

Indirect Comparison of Nipocalimab Safety Versus FcRn Blockers, C5 Complement Inhibitors, Rituximab and IVIg in Generalized Myasthenia Gravis

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Key Takeaways

- In the absence of head-to-head trials in gMG, ITCs suggest that nipocalimab shows a comparable overall AE profile versus approved and off-label therapies, while SAE outcomes consistently favor nipocalimab

Conclusions

- Nipocalimab demonstrated, versus placebo, a consistent safety profile with a favorable profile for SAEs
- Nipocalimab showed, versus active comparators, comparable rates of any AEs, while SAE outcomes consistently favored nipocalimab across analyses
- Overall, these findings support a favorable benefit-risk profile for nipocalimab within the gMG treatment landscape

Limitations

- The network of evidence is sparse, with most comparisons informed by a single clinical trial
- Heterogeneity in study populations and study designs may introduce bias

Introduction

- Generalized myasthenia gravis (gMG) is a rare, chronic autoimmune disease associated with fluctuating muscle weakness and significant morbidity
- Multiple add-on therapies are used in gMG, including neonatal Fc receptor (FcRn) blockers, C5 complement inhibitors, and off-label therapies such as intravenous immunoglobulin (IVIg) and rituximab; yet no head-to-head randomized comparisons are available
- Nipocalimab demonstrated a favorable safety profile versus placebo + standard-of-care (SOC) in the phase 3 Vivacity-MG3 trial¹
- Indirect treatment comparisons (ITCs) are required to assess comparative safety across available gMG therapies

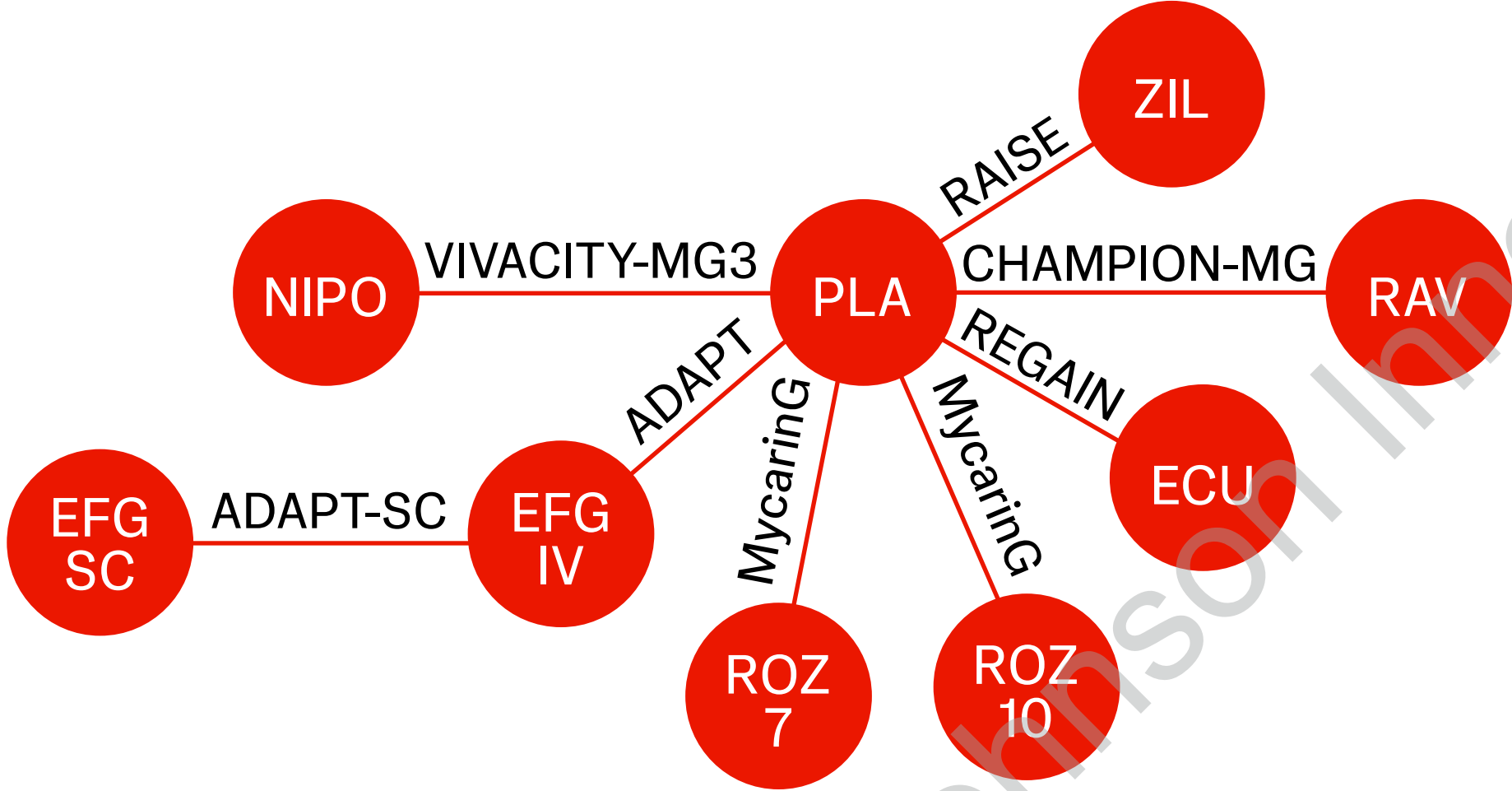
Objective

To assess the comparative safety of nipocalimab versus approved FcRn blockers, C5 complement inhibitors, and off-label therapies (IVIg and rituximab) in adults with anti-acetylcholine receptor antibody-positive (AChR+) gMG using ITCs

Methods

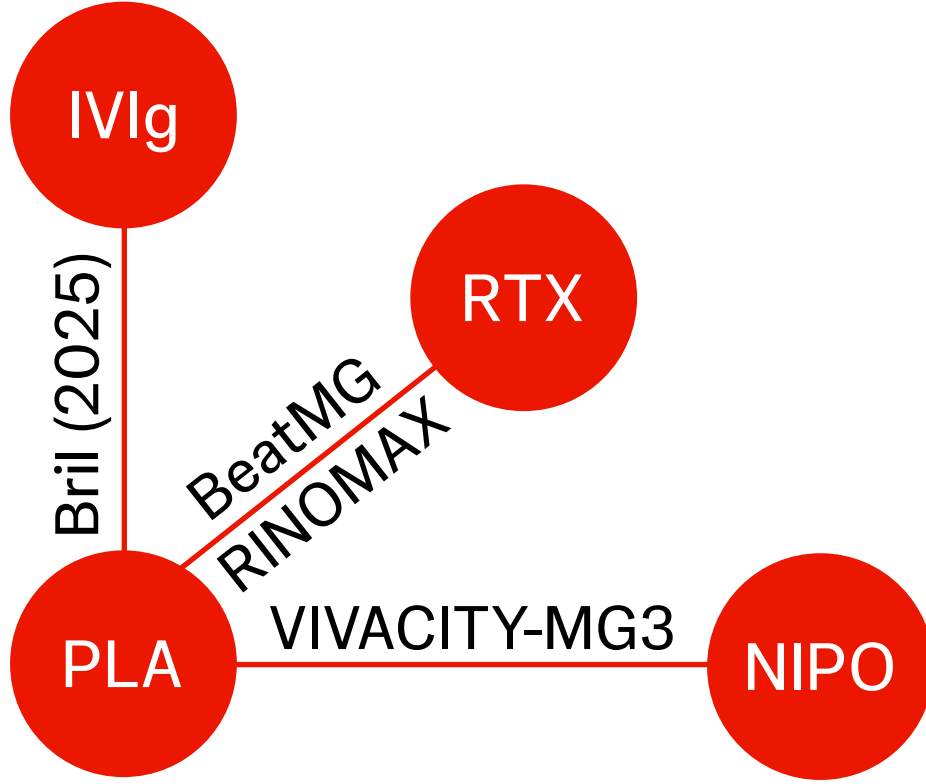
- A feasibility assessment was performed to inform methodological decisions. A Bayesian network meta-analysis (NMA) was conducted on the AChR+ population, selected to ensure comparability across eligible trials (Figure 1 and 2)
- Model selection was based on best-fit criteria. Base-case analyses included eligible trials with similar follow-up duration and sensitivity analyses included all trials independent of trial duration
- Comparisons were performed by Bayesian NMAs
- Results are reported as odds-ratio (OR) with 95% credible intervals (CrI) and probability (P) of OR<1 favoring nipocalimab, interpreted according to Cope et al. 2013²
- Safety outcomes assessed were:**
 - Any adverse event (AE)
 - Any serious adverse event (SAE)

Figure 1. A Network Diagram Representing the any AE and SAE Networks in the AChR+ Population for FcRn inhibitors and C5 Complement Inhibitors



AChR+=anti-acetylcholine receptor antibody-positive, AE=adverse event, C5=complement component 5, ECU=eculizumab, EFG=efgartigimod, FcRn=neonatal Fc receptor, IV=intravenous, NIPO=nipocalimab, PLA=placebo, RAV=ravulizumab, ROZ=rozanolixizumab, SAE=serious adverse event, SC=subcutaneous, ZIL=zilucoplan.

Figure 2. A Network Diagram Representing the AE and SAE Networks in the AChR+ Population for Off-label Treatments (IVIg and Rituximab)



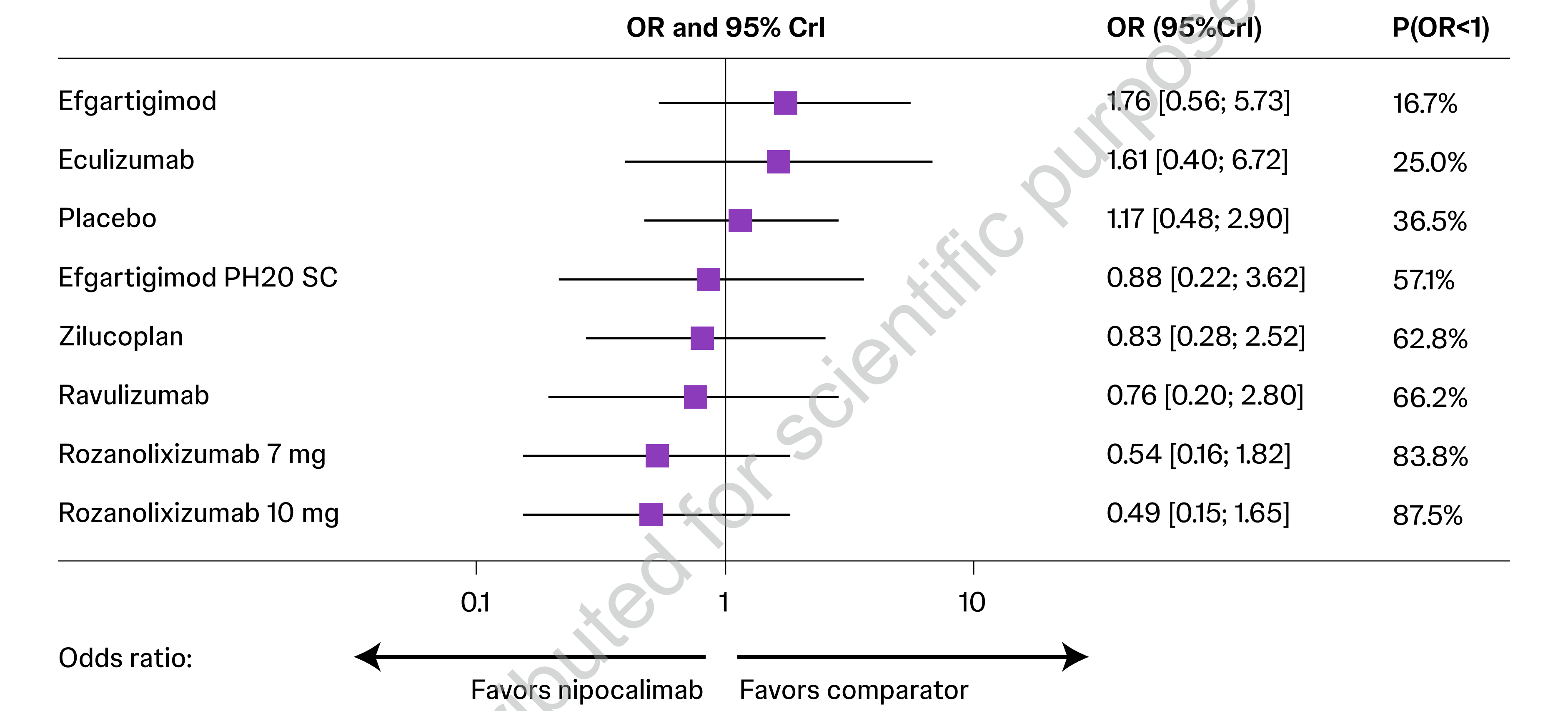
AChR+=anti-acetylcholine receptor antibody-positive, AE=adverse event, IVIg=intravenous immunoglobulin, MG=myasthenia gravis, NIPO=nipocalimab, PLA=placebo, RTX=rituximab, SAE=serious adverse event.

Results

Any adverse event

- The Bayesian NMA for AEs showed comparable results for nipocalimab versus other FcRn blockers and C5 inhibitors (P[OR<1]=16.7–83.8%) except for rozanolixizumab 10 mg where nipocalimab was likely favorable (P[OR<1]=87.5%) (Figure 3)

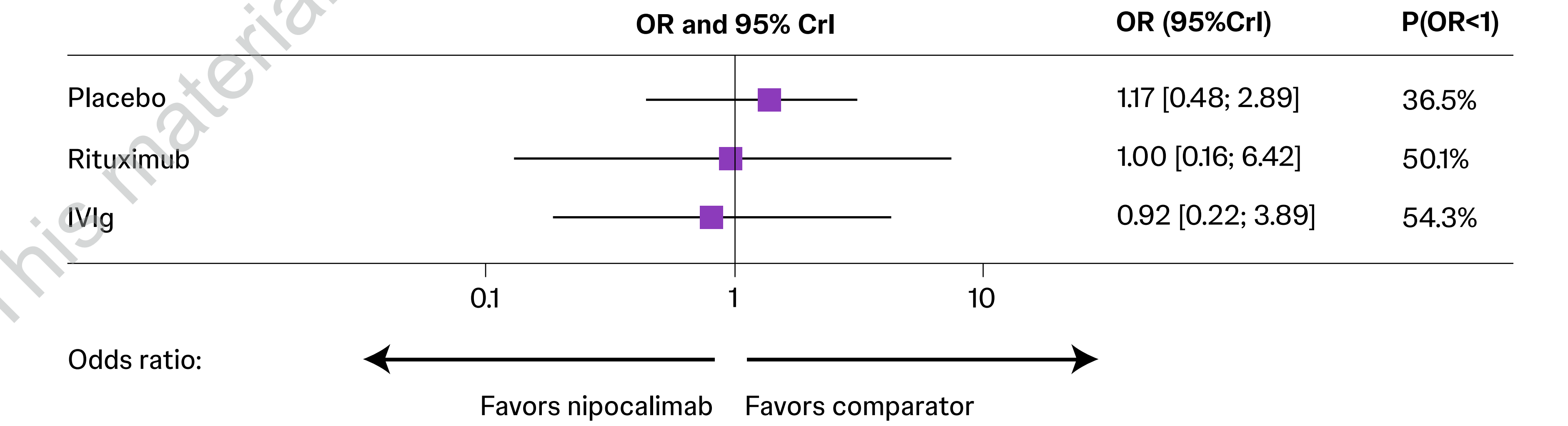
Figure 3. OR and Bayesian probabilities for OR<1 for nipocalimab versus FcRn blockers and C5 inhibitors for experiencing any AE



AE=adverse event, C5=complement component 5, CrI=credible interval, FcRn=neonatal Fc receptor, NMA=network meta-analysis, OR=odds ratio, P=probability.

- The results vs IVIg and rituximab showed comparable AE profiles with probabilities of lower odds of any AEs of 50.1% versus rituximab and 54.3% versus IVIg (Figure 4)

Figure 4. OR and Bayesian probabilities for OR<1 for nipocalimab versus IVIg and rituximab for experiencing any AE

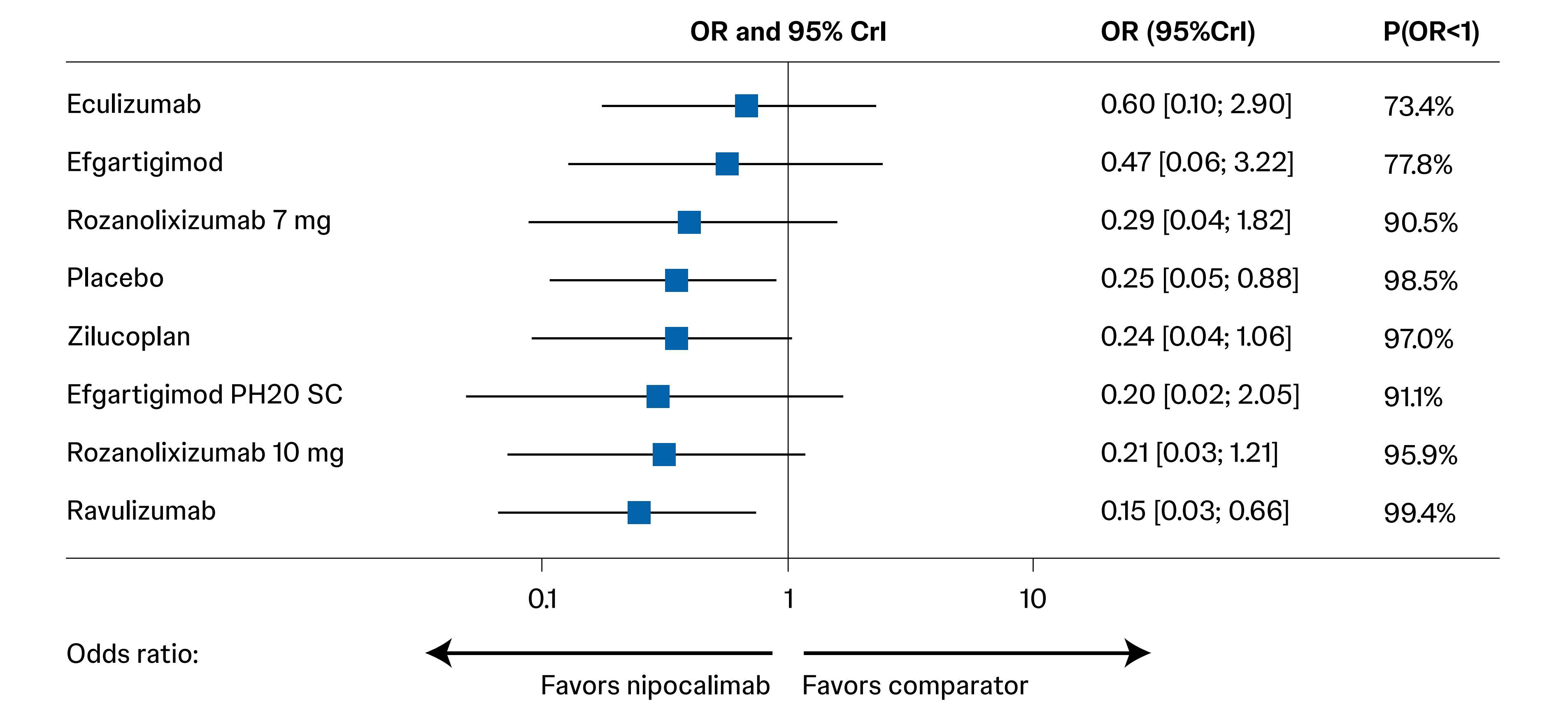


AE=adverse event, CrI=credible interval, IVIg=intravenous immunoglobulin, OR=odds ratio, P=probability.

Any serious adverse event

- For SAEs, nipocalimab results were comparable with eculizumab and efgartigimod (P[OR<1]=73.4%; 77.8%) and likely favorable versus other comparators (P[OR<1]=90.5%–99.4%) (Figure 5)

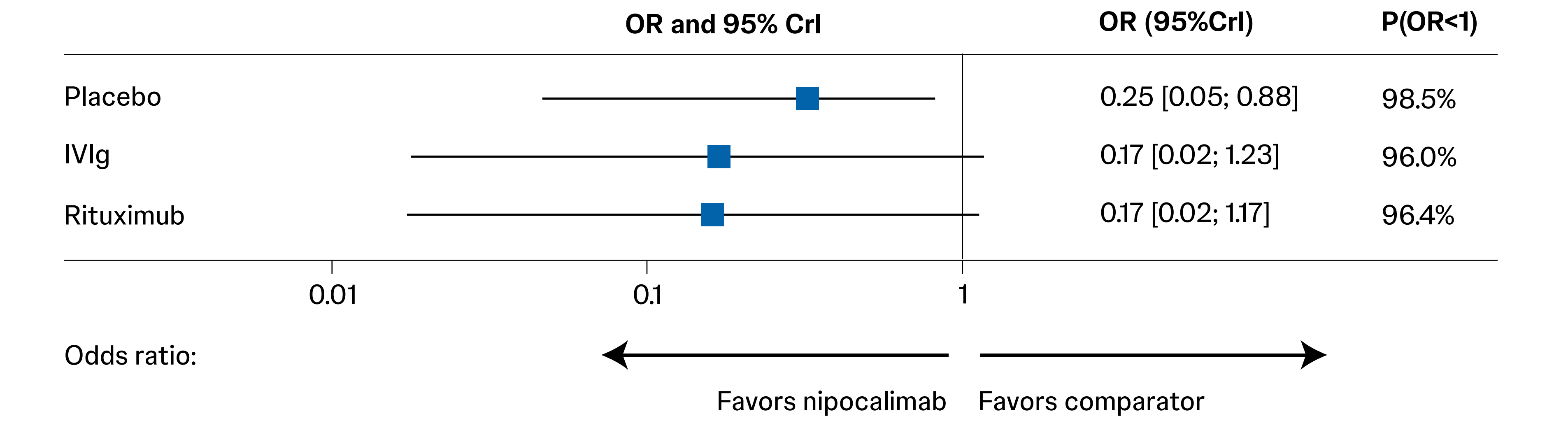
Figure 5. OR and Bayesian probabilities for OR<1 for nipocalimab versus FcRn blockers and C5 inhibitors for experiencing any SAE



C5=complement component 5, CrI=credible interval, FcRn=neonatal Fc receptor, OR=odds ratio, P=probability, SAE=serious adverse event.

- For SAEs, the results were favorable for nipocalimab compared with IVIg and rituximab, with probabilities of lower odds of any SAEs of 96.4% versus rituximab and 96.0% versus IVIg (Figure 6)

Figure 6. OR and Bayesian probabilities for OR<1 for nipocalimab versus IVIg and rituximab for experiencing any SAE



CrI=credible interval, IVIg=intravenous immunoglobulin, OR=odds ratio, P=probability, SAE=serious adverse event.