



Transforming the Treatment Paradigm in Neurologic Autoimmune Diseases

September 2026

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



Transformative Impact of Miv-cel

A **differentiated single-dose CAR T** therapy designed to **reset the immune system** and deliver the potential for **durable, drug-free, disease-free remission**

Focused Neurologic Autoimmune Strategy

Focused strategy, with potential to be the **first CAR T approval in autoimmune** and **first approved therapy for SPS**, with planned expansion into **gMG** and **PMS**

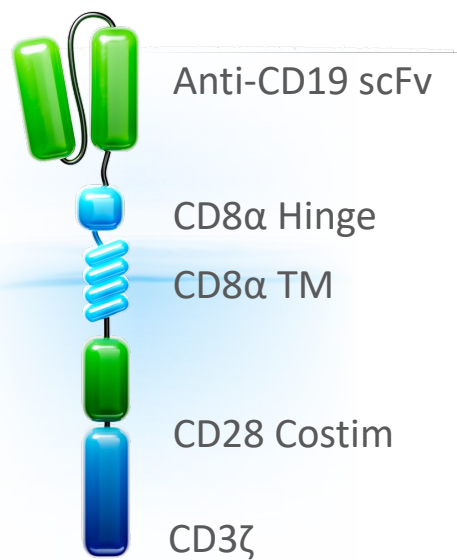
Innovating to Expand Access

Extend leadership by **broadening access and choice for patients**
(e.g., indication expansion, alternative preconditioning regimens, manufacturing enhancements)

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®

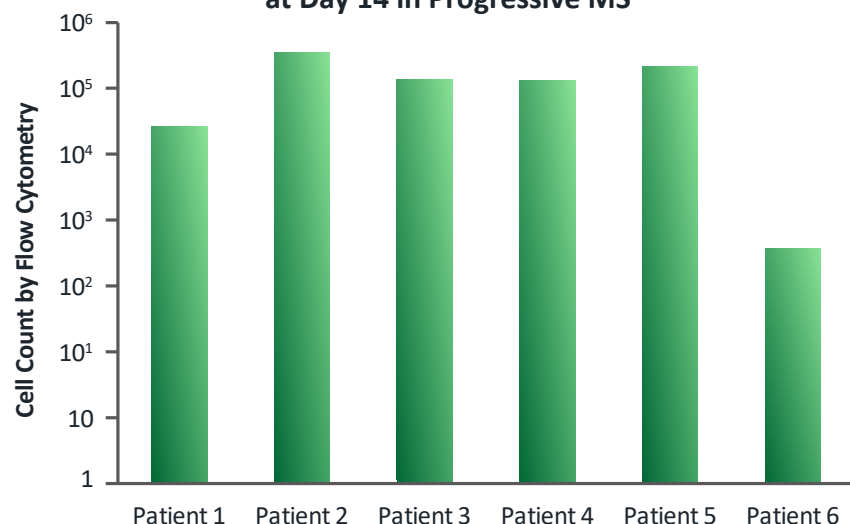


Minaris
Advanced Therapies

Miv-cel's Profound MOA and Ability to Penetrate the CNS

CNS Penetration and Expansion

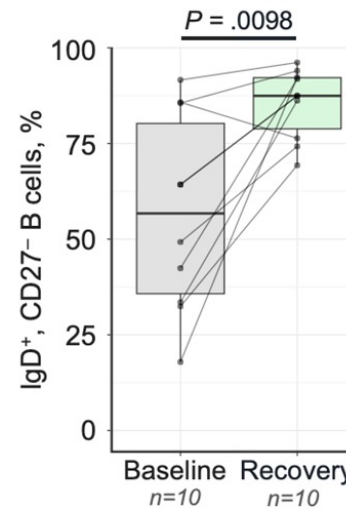
CAR⁺ Miv-cel Expansion Detected in CSF at Day 14 in Progressive MS^a



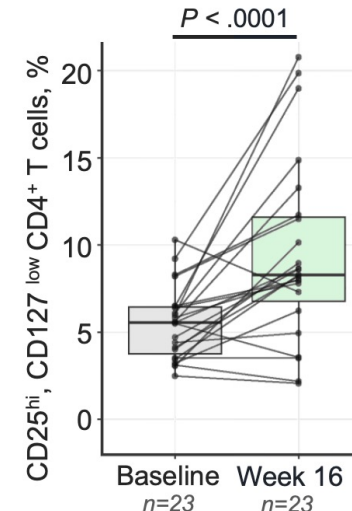
Acts directly on cells in the CNS at the site of disease¹

Broad Immune Reset

Naïve B Cells in SPS



Regulatory T Cells in SPS



Resets B cells and upregulates regulatory T cells, important suppressors of CNS disease inflammation²⁻⁴

^aAbsolute numbers of CAR T cells in CSF assumed a volume of 140 mL and 150 mL for female and male, respectively.

CAR, chimeric antigen receptor; CNS, central nervous system; CSF, cerebrospinal fluid; miv-cel, mivocabtagene autoleucel; SPS, stiff person syndrome.

1. Dunn J, et al. Presented at the ACTRIMS Forum 2026; February 5-7, 2026; San Diego, CA. Poster 112. 2. Piquet A, et al. Presented at the AAN Annual Meeting 2026; April 18-22, 2026; Chicago, IL. LBA Poster 8. 3. Goverman JM. *N Engl J Med.* 2021;384:578-580. 4. Harkins AL, et al. *Crit Rev Immunol.* 2022;42:1-27.

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®.

Robust Near-Term Catalysts for Prioritized Neurologic Pipeline Indications

Indication	Anticipated Milestones
Stiff Person Syndrome RMAT, ODD	+ Complete rolling BLA submission in Q4 2026 + Positioned for potential commercial launch in 2027
Generalized Myasthenia Gravis RMAT, ODD*, FTD [†]	+ Complete enrollment in Phase 3 expected mid-2027
Progressive Multiple Sclerosis RMAT for naSPMS	+ Share development strategy by early 2027 + Report additional data from Phase 1 IIT in Q4 2026



Stiff Person Syndrome (SPS)

SPS is a Debilitating, Progressive Autoimmune Disease with No FDA-Approved Therapies



SPS impacts the inhibitory signaling pathways, which are the body's braking system and the **target of autoantibodies** produced by B cells in SPS^{1,2}



Symptoms characterized by **muscle stiffness** and **painful muscle spasms**, impacting mobility¹⁻³



Inadequate response with off-label symptomatic and immunomodulatory therapies^{1,2,5}

Devastating Impact on Patients

80% of patients lose mobility, needing walking aid assistance or wheelchair¹⁻³

Only ~19% of patients remained able to work after 4 years⁴

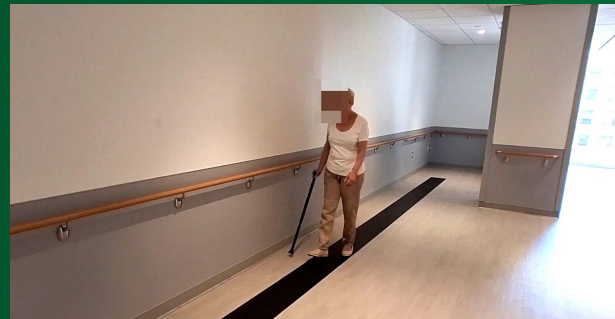
“Freezing attacks” and sudden falls requiring ER care^{1,2}

Risk of **permanent disability** and **increased mortality**³

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



[View Video](#)



[View Video](#)

Potential for Miv-cel to Quickly Set Treatment Standard in SPS with >2,000 Patients Immediately Addressable



~6k

U.S. Diagnosed
SPS Patients^{1,2}



Miv-cel
Addressable Market^{2,3}

Immediately Addressable
Market

~2.0 to 2.5k Patients

*30-40% of total diagnosed
Patients treated with
off-label immunotherapy*

Total Miv-cel
Addressable Market

~5.5k Patients

*90% of total diagnosed
Patients treated with
symptomatic therapies*

Expect to Capture Total Addressable Market Over Time Due to Progressive Nature of Disease

SPS Treators Show Strong Enthusiasm for Early Adoption of Miv-cel



Survey of 20 high volume
SPS treators in U.S.



Product profile based on
miv-cel topline data

80% view efficacy data
and one-time treatment
as key attributes

90% view profile as
compelling versus current
treatment options

85% would use miv-cel
for moderate-to-severe
patients at launch

Focused Launch Strategy Targeting ~10 High-Value SPS Centers



Neuro Leadership

- Thought leaders / SPS high-volume treaters
- Institutional support for miv-cel



Addressable Patients

- Meaningful portion of immediately addressable patients at ~10 centers
- Strong referral network



CAR T Expertise

- Commercial CAR T experience
- Accreditation



Economic Potential

- Robust inpatient and outpatient models
- Commercial payer and Medicare dynamics

Targeted Launch Expected to Enable Efficient Go-to-Market Approach

SPS Registrational Trial – Rolling BLA Submission Underway; On track to Complete Submission in Q4 2026



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)



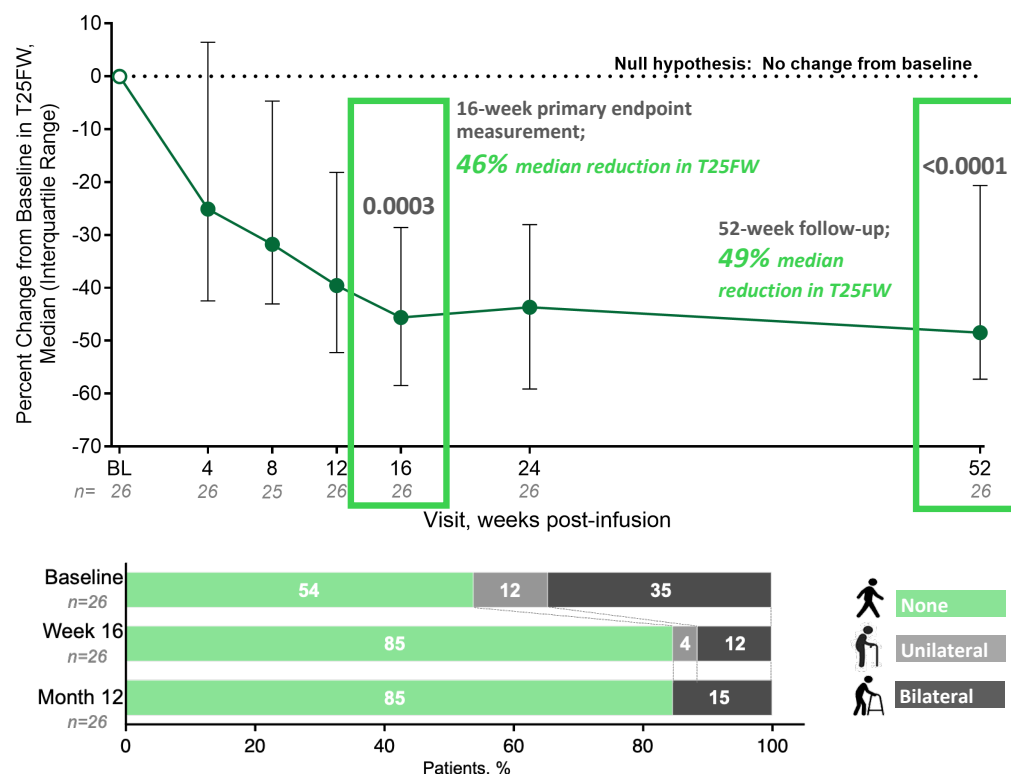
One-
year
Follow
Up

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

Primary Endpoint Met - Continued Reversal of Disability and Nearly All Patients Remaining Off Chronic Immunotherapies 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. Topline 1-year follow-up data. 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



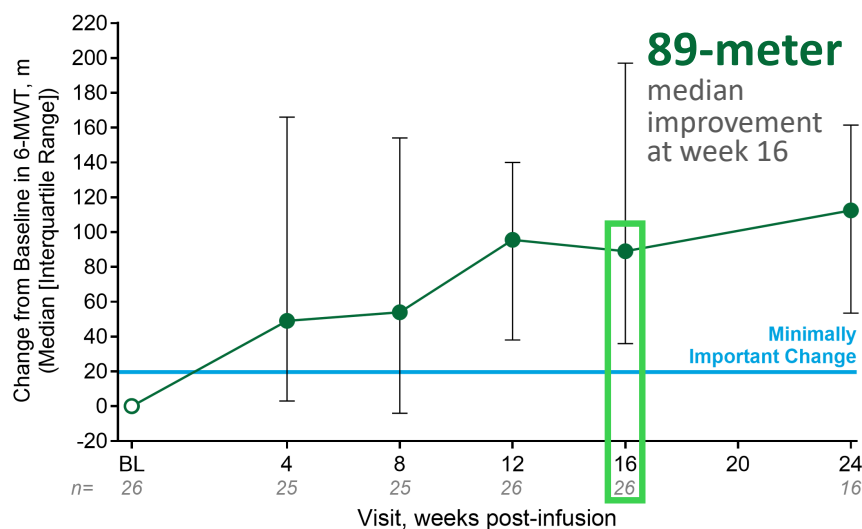
		16-wk timepoint	1-Yr follow-up
Primary Endpoint		<i>P</i> Value	<i>P</i> Value
✓	Timed 25-Foot Walk	0.0003	<0.0001
Secondary Endpoints		<i>P</i> Value	<i>P</i> Value
✓	Modified Rankin Scale	<0.0001	0.0003
✓	Distribution of Stiffness Index	<0.0001	<0.0001
✓	Hauser Ambulation Index	<0.0001	<0.0001
✓	Heightened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

N=26. Topline 1-year follow-up data. Database lock: July 2026.

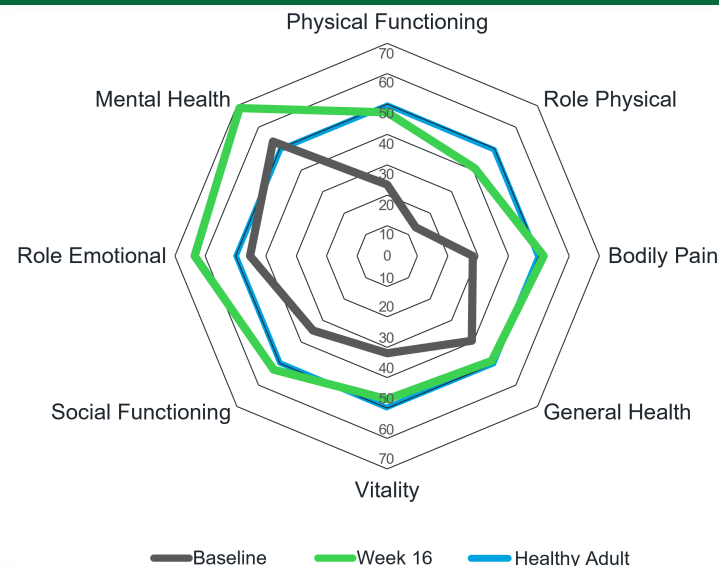
Single-dose Miv-cel Led to Substantial Improvements in Physical and Mental Functioning



6-Minute Walk Test (MWT): >4-fold improvement over clinical minimally important change¹



36-Item Short Form Health Survey (SF-36): Week 16 scores comparable to healthy adults for most domains^{2,3}



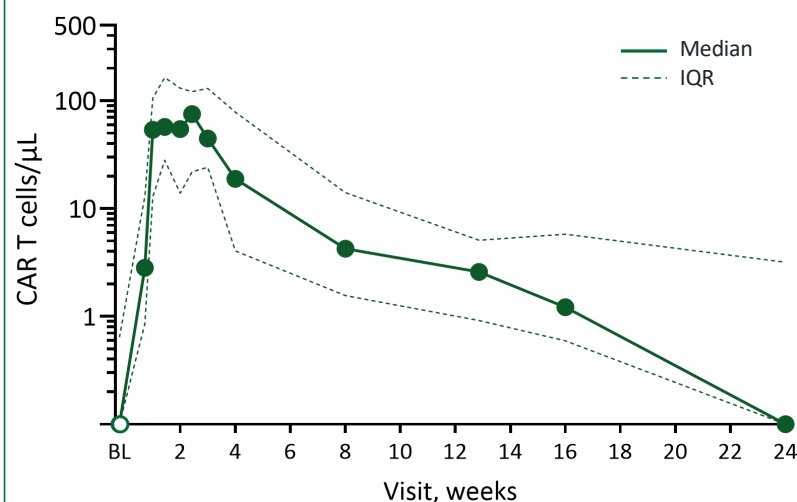
N= 26; Primary Analysis; Data cutoff: 26Nov2025.

1. Oosterveer DM, et al. Mult Scler Relat Disord. 2022;57:103438. 2. Maglinte GA, et al. J Clin Epidemiol. 2012;65(5):497-502. 3. Wu Q, et al. Medicine (Baltimore). 2023;102(24):e33979.

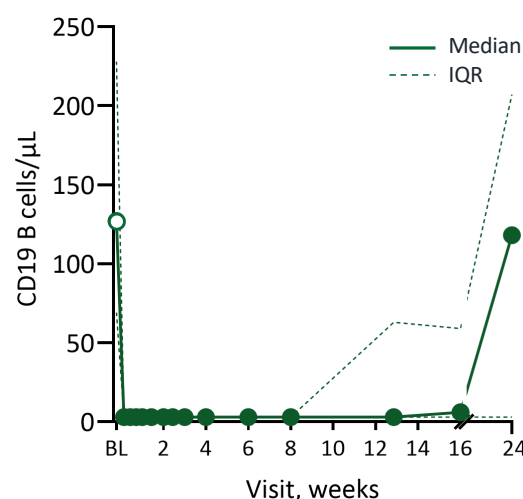
Robust Miv-cel Expansion Led to Complete Peripheral B-cell Depletion and Significant Reductions in Autoantibody Titers



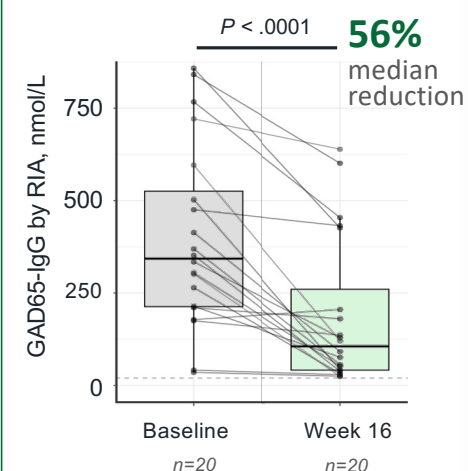
Robust CAR T-cell Expansion



Deep B-cell Depletion



Reduced GAD65-IgG



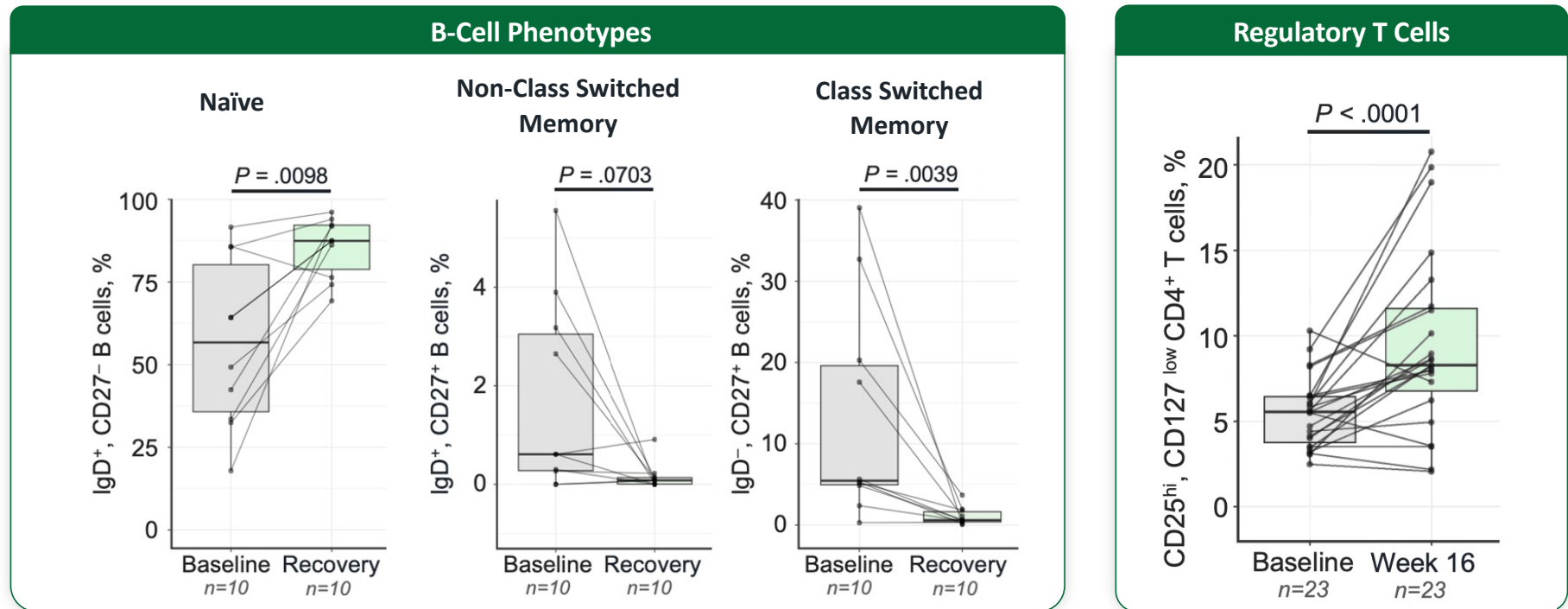
- CAR-positive T cells peaked by day 14

- 54% of patients had B-cell reconstitution by week 16
- Efficacy was maintained with B-cell reconstitution

- GAD65-IgG was reduced in 19/20 patients with ≥ 20 nM GAD65 at baseline

N=26. Primary Analysis; Data cutoff: 26Nov2025. Box and whisker plots showing median line (dark line), and interquartile range (box), and min/max (bars).
CAR, chimeric antigen receptor; IgG, immunoglobulin G; GAD65, glutamic acid decarboxylase 65.

Single-dose Miv-cel Induced Markers of Broad Immune Reset



- Newly emerging B-cell population showed significantly increased naïve phenotype with concomitant decrease in memory phenotype
- Significant increase in regulatory T cells at week 16

N= 26; Primary Analysis; Data cutoff: 26Nov2025. Data cutoff: 26Nov2025. Box and whisker plots showing median line (dark line), and interquartile range (box), and min/max (bars). IgD, immunoglobulin D.

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

Natural History Study Contextualizes Transformative Miv-cel Data and its Opportunity to Change the Treatment Paradigm



Natural History Study

Large, multicenter, retrospective study assessing T25FW in patients with SPS (n=153) over 10-year period

Patient Population

Earlier in disease course
(mRS mean 2.6; 55% immunotherapy at index date*)

T25FW

✗ No or minimal improvement[†]

Walking Aid Use

↗ 73% increase over average 5 years

mRS score

✗ No improvement

Immunotherapy Use

↗ 81% had immunotherapy by last datapoint
(47% increased usage)

KYSA-8 SPS Registrational Trial

More severe
(mRS mean 3.6; all have failed immunotherapy)

✓ 46% improvement at 16 weeks, sustained at 24 weeks

↘ 67% decrease at 16 weeks

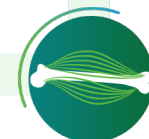
✓ Improvement in disability scores

↘ No immunotherapy after single-dose of miv-cel



Generalized Myasthenia Gravis (gMG)

Despite Available Treatment Options, High Disease Burden Remains



- gMG is a B-cell and antibody-mediated neuromuscular autoimmune disease that causes fluctuating muscle weakness and fatigue^{1,2}

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

Current State of Treatment



Inadequate symptom control^{3,4}



Few reach minimal symptom expression (MSE)^{1,5-6}



Majority require ongoing immunosuppressant therapy¹⁻⁴



Costly and chronic treatment options^{1,7}

Miv-cel's Potential: Durable, Drug-free, Disease-free Remission with Single Dose



~80k

**U.S. Diagnosed
gMG Patients^{1,2}**



**Miv-cel
Addressable Market^{1,3}**



**Initial
Priority**

~12k Patients

*15% of total diagnosed
Patients with inadequate
response to ≥ 1 biologic**

**Total Miv-cel
Addressable Market**

~40k Patients

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

SPS Lays Foundation for Rapid and Efficient Market Entry in gMG



SPS

Target ~10 centers at launch

- Meaningful portion of SPS patients at approximately 10 centers
- High-volume SPS treaters, including clinical trial sites
- Continue to activate more centers post SPS launch

gMG

Expand to ~50-75 total centers at peak

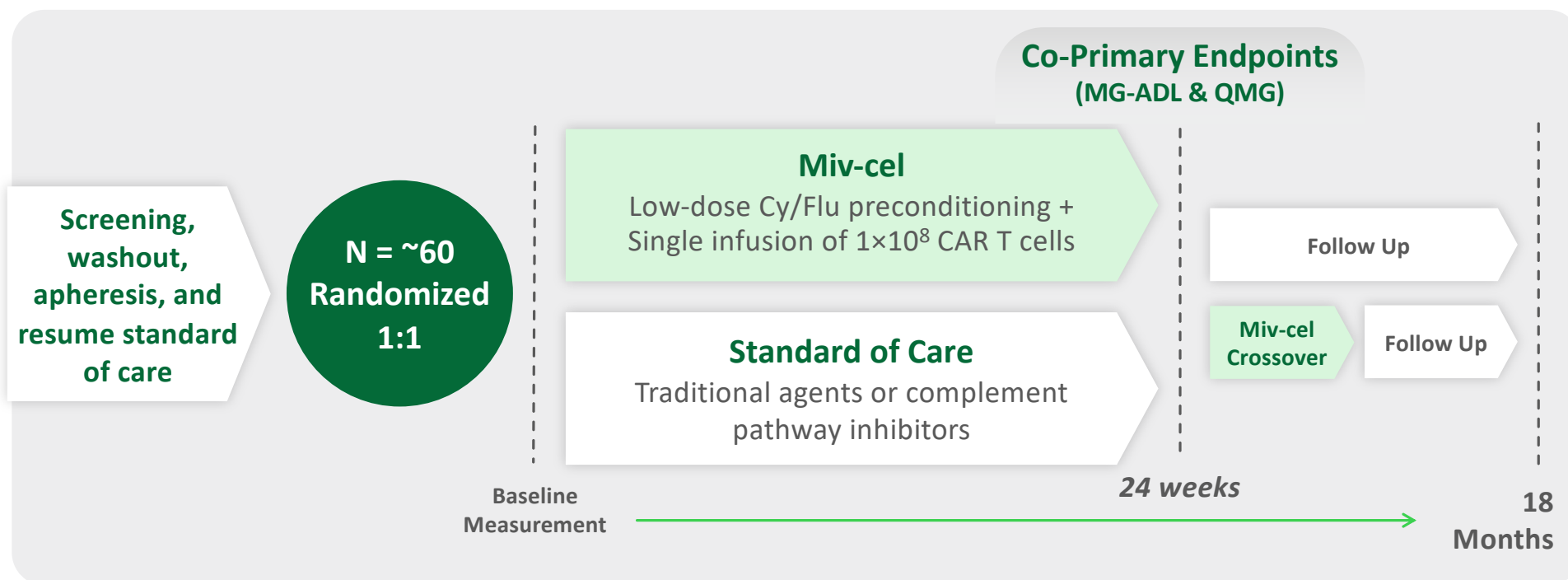
- MG/neuro centers of excellence and high-volume treaters
- Centers that also treat SPS patients
- Centers with existing referral networks for patients

..... ***Centers with Deep CAR T Expertise, Strong Neurology Partnership
And Positive Site Economics Potential***

Phase 3 Ongoing with Enrollment Expected to be Completed Mid-2027



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

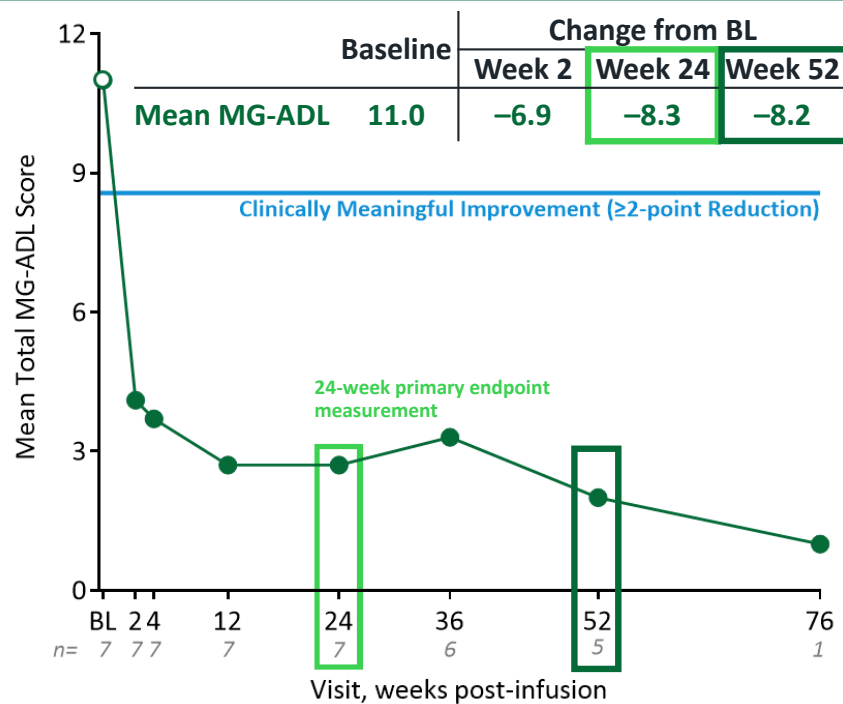


Standard of care may consist of traditional agents (e.g., prednisone, azathioprine, mycophenolate, methotrexate, chronic IVIg/PLEX) or complement pathway inhibitors (e.g., eculizumab, ravulizumab). Anti-CD20 or -CD19 monoclonal antibodies or FcRn inhibitors not allowed as defined in inclusion criteria.

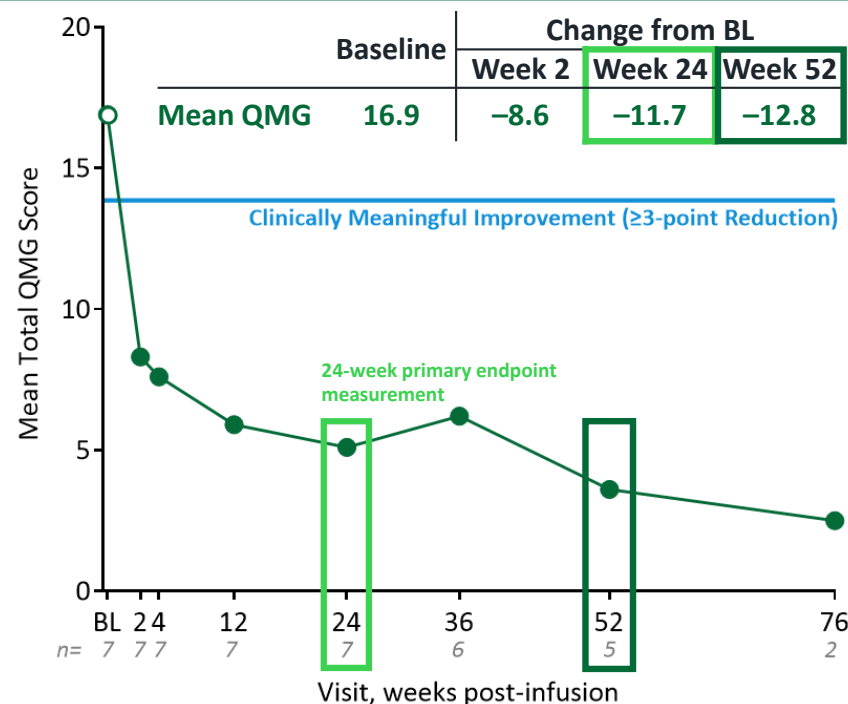
Robust and Durable Effects Sustained Through At Least 1-Year Across MG-ADL and QMG



MG-ADL Score



QMG Score



N=7. Topline longer-term follow-up data; 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 24weeks; –16.8 at 1year

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. Topline longer-term follow-up data; 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.

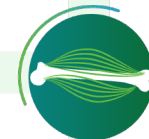
Consistent Safety Profile Maintained in Long-term Follow-Up With No High-Grade CRS and No ICANS or IEC-HS



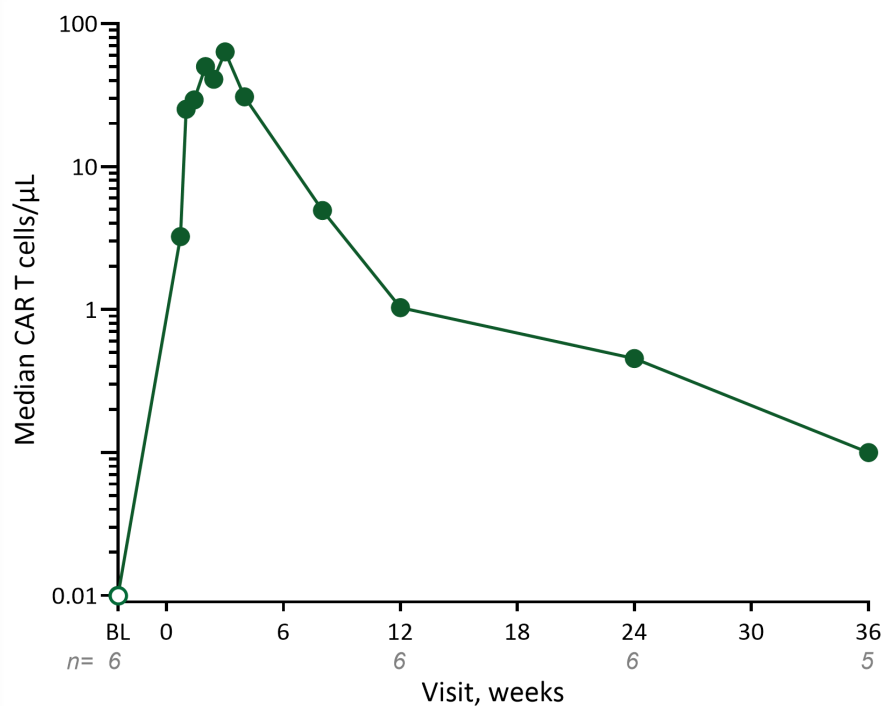
Treatment-related AEs, n (%)	Patients (n=7)
Any grade ≥ 3 CRS	0 (0)
Any grade ICANS	0 (0)
Any grade IEC-HS	0 (0)
SAE, any grade ^a	0 (0)
CRS (any grade)	7 (100)
Grade 1	5 (71)
Grade 2	2 (29)
Grade 3/4 events	3 (43)
Neutropenia	2 (29)
Lymphopenia	2 (29)

- 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

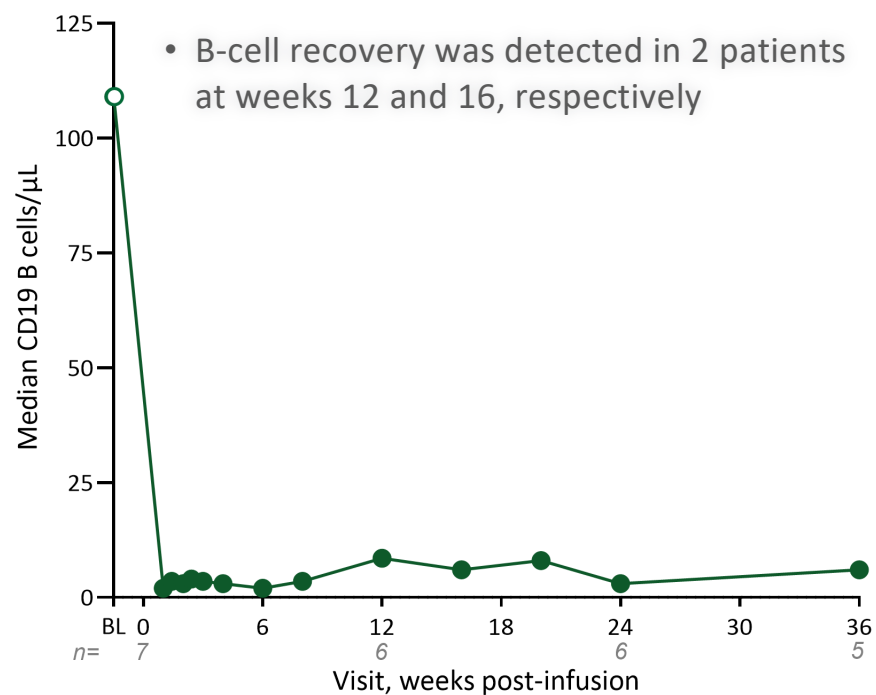
Robust CAR T-cell Expansion Led to Deep B-cell Depletion



Robust CAR T-cell expansion



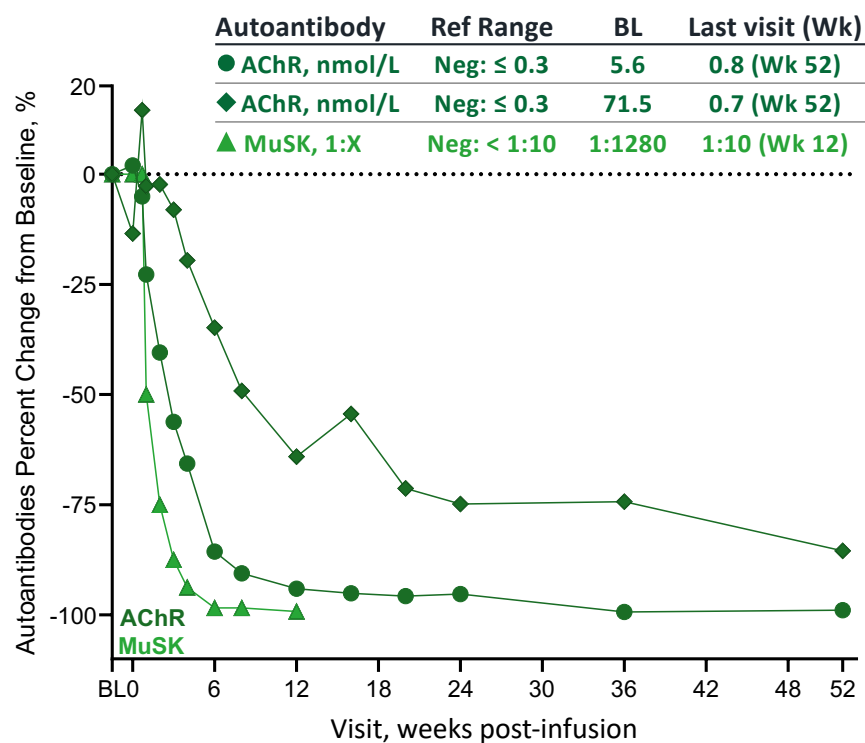
Deep B-cell depletion



Miv-cel Reduced Autoantibody Levels While Preserving Humoral Immune Responses

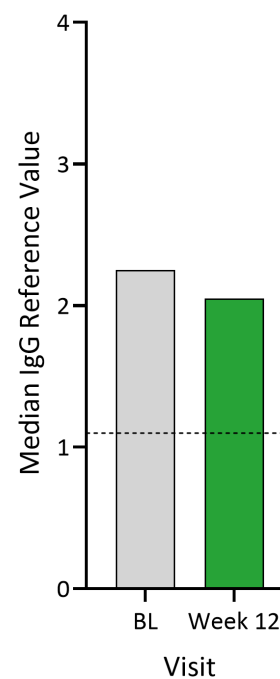


Reduction of autoantibodies

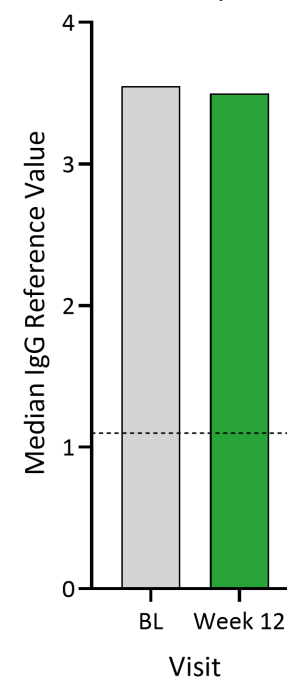


Preservation of humoral immunity

Measles



Mumps



Data cutoff: February 2026. Humoral immunity data was not available for patient 7; dashed line on humoral immunity graph shows the threshold above which indicates prior exposure or vaccination. AChR, acetylcholine receptor; BL, baseline; IgG, immunoglobulin G; MuSK, muscle-specific kinase; neg, negative value; Ref, reference; Wk, week.

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.



Progressive Multiple Sclerosis (PMS)

Progressive Multiple Sclerosis (PMS): Encouraging IIT Data Highlight Broad Opportunity with Miv-cel in Neuroimmunology



Phase 1 IIT Studies at Stanford (N=6) and UCSF (N=2)

Stanford uses alternative bendamustine lymphodepletion regimen

Biological Activity

- **Robust CAR T cell expansion** in blood and penetration into CNS
- Reconstitution of naïve B cells supportive of **immune reset**

Efficacy

- All patients with available data **showed improved or stable EDSS**
- All patients remained **off other immunotherapies**
- **Improvement in fatigue scores** from baseline in all patients with available data

Safety

- Reinforces **established tolerability profile**
- **No high-grade CRS/ICANS**

RMAT Designation Granted for naSPMS

Broader PMS Development Strategy Expected to be Shared by early 2027

Data from 8 patients treated at dose levels 33M (n=3) and 100M (n=5) CAR+ T cells

EDSS, expanded disability status scale scores; UCSF, University of California, San Francisco, Weill Institute for Neurosciences; CNS, central nervous system; CRS, cytokine release syndrome; ICANS, immune effector cell associated neurotoxicity syndrome; naSPMS, non-active secondary progressive multiple sclerosis.

Dunn J, et al. Poster Presentation at ACTRIMS 2026. ID# P112. Dunn, J, et al. Presentation at Stanford Blood and Marrow Transplantation and Cellular Therapy Symposium May 2026. Galleta K, et al. Poster Presentation at ACTRIMS 2026. ID#121 O027.

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

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