



# Interim Data for KYSA-6 Phase 2 Clinical Trial of KYV-101 in Generalized Myasthenia Gravis

## Conference Call

October 29, 2025

Cindy  
MG Warrior



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# Introduction

Warner Biddle – Chief Executive Officer

# Today's Agenda

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- Introduction
  - Interim Phase 2 gMG Data Results
  - Neuroimmunology Franchise and Future Growth Opportunities
  - Q&A
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## Speakers



**Warner Biddle**  
Chief Executive Officer



**Naji Gehchan M.D., MSc, MBA**  
Chief Medical  
& Development Officer

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## Q&A

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**Marc Grasso M.D.**  
Chief Financial Officer



**Sri Muppidi M.D.**  
Stanford Medicine

# Despite Available Treatment Options, High Disease Burden Remains in Generalized Myasthenia Gravis (gMG)

- MG is a B-cell and antibody-mediated neuromuscular autoimmune disease that causes fluctuating muscle weakness and fatigue<sup>1,2</sup>

**Novel therapies are needed that minimize or eliminate symptoms of disease while reducing risks associated with chronic immunosuppression**

## Current State of Treatment for Patients With gMG



Inadequate symptom control<sup>3,4</sup>



Few reach minimal symptom expression (MSE)<sup>1,5-6</sup>



Majority require ongoing immunosuppressant therapy<sup>1-4</sup>



Costly and chronic treatment options<sup>1,7</sup>

# KYV-101: Upstream Targeting at the Disease Source – A Fundamentally Different Approach to Treating gMG

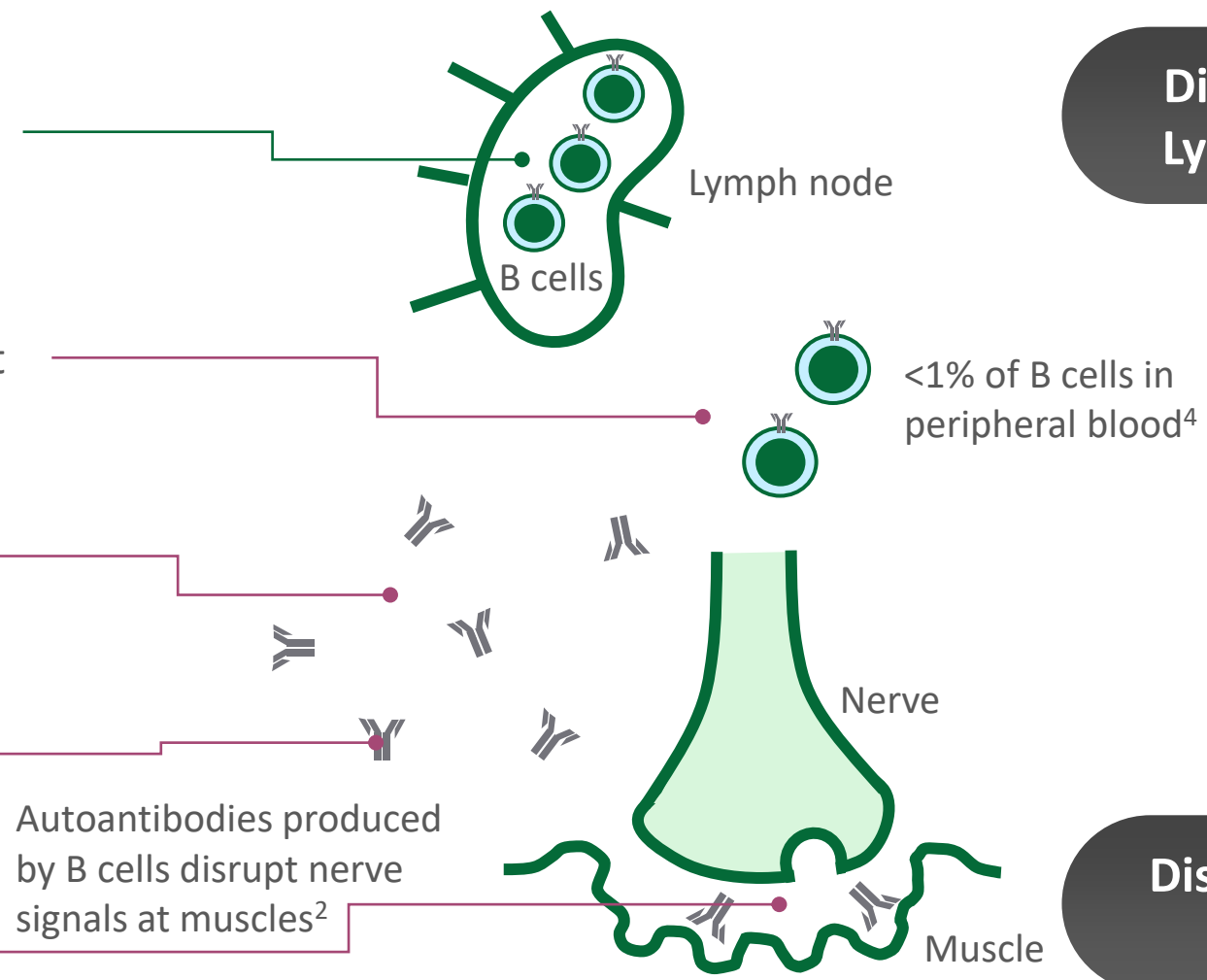
**KYV-101** deeply depletes B cells including in tissues<sup>1</sup>

**B-cell targeting mAbs** cannot fully penetrate tissues and primarily target peripheral blood B cells<sup>1</sup>

**FcRn inhibitors** transiently reduce autoantibody accumulation<sup>2</sup>

**Complement inhibitors** transiently inhibit autoantibody immune activity<sup>2</sup>

**Acetylcholinesterase inhibitors** increase concentration of nerve signaling molecules<sup>3</sup>



**Disease Source in Lymphoid Tissues**

**Upstream**

**Downstream**

**Disease Symptoms at Muscles**

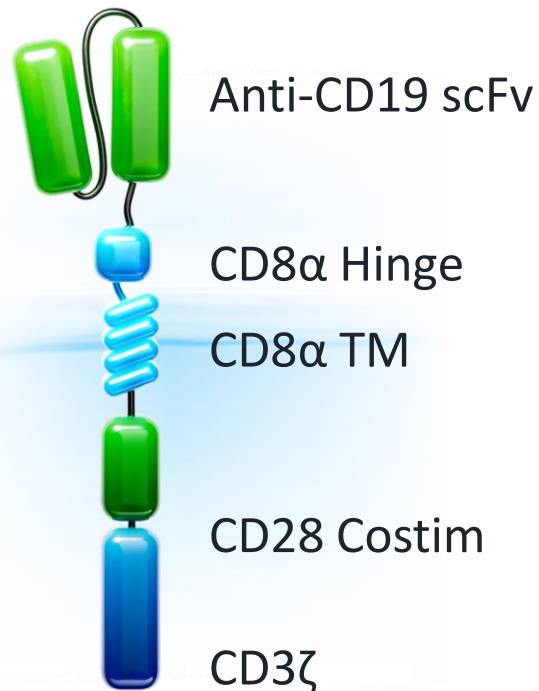
FcRn, neonatal fragment crystallizable receptor; mAb, monoclonal antibody.

1. Tur C, et al. *Ann Rheum Dis*. 2025;84(1):106-114. 2. DeHart-McCoyle M, et al. *BMJ Med*. 2023;2(1):E241. 3. Myasthenia Gravis. NIH – NINDS. <https://www.ninds.nih.gov/health-information/disorders/myasthenia-gravis>. 4. Sender R, et al. *Proc. Natl. Acad. Sci. U.S.A.* 2023;120(44):e2308511120.

# KYV-101: Unique CAR Designed for Potency & Tolerability in Autoimmune Diseases

## Fully Human Autologous CD19 CAR T With CD28 Costim

### KYV-101 CAR Construct<sup>1,2</sup>



- More than 100 patients dosed with KYV-101 across multiple indications; no high-grade CRS or ICANS have been observed<sup>3</sup>
- KYV-101 has been shown to induce deep and broad depletion of blood- and tissue-resident B cells,<sup>4,5</sup> which are an upstream therapeutic target in MG
- Initial 3 patients with gMG treated under expanded access pathway have achieved stable MSE with no background immunosuppressive therapies ongoing for 15 to 24 months<sup>3</sup>

# Compelling Phase 2 Results Reinforce KYV-101's Potential to Change the Treatment Paradigm in gMG

Only KYV-101 Has the Potential to Deliver ALL Four Components of a Paradigm-Shifting Therapy

**1.**

Unprecedented  
Disease Control +  
Manageable Safety  
Profile

**2.**

More Patients to  
Minimal Symptom  
Expression (MSE)

**3.**

Opportunity to  
Remove Background  
Therapies

**4.**


Single-Dose  
Treatment

# Changing the Treatment Paradigm in gMG

Naji Gehchan, MD, MSc, MBA – Chief Medical and Development Officer

# KYSA-6: Phase 2/3 Study of KYV-101 in gMG

## Phase 2 design: Open-label, single-arm, multicenter study

 **N = 6**

- Age 18 to 75 years
- Diagnosis of gMG, Class IIB-IV per MGFA criteria
- Autoantibodies to AChR, MuSK, or LRP4
- MG-ADL  $\geq 6$
- Failed  $\geq 2$  immunosuppressive/immunomodulatory therapies OR failed  $\geq 1$  immunosuppressive therapy and required chronic plasmapheresis or IVIg to control symptoms

### KYV-101

Cy/Flu lymphodepletion  
+  
Single infusion of  
 $1 \times 10^8$  CAR T cells

### Primary endpoints

- MG-ADL at 24 weeks
- Adverse events

### Key secondary endpoints

- QMG and MGC scores
- PK/PD



**18-month follow up**

*Interim analysis of ongoing phase 2 study with data cutoff of October 3, 2025*

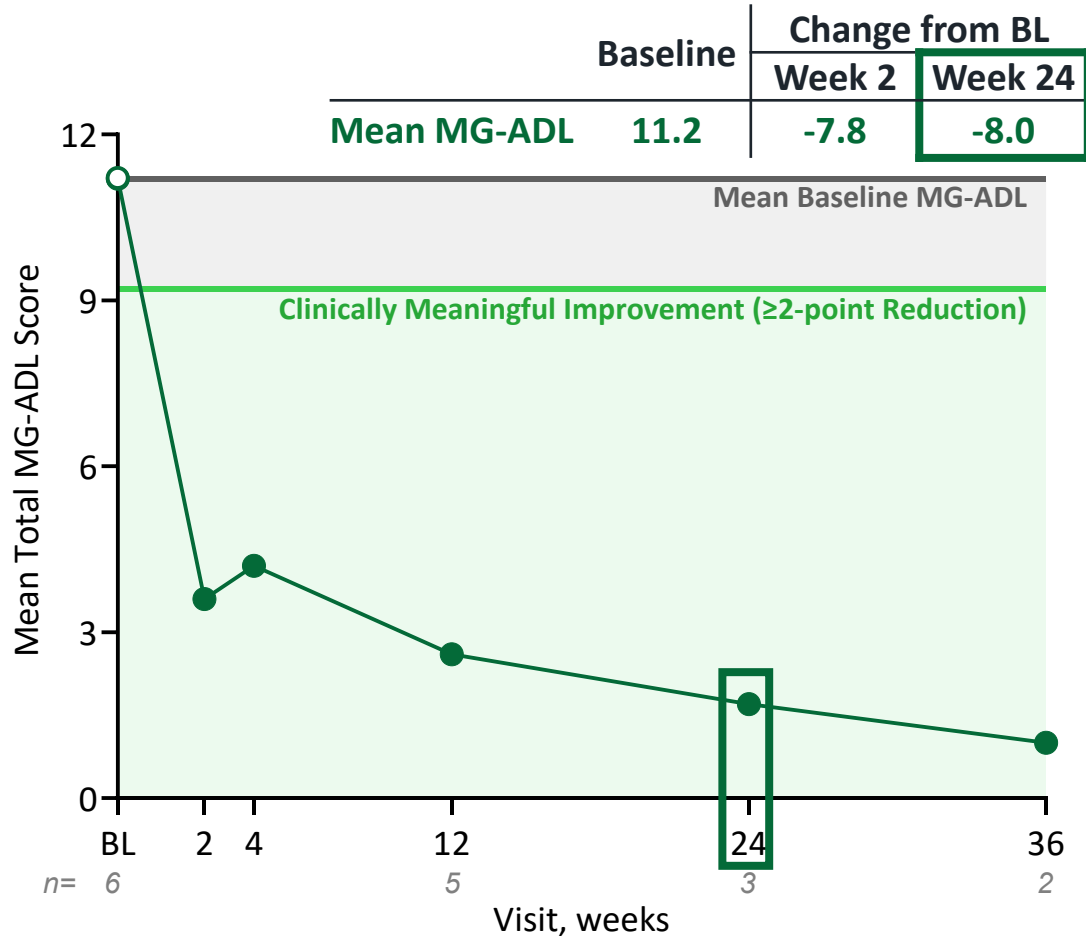
# Patients Treated With KYV-101 Had Moderate to Severe gMG

Characteristic	N=6
Age, mean years (range)	45.5 (21-62)
Sex, female   male, n (%)	5 (83%)   1 (17%)
Duration of MG, mean years (range)	5.3 (1.7-13.3)
Total outcome score, mean (range)	
MG-ADL	11.2 (7-16)
QMG	17.3 (9-28)
MGC	21.8 (15-30)
MGFA Class IIIb   Class IV at screening, n (%)	4 (67%)   2 (33%)
AChR   MuSK-positive at screening/historically, n (%)	5 (83%)   1 (17%)
Prior therapies, n (%)	
AChE inhibitors	6 (100%)
NSISTs	6 (100%)
FcRn and/or complement inhibitors	5 (83%)
Steroids	6 (100%)
IVIg and/or PLEX	4 (67%)
Rituximab	3 (50%)

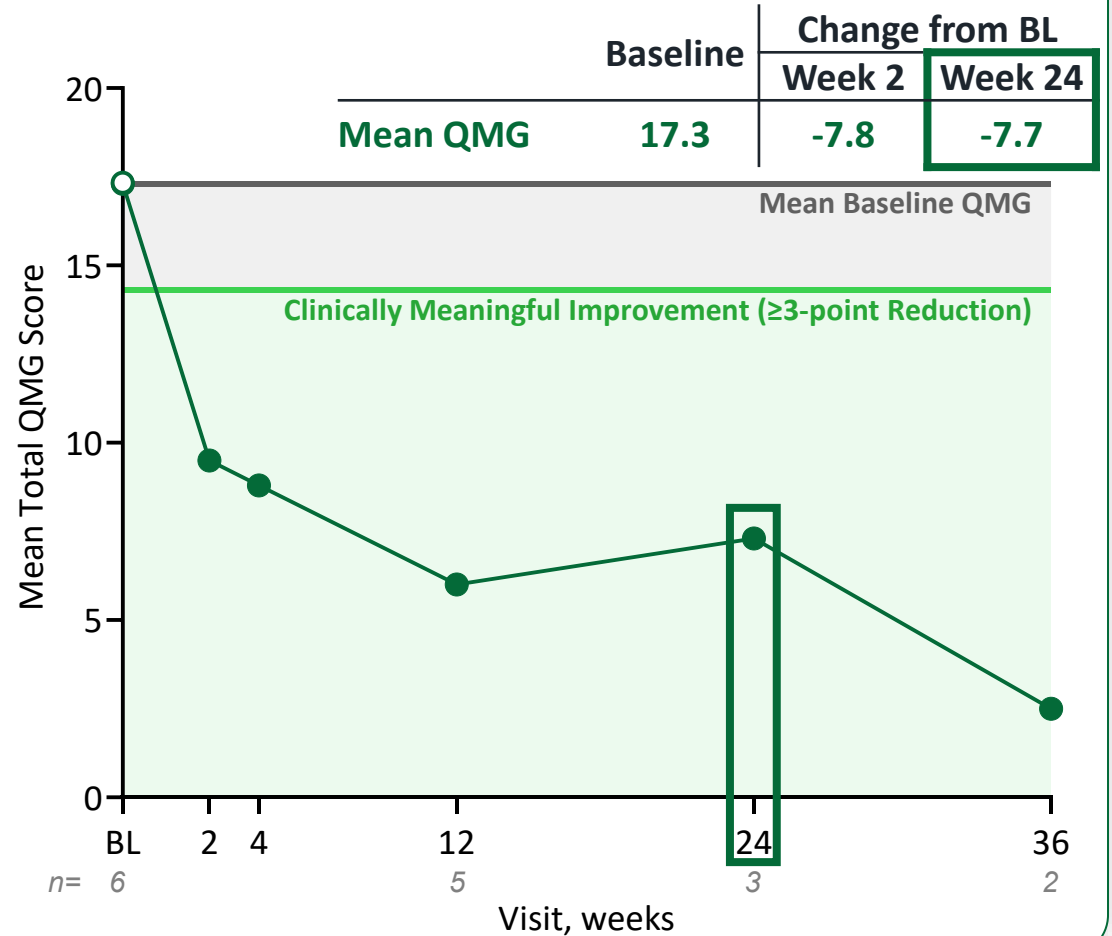
- All patients had robust CAR T-cell expansion and B-cell depletion

# KYV-101 Demonstrated Rapid, Robust, and Sustained Reductions in MG-ADL and QMG

## MG-ADL score



## QMG score



Data cutoff: October 3, 2025.

BL, baseline; MG-ADL, myasthenia gravis activities of daily living; QMG, quantitative myasthenia gravis.

# After a Single Dose of KYV-101, Patients Achieved Substantial and Clinically Meaningful Reductions in MG Outcome Scores and Treatment Burden

## Substantially Improved MG-ADL, QMG, and MGC

- **100% clinically meaningful response by MG-ADL & QMG**  
(Reduction of  $\geq 2$  by MG-ADL,  $\geq 3$  by QMG)
- **100% responders by MG-ADL**  
( $\geq 3$  point reduction by MG-ADL)
- **67% reached MSE (MG-ADL of 0 or 1)**  
(n=3 with  $\geq 24$  weeks follow-up)
- **100% clinically meaningful response by MGC with -12.0 mean reduction at 24 weeks**  
(Reduction of  $\geq 3$  by MGC)

## Reduced Treatment Burden

- **100% free of nonsteroidal immunosuppressants (NSISTs), high-dose steroids (>10 mg), and FcRn and complement inhibitors up to 24 weeks**
  - Of the 6 patients, 5 remained free of these agents as of their last follow-up

# KYV-101 was Well-Tolerated with No High-Grade CRS and No ICANS Observed

Safety	Patients (n=6)
CRS (any Grade), n (%)	6 (100)
Grade 1	4 (67)
Grade 2	2 (33)
ICANS (any Grade), n (%)	0 (0)
Grade 3/4 TEAEs, n (%)	3 (50)
Neutropenia	3 (50)
Lymphopenia	1 (17)
Lymphocyte count decreased	1 (17)
Any treatment-related serious AE, n (%)	1 (17)

- No ICANS observed
- CRS was low-grade and manageable in all patients
  - 4 of 6 patients only experienced fever (Grade 1 CRS)
- 3 patients with expected AEs associated with lymphodepletion and CAR T-cell therapy
  - 2 patients had transient Grade 3/4 neutropenia that resolved within 10 days of infusion
  - 1 Grade 4 neutropenia SAE was manageable with G-CSF, not associated with infections, and had improved to Grade 1 by data cutoff

# Well-Positioned to Achieve Best-in-Class Results in gMG with Phase 3 Trial

In 6 patients with moderate to severe gMG, a single dose of KYV-101 resulted in:



**Robust, rapid, and sustained improvements regardless of prior biologic exposure**

- Reduction of MG disease scores at 24 weeks: -8.0 for MG-ADL and -7.7 for QMG
- 100% responders by MG-ADL score ( $\geq 3$ -point reduction)
- Mean reductions at Week 2: -7.8 for MG-ADL and -7.8 for QMG

**At interim readout, most patients at or trending to MSE**

- MSE achieved in 2/3 patients with  $\geq 24$  weeks of follow-up



**100% free of NSISTs, high-dose steroids (>10mg), and FcRn and complement inhibitors up to 24 weeks**



**Consistent, well-tolerated, and manageable safety profile**

# Robust Phase 2 Results Strengthen Confidence in Phase 3 Powering Assumptions, Efficient Trial-Size, and Co-primary Endpoint Measurement



Reductions in MG-ADL and QMG **exceeded the magnitude of effect** assumed for Phase 3 co-primary endpoints

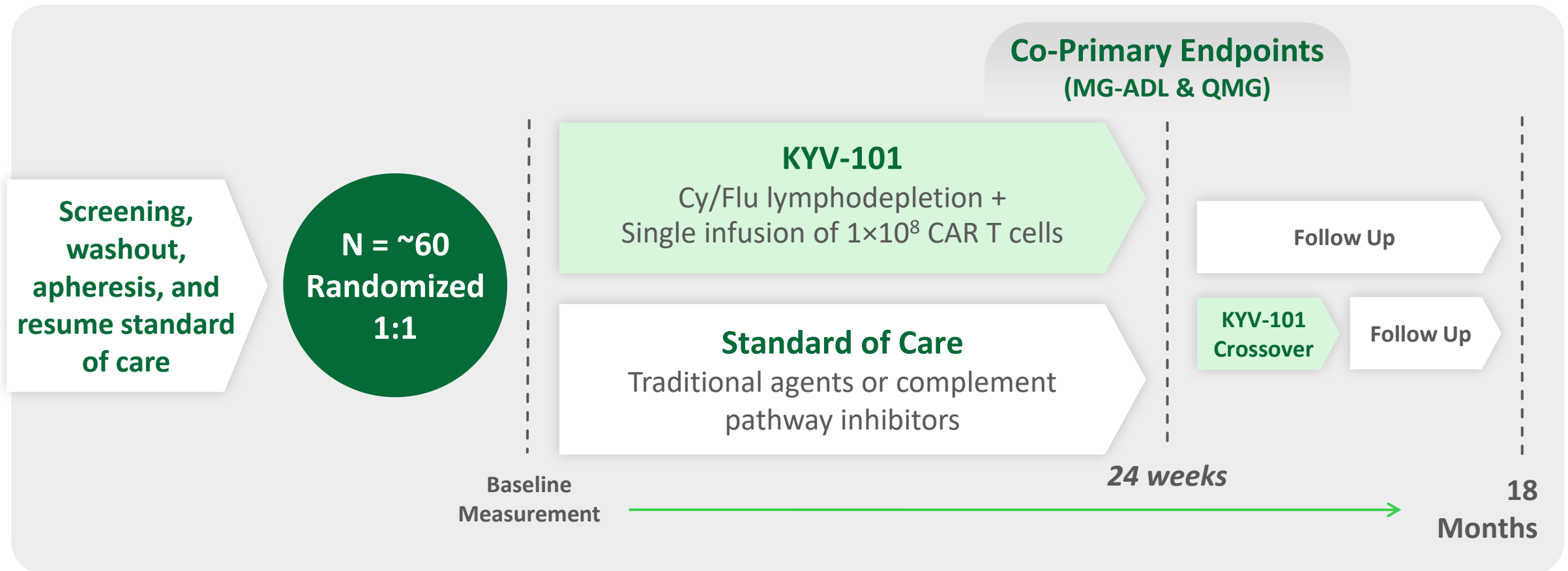


**Deep, sustained treatment effect** was observed at **week 24** - the timepoint of assessment for Phase 3 co-primary endpoints

**Interim Phase 2 Results Increase Phase 3 Probability of Success**

# Innovative and FDA-Aligned Registrational Phase 3 Trial Design

~60-patient, global, open-label, randomized controlled Phase 2/3 trial with crossover design



*Standard of care may consist of traditional agents (e.g., prednisone, azathioprine, mycophenolate, methotrexate, chronic IVIG/PLEX) or complement pathway inhibitors (e.g., eculizumab, ravulizumab). Anti-CD20 or -CD19 monoclonal antibodies or FcRn inhibitors not allowed as defined in inclusion criteria.*

# Unprecedented MG Clinical Outcome Measures Achieved with a Single Dose of KYV-101

		Approved		Investigational*		
		FcRn Inhibitor <sup>1</sup> VYVGART <sup>®</sup>	Complement Inhibitor <sup>2,3</sup> ULTOMIRIS <sup>®</sup>	CD19 mAb <sup>4,5</sup> UPLIZNA <sup>®</sup>	BCMA mRNA CAR T <sup>6</sup> Descartes-08	<b>KYV-101 CD19 CAR T (KYSA-6, n=3)</b>
<b>Primary Endpoint</b>		4 weeks	6 months	6 months	3 months	<b>6 months</b>
<b>Depth of Response</b> <i>Mean reduction from baseline to primary endpoint (non-placebo adjusted)</i>	<b>MG-ADL Reduction</b>	~4.6	3.1	4.2	~4.2	<b>8.0</b>
	<b>QMG Reduction</b>	~6.2	2.8	4.8	~3.9	<b>7.7</b>
<b>% Responders</b> <i>Patients with ≥3-point MG-ADL improvement from baseline to primary endpoint (non-placebo adjusted)</i>		~73%	~57%	~79%	~70%	<b>100%</b>
<b>Achieve Minimal Symptom Expression (MSE)</b> <i>% of patients achieving MG-ADL of 0 or 1</i>		40% <i>At any point before primary endpoint</i>	43%	Not reported	33% <i>6 months to 1 year</i>	<b>67%</b> <i>At any point before primary endpoint</i>

Note: These observations are derived from separate clinical settings; comparisons across trials are not based on head-to-head studies.

BCMA, b-cell maturation antigen; FcRn, neonatal fragment crystallizable receptor; mAb, monoclonal antibody; MG-ADL, myasthenia gravis activities of daily living; mRNA, messenger RNA; QMG, quantitative myasthenia gravis score.

\*Under investigation in MG.

1. Howard Jr JF, et al. *Lancet Neurol.* 2021;20(7):526-536. 2. Vu T, et al. *NEJM Evid.* 2022;1(5):EVIDo0a2100066. 3. AstraZeneca. ULTOMIRIS<sup>®</sup> efficacy data from CHAMPION-MG. <https://ultomirishcp.com/gmg/efficacy>. Accessed 20 Aug 2025.

4. Nowak RJ, et al. *N Engl J Med.* 2025;392(23):2309-2320. 5. Nowak RJ, et al. *AAN* 2025. LS2.002. 6. Vu T, et al. *AAN* 2025. S34.002.



# Accelerating Potential First-in-Class CAR T Franchise with MG and SPS

Warner Biddle – Chief Executive Officer

# Potential to Change the Treatment Paradigm in a Large and Growing Market with KYV-101



**~80k**

**U.S. Diagnosed  
gMG Patients<sup>1,2</sup>**



**KYV-101  
Addressable Market<sup>1,3</sup>**

**Initial  
Priority**

**~12k Patients**

*15% of total diagnosed  
Patients with inadequate  
response to  $\geq 1$  biologic\**

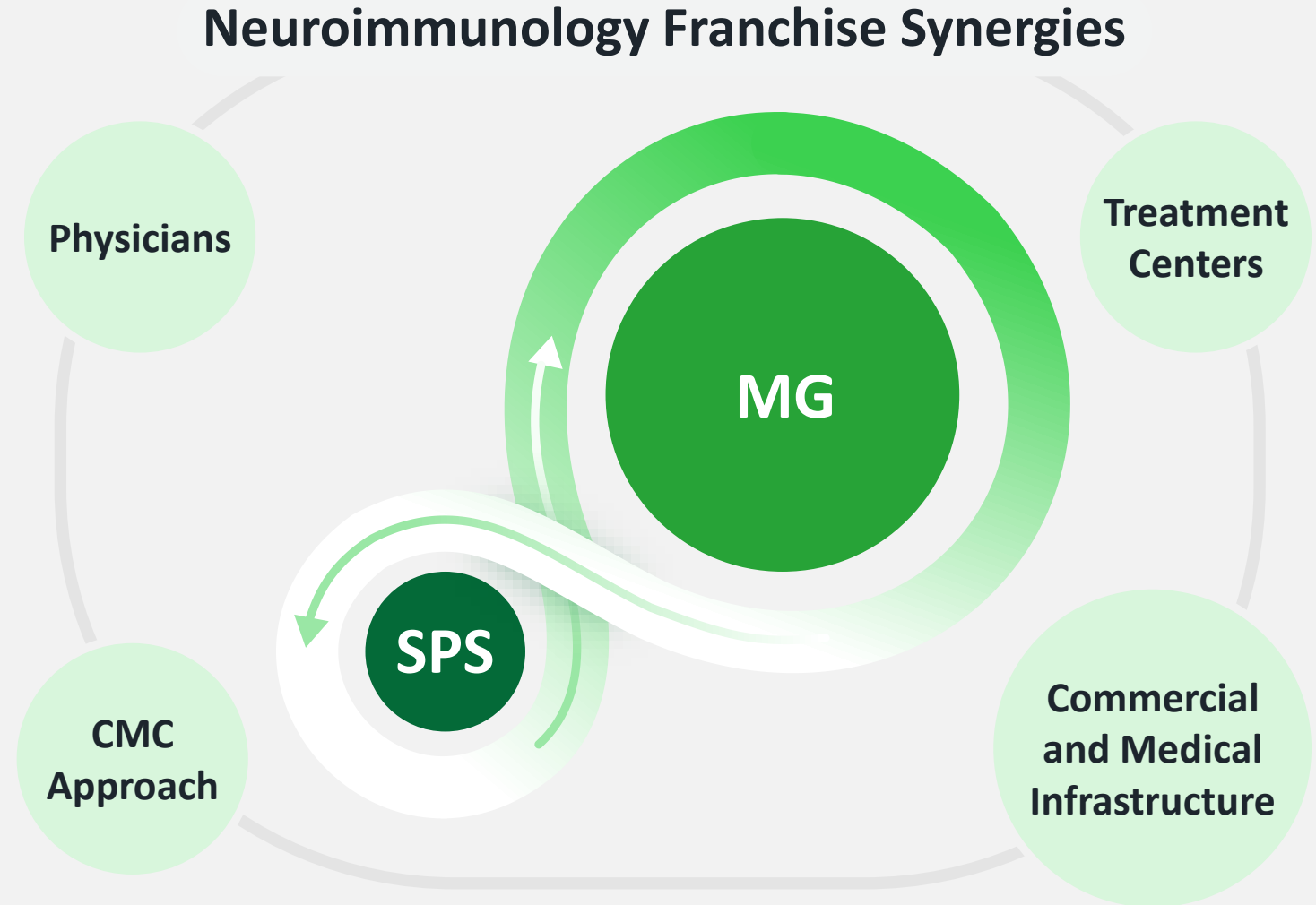
**Total KYV-101  
Addressable Market**

**~40k Patients**

*50% of total diagnosed  
Patients with inadequate  
response to immunosuppressants*

# Robust Market Opportunity Supported by Efficient and Scalable Commercial Strategy in Neuroimmunology

Rapid market entry and uptake in MG to be supported by first-mover advantage in stiff person syndrome (SPS) and neuroimmunology franchise synergies



# Our Focus and Strong Execution Position Kyverna for Future Growth

## NEUROIMMUNOLOGY

Accelerating potential first-in-class CAR T franchise, beginning with MG and SPS

**MG:** Clear path to BLA with FDA-aligned Phase 3 trial that is further de-risked by strong Phase 2 results

**SPS:** Trial fully enrolled, topline data anticipated 1H 2026; valuable commercial opportunity with no approved therapies, significant unmet need

## BROADER PIPELINE

Strategically pursuing expansive opportunity in autoimmune disease

**MS and RA:** Promising early IIT data reinforce KYV-101's broad potential across multiple autoimmune indications

**KYV-102:** On track to broaden access with rapid whole-blood manufacturing process; IND filing targeted in Q4 2025

**Strong cash position into 2027** supporting SPS BLA filing, MG Phase 3 trial, and pre-launch activities

# Multiple, Value-Creating Near-Term Catalysts

Program	Anticipated Milestones
<p><b>Stiff Person Syndrome</b> RMAT, ODD</p>	<ul style="list-style-type: none"> <li>✓ Complete Pivotal Phase 2 Enrollment mid-2025</li> <li>✦ Report Topline Pivotal Phase 2 Data 1H 2026</li> <li>✦ BLA filing in 1H 2026</li> </ul>
<p><b>Myasthenia Gravis</b> RMAT, ODD*, FTD<sup>†</sup></p>	<ul style="list-style-type: none"> <li>✓ Confirm Registrational Path with Regulators 1H 2025</li> <li>✓ Reported Positive Interim Phase 2 Data Q4 2025</li> <li>✦ Initiate Patient Enrollment for Phase 3 Registrational Trial by Year-End 2025</li> </ul>
<p><b>Additional Indications</b></p>	<ul style="list-style-type: none"> <li>✓ Multiple Sclerosis (MS): Reported Positive Phase 1 IIT Data Q3 2025</li> <li>✓ Rheumatoid Arthritis (RA): Reported Positive Phase 1/2 IIT Data Q4 2025</li> <li>✦ Lupus Nephritis (LN): Report Phase 1 Data in a Peer-Reviewed Publication in 2026</li> </ul>
<p><b>Future Pipeline</b></p>	<ul style="list-style-type: none"> <li>✦ File KYV-102 IND Application Q4 2025</li> </ul>

✓ COMPLETED

RMAT, Regenerative Medicine Advanced Therapy; ODD, Orphan Drug Designation; FTD, Fast Track Designation.  
\*EU & US. †Fast track designation does not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures.

Q&A



# Key Takeaways from Today

1

**Kyverna is uniquely positioned to fundamentally change the treatment paradigm in gMG**

*Data reinforces KYV-101's potential to deliver durable, drug-free, disease-free remission with a single dose*

2

**Today's unprecedented clinical trial results increase confidence in Kyverna's registrational Phase 3 superiority trial and path to BLA**

3

**Kyverna is well positioned to deliver on a compelling commercial opportunity in gMG, a large and growing market**