Long-Term Safety and Efficacy of Nipocalimab: Approximately 2 Years Follow-Up Results From Vivacity-MG3 Open-Label Extension

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Key Takeaways

- **Nipocalimab demonstrated clinically meaningful and sustained disease control over 120 weeks in a broad population of autoantibody-positive patients with gMG, while maintaining an acceptable safety profile**

Conclusions

- **In autoantibody-positive patients with gMG, long-term treatment with nipocalimab demonstrated sustained disease control through the 24-week phase 3 Vivacity-MG3 study and the 96-week OLE (120 weeks total)**
- **Dose reductions in corticosteroid usage were observed through the study with the majority of patients reaching 10 mg or less of prednisone equivalent per day**
- **There are no new safety concerns and event rates of adverse events were comparable in the double-blind and open-label extension phases**

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
- Nipocalimab is the first approved FcRn blocker for the treatment of generalized myasthenia gravis (gMG) in adult and adolescent (≥12 years of age) patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase-(MuSK) antibody positive[1,2]
- In Vivacity-MG3, a double-blind, placebo-controlled, phase 3 study, nipocalimab treatment demonstrated symptom improvement sustained over 24 weeks[3] and up to a further 60 weeks in the open label extension (OLE)[4]
- Results with additional follow-up through Week 96 of OLE of nipocalimab treatment (or week 120 overall), with a data cut-off at August 24, 2024, are presented

Objective

To assess the long-term safety and efficacy of nipocalimab in patients with gMG from the ongoing Vivacity-MG3 (NCT04951622) OLE phase through Week 96 (120 weeks overall)

Methods

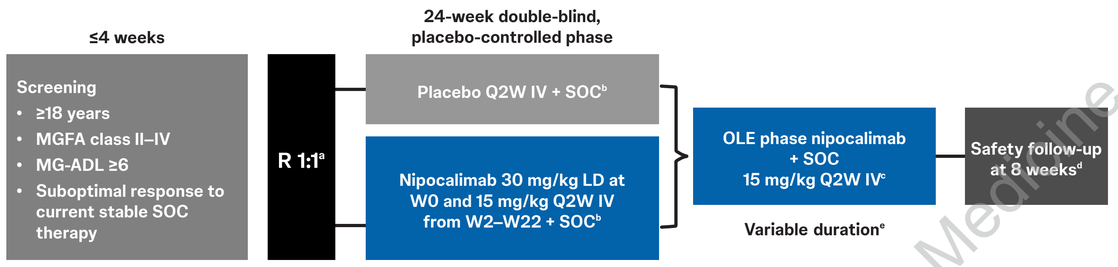
Population

- In Vivacity-MG3, adult patients with gMG (MGFA Class II-IV), inadequately controlled (MG-ADL ≥6) on standard-of-care (SOC) therapy, were randomized 1:1 to nipocalimab+SOC or placebo+SOC in the 24-week double-blind phase[3]
- Participants could continue to receive stable SOC treatment during the study
- Participants who completed the double-blind phase were eligible to enter the OLE phase with nipocalimab+SOC treatment

Assessments

- Efficacy and safety results are presented for seropositive (anti-AChR positive, anti-MuSK positive, and/or anti-LRP4 positive) patients who received ≥1 dose of study treatment

Figure 1. Study Design[3]



[a]Randomization was stratified by autoantibody status (anti-AChR+ and/or anti-MuSK+, anti-AChR negative and anti-MuSK negative), Day 1 MG-ADL total score (≤9, >9), and region (East Asia, US, rest of world). [b]SOC includes acetylcholinesterase inhibitor, glucocorticosteroid, and/or immunosuppressant. [c]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. [d]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. [e]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.

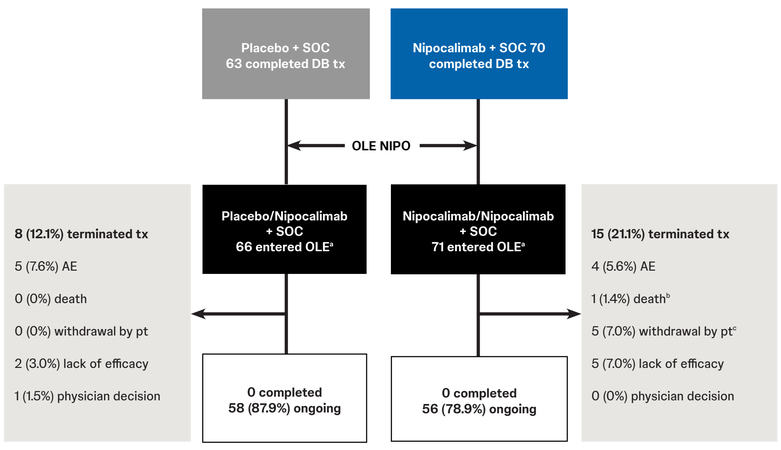
- ***Tapering one of the participant's concomitant gMG medications*** *was allowed only in the OLE phase at every 4 weeks, if the disease has been stable in the past 4 weeks as reflected by MG-ADL scores and based on the investigator's discretion*
- ***Corticosteroid tapering:***
  - *For participants on a corticosteroid dose >30 mg per day, the dose was decreased by no more than 10 mg every 4 weeks, until a dose of ≤30 mg per day is reached*
  - *For participants on a corticosteroid dose of ≤30 mg per day, the dose was decreased by no more than 5 mg every 4 weeks*

Results

Patient disposition

- The OLE phase is ongoing
- ~83% of participants entering the OLE phase were still receiving treatment at data cut-off (August 2024)

Figure 2. Disposition (Seropositive population)



[a]Per protocol, participants requiring rescue treatment during the DB phase completed the DB end-of-phase visit and were eligible to enter the OLE per investigator's discretion. Four patients discontinued the double-blind phase prior to Week 24, but entered the open-label phase: 3 PBO/NIPO and 1 NIPO/NIPO. [b]Cardiac failure (unrelated to treatment) occurred 2 days after the last dose of study treatment on study day 422; [c]Reasons for withdrawal: lack of improvement; participant was unsatisfied; travel to site was too tiring after surgery; personal reasons; and participant concern about poor vascular access.
AE=adverse event, ***DB***=double-blind, ***LRP4***=low-density lipoprotein receptor-related protein 4, ***OLE***=open-label extension, ***pt***=participant, ***SOC***=standard-of-care, ***tx***=treatment.

Baseline characteristics

- Baseline characteristics of participants entering the OLE are similar to that of the overall population at DB baseline

Table 1. Baseline demographics and characteristics (Seropositive population)

	Double-blind[†]		Open-label	
	Placebo+SOC	Nipocalimab+ SOC	Placebo/ Nipocalimab+ SOC	Nipocalimab/ Nipocalimab+ SOC
Analysis Set: Seropositive efficacy (DB and OLE)[a]	76	77	66	71
Age, mean (range), years	52.3 (20, 81)	52.5 (20, 81)	51.6 (20, 81)	51.1 (20, 81)
Female, n (%)	42 (55.3%)	50 (64.9%)	38 (57.6%)	46 (64.8%)
Race, n (%)				
American Indian or Alaska native	0	1 (1.3%)	0	1 (1.4%)
Asian	25 (32.9%)	24 (31.2%)	21 (31.8%)	22 (31.0%)
Black/African American	1 (1.3%)	1 (1.3%)	1 (1.5%)	1 (1.4%)
White	47 (61.8%)	49 (63.6%)	41 (62.1%)	45 (63.4%)
Not reported	3 (3.9%)	2 (2.6%)	3 (4.5%)	2 (2.8%)
BMI, mean (SD), kg/m^2	28.5 (5.78)	27.6 (5.39)	28.6 (5.99)	27.5 (5.30)
Baseline MG-ADL total score, mean (SD)	9.0 (1.97)	9.4 (2.73)	9.0 (1.98)	9.3 (2.75)
Baseline QMG total score, mean (SD)	15.7 (4.92)	15.1 (4.78)[b]	15.6 (4.90)	15.2 (4.85)[c]
Anti-AChR$^+$/Anti-MuSK$^-$/Anti-LRP4$^-$, n	71/4/1	63/12/2	61/4/1	59/10/2

[a]All randomized seropositive participants who received ≥1 dose of study intervention in the DB phase or all seropositive participants who received ≥1 dose of nipocalimab in the OLE phase; [b]n=73; [c]n=67.
AChR=acetylcholine receptor antibody-positive, ***BMI***=body mass index, ***DB***=double-blind, ***gMG***=generalized myasthenia gravis, ***LRP4+***=low-density lipoprotein receptor-related protein 4-positive, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***MuSK+***=muscle-specific kinase antibody-positive, ***OLE***=open-label extension, ***QMG***=Quantitative Myasthenia Gravis, ***SD***=standard deviation, ***SOC***=standard-of-care.

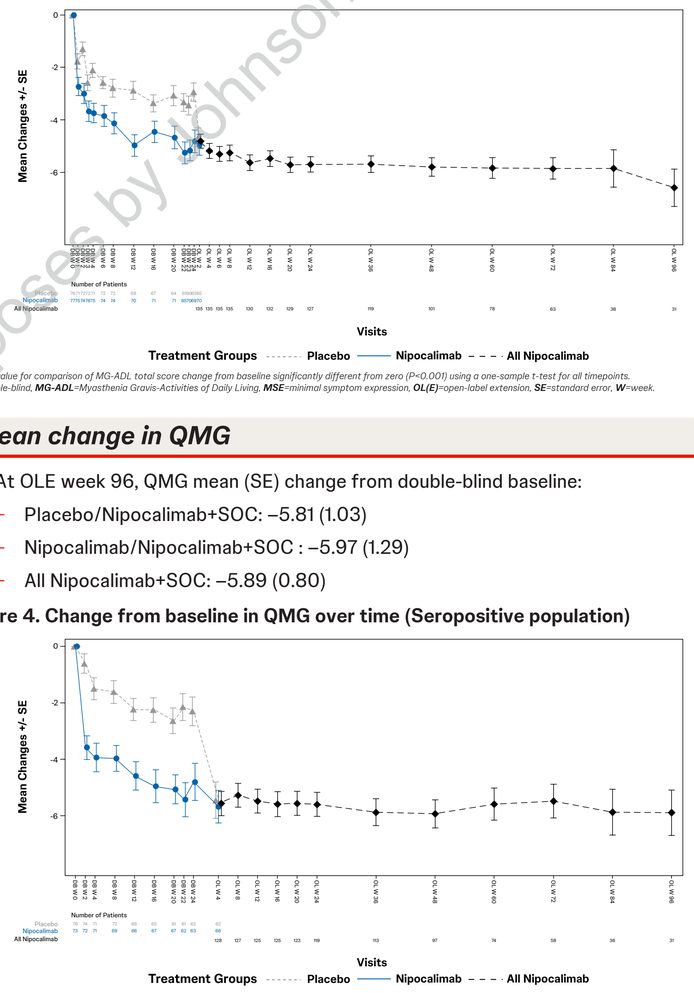
Treatment exposure

- 137 antibody-positive participants were treated with nipocalimab during OLE phase
- Total median (range) duration of treatment for
  - Placebo/Nipocalimab (n=66): 69.1 weeks (8–128)
  - Nipocalimab/Nipocalimab (n=71): 62.1 weeks (8–128)
- Treatment at data cut-off, represents ~87–90 patient-years after completion of DB phase in both the Placebo/Nipocalimab and Nipocalimab/Nipocalimab groups
- Among participants in OLE phase, follow-up duration was over 96 weeks

Mean change in MG-ADL

- At OLE week 96, MG-ADL mean (SE) change from double-blind baseline:
  - Placebo/Nipocalimab+SOC: –6.69 (0.85)
  - Nipocalimab/Nipocalimab+SOC: –6.47 (1.20)
  - All Nipocalimab+SOC: –6.58 (0.71)
- 52.6% (72/137) of all patients (Placebo/Nipocalimab and Nipocalimab/Nipocalimab) achieved MSE[5] at any time during the OLE phase
- 35.8% (49/137) of all patients achieved sustained MSE[5] for ≥8 weeks during the OLE phase

Figure 3. Change from baseline in MG-ADL over time (Seropositive population)



Note: P-value for comparison of MG-ADL total score change from baseline significantly different from zero (P<0.001) using a one-sample t-test for all timepoints.
DB=double-blind, ***MG-ADL***=Myasthenia Gravis-Activities of Daily Living, ***MSE***=minimal symptom expression, ***OL(E)***=open-label extension, ***SE***=standard error, ***W***=week.

Mean change in QMG

- At OLE week 96, QMG mean (SE) change from double-blind baseline:
  - Placebo/Nipocalimab+SOC: –5.81 (1.03)
  - Nipocalimab/Nipocalimab+SOC : –5.97 (1.29)
  - All Nipocalimab+SOC: –5.89 (0.80)

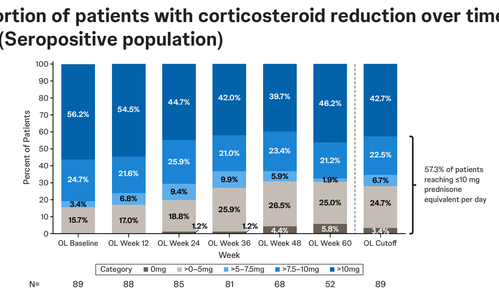
Figure 4. Change from baseline in QMG over time (Seropositive population)

Note: P-value for comparison of QMG total score change from baseline significantly different from zero (P<0.001) using a one-sample t-test, for all timepoints except double-blind week 2 in the placebo group.
DB=double-blind, ***OL(E)***=open-label extension, ***QMG***=Quantitative Myasthenia Gravis, ***SE***=standard error, ***W***=week.

Corticosteroid-sparing outcomes among treated individuals

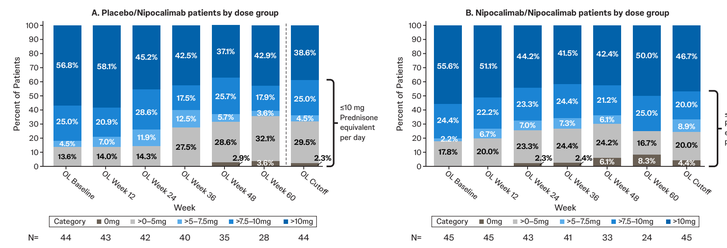
- Corticosteroid use decreased over time in the OLE phase with increasing proportions reaching ≤10 mg prednisone equivalent (eq) per day
- 45% (40/89) of patients receiving corticosteroids at open-label baseline were able to decrease or discontinue corticosteroids at data cut-off
  - Among these patients the mean dose of prednisone decreased from 23 to 10 mg eq per day
- 57% of all patients reached ≤10 mg prednisone eq per day at data cut-off

Figure 5. Proportion of patients with corticosteroid reduction over time – All patients by dose group (Seropositive population)



Note: Prednisone (mg) at each week equals the mean daily prednisone dose for the 28 days prior to and including that week. Cut-off is the analysis reference end date for patient. Steroid dose equivalents were calculated as described.[6,7]
OL=open-label.

Figure 6. Proportion of patients with steroid reduction over time, groupwise (Seropositive population)



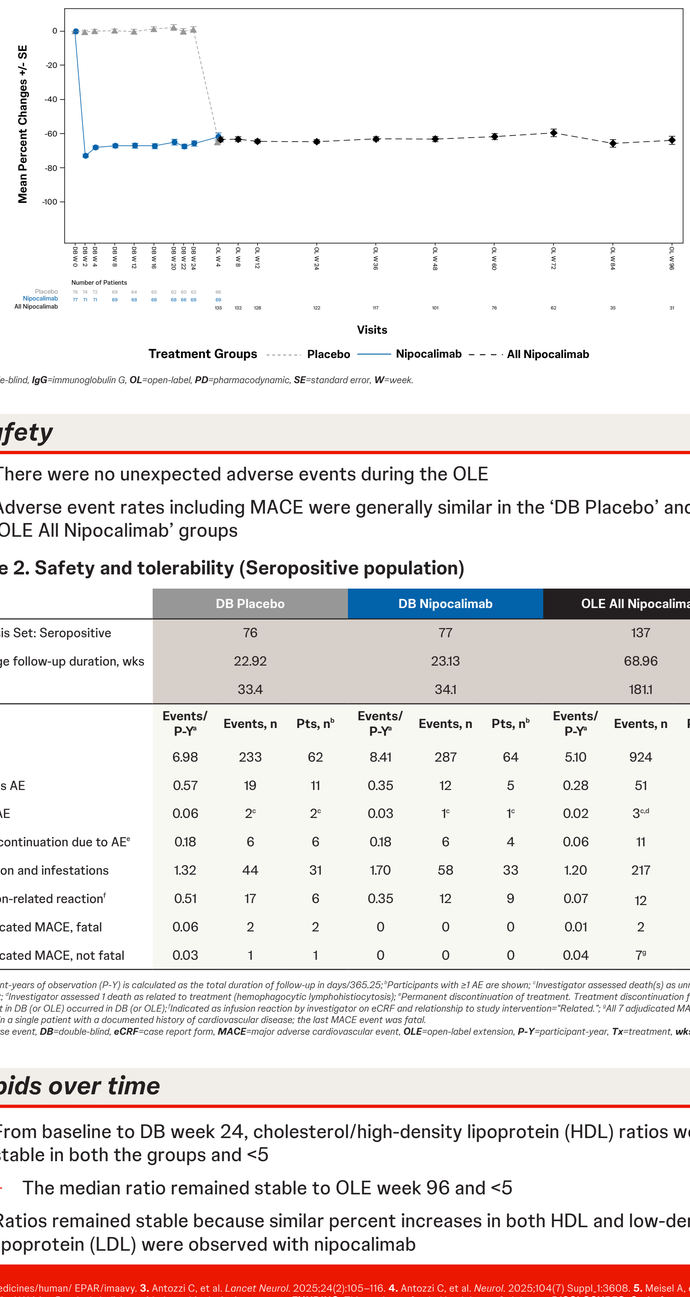
Note: Prednisone (mg) at each week equals the mean daily prednisone dose for the 28 days prior to and including that week. Cut-off is the analysis reference end date for patient.
OL=open-label.

- Patients in the Nipocalimab/Nipocalimab group started to discontinue steroids as early as week 24

PD biomarkers (mean percentage change in IgG levels)

- Nipocalimab demonstrated rapid and sustained lowering of IgG in DB phase
  - The median predose (minimal) total IgG percent change from baseline after the loading dose was –74.6% (IQR –79.4 to –68.7) at DB week 2
- At 2-year (OLE week 96, n=31), mean (SD) predose (minimal) IgG percentage change from double-blind baseline:
  - Placebo/Nipocalimab+SOC: –63.24% (14.32)
  - Nipocalimab/Nipocalimab+SOC: –64.06% (12.91)

Figure 7. PD biomarker: total IgG reduction from DB baseline (Seropositive population)



DB=double-blind, ***IgG***=immunoglobulin G, ***OL***=open-label, ***PD***=pharmacodynamic, ***SE***=standard error, ***W***=week.

Safety

- There were no unexpected adverse events during the OLE
- Adverse event rates including MACE were generally similar in the 'DB Placebo' and 'OLE All Nipocalimab' groups

Table 2. Safety and tolerability (Seropositive population)

	DB Placebo			DB Nipocalimab			OLE All Nipocalimab		
Analysis Set: Seropositive	76			77			137		
Average follow-up duration, wks	22.92			23.13			68.96		
P-Y[a]	33.4			34.1			181.1		
	Events/ P-Y[a]	Events, n	Pts, n[b]	Events/ P-Y[a]	Events, n	Pts, n[b]	Events/ P-Y[a]	Events, n	Pts, n[b]
All AE	6.98	233	62	8.41	287	64	5.10	924	124
Serious AE	0.57	19	11	0.35	12	5	0.28	51	31
Fatal AE	0.06	2[c]	2[c]	0.03	1[c]	1[c]	0.02	3[c,d]	3[c,d]
Tx discontinuation due to AE[e]	0.18	6	6	0.18	6	4	0.06	11	11
Infection and infestations	1.32	44	31	1.70	58	33	1.20	217	93
Infusion-related reaction[f]	0.51	17	6	0.35	12	9	0.07	12	7
Adjudicated MACE, fatal	0.06	2	2	0	0	0	0.01	2	2
Adjudicated MACE, not fatal	0.03	1	1	0	0	0	0.04	7[g]	1

[a]Participant-years of observation (P-Y) is calculated as the total duration of follow-up in days/365.25; [b]Participants with ≥1 AE are shown; [c]Investigator assessed death(s) as unrelated to treatment; [d]Investigator assessed 1 death as related to treatment (hemophagocytic lymphohistiocytosis); [e]Permanent discontinuation of treatment. Treatment discontinuation for an AE with onset in DB (or OLE) occurred in DB (or OLE); [f]Indicated as infusion reaction by investigator on eCRF and relationship to study intervention="Related."; [g]All 7 adjudicated MACE events occurred in a single patient with a documented history of cardiovascular disease; the last MACE event was fatal.
AE=adverse event, ***DB***=double-blind, ***eCRF***=case report form, ***MACE***=major adverse cardiovascular event, ***OLE***=open-label extension, ***P-Y***=participant-year, ***Tx***=treatment, ***wks***=weeks.

Lipids over time

- From baseline to DB week 24, cholesterol/high-density lipoprotein (HDL) ratios were stable in both the groups and <5
  - The median ratio remained stable to OLE week 96 and <5
- Ratios remained stable because similar percent increases in both HDL and low-density lipoprotein (LDL) were observed with nipocalimab

PRESENTED AT: International Congress on Neuromuscular Diseases (ICNMD); July 7–11, 2026; Florence, Italy. **REFERENCES: 1.** IMAAVY™ (nipocalimab-aahu) injection for intravenous use [Package Insert] Horsham, PA; Janssen Pharmaceutical Companies, 2025. **2.** European Medicines Agency, Imaavy™. European Medicines Agency; 2025 Sep 22.https://www.ema.europa.eu/en/medicines/human/ EPAR/imaavy. **3.** Antozzi C, et al. *Lancet Neurol.* 2025;24(2):105–116. **4.** Antozzi C, et al. *Neurol.* 2025;104(7) Suppl_1:3608. **5.** Meisel A, et al. *Eur J Neurol.* 2026:33(3):e70563. **6.** Maggio, MC, et al. *Int J Mol Sci.* 2023;24(17):13192. **7.** Nayak S and Acharjya B. *Indian J Dermatol.* 2008;53(4):167–170. **ACKNOWLEDGMENTS:** Kalpana Tilekar (SIRO Medical Writing Pvt. Ltd., India) provided medical writing assistance and Doyel Mitra, PhD CMPP (Johnson & Johnson) provided additional editorial support. Mugdha Rokade (SIRO Medical Writing Pvt. Ltd., India) provided graphic designing support. **FUNDING**: This work was funded by Johnson & Johnson. **DISCLOSURES: Carlo Antozzi:** Funding travel, meeting attendance & advisory board participation: Alexion, argenx, Momenta, Sanofi, and UCB. **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. **Sindhu Ramchandren, Panna Sanga, Ibrahim Turkoz, Yaowei Zhu, Marie Fitzgibbon,** and **Michel Burcklen:** Are/were employees of Johnson & Johnson; may hold stock or stock options in Johnson & Johnson. **Richard J. Nowak:** Research support: National Institutes of Health, Genentech, Inc., Alexion Pharmaceuticals, Inc., argenx, Annexon Biosciences, Inc., Cour Pharmaceuticals, Ra Pharmaceuticals, Inc. (now UCB S.A.), the Myasthenia Gravis Foundation of America, Inc., Momenta Pharmaceuticals, Inc. (now Johnson & Johnson), Immunovant, Inc., Grifols, S.A., and Viela Bio, Inc. (Horizon Therapeutics, now Amgen Inc.); consultant/advisor: Alexion Pharmaceuticals, Inc., argenx, Cabaletta Bio, Inc., Cour Pharmaceuticals, Ra Pharmaceuticals, Inc. (now UCB S.A.), Immunovant, Inc., Momenta Pharmaceuticals, Inc. (now Johnson & Johnson), and Viela Bio, Inc. (Horizon Therapeutics, now Amgen Inc.). **Constantine Farmakidis:** Medical advisory board participation: Argenx, Johnson & Johnson, UCB; Consulting: the Muscular Dystrophy Association, **Vera Bril:** Research support: argenx, Akcea, AZ-Alexion, CSL, Grifols, Immunovant, Ionis and Viela, Momenta (Johnson & Johnson), Octapharma, Takeda, UCB. **Jan De Bleecker:** Medical advisory board participation: Alnylam Pharmaceuticals Inc, Amgen, argenx, Alexion Pharmaceuticals Inc., CSL Behring, Johnson & Johnson, Sanofi Genzyme, UCB. JLDB is a member of the European Reference Network for Neuromuscular Disorders (EURO-NMD). **Huan Yang, Eduard Minks, Jin-Sung Park, Mariusz Grudniak, Marek Smilowski, and Kumaraswamy Sivakumar:** No competing interests. **Teresa Sevilla:** Honoraria/attendance at advisory boards: argenx, UCB. **Sarah Hoffmann:** Speakers' honoraria: Alexion, argenx, Grifols, Johnson & Johnson, Kyverna, Roche, UCB; honoraria/attendance at advisory boards: Alexion, argenx, Johnson & Johnson, Novartis, Roche; member of the medical advisory board: the German Myasthenia Society, DMG. **PREVIOUSLY PRESENTED AT**: AAN Annual Meeting; April 18–22, 2026; Chicago, IL, USA.