

# UCB VIRTUAL BRIEFING

UCB's gMG Portfolio  
RYSTIGGO® & ZILBRYSQ®

Capital Market Call  
12<sup>th</sup> June 2024



Inspired by patients.  
Driven by science.



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Clinical Notes. *Minimal Symptom Expression (MSE):* For rozanolixizumab (Rystiggo), MSE was an exploratory endpoint and not controlled for multiplicity. For zilucoplan (Zilbrysq), MSE was specified as a secondary efficacy endpoint in the RAISE study. Accordingly, MSE results in Rystiggo and Zilbrysq studies should be interpreted with caution. *Mechanisms of Action (MOA).* As is common with many medications and drugs on the market, the precise mechanism through which Rystiggo and Zilbrysq exert therapeutic effect in gMG is unknown. Product data derived from primary endpoint, secondary endpoint, tertiary endpoint, exploratory analysis, and/or post hoc analysis.



# Agenda

<p><b>Antje Witte</b> Head of Investor Relations, UCB</p>	<b>WELCOME</b>
<p><b>Kimberly Moran</b> <b>PhD, MBA, CDP</b> Head of US Rare Diseases</p>	<b>INTRODUCTION: UCB IN GENERALIZED MYASTHENIA GRAVIS</b>
<p><b>Michelle Mackechnie</b> <b>PhD</b> Global Medical Indication Lead Myasthenia Gravis</p>	<b>UCB'S GENERALIZED MYASTHENIA GRAVIS PORTFOLIO: RECENT DATA SNAPSHOTS (AAN)</b>
<p><b>Dr. Suraj Muley</b> Professor, Clinical Scholar, Neurology Faculty, College of Medicine, Phoenix, Arizona</p>	<b>EXPERIENCE WITH RYSTIGGO® &amp; ZILBRYSQ® IN CLINICAL SETTING</b>
<b>Q &amp; A Session</b>	

# INTRODUCTION

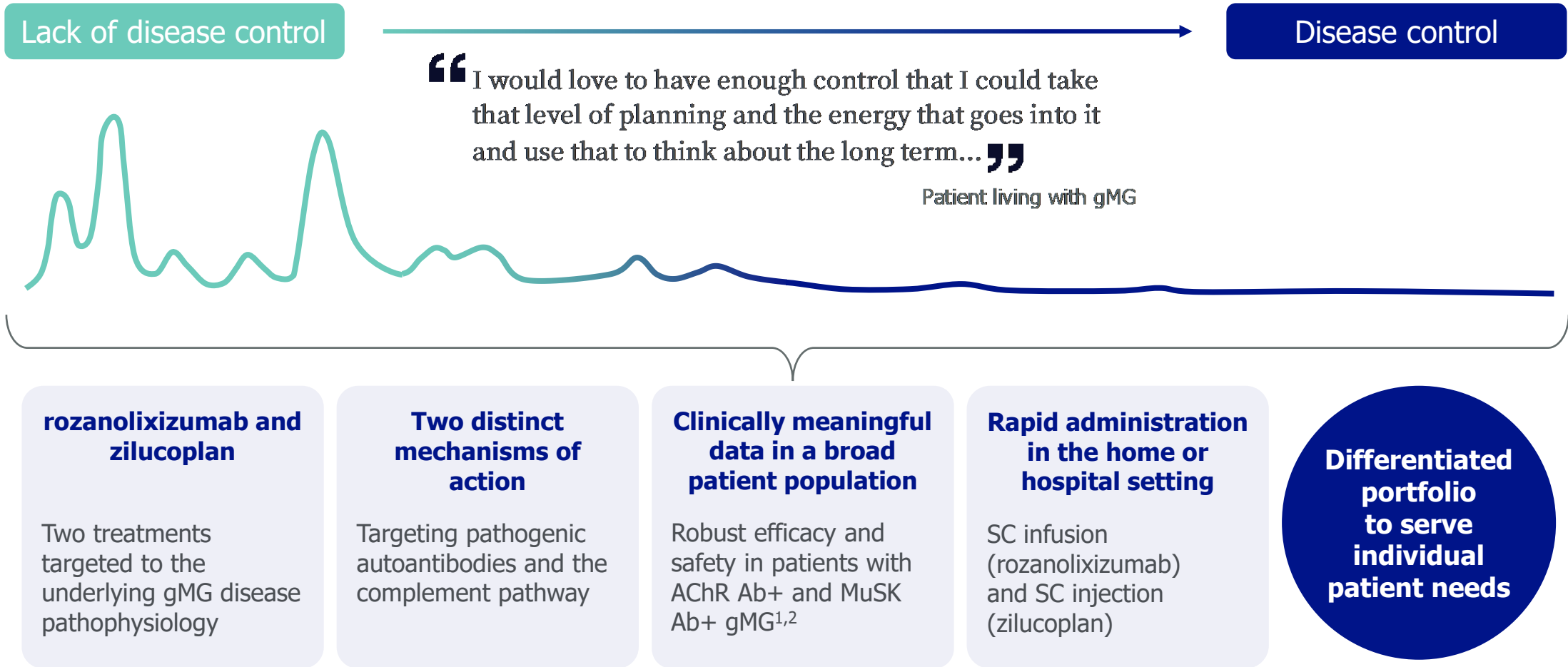
Kimberly Moran

PhD, MBA, CDP

Head of US Rare Diseases

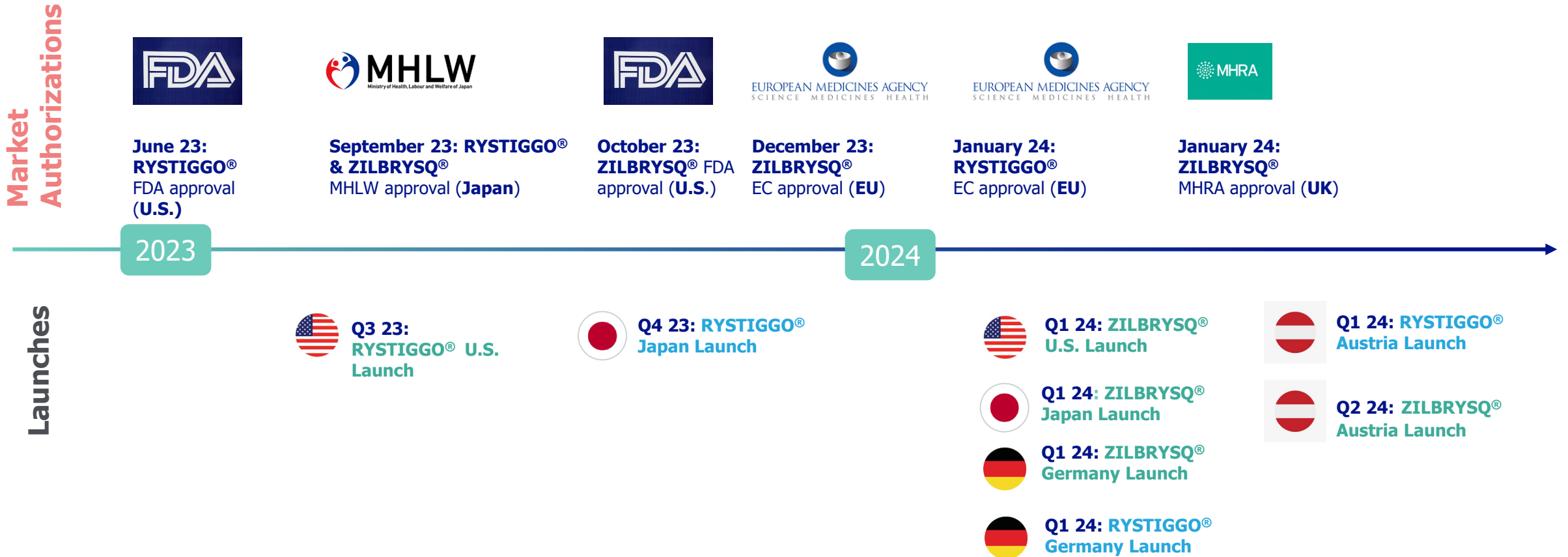
# UCB in generalized Myasthenia Gravis (gMG)

Offering choice to patients living with an unpredictable and heterogenous disease to address individual needs



# UCB's Differentiated GMG Portfolio: Strong Launch Trajectory

- RYSTIGGO® & ZILBRYSQ® market authorization in >20 countries
- EU Early Access Program underway in several countries



# UCB'S gMG PORTFOLIO: RECENT DATA (AAN)

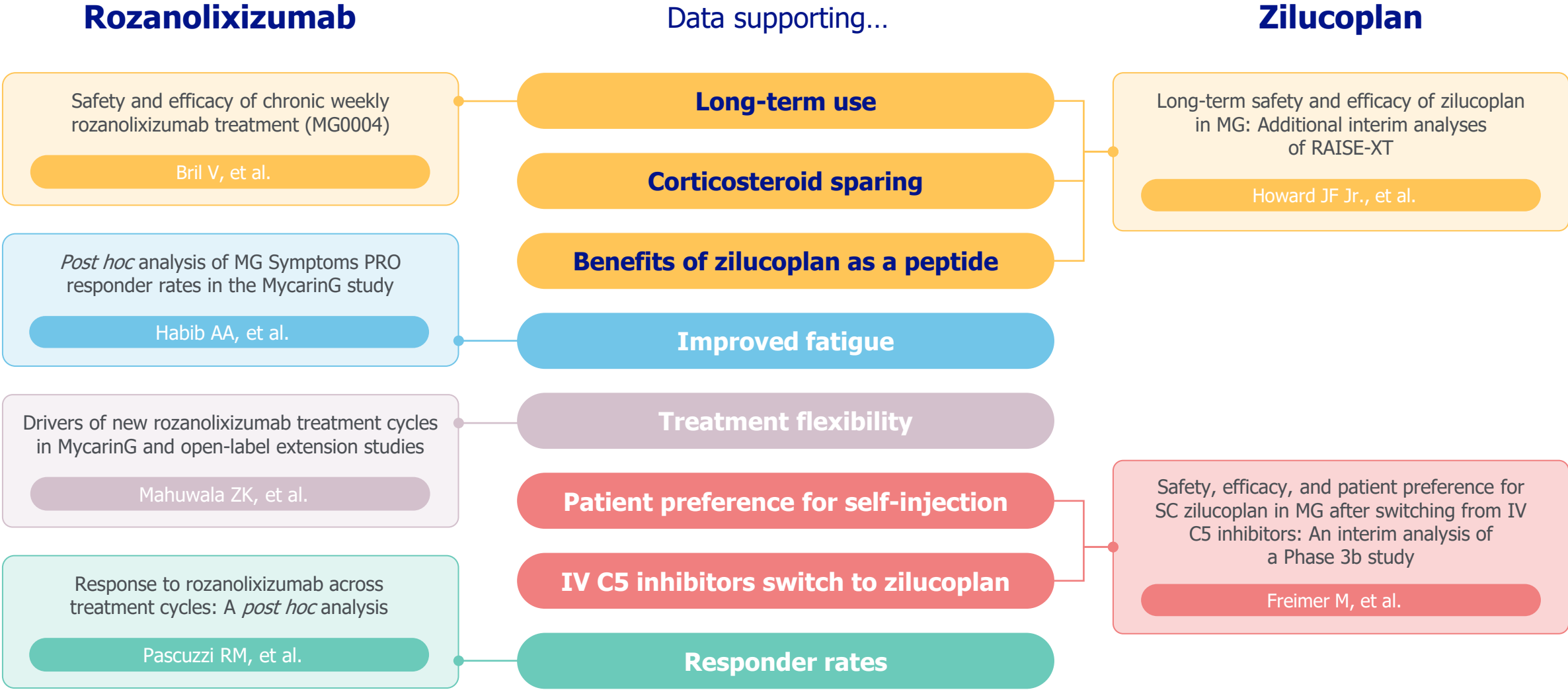
Michelle Mackechnie

PhD

Global Medical Indication Lead

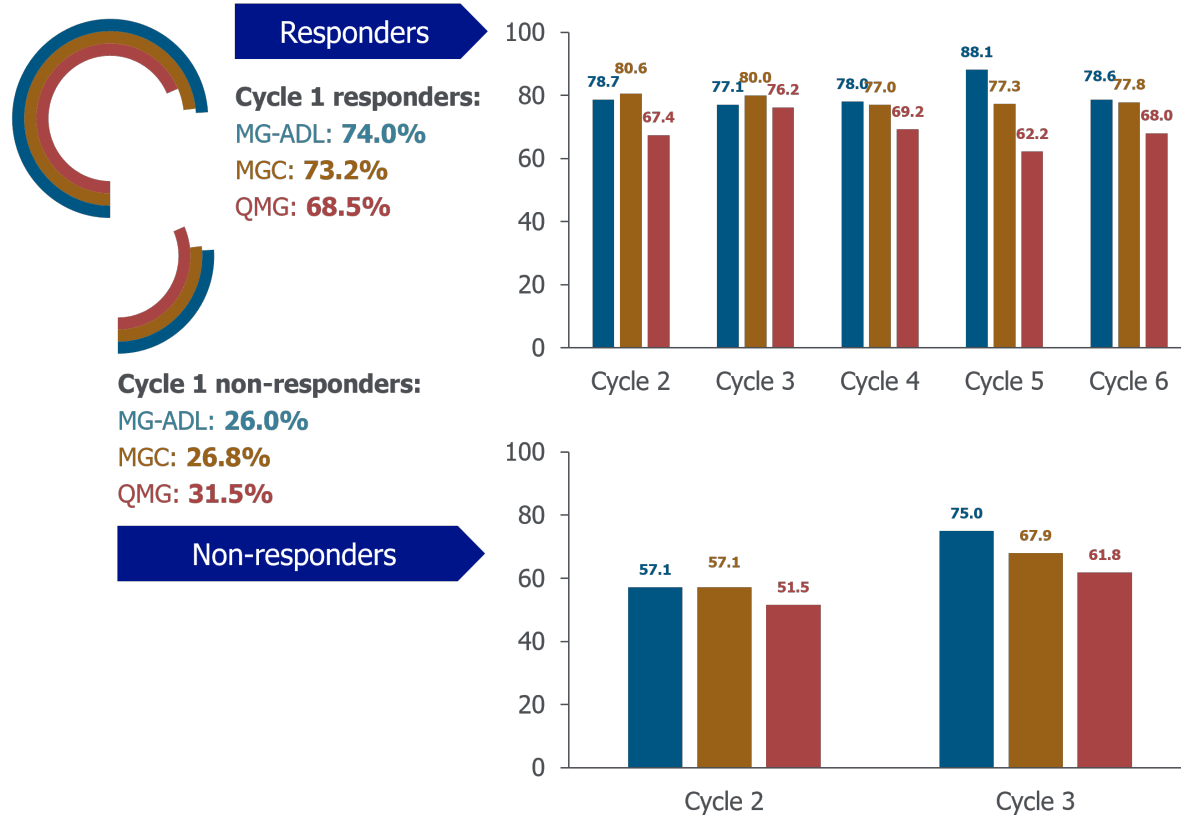
Myasthenia Gravis

# Advancing the science with the UCB portfolio at AAN 2024





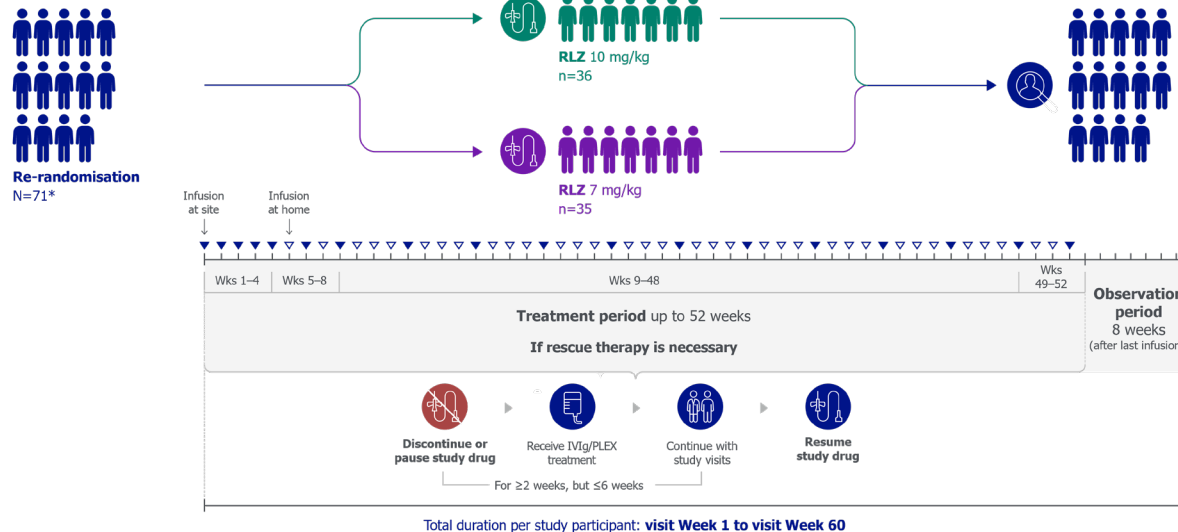
# High responder\* rates across subsequent cycles of rozanolixizumab



- The **majority** of patients were responders after the first cycle of rozanolixizumab
- MG-ADL, MGC and QMG response rates remained high across subsequent treatment cycles
- **>50%** of the non-responders to Cycle 1 achieved a response to a subsequent treatment cycle

\*Response to rozanolixizumab was defined as an improvement from baseline of  $\geq 2.0$  points in MG-ADL score and  $\geq 3.0$  points in MGC and QMG scores at the end of each cycle (Day 43).  
 MG-ADL, Myasthenia Gravis Activities of Daily Living; MGC, Myasthenia Gravis Composite; QMG, Quantitative Myasthenia Gravis.  
 Pascuzzi RM, et al. Poster presented at AAN 2024. P10-11-005.

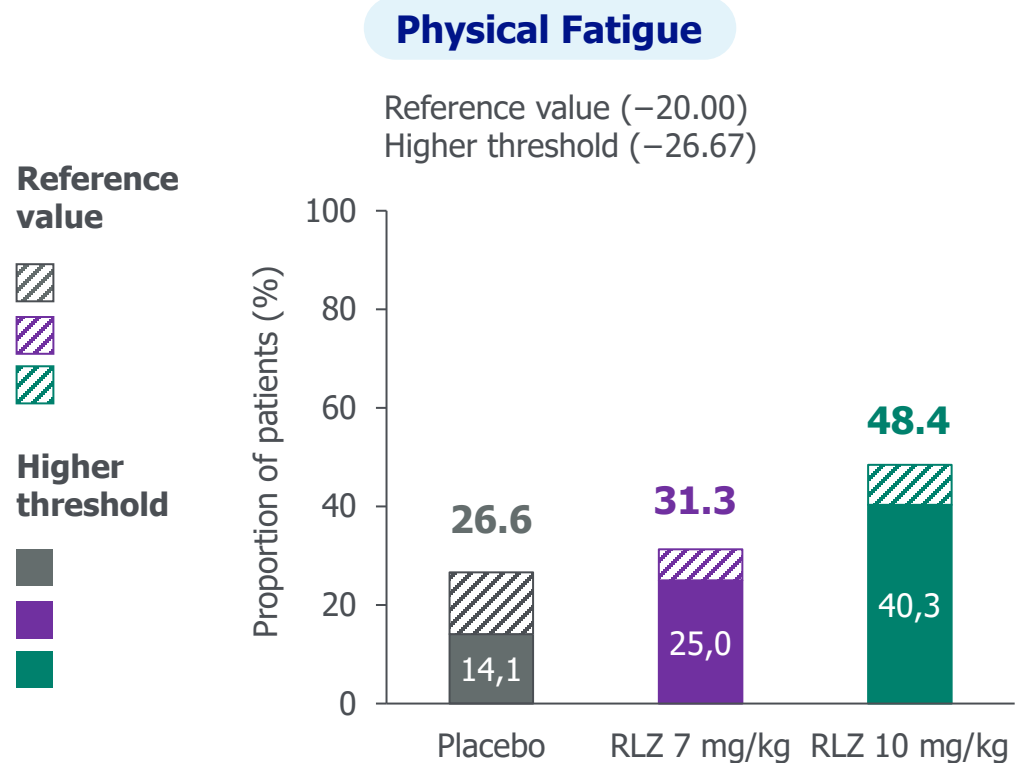
# In MG0004, chronic weekly dosing study, the long-term safety and tolerability of rozanolixizumab was reinforced



- In this Phase 3 OLE chronic weekly study, rozanolixizumab was **generally well tolerated**, with a safety profile consistent with repeated cycles
- **No serious, severe or opportunistic infections**, and no infections led to study discontinuation
- **No** clinically relevant reductions in albumin observed

# Rozanolixizumab is the only targeted therapy that has demonstrated clinically meaningful improvement in physical fatigue

Patients (N=200) achieving a meaningful improvement\* from baseline to Day 43<sup>1</sup>



- **Physical fatigue** has been identified as one of the most salient symptoms for patients with gMG<sup>2</sup>
- Recent gMG clinical guidelines suggest that **better recognition and understanding of fatigue** is needed<sup>3</sup>
- The MG Symptoms PRO was developed to provide a more granular measurement of MG symptoms than existing measures, including **physical fatigue**<sup>4</sup>
- A higher percentage of patients had clinically meaningful improvements in **Physical Fatigue** with rozanolixizumab vs placebo<sup>1</sup>

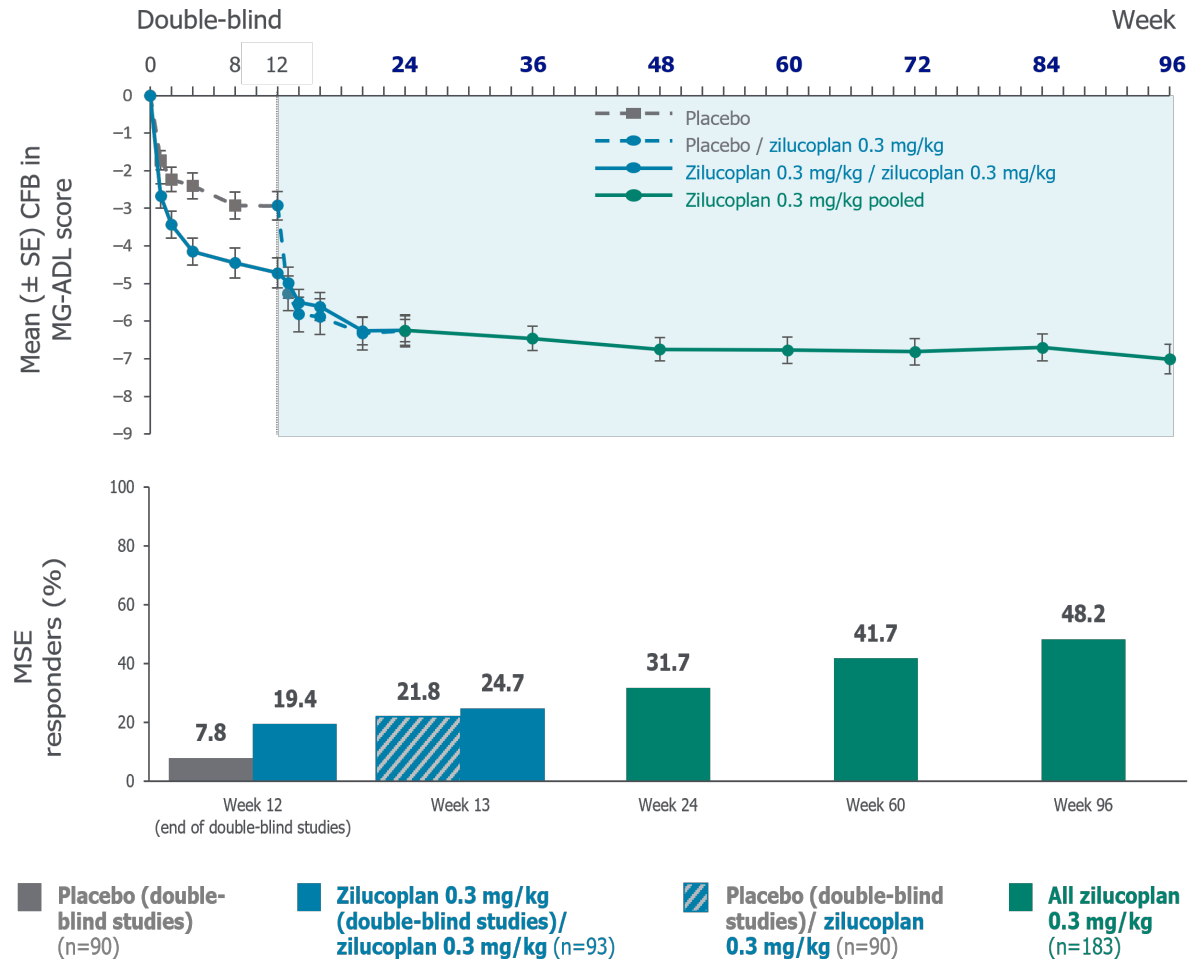
\*Defined using the preliminary reference value and the higher (most stringent) threshold of the range of values for each scale.

MG, myasthenia gravis; PRO, patient-reported outcome; RLZ, rozanolixizumab.

1. Habib AA, et al. Poster presented at AAN 2024. P4-11-001; 2. Hartford CA, et al. Neurol Ther. 2023;12(6):2079–2099; 3. Wiendl H, et al. Ther Adv Neurol Disord. 2023;16:17562864231213240; 4. Cleathous S, et al. Orphanet J Rare Dis. 2021;16(1):457.

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# Sustained long-term efficacy and favourable safety profile for ziluoplan



- **Favourable safety profile** for ziluoplan demonstrated for up to 5 years\*
- **Sustained symptom improvement** through to Week 96
- **High and sustained responder rates** through to Week 96
- Almost **50%** of patients achieved **MSE** by Week 96

\*Median duration of exposure: 1.8 years (range: 0.11–5.1).

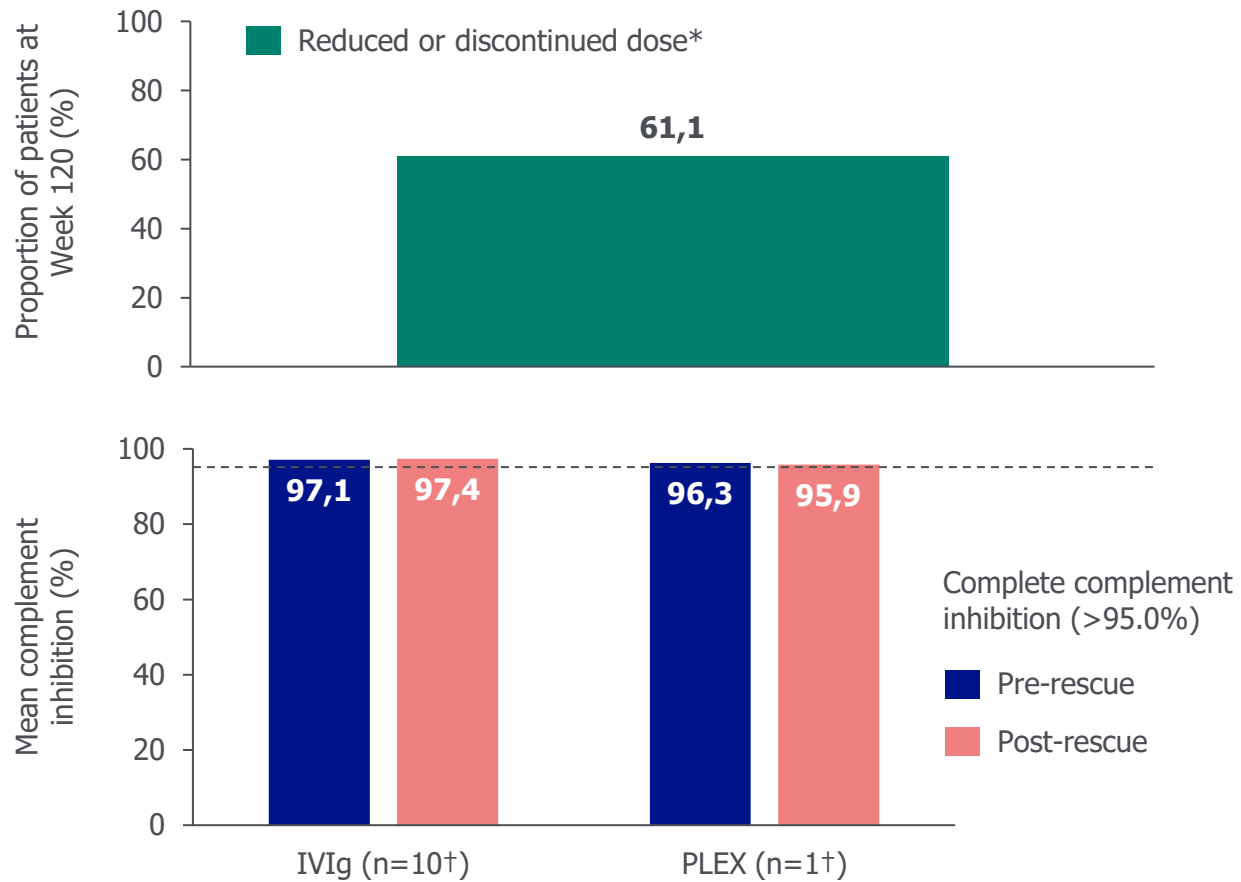
CFB, change from baseline; MG-ADL, Myasthenia Gravis Activities of Daily Living; MSE, minimal symptom expression; SE, standard error.

Howard JF Jr., et al. Presentation at AAN 2024. S15:002.

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# Corticosteroid reduction or discontinuation and concomitant use of IVIg and PLEX with zilucoplan

Mean dose reduction from BL: 15.49 mg/day  
Mean CFB in MG-ADL score: -6.55



- **60%** of patients reduced or discontinued corticosteroid dose during zilucoplan treatment with maintained efficacy
- **Complete complement inhibition** was maintained during concomitant use of zilucoplan with IVIg and PLEX without the need for supplemental dosing

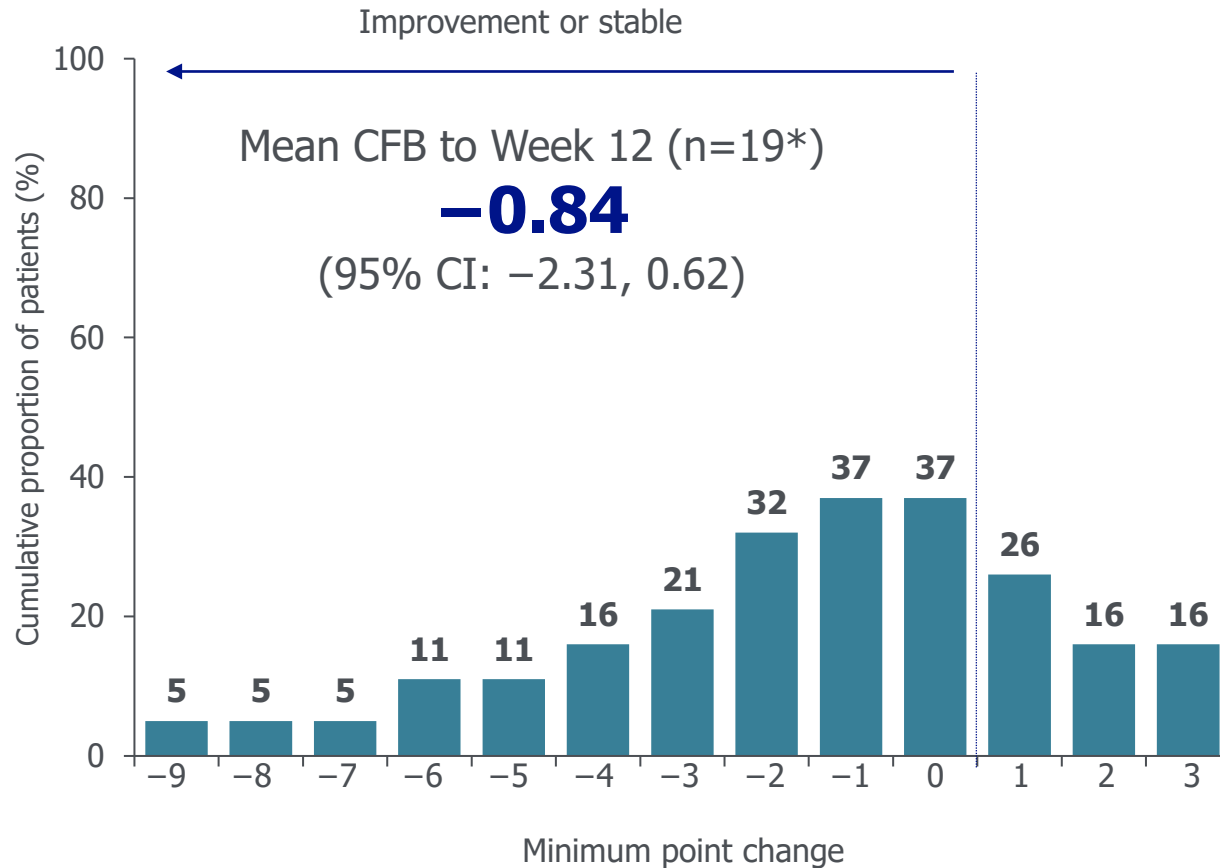
\*Among patients receiving corticosteroid treatment at double-blind BL (N=54). Data cutoff: November 11, 2023. <sup>+</sup>Events with available data. Complement activity was measured by sRBC lysis assay, with post-administration measurement taken up to 1 day after rescue treatment. Data cutoff: September 8, 2022.

BL, baseline; CFB, change from baseline; MG-ADL, Myasthenia Gravis Activities of Daily Living; MSE, minimal symptom expression; IVIg, intravenous immunoglobulin; PLEX, plasma exchange; sRBC, sheep red blood cell. Howard JF Jr., et al. Presentation at AAN 2024. S15:002.

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# First data reported from Phase 3b switch study supporting SC zilucoplan self-injection

## MG-ADL



- Zilucoplan demonstrated **favourable safety profile** upon switch as previously observed in clinical studies
- Upon switching from an IV C5 inhibitors to SC zilucoplan, symptoms either remained **stable or improved in 3 out of 4 patients**
- **80%** patients preferred SC zilucoplan to IV C5 inhibitors and reported higher treatment satisfaction

# Data builds on the evidence supporting the efficacy and safety profiles of the UCB portfolio in gMG

Providing more choices for patients living with gMG

## Rozanolixizumab

- First and only anti-FcRn indicated in a broad gMG adult population – including anti-AChR Ab and anti-MuSK Ab<sup>1</sup>
- Consistent efficacy improvements at Day 43 in all MG-specific outcomes – improvements observed as early as 1 week after the first infusion<sup>1</sup>
- Clinically meaningful improvements in fatigue<sup>2</sup>
- ~10% of patients had a treatment-free interval of <4 weeks<sup>4</sup>
- Well tolerated<sup>1,5</sup>



## Zilucoplan

- Clinically meaningful improvements at week 12 with decreases in MG symptoms observed within 1 week.<sup>6</sup>
- Sustained long-term efficacy with high responder rates<sup>7</sup>
- Favourable long-term safety<sup>7</sup>
- Corticosteroid sparing with maintained efficacy<sup>7</sup>
- Clinically meaningful, sustained improvements in fatigue severity<sup>8</sup>
- Unique benefits of C5 inhibitor peptide<sup>7</sup>
- Patient preference for SC over IV C5 inhibitor administration<sup>9</sup>

**A differentiated targeted portfolio to serve patients' individual needs**

AChR Ab, autoantibodies against acetylcholine receptor; C5, complement component 5; FcRn, neonatal Fc receptor; (g)MG, (generalised) myasthenia gravis; IV, intravenous; MuSK Ab, autoantibodies against muscle-specific tyrosine kinase; SC, subcutaneous.

1. Brill V, et al. Lancet Neurol. 2023;22:383–394; 2. Habib AA, et al. Poster presented at AAN 2024. P4-11-001; 3. Pascuzzi RM, et al. Poster presented at AAN 2024. P10-11-005; 4. Vissing J, et al. Poster presented at EAN 2023. Poster EPO-412; 5. Brill V, et al. Poster presented at AAN 2024. P4-14-017; 6. Howard JF Jr., et al. Lancet Neurol. 2023;22:395–406; 7. Howard JF Jr., et al. Presentation at AAN 2024. S15:002; 8. Weiss MD, et al. J Neurol. 2024;271:2758–2767; 9. Freimer M, et al. Poster presented at AAN 2024. P10-11-006.

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# **EXPERIENCE WITH RYSTIGGO® & ZILBRYSQ® IN CLINICAL SETTING**

**Dr. Suraj Muley**

Professor, Clinical Scholar, Neurology Faculty, College of  
Medicine, Phoenix, Arizona



# Q&A – your questions, please