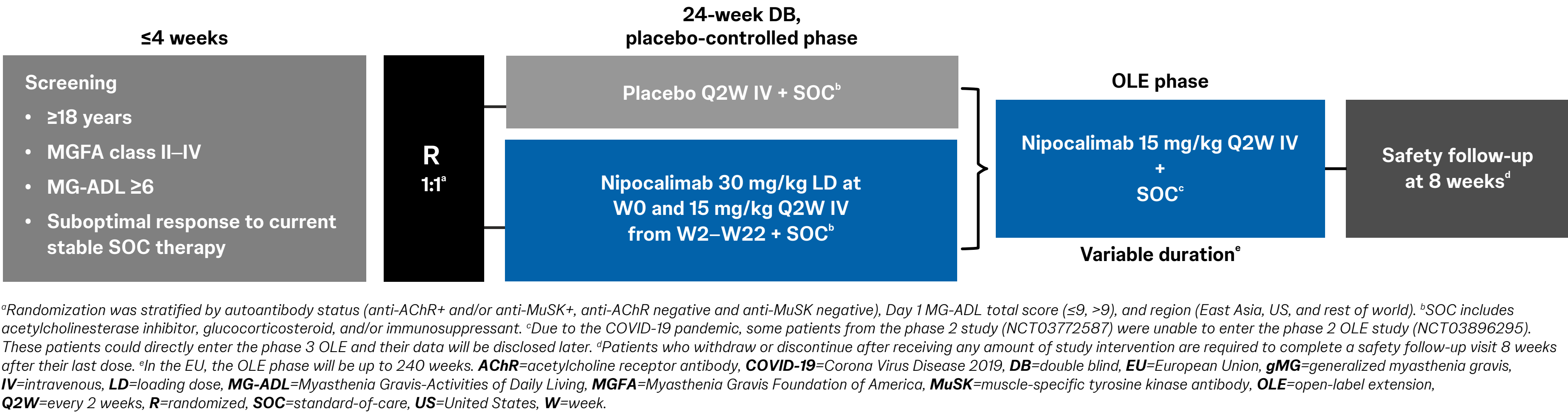
To evaluate the efficacy of nipocalimab+SOC treatment in patients who demonstrated initial clinical response after first 2-weeks of treatment initiation in the double-blind (DB) phase

Methods

Study Design

- Vivacity-MG3 (NCT04951622) was a multicenter, randomized, DB, placebo-controlled study evaluating efficacy, safety, pharmacokinetics, and pharmacodynamics of nipocalimab in adults with gMG⁵

Figure 1. Study design⁵



Population

- This post-hoc analysis utilized data from the Vivacity-MG3 study, specifically evaluating patients with gMG who did not achieve a ≥2-point improvement in Myasthenia Gravis-Activities of Daily Living (MG-ADL) score at week-1 or week-2 during DB phase

Assessments

- The proportion of patients achieving meaningful clinical improvement (MCI) in MG-ADL (MCI-2 and MCI-3) and the duration of sustained MCI (defined as the longest uninterrupted period of improvement) were assessed
- MCI-2 is meaningful improvement in MG-ADL total score of at least 2 points. MCI-3 is substantial improvement in MG-ADL total score of at least 3 points from baseline during week-3 to week-24

Results

Baseline characteristics

- By week-24 of the study, 71/77 (92%) patients in the nipocalimab+SOC group achieved clinical response.
- 48/77 (62%) achieved clinical response at week-1 or week-2 of treatment
- Of the remaining 29 patients, 23 demonstrated initial response after week-2 of the treatment
- Amongst 23 patients, mean age was 52.9 years (range 24–79); 60.9% were female (**Table 1**)

Table 1. Baseline demographics and characteristics of patients who demonstrated initial response after 2 weeks

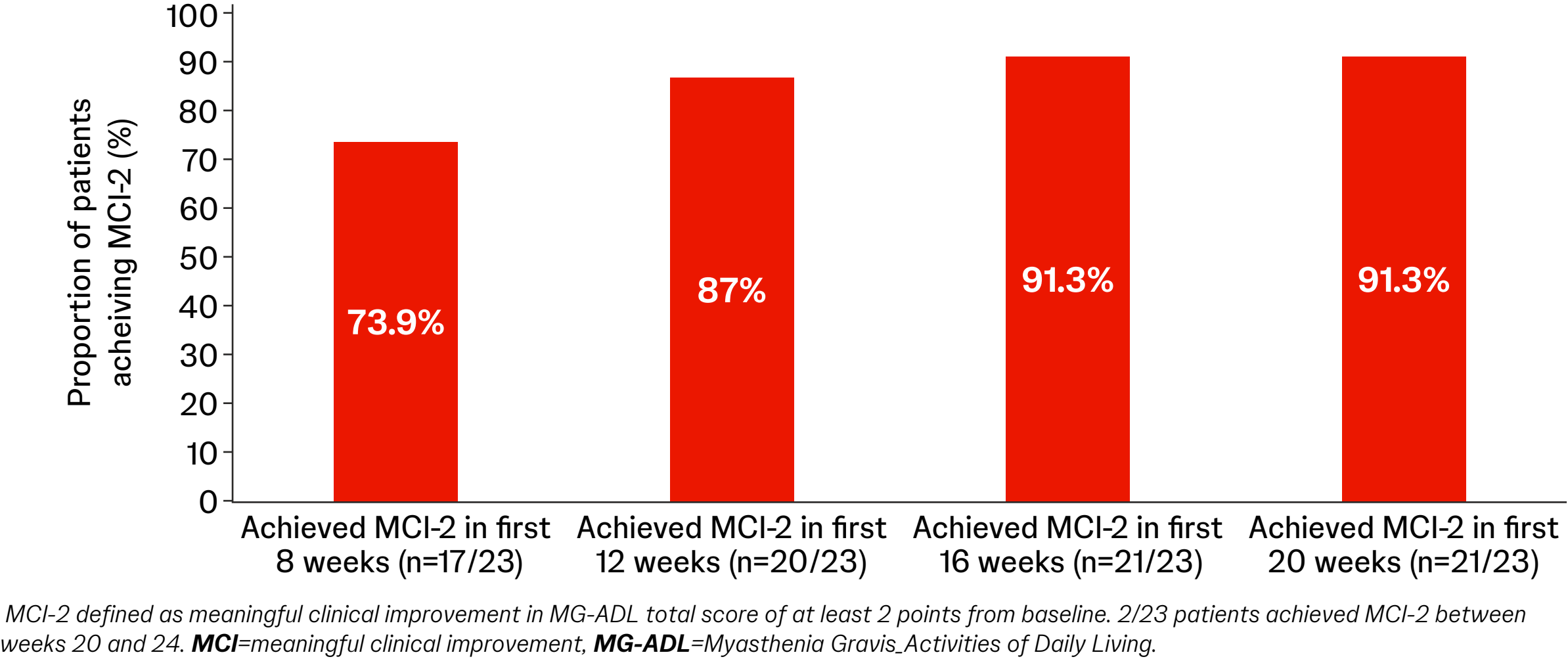
	Nipocalimab+SOC (N=23)
Analysis Set	
Age , mean (range), years	52.9 (24–79)
Female , n (%)	14 (60.9)
Race , n (%)	
Asian	7 (30.4)
Black/African American	1 (4.3)
White	15 (65.2)
BMI , mean (SD), kg/m ²	28.1 (5.89)
Age at onset , mean (SD), years	44.3 (18.09)
Duration of MG , mean (SD), years	8.8 (10.93)
MGFA class , n (%)	
IIa	1 (4.3)
IIb	8 (34.8)
IIIa	11 (47.8)
IIIb	1 (4.3)
IVa	1 (4.3)
IVb	1 (4.3)
Baseline MG-ADL total score , mean (SD)	8.9 (2.31)
Baseline QMG total score , mean (SD)	15.0 (5.23)
Seropositive , n (%)	23 (100.0)
Anti-AChR ⁺	16 (69.6)
Anti-MuSK ⁺	6 (26.1)
Anti-LRP4 ⁺	1 (4.3)

AChR⁺=acetylcholine receptor antibody positive, **BMI**=body mass index, **LRP4**⁺=low density lipoprotein receptor-related protein 4 positive, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MuSK**⁺=muscle-specific kinase antibody positive, **NIPO**=nipocalimab, **QMG**=Quantitative Myasthenia Gravis, **SD**=standard deviation, **SOC**=standard-of-care.

MCI-2 from week-3 to week-24

- Of the remaining 29 patients in the nipocalimab+SOC group, 23 (79.3%) demonstrated initial response after week-2 of treatment (by week 24)
 - 17 (73.9%) patients achieved MCI-2 in first 8 weeks
 - 20 (87.0%) patients achieved MCI-2 in first 12 weeks
 - 21 (91.3%) patients achieved MCI-2 in first 16 weeks
 - 21 (91.3%) patients achieved MCI-2 in first 20 weeks (**Figure 2**)
- Mean (SD) earliest week MCI-2 occurred at 7.7 (5.80) weeks

Figure 2. Proportion of patients who achieved MCI-2 from week-3 to week-24

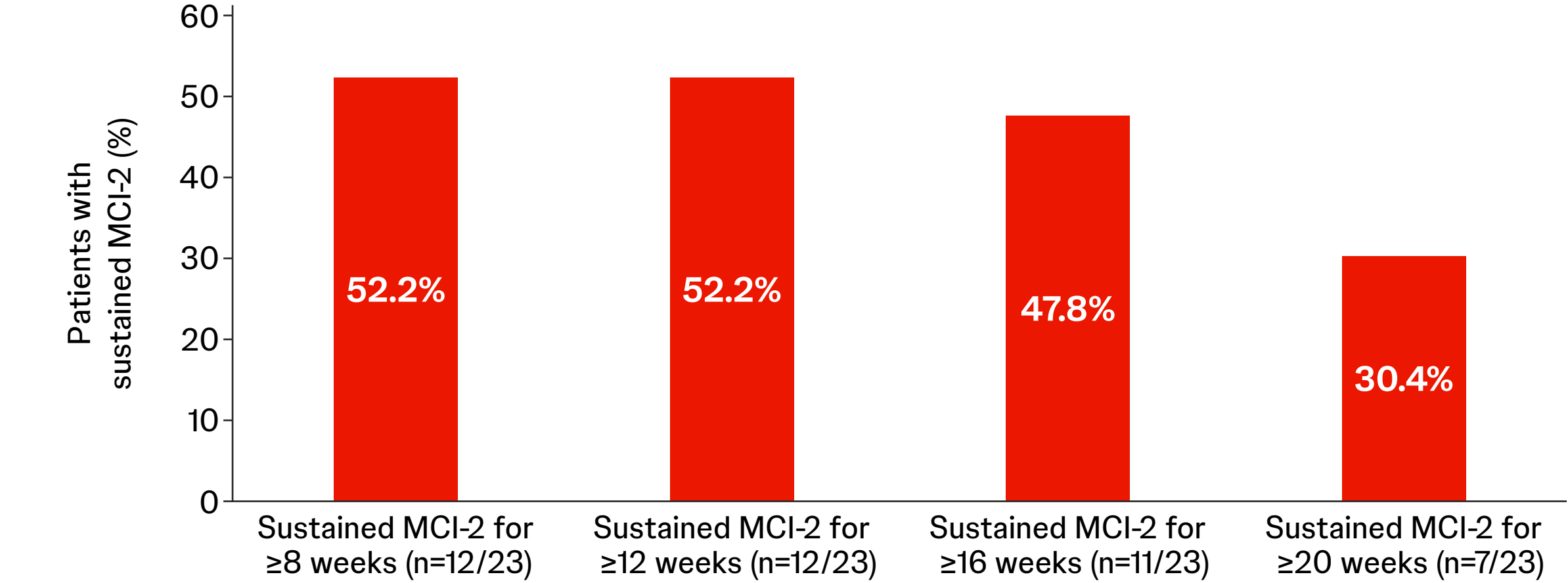


MCI-2 defined as meaningful clinical improvement in MG-ADL total score of at least 2 points from baseline. 2/23 patients achieved MCI-2 between weeks 20 and 24. **MCI**=meaningful clinical improvement, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living.

Sustained MCI-2 from week-3 to week-24

- During the DB phase, of the 23 nipocalimab-treated patients who demonstrated initial response after week-2 of the treatment with nipocalimab+SOC
 - 12 (52.2%), sustained MCI-2 for at least 8-weeks
 - 12 (52.2%), sustained MCI-2 for at least 12-weeks
 - 11 (47.8%) sustained MCI-2 for at least 16-weeks
 - 7 (30.4%) sustained MCI-2 for at least 20-weeks (**Figure 3**)

Figure 3. Proportion of patients with sustained MCI-2 from week-3 to week-24



MCI=meaningful clinical improvement.



<https://www.congresshub.com/Neuroscience/AANEM2026/Nipocalimab/Weiss>

Scan the QR code
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

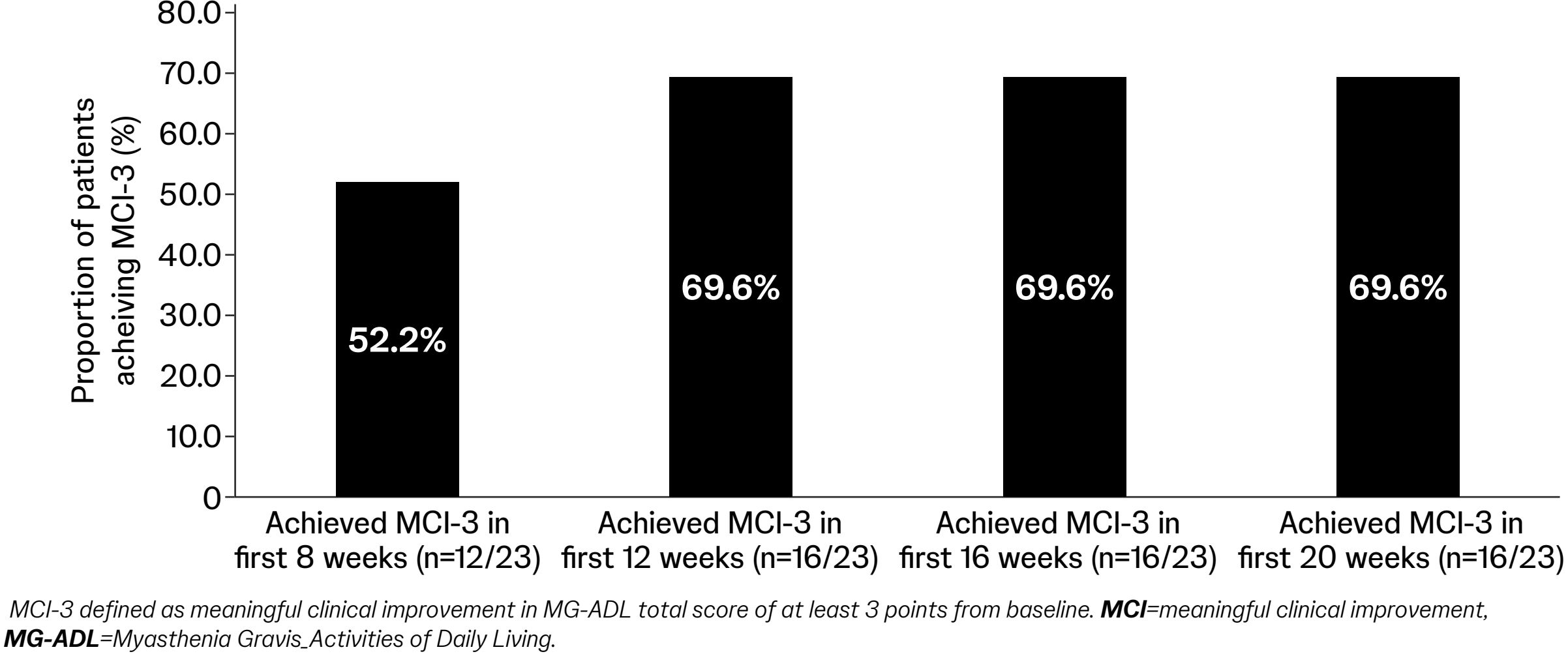
Key Takeaways

- Overall, 92% of nipocalimab-treated patients achieved meaningful clinical improvement during the 24-week study; most patients demonstrated rapid response
- The majority of patients who had not achieved an early response before week-2, subsequently improved after week-2
- Among patients who responded after week-2, once response was achieved, improvement was sustained for up to 20-weeks in a substantial proportion of patients; these findings are limited by the small sample size and post hoc nature of analysis

MCI-3 from week-3 to week-24

- During the DB phase, of the 23 nipocalimab-treated patients who demonstrated initial response after week-2 of treatment with nipocalimab+SOC
 - 12 (52.2%) patients achieved MCI-3 in first 8 weeks
 - 16 (69.6%) achieved MCI-3 in first 12 weeks
 - 16 (69.6%) achieved MCI-3 in first 16 weeks
 - 16 (69.6%) achieved MCI-3 in first 20 weeks (**Figure 4**)
 - 19 (82.6%) achieved MCI-3 by week 24
- Mean (SD) earliest week MCI-3 occurred at 9.3 (6.86) weeks

Figure 4. Proportion of patients who achieved MCI-3 from week-3 to week-24

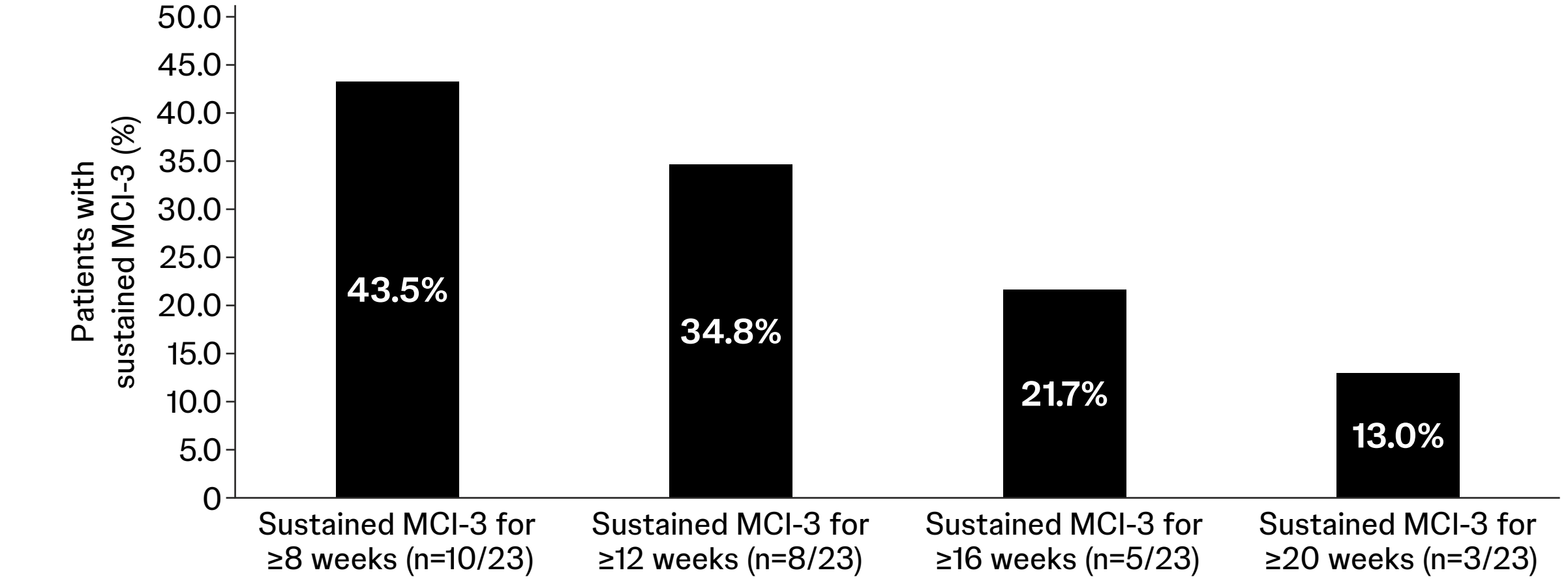


MCI-3 defined as meaningful clinical improvement in MG-ADL total score of at least 3 points from baseline. **MCI**=meaningful clinical improvement, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living.

Sustained MCI-3 from week-3 to week-24

- During the DB phase, of the 23 nipocalimab-treated patients who demonstrated initial response after week-2 of the treatment with nipocalimab+SOC
 - 10 (43.5%) sustained MCI-3 for at least 8-weeks
 - 8 (34.8%) sustained MCI-3 for at least 12-weeks
 - 5 (21.7%) sustained MCI-3 for at least 16-weeks
 - 3 (13.0%) sustained MCI-3 for at least 20-weeks (**Figure 5**)

Figure 5. Proportion of patients with sustained MCI-3 from week-3 to week-24



MCI=meaningful clinical improvement.