Session: Muscle and Neuromuscular Junction Disorder 3
Monday, 23 June 2025; 14:30 to 14:35 EEST

Comparative Efficacy of Nipocalimab and Other FcRn Blocker Therapies in Generalized Myasthenia Gravis

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DISCLOSURES

> S. Jacob has served as an international advisory board member or has been in the data monitoring committee for clinical trials for Alexion, Alnylam, Argenx, Johnson and Johnson, Immunovant, Merck, Novartis, Regeneron and UCB, is currently an expert panel member of Myasthenia Gravis consortium for Argenx and has received speaker fees from Argenx, Eisai, Terumo BCT, and UCB. He is also a board member (trustee) of the UK myasthenia patient charity, Myaware.

> M. Hashim, K. Gandhi, R. Slowik, A. C. El Khoury, M. J. Keng, and X. Lin are employees of Johnson and Johnson and may hold stock/stock options of Johnson and Johnson. M. Ait-Tihyaty was an employee of Johnson and Johnson at the time of study completion.

> B. Hutton has previously received honoraria from EVERSANA, Maple Health Group, Stratenym, and Evidinno Outcomes Research Inc. for provision of methodologic advice related to the conduct of systematic reviews, meta-analyses and ITCs.

> C. Drudge and S. Singh are employees of EVERSANA. EVERSANA receives consultancy fees from pharmaceutical and device companies, including Johnson and Johnson.

> N. E. Gilhus has received consultative or speaker's honoraria from Johnson and Johnson, UCB, Argenx, Alexion, Merck, Dianthus, Amgen, Roche, Grifols, Immunovant, Huma, Denka, and Takeda.

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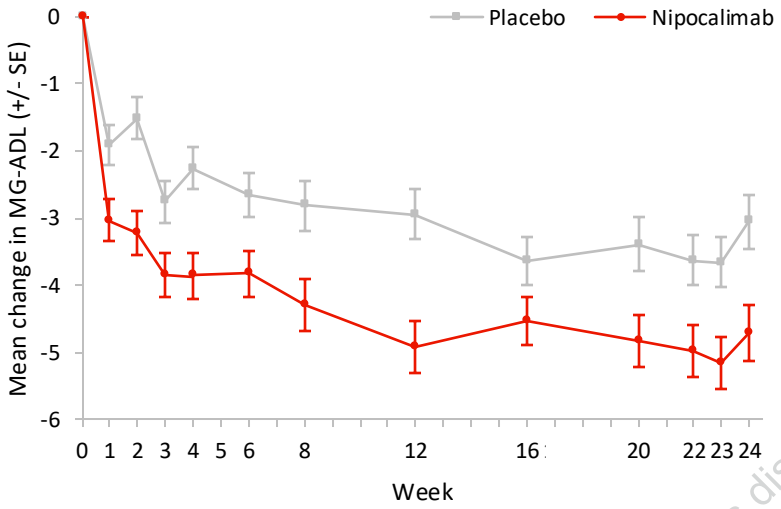
Indirect comparisons of FcRn blockers are needed despite differences across trials for these therapies

Background:

- The FcRn blockers nipocalimab, efgartigimod, and rozanolixizumab have been approved by the US FDA for the treatment of gMG
- Despite differences across trials for these therapies, including in dosing schedules and study duration, there is a need to indirectly compare their efficacy
- Sustained disease control is an important goal of gMG treatment[1]

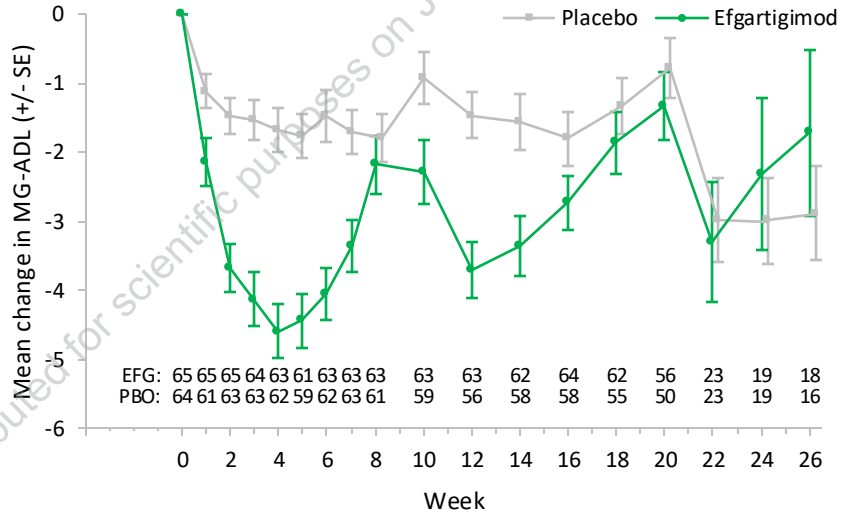
Objective: Assess sustained disease control by indirectly comparing the efficacy of nipocalimab with efgartigimod and rozanolixizumab using MG-ADL change from baseline

Nipocalimab (VIVACITY-MG3)[2]



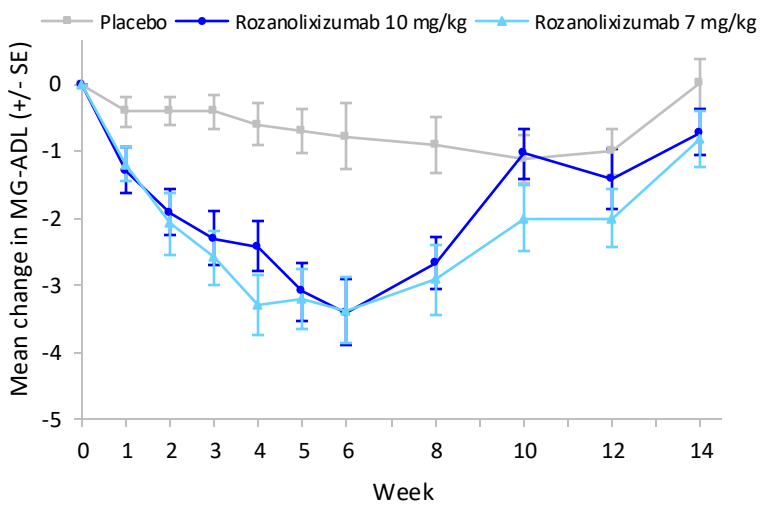
Continuous nipocalimab Q2W vs. placebo for 24 weeks

Efgartigimod (ADAPT)[3,4]



Three cycles of efgartigimod vs. placebo for 26 weeks

Rozanolixizumab (MycarinG)[5]



One cycle of rozanolixizumab QW vs. placebo for 14 weeks (6 weeks of treatment)

1) Casasnovas C et al. EMJ Neurol. 2025;13(Suppl 1):2-7. 2) Antozzi C et al. Lancet Neurol .2025;24(2):105-116. 3) Howard et al. Lancet Neurol. 2021;20(7):526-536. 4) Efgartigimod alfa (Vyvgart) Benefit Assessment Dossier - Module 4 A. https://www.g-ba.de/downloads/92-975-6020/2022_08_31_Modul4A_Efgartigimod_alfa.pdf. 5) Bril et al. Lancet Neurol. 2023;22(5):383-394.

Note: Figures were generated using data digitized from referenced sources.

FcRn, anti-neonatal Fc receptor; gMG, generalized myasthenia gravis; MG-ADL, Myasthenia Gravis Activities of Daily Living; Q2W, every two weeks; QW, every week.

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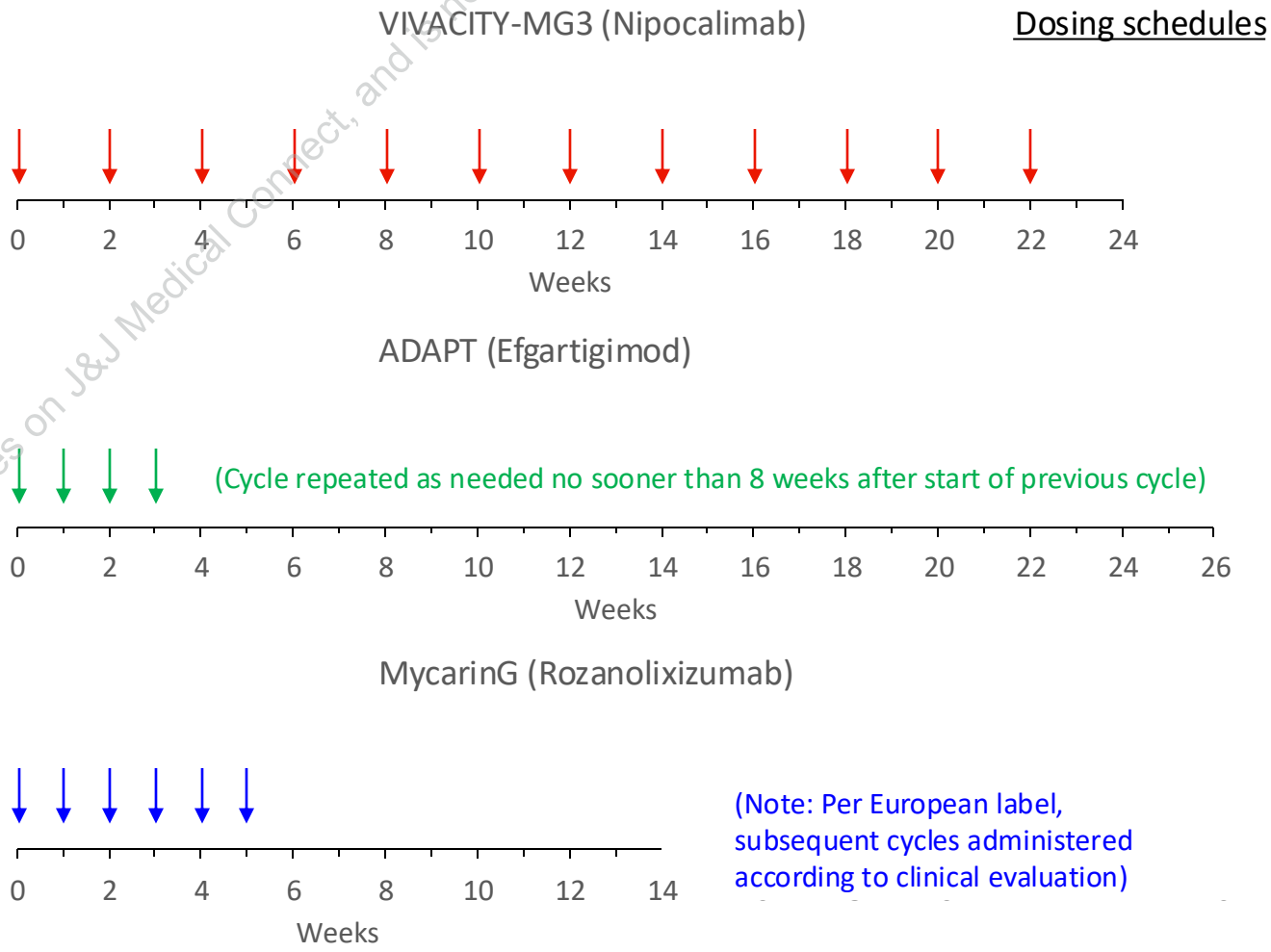
Multiple timepoint analyses to compare efficacy onset and consistency of disease control

- **Data Source:** Published phase III trial data for nipocalimab (VIVACITY-MG3), efgartigimod (ADAPT) and rozanolixizumab (MycarinG)
  - Nipocalimab vs. efgartigimod: AChR+ patients
  - Nipocalimab vs. rozanolixizumab (7 and 10 mg/kg): AChR+ and MuSK+ patients
- **Outcome for Comparison:** MG-ADL CFB as measured at multiple time points: weeks 1-4 and every two weeks thereafter
  - To evaluate onset, consistency, and sustainment of disease control
- **Two ITC Methods:**
  A. Unanchored MAIC adjusting for patient characteristics[a] using individual patient data for nipocalimab and aggregate data for comparators
  B. Placebo-anchored Bucher ITCs using aggregate published data (no adjustment)



[a]Factors adjusted for in the MAICs based on clinical expert input: Time since diagnosis, sex, geographic region, prior corticosteroids, prior immunosuppressants, MG-ADL score, and Quantitative Myasthenia Gravis score.
AChR+, anti-acetylcholine receptor antibody positive; CFB, change from baseline; ITC, indirect treatment comparison; MAIC, matching-adjusted indirect comparison; MG-ADL, Myasthenia Gravis Activities of Daily Living; MuSK+, anti-muscle-specific tyrosine kinase antibody positive.

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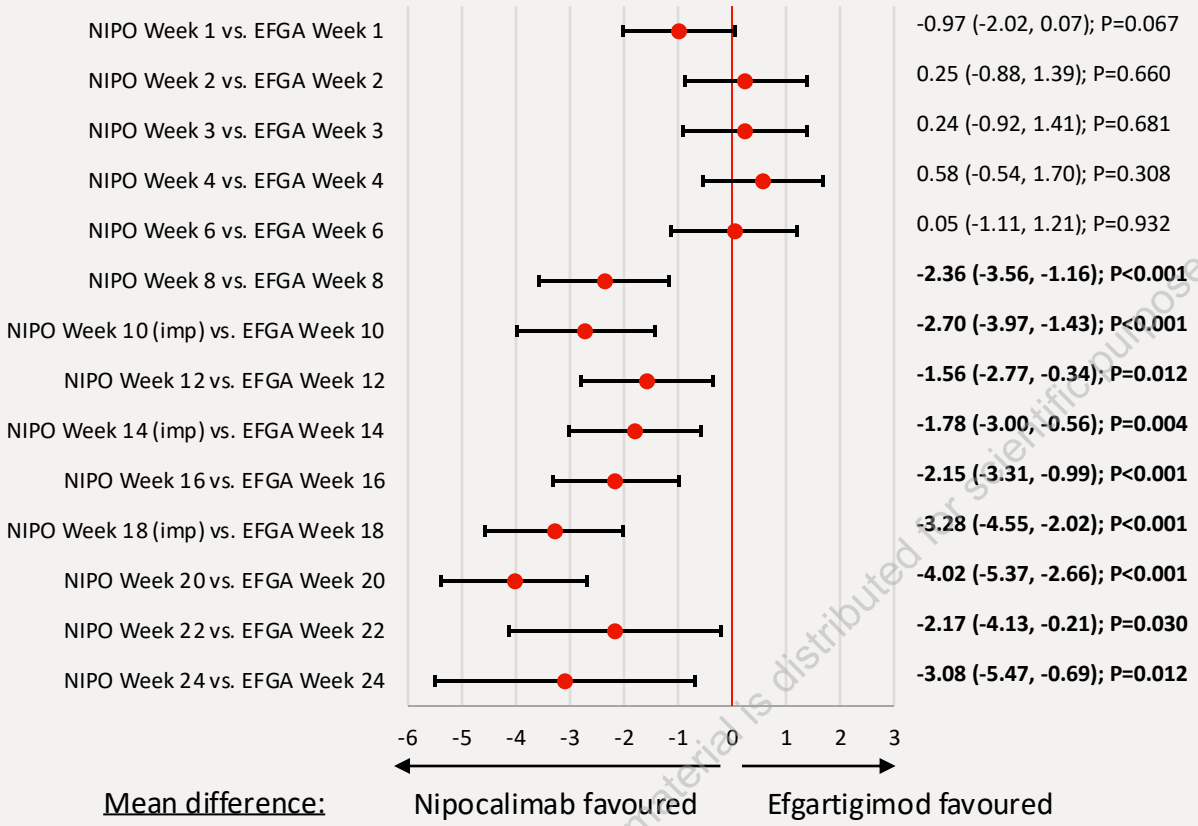
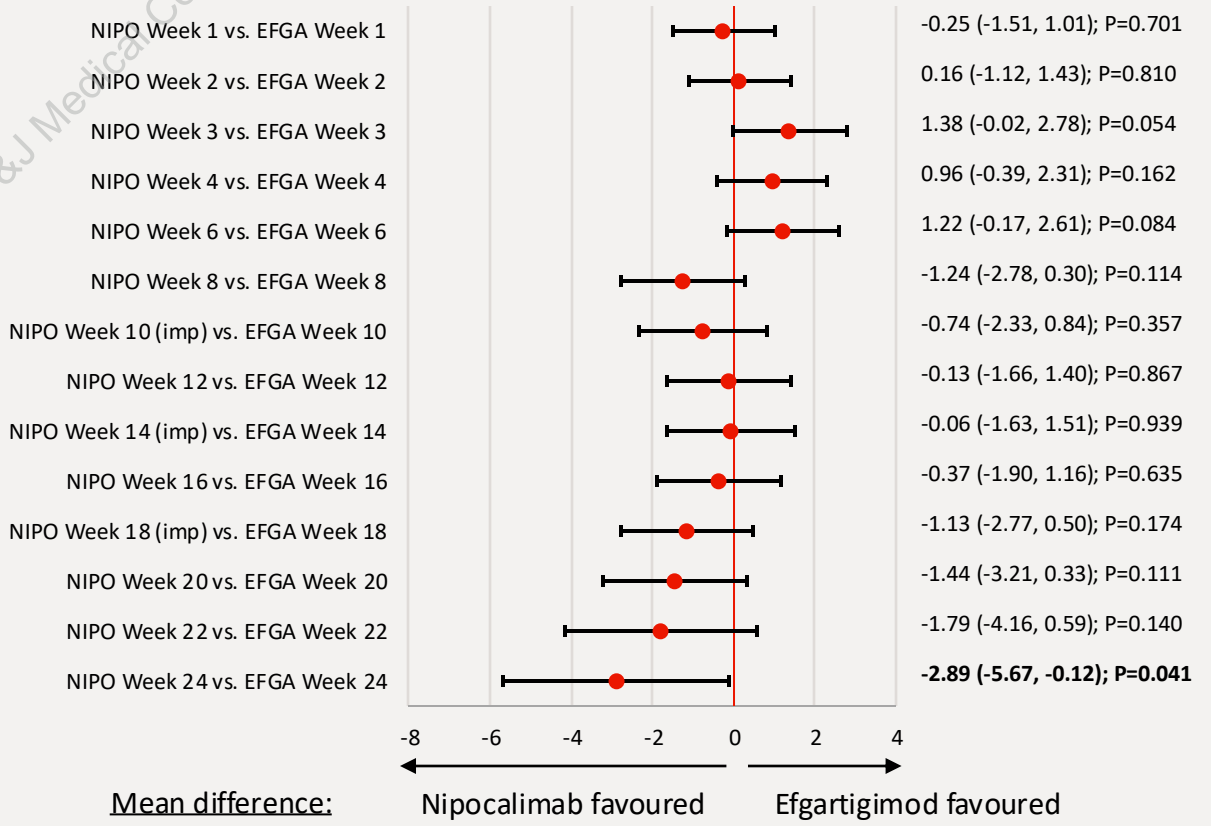
Evaluation of sustained efficacy of nipocalimab vs. efgartigimod up to week 24

- For unanchored MAICs, the mean MG-ADL CFB difference significantly favoured nipocalimab at week 8 and this result was sustained up to week 24
- For Bucher ITCs, the difference was comparable at week 1 and numerically favoured nipocalimab at week 8 and weeks 18-24

Unanchored MAIC 0-24 weeks



Placebo-anchored Bucher ITC 0-24 weeks



CFB, change from baseline; CI, confidence interval; EFGA, efgartigimod; imp, imputed; MAIC, matching-adjusted indirect comparison; MG-ADL, Myasthenia Gravis Activities of Daily Living; NIPO, nipocalimab.

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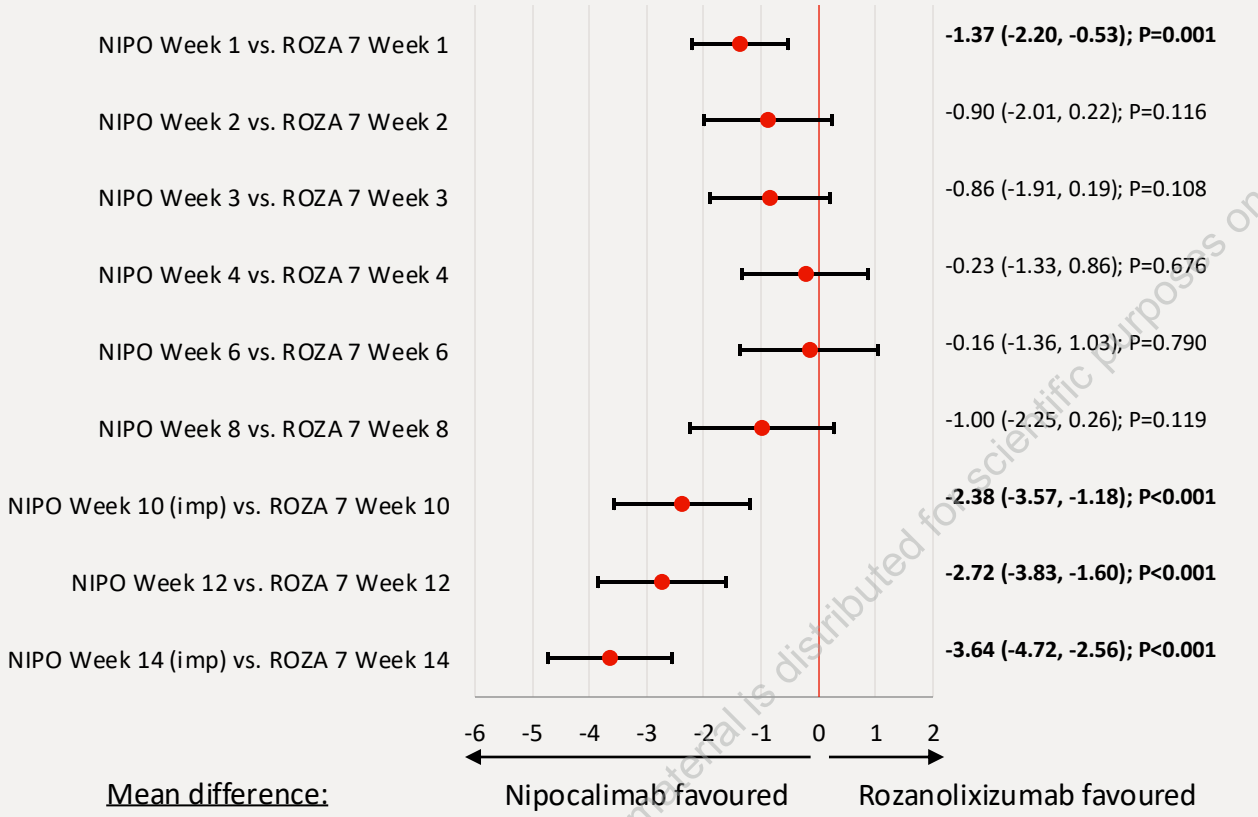
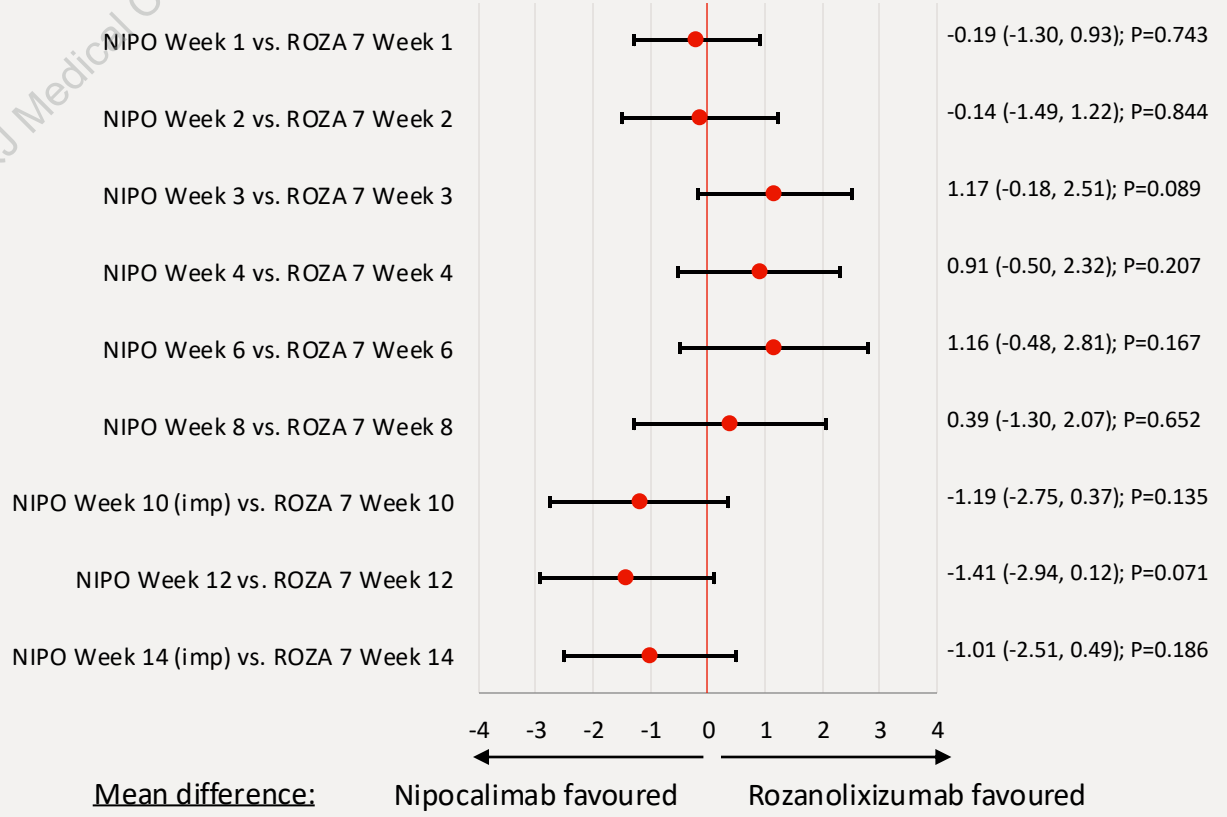
Evaluation of sustained efficacy of nipocalimab vs. rozanolixizumab 7 mg/kg up to week 14

- For unanchored MAICs, the mean MG-ADL CFB difference significantly favoured nipocalimab at week 10 and this result was sustained up to week 14
- For Bucher ITCs, the difference was comparable at week 1 and numerically favoured nipocalimab at weeks 10-14

Unanchored MAIC 0-14 weeks



Placebo-anchored Bucher ITC 0-14 weeks



CFB, change from baseline; CI, confidence interval; imp, imputed; MAIC, matching-adjusted indirect comparison; MG-ADL, Myasthenia Gravis Activities of Daily Living; NIPO, nipocalimab; ROZA 7, rozanolixizumab 7 mg/kg.

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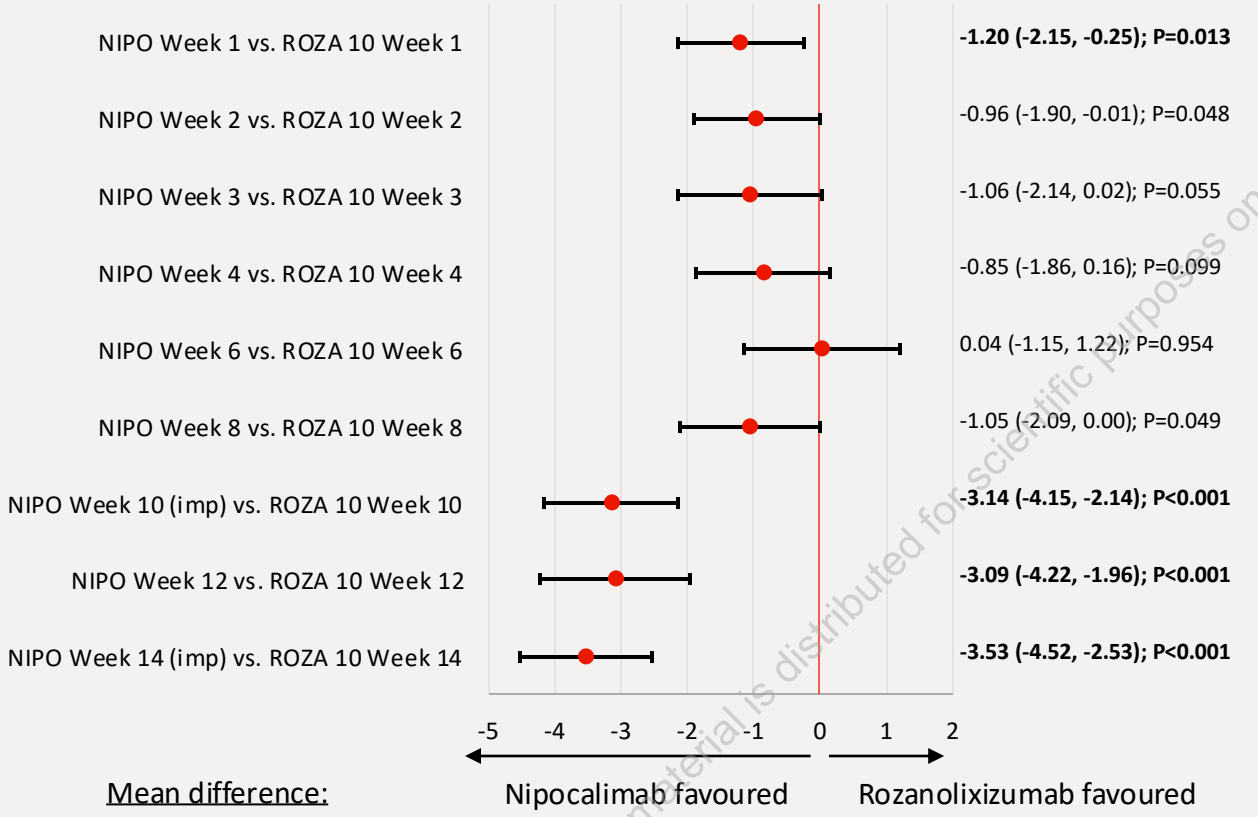
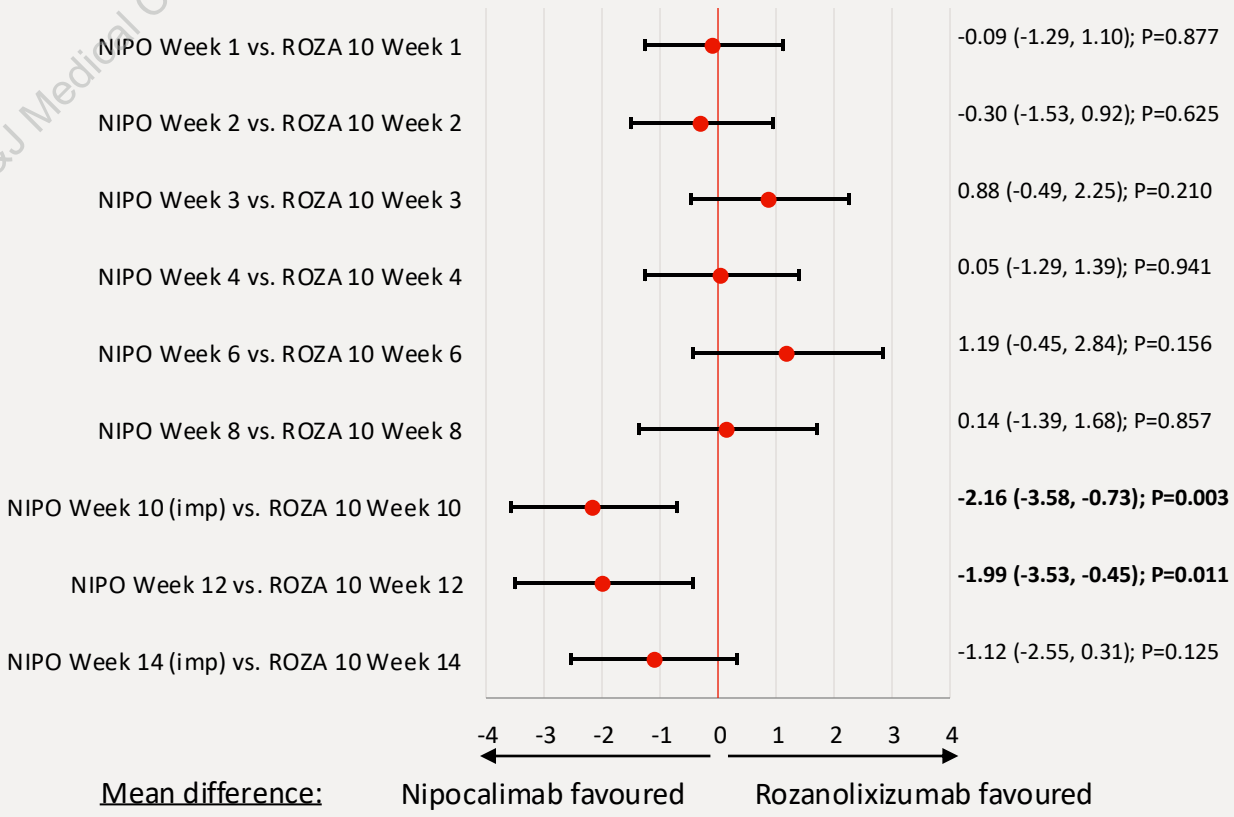
Evaluation of sustained efficacy of nipocalimab vs. rozanolixizumab 10 mg/kg up to week 14

- For unanchored MAICs, the mean MG-ADL CFB difference significantly favoured nipocalimab at week 10 and this result was sustained up to week 14
- For Bucher ITCs, the difference was comparable at week 1 and numerically favoured nipocalimab at weeks 10-14

Unanchored MAIC 0-14 weeks



Placebo-anchored Bucher ITC 0-14 weeks



CFB, change from baseline; CI, confidence interval; imp, imputed; MAIC, matching-adjusted indirect comparison; MG-ADL, Myasthenia Gravis Activities of Daily Living; NIPO, nipocalimab; ROZA 10, rozanolixizumab 10 mg/kg.

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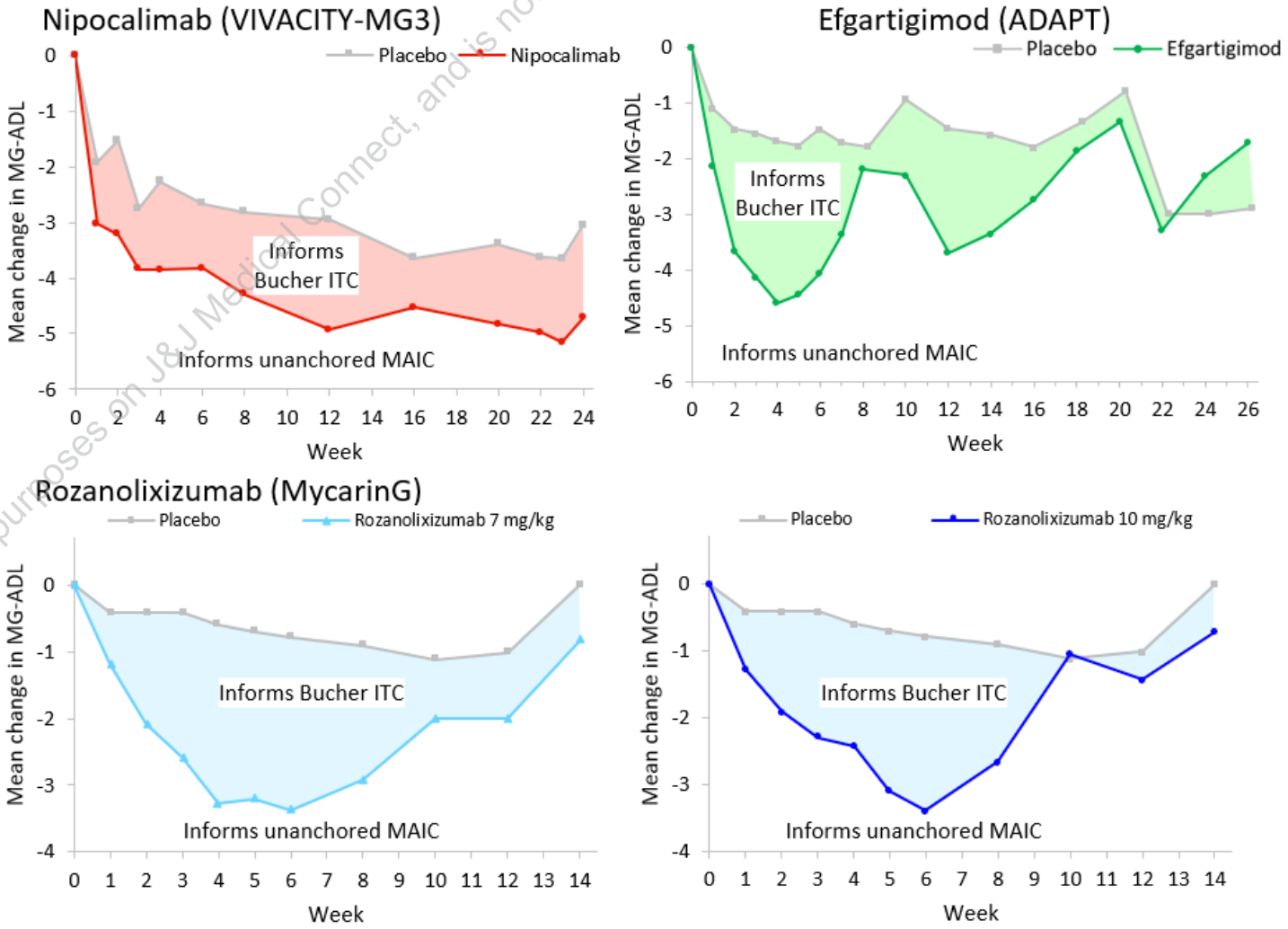
Standardized area under the curve analyses to compare cumulative treatment effect over time

- **Data Source:** Published phase III trial data for nipocalimab (VIVACITY-MG3), efgartigimod (ADAPT) and rozanolixizumab (MycarinG)
  - AChR+ patients for nipocalimab vs. efgartigimod; AChR+ and MuSK+ for nipocalimab vs. rozanolixizumab
- **Outcome for Comparison:** MG-ADL CFB as measured using the area under the curve standardized per week
  - To evaluate cumulative effect over time
- **Two ITC Methods:**
  - A. Unanchored MAIC adjusting for patient characteristics[a] using individual patient data for nipocalimab and aggregate data for comparators
  - B. Placebo-anchored Bucher ITCs using aggregate published data (no adjustment)



[a]Factors adjusted for in the MAICs based on clinical expert input: Time since diagnosis, sex, geographic region, prior corticosteroids, prior immunosuppressants, MG-ADL score, and Quantitative Myasthenia Gravis score.

AChR+, anti-acetylcholine receptor antibody positive; CFB, change from baseline; ITC, indirect treatment comparison; MAIC, matching-adjusted indirect comparison; MG-ADL, Myasthenia Gravis Activities of Daily Living; MuSK+, anti-muscle-specific tyrosine kinase antibody positive.

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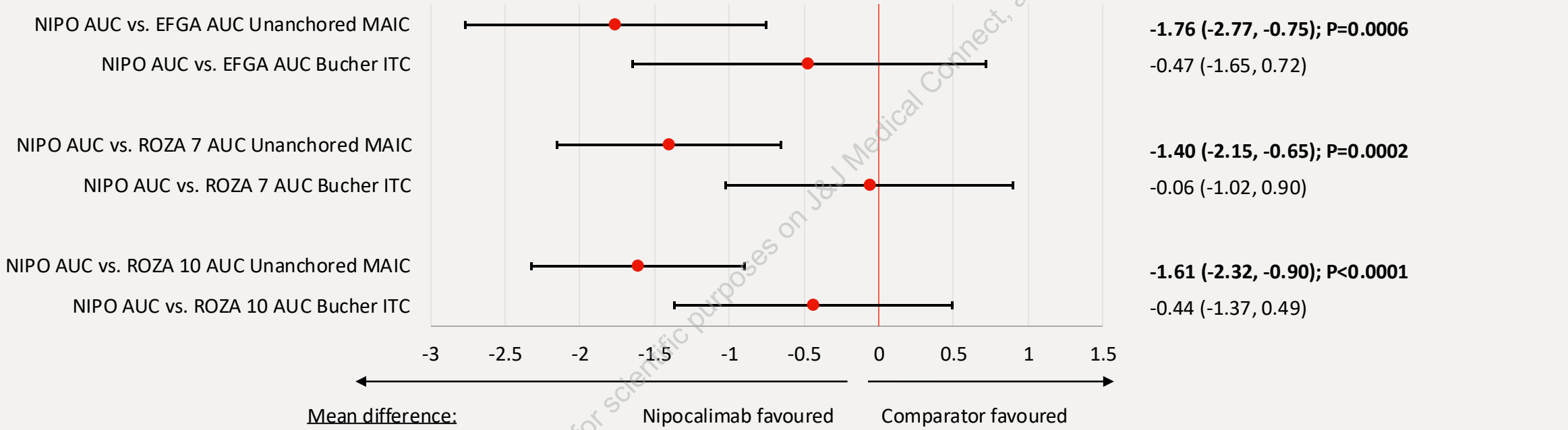
The cumulative standardized mean AUC MG-ADL difference was greater with nipocalimab versus other FcRn blockers



For the nipocalimab vs. efgartigimod Bucher ITC, the cumulative mean AUC MG-ADL difference vs. placebo was -1.76 (95% CI: -2.63, -0.88) for nipocalimab and -1.29 (-2.09, -0.49) for efgartigimod.
For the nipocalimab vs. rozanolixizumab Bucher ITCs, the cumulative mean AUC MG-ADL difference vs. placebo was -1.66 (-2.32, -1.00) for nipocalimab, -1.60 (-2.30, -0.91) for rozanolixizumab 7 mg/kg, and -1.22 (-1.88, -0.57) for rozanolixizumab 10 mg/kg.

AUC, area under the curve; CFB, change from baseline; CI, confidence interval; EFGA, efgartigimod; ITC, indirect treatment comparison; MAIC, matching-adjusted indirect comparison; MG-ADL, Myasthenia Gravis Activities of Daily Living; NIPO, nipocalimab; ROZA 7, rozanolixizumab 7 mg/kg; ROZA 10, rozanolixizumab 10 mg/kg.

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Nipocalimab provided consistent and sustained disease control in gMG versus other FcRn blockers

- Nipocalimab provided **consistent** and **sustained disease control** in gMG as **evidenced by greater MG-ADL CFB reductions** versus other FcRn blockers at multiple individual time points
- Cumulative effect over time was greater with nipocalimab versus other FcRn blockers
- Nipocalimab delivered a **comparable rapid onset of action (at week 1)** versus other FcRn blockers

- Limitations: Placebo-anchored Bucher ITC estimates may have been biased by cross-trial heterogeneity and patient dropout rates starting at week 22 in ADAPT (efgartigimod); for this reason, unanchored MAICs were used to adjust for heterogeneity where possible.

CFB, change from baseline; FcRn, anti-neonatal Fc receptor; gMG, generalized myasthenia gravis; ITC, indirect treatment comparison; MAIC, matching-adjusted indirect comparison; MG-ADL, Myasthenia Gravis Activities of Daily Living.

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