



Positive Longer-Term Durability and Safety Data of Miv-cel in SPS and gMG

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Today's Agenda

- Miv-cel – Setting a New Benchmark for Autoimmune CAR T
- Stiff Person Syndrome (SPS) – 1-Year Topline Data
- Generalized Myasthenia Gravis (gMG) – Phase 2 Longer-term Topline Follow-up Data
- Transforming the Treatment Paradigm in Neurologic Autoimmune Diseases
- Q&A

Speakers



Warner Biddle
Chief Executive Officer



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

Single Dose Miv-cel Continues to Establish a New Clinical Response Benchmark for Autoimmune CAR T



Durable results for at **least 1 year** in both SPS and gMG with **nearly all patients remaining off chronic immunotherapies**



Consistent, well-tolerated safety profile maintained in 1-year follow-up with **no high-grade CRS or ICANS and no cases of IEC-HS**



Potential for **broad immune reset through deep B-cell depletion** achieved with a **single dose** underscores miv-cel's **unique construct** and **differentiated profile**



Data further **strengthens SPS BLA; submission expected Q4 2026**, paving way for the **first** potential CAR T launch in autoimmune in 2027, unlocking a **multi-billion-dollar SPS market**



Data further reinforces miv-cel's **differentiation in gMG; Phase 3 trial further de-risked** with enrollment expected to be completed **mid-2027**

CRS, cytokine release syndrome; IEC-HS, immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome.

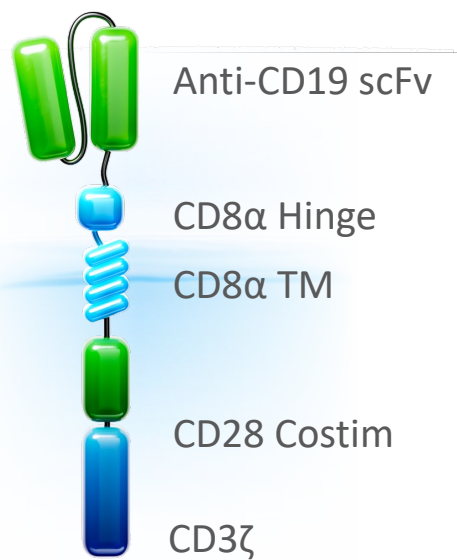
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Miv-cel's Differentiated CAR Construct Reinforces Potential First-in-Class and Best-in-Class Profile in Autoimmune

Mivocabtagene Autoleucel (miv-cel)^{1,2}

Only Fully Human Autologous CD19
CAR T With CD28 Costim



- Deep depletion of peripheral and tissue-resident B cells to support broad immune reset and durable remission³⁻⁴
- First SPS and gMG patients treated with a single dose of miv-cel achieved **durable efficacy beyond 24 months without the need for chronic immunotherapies**⁵
- **>100** patients dosed with miv-cel across multiple indications⁶
- **No high-grade CRS or ICANS³ and no IEC-HS reported⁶**

Established, Validated, and Scalable Manufacturing Process

- ✓ Miv-cel is produced using a **well-established, and validated manufacturing process** similar to those used in commercially available CD19 autologous CAR T-cell therapies
- ✓ **Dual-source** U.S. manufacturing strategy
- ✓ **>98% manufacturing success rate** driven by robust process, quality systems, and technical expertise
- ✓ Commercial agreement with Elevate **supports SPS and future commercial launches and clinical demand**



elevatebio®



Minaris
Advanced Therapies



SPS – 12- Month Topline Data from KYSA-8 Registrational Trial

Naji Gehchan, M.D., MSc, MBA – Chief Medical and Development Officer

KYSA-8 Registrational Trial in SPS – Study Design

KYSA-8: Open-label, single-arm, multicenter study



N = 26

- Age 18 to 75 years
- Diagnosis of SPS
- Inadequate response to immunomodulatory therapy
- Stiffness index ≥ 2

Miv-cel

Low-dose Cy/Flu
preconditioning
+
Single infusion of
 1×10^8 CAR T cells

SPS immunotherapies are
discontinued



Primary endpoints:

- Change from baseline in T25FW at 16 weeks
- Safety



Secondary endpoints: change from baseline at 16 weeks

- Modified Rankin Scale (mRS)
- Distribution of Stiffness Index (DSI)
- Hauser Ambulation Index (HAI)
- Heightened Sensitivity Scale (HSS)

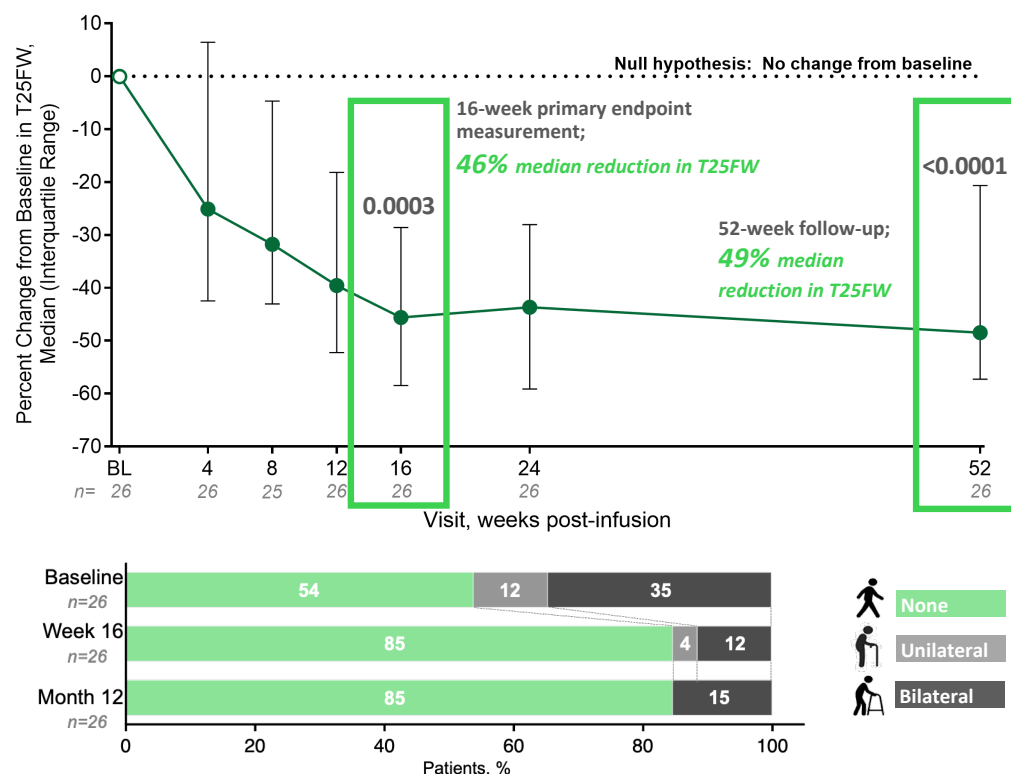


**One-
year
Follow
Up**

Miv-cel Granted ODD and RMAT Designations by FDA for SPS

Continued Reversal of Disability with Nearly All Patients Remaining Off Chronic Immunotherapies Sustained Through 1 Year

Significant T25FW Improvement and Reduced Walking Aid Use



- **95%** of patients who achieved a clinically meaningful improvement ($\geq 20\%$ reduction from baseline)¹ at primary analysis **sustained their benefit at 1 year**
- **At 1 year, over one-third of patients** completed T25FW in < 5 seconds, comparable to a **typical time for healthy adults**²
- Of the 12 patients requiring a walking aid for T25FW at baseline, **67% continue not to require assistance at 1 year**
- **92% (24/26)** of patients continue to remain **free of immunomodulatory or immunosuppressant therapies** for SPS* at 1 year

*Includes IVIg/SCIg, PLEX, rituximab and/or prednisone (≥ 20 mg/day) for SPS symptoms.

N=26. Database lock: July 2026. Percentages may not total 100% due to rounding. BL, baseline; T25FW, timed 25-foot walk.

1. Hobart J, et al. *Neurology*. 2013;80(16):1509-17. 2. Motl RW, et al. *Mult Scler*. 2017;23(5):704-710.

Statistically Significant Improvements Continued in All Primary and Secondary Endpoints Through 1 Year

		16-wk timepoint	1-Yr follow-up
Primary Endpoint		P Value	P Value
✓	Timed 25-Foot Walk	0.0003	<0.0001
Secondary Endpoints		P Value	P Value
✓	Modified Rankin Scale	<0.0001	0.0003
✓	Distribution of Stiffness Index	<0.0001	<0.0001
✓	Hauser Ambulation Index	<0.0001	<0.0001
✓	Heightened Sensitivity Scale	<0.0001	<0.0001

Consistent Safety Profile Maintained in 1-Year Follow-Up With No High-Grade CRS or ICANS and No IEC-HS

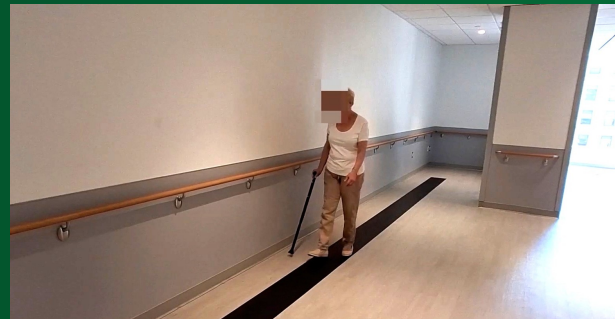
Treatment-Related Adverse Events, n (%)	N = 26
Any grade ≥ 3 CRS	0 (0)
Any grade ≥ 3 ICANS	0 (0)
Any grade IEC-HS	0 (0)
CRS (any Grade)	24 (92)
Grade 1	10 (38)
Grade 2	14 (54)
ICANS (any Grade)	3 (12)
Grade 1	3 (12)
Grade 3/4 neutropenia	5 (19)
Any treatment-related serious AE	3 (12)

- No high-grade CRS or ICANS observed
- No IEC-HS observed
- All Grade 3/4 neutropenia (5/26), an expected AE with lymphodepletion and CAR T-cell therapies, were manageable
- All treatment-related serious AEs (3/26) have fully resolved

KYSA-8 Patient Perspectives: Before and After Treatment with Miv-cel Case Studies



[View Video](#)



[View Video](#)

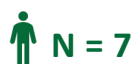


gMG – Longer-Term Data from Phase 2 KYSA-6 Trial

Naji Gehchan, M.D., MSc, MBA – Chief Medical and Development Officer

KYSA-6 Phase 2/3 Trial in gMG – Phase 2 Study Design

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



N = 7

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

KYV-101

Cy/Flu lymphodepletion

+

Single infusion of 1×10^8 CAR T cells



Primary endpoints

- MG-ADL at 24 weeks
- Adverse events



Key secondary endpoints

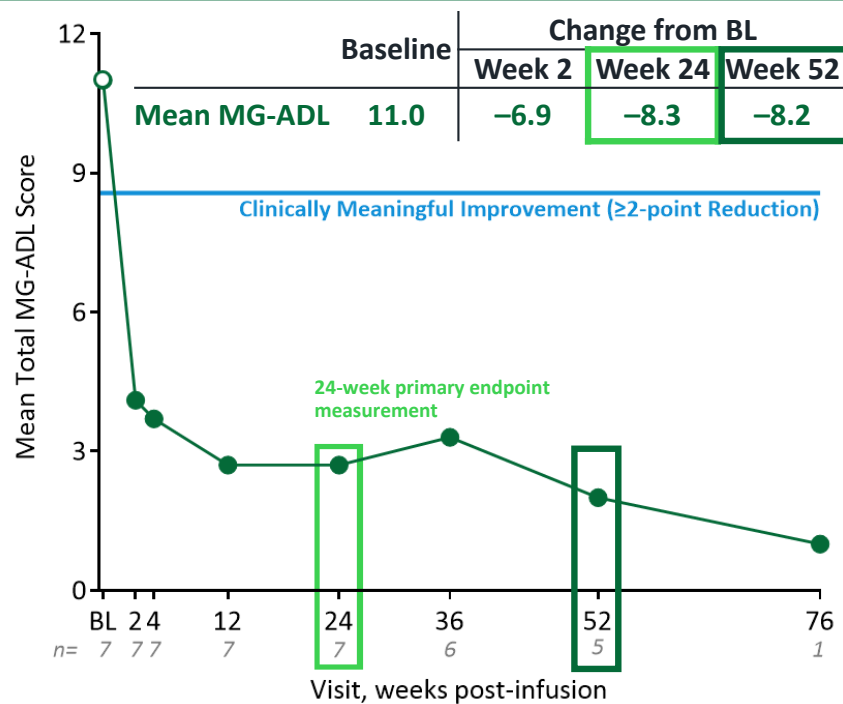
- QMG and MGC scores
- PK/PD



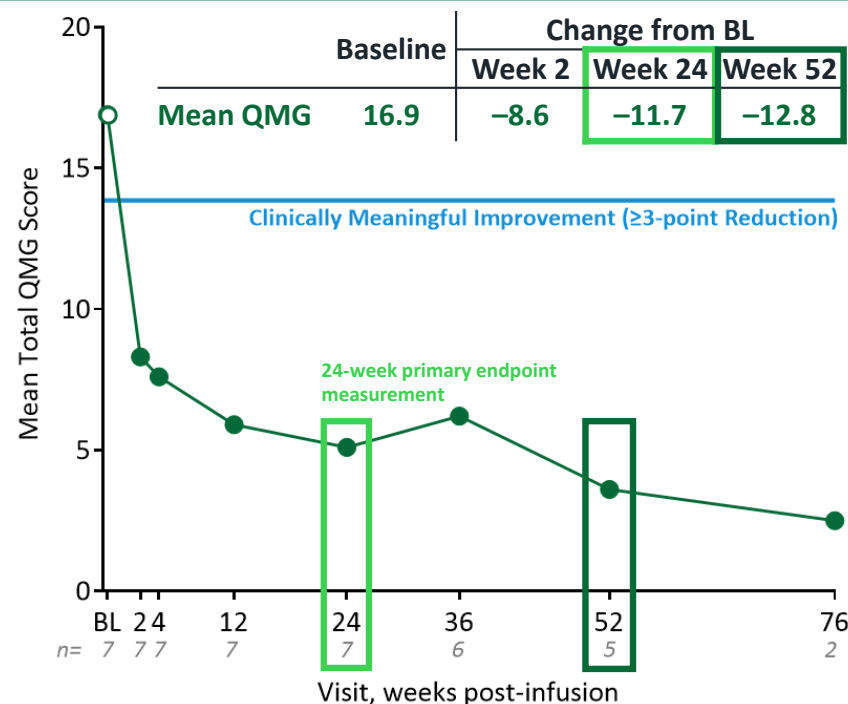
18-month follow up

Robust and Durable Effects Sustained Through At Least 1-Year Across MG-ADL and QMG

MG-ADL Score



QMG Score



N=7. Data cutoff: June 2026. One patient has not yet reported their MG-ADL score at 76 weeks as of the June 2026 data cutoff. Change from baseline is calculated using the baseline values of the corresponding patients at a specified timepoint. MG-ADL, myasthenia gravis activities of daily living; QMG, quantitative myasthenia gravis.

Single-dose Miv-cel Continues to Deliver Robust and Clinically Meaningful Reductions in MG Outcome Scores and Treatment Burden

Substantially improved clinical outcomes

MG-ADL

100% had clinically meaningful response
(≥ 2 -point reduction vs baseline)

100% were responders
(≥ 3 -point reduction vs baseline)

57% sustained MSE at last follow-up
(MG-ADL score of 0-1)

QMG

100% had clinically meaningful response
(≥ 3 -point reduction vs baseline)

MGC

100% had clinically meaningful response
(≥ 3 -point reduction vs baseline)
–16.4 mean reduction at 24 weeks; –16.8 at 1 year

Substantially reduced gMG treatment burden

**100% free of immunotherapies, including NSISTs, high-dose steroids (>10 mg),
and FcRn and complement inhibitors up to 24 weeks**
6 of 7 patients remained free of these agents at last follow-up

N=7. Data cutoff: June 2026

BL, baseline; FcRn, neonatal fragment crystallizable receptor; MG-ADL, myasthenia gravis activities of daily living; MGC, Myasthenia Gravis Composite; MSE, minimal symptom expression; NSIST, nonsteroidal immunosuppressive therapy; QMG, quantitative myasthenia gravis.

Consistent Safety Profile Maintained in Long-term Follow-Up With No High-Grade CRS and No ICANS or IEC-HS

Treatment-related AEs, n (%)	Patients (n=7)
Any grade ≥ 3 CRS	0 (0)
Any grade ICANS	0 (0)
Any grade IEC-HS	0 (0)
SAE, any grade ^a	0 (0)
CRS (any grade)	7 (100)
Grade 1	5 (71)
Grade 2	2 (29)
Grade 3/4 events	3 (43)
Neutropenia	2 (29)
Lymphopenia	2 (29)

- No high-grade CRS and no ICANS observed
- No IEC-HS observed
- All Grade 3/4 treatment-related AEs of neutropenia (2/7), an expected AE with lymphodepletion and CAR T-cell therapies; were not associated with infections, were manageable, and fully resolved

N=7. Data cutoff: June 2026.

^aAfter the prior data cut (October 3, 2025), a previously reported treatment-related SAE was reclassified by the Investigator as 'not serious', reflecting his clinical assessment of the AE per protocol-defined seriousness criteria.

CRS, ICANS, IEC-HS assessed using ASTCT criteria; other AEs graded using CTCAE criteria.

AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy; CTCAE, Common Terminology Criteria for Adverse Events; CRS, cytokine release syndrome; IEC-HS, Immune Effector Cell-Associated Hemophagocytic Lymphohistiocytosis-Like Syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; SAE, serious adverse event.

Opportunity to Achieve Drug-Free, Disease-Free Remission with Single Dose Miv-cel

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

Note: These observations are derived from separate clinical settings; comparisons across trials are not based on head-to-head studies.		Approved			Investigational	
		FcRn Inhibitor ¹ VYVGART®	Complement Inhibitor ^{2,3} ULTOMIRIS®	CD19 mAb ⁴ UPLIZNA®	BCMA mRNA CAR T ⁵ Descartes-08	Miv-cel CD19 CAR T (KYSA-6, n=7)
Primary Endpoint		4 weeks	6 months	6 months	3 months	6 months
Depth of Response <i>Mean reduction from baseline to primary endpoint (non-placebo adjusted)</i>	MG-ADL Reduction	~4.6	3.1	4.2	4.1	8.3
	QMG Reduction	~6.2	2.8	4.8	3.9	11.7
% Responders <i>Patients with ≥3-point MG-ADL improvement from baseline to primary endpoint (non-placebo adjusted)</i>		~73%	~57%	69%	64%	100%
Achieve MSE <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>	57% <i>At any point before primary endpoint</i>
Free from chronic background immunotherapies		✗	✗	✗	✗	✓

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

1. Howard Jr JF, et al. *Lancet Neurol.* 2021;20(7):526-536. 2. Vu T, et al. *NEJM Evid.* 2022;1(5):EVID0a2100066. 3. AstraZeneca. ULTOMIRIS® 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. Vu T, et al. *Nat Med.* 2026;32:1131-1141.



Transforming the Treatment Paradigm in Neurologic Autoimmune Diseases

Warner Biddle – Chief Executive Officer

Miv-cel's Compelling Value Proposition Supports Strong Commercial Potential Across Multiple Autoimmune Diseases

Today's Treatment Paradigm

Chronic therapy

Inadequate disease management

Transient benefit

Reliance on additional immunotherapies



Miv-cel's Potential - *Drug-Free, Disease-Free Remission*

✓ Single dose

✓ Immune reset

✓ Durable benefit beyond one year

✓ Elimination of background immunotherapies

Beyond Efficacy, Miv-cel's Consistent and Well-Tolerated Safety Profile Increasingly Differentiates the Therapy in the Competitive Landscape

Potential First-Approved Therapy for SPS Represents a Valuable Commercial Neuroimmunology Opportunity

Compelling SPS Market Dynamics

- **Progressive rare disease** with **no approved therapies**
- **~6K** U.S. diagnosed patients¹; **2-2.5K** immediately addressable^{*2}
- Patients **concentrated** at academic centers
- Potential **diagnosis upside**
- Chronic treatment, disability/job loss drive **substantial economic burden on patients and society**



Targeted Launch Strategy to Maximize Value Creation

- **First-in-indication rare disease launch**
- Expect to price miv-cel at a **significant premium to existing oncology CAR T (~\$500-\$600K WAC³)**
- Targeting **~10 centers** where patients are concentrated
- ATC footprint expected to enable **cost-effective, scalable launch execution and biologics-like margins in SPS**



Total U.S. Diagnosed SPS Market Represents a Multi-Billion-Dollar Rare Disease Opportunity[‡]

^{*}Reflects patients who are treated with off-label immunotherapies defined as off-label immunosuppressants (e.g., prednisone), rituximab and/or intravenous immunoglobulin.

[‡]Internal cumulative estimate based on assumed miv-cel pricing (premium to oncology CAR T pricing) and total diagnosed SPS patients in U.S.

ATC, Academic Treatment Centers

1. Crane PD, et al. *Neurology*. 2024;103(12):e210078. 2. HCP qualitative data and U.S. Claims Data. 3. WAC price for Yescarta®, Breyanzi®, Kymriah®, Carvykti®, Abecma®, and Aucatzyl®.

Pioneering Differentiated Therapies with Curative Potential to Free People from Life-long Autoimmune Diseases and Chronic Therapy

Miv-cel BLA Submission Underway for SPS

Further strengthened by 1-year efficacy and safety data; Potential 1st approved CAR T for autoimmune and 1st approved treatment for SPS

Best-in-Class Profile

Unique miv-cel construct and validated manufacturing process supporting potential for durable drug-free, disease-free remission with single, well-tolerated dose

Valuable Commercial Opportunity in SPS

Commercial readiness underway; immediately addressable patients; premium pricing potential

Neurologic Autoimmune Strategy

Focused franchise strategy prioritizing SPS, MG, and PMS

Innovation to Expand Access

Potential for new indications and delivery mechanisms, including alternative preconditioning and manufacturing enhancements

Capitalized to Support Initial Miv-cel Launch

Operating runway into 2028 supporting SPS launch and gMG Phase 3 trial



Q&A



Warner Biddle
Chief Executive Officer



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



Greg Martini
Chief Financial Officer

Appendix

Single Dose Miv-cel Demonstrates Potential To Deliver Drug-Free, Disease-Free Remission to Patients with SPS, a Disease with No Approved Therapies



Sustained improvements through 1 year across all primary and secondary endpoints resulting from **deep B-cell depletion and potential for immune reset**



Continued **reversal of disability** observed out to 1 year



Nearly all patients treated remain free of chronic immunomodulatory or immunosuppressant therapies for SPS, substantially reducing treatment burden



Consistent, well-tolerated, and manageable **safety profile**, continues to support potential for outpatient administration

1-Year Durability and Safety Data Further Strengthen BLA Submission, Anticipated to be Completed in Q4 2026

Immunomodulatory or immunosuppressant therapies include IVig/SClg, PLEX, rituximab and/or prednisone (≥ 20 mg/day) for SPS symptoms.

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gMG Data Further Reinforces Potential for Miv-Cel to Provide Broad Immune Reset with a Single Dose, Increasing Confidence in Phase 3 Trial



Robust and durable effects sustained through at least 1 year further differentiate miv-cel from existing chronic therapies



Majority of patients maintained MSE as of last follow-up



Nearly all patients remain free of chronic immunotherapies, substantially reducing treatment burden



Consistent, well-tolerated, and manageable safety profile continues to support potential for outpatient administration

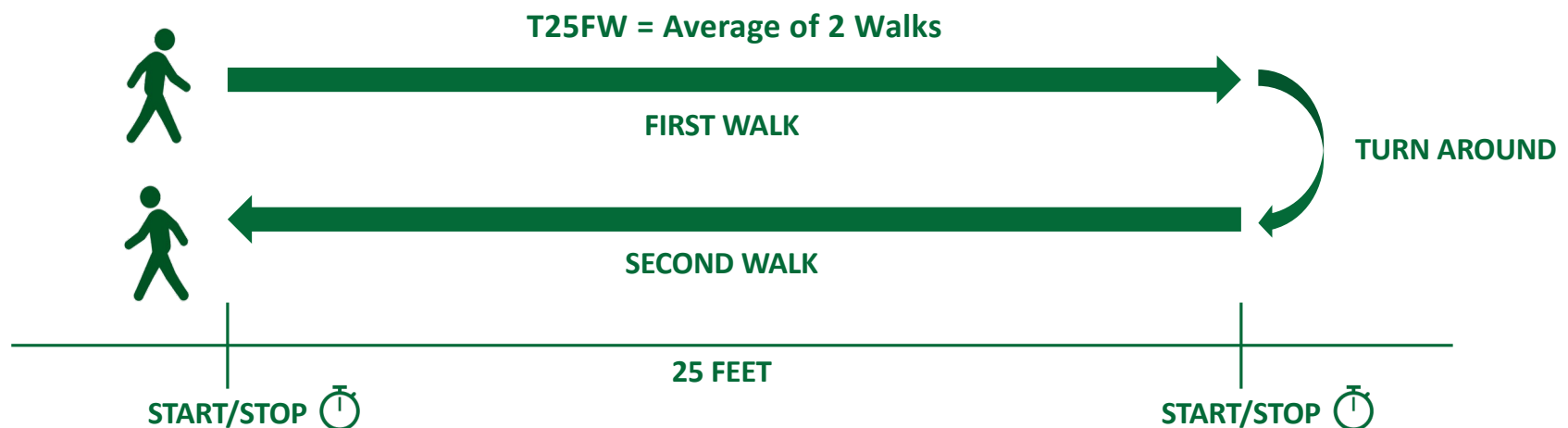
Positioned to Potentially be the First CD19 Autologous CAR T to be Approved in gMG, Transforming the Treatment Paradigm

Primary Endpoint Outcome Assesses Impact of SPS on Walking Ability

Timed 25-Foot Walk (T25FW)

- Validated tool to assess walking ability¹
- Used to evaluate stiffness and loss of mobility in SPS²
- Healthy adults can perform the T25FW in ~4-5 seconds³

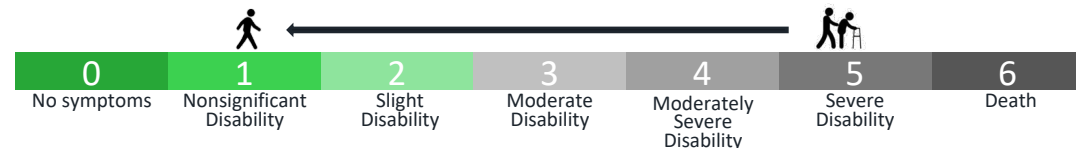
20% improvement
considered clinically
meaningful¹



Secondary Endpoint Outcomes Assess Extent of Disability and SPS-Specific Symptoms

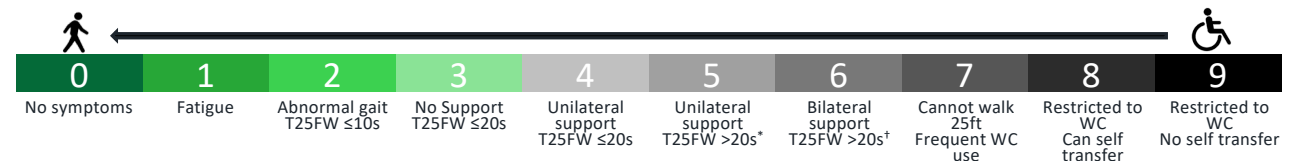
Modified Rankin Scale (mRS)

Degree of disability¹



Hauser Ambulation Index (HAI)

Time and degree of assistance to complete T25FW²



Distribution-of-Stiffness Index (DSI)

Muscle stiffness across body regions^{3,4}

1 point for each stiff body region (0-6)



Heightened Sensitivity Scale (HSS)

Number of triggers of muscle spasms^{3,4}

1 point for each trigger/stimulus (1-7)

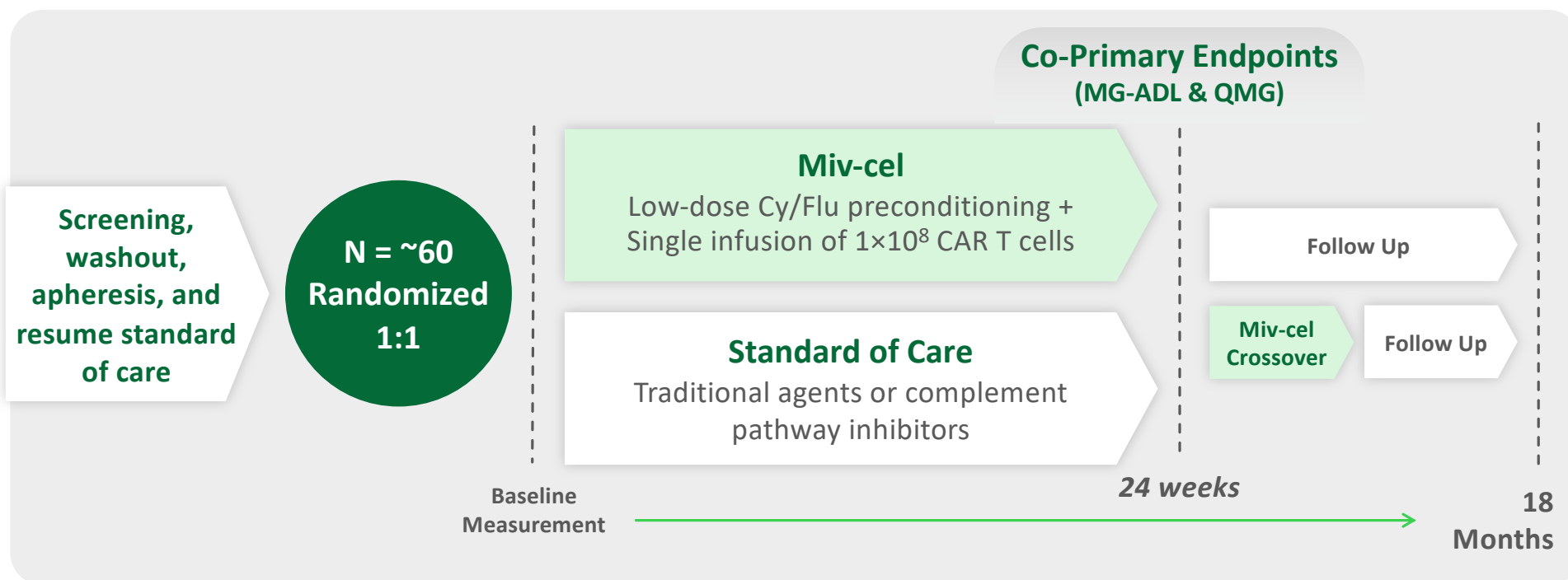


T25FW, timed 25-foot walk; WC, wheelchair.

1. van Swieten JC, et al. *Stroke*. 1988; 19(5): 604-607. 2. Hauser SL, et al. *New Engl J Med*. 1983; 308(4): 173-180. 3. Dalakas MC, et al. *N Engl J Med*. 2001; 345(26): 1870-1876. 4. Dalakas MC, et al. *Ann Neurol*. 2017; 82(2): 271-277.

KYSA-6 Phase 2/3 Trial in gMG – Phase 3 Study 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.