



**Topline Data:  
KYSA-8 Registrational Trial of  
Miv-cel (KYV-101) in Stiff Person  
Syndrome (SPS)**

December 15, 2025

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# Today's Agenda

- Setting the Stage for Miv-cel's Transformative Impact in SPS
- Registrational Topline Results
- Expanding Our Leadership in Autoimmune CAR T
- Q&A

## Speakers



**Warner Biddle**  
Chief Executive Officer



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

## Q&A



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



**Sham Dholakia, M.D., Ph.D.**  
Chief Product Officer



**Amanda Piquet, M.D., FAAN**  
University of Colorado Anschutz  
Céline Dion Foundation Endowed Chair

# Kyverna's Leadership in Autoimmune CAR T: Miv-cel's Transformative Impact in SPS

-  SPS is a **debilitating, progressive** autoimmune disease with **no FDA-approved therapies** and significant unmet medical need
-  Miv-cel achieved **statistically significant clinical benefit across all primary and secondary endpoints, reversing disability scores**; patients remained **free of immunotherapies** as of last follow up; data supports **BLA submission expected in 1H 2026**
-  **FIRST completed registration-enabling CAR T trial for autoimmune disease** could pave the way for miv-cel to become the **FIRST and ONLY** approved therapy in SPS and CAR T-cell therapy for autoimmune disease
-  **Valuable commercial opportunity in SPS**, supported by attractive market dynamics and focused commercialization strategy

**First-to-market opportunity in SPS lays foundation for expansion into broader indications**

# Miv-cel Achieved Statistically Significant Benefit on Primary and All Secondary Efficacy Endpoints

Primary Endpoint		P Value
	Timed 25-Foot Walk	0.0003

Secondary Endpoints		P Value
	Modified Rankin Scale	<0.0001
	Distribution of Stiffness Index	<0.0001
	Hauser Ambulation Index	<0.0001
	Heightened Sensitivity Scale	<0.0001

Data cutoff: 26Nov2025

# Patient Video

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KYSA-8 Clinical Trial

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



SPS impacts the **GABA signaling pathway** which is the body's braking system and the **target of autoantibodies** produced by B cells in SPS<sup>1,2</sup>



Substantial disease burden; symptoms characterized by **muscle stiffness** and **painful muscle spasms**, impacting mobility<sup>1-3</sup>



Significant unmet medical need; **no approved therapies**<sup>2</sup>

## Devastating Impact on Patients

**80% of patients lose mobility**, needing walking aid assistance or wheelchair<sup>1-3</sup>

**“Freezing attacks” and sudden falls** requiring ER care<sup>1,2</sup>

Risk of **permanent disability** and **increased mortality**<sup>3</sup>

# Off-Label Treatments Fail Majority of Patients and Have Serious Safety Risks

Most patients with SPS receive symptomatic treatments and many try off-label immunotherapies



## Symptomatic Treatments<sup>1-3</sup>

Muscle relaxants, benzodiazepines, and anti-seizures



## Immunotherapy<sup>1-3</sup>

Off-label immunosuppressants, rituximab, and IVIg



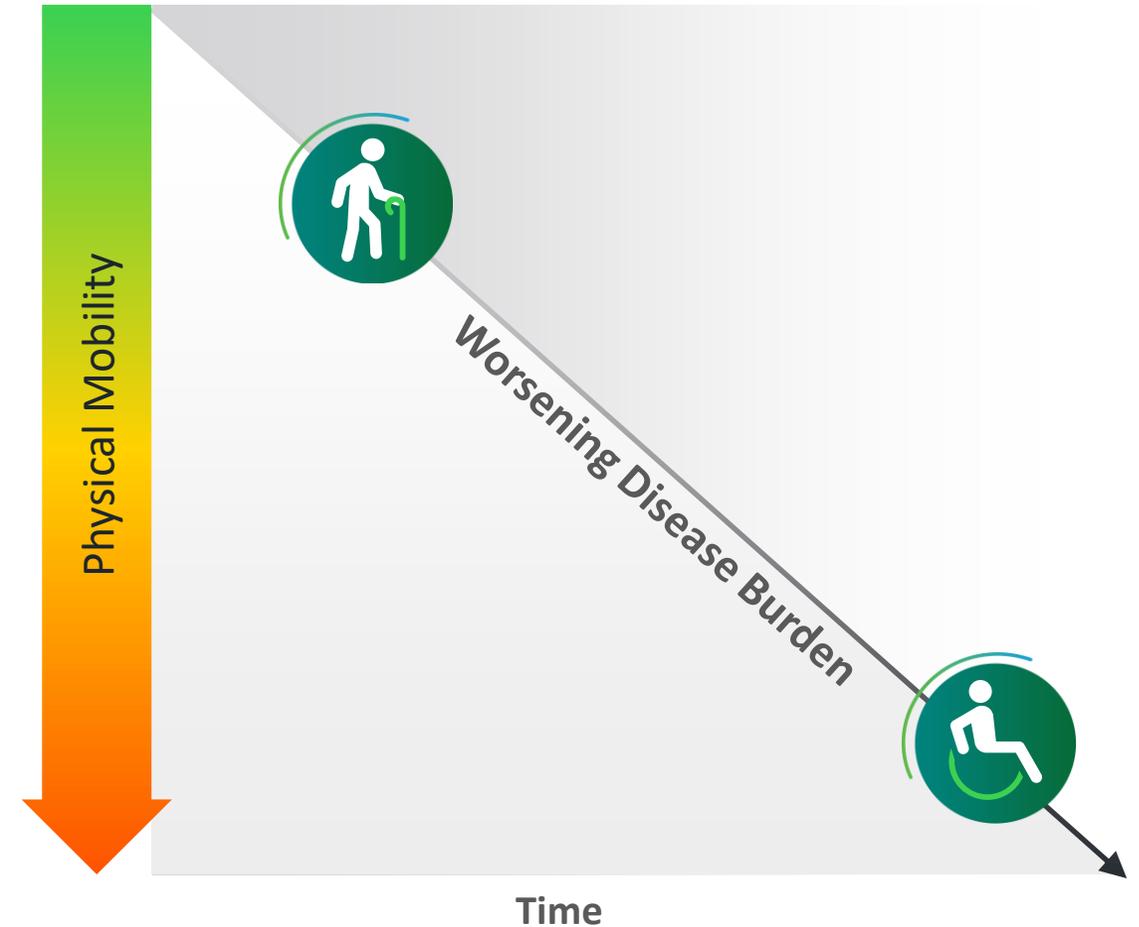
## Therapy and Supportive Care<sup>3-5</sup>

Physical, speech, and occupational therapy



## Psychiatric Therapy<sup>1-4</sup>

Anti-depressants and non-pharmacologic approaches

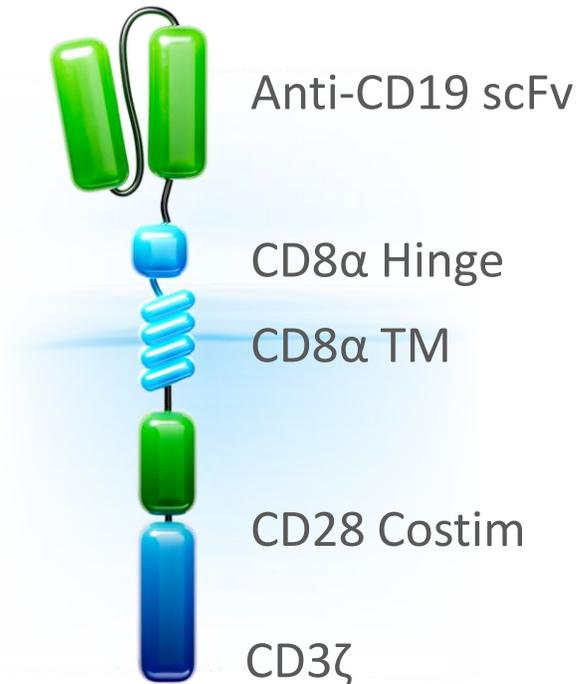


1. Dalakas MC. *Nat Rev Neurol*. 2024;20(10):587-601. 2. Alexopoulos H, Dalakas MC. *Eur J Clin Invest*. 2010;40(11):1018-25. 3. Dalakas MC. *Neurol Neuroimmunol Neuroinflamm*. 2023;10(3):e200109. 4. Yale Medicine. Stiff Person Syndrome (SPS). Accessed 21 Aug 2025. 5. National Institute of Neurological Disorders and Stroke. Stiff-Person Syndrome. Accessed 21 Aug 2025.

# Miv-cel: Unique CAR Designed for Potency & Tolerability in Autoimmune Diseases

## Mivocabtagene Autoleucel (miv-cel)<sup>1,2</sup>

Fully Human Autologous CD19 CAR T  
With CD28 Costim



- **More than 100** patients dosed with miv-cel across multiple indications<sup>3</sup>
- Observed **deep and broad depletion of peripheral- and tissue-resident B cells**<sup>4,5</sup>
- First SPS and gMG patients treated with a single dose of miv-cel achieved **lasting efficacy beyond 24 months without the need for background therapies**<sup>6</sup>
- No high-grade CRS or ICANS have been observed<sup>3</sup>

# Topline Data Positions Miv-cel to Potentially be FIRST and ONLY Approved Therapy for SPS

Miv-cel Has the Potential to Deliver Transformative Outcomes for SPS Patients

1. Reversing progressive disability
2. Eliminating chronic immunotherapies
3. Well-tolerated and manageable safety profile
4. Durable, single-dose treatment



# Registrational Topline Results

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

# Registrational Trial Designed to Support Rapid Path to BLA

## *Received Both ODD and RMAT Designation*

### 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  $\geq 2$

#### Miv-cel

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



#### 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**

**Rapid clinical enrollment underscores significant unmet need and Kyverna's ability to execute**

# Baseline Characteristics Representative of a Real-World Spectrum of SPS Patients

Baseline Characteristics	N=26
Age, median years (range)	56 (32–73)
Sex, female   male, n (%)	16 (62%)   10 (38%)
Time since SPS diagnosis, median years (range)	3.2 (0.6–25.0)
Timed 25-foot walk, median seconds (range)	11.1 (6.1–89.5)
Distribution-of-stiffness index, median (range)	3 (2–6)
Anti-GAD65 or anti-GlyR (%)	
GAD65-positive	23 (88%)
GlyR-positive	3 (12%)
Prior immunomodulatory therapy (IVIg/SCIg, PLEX, rituximab), n (%)	26 (100%)

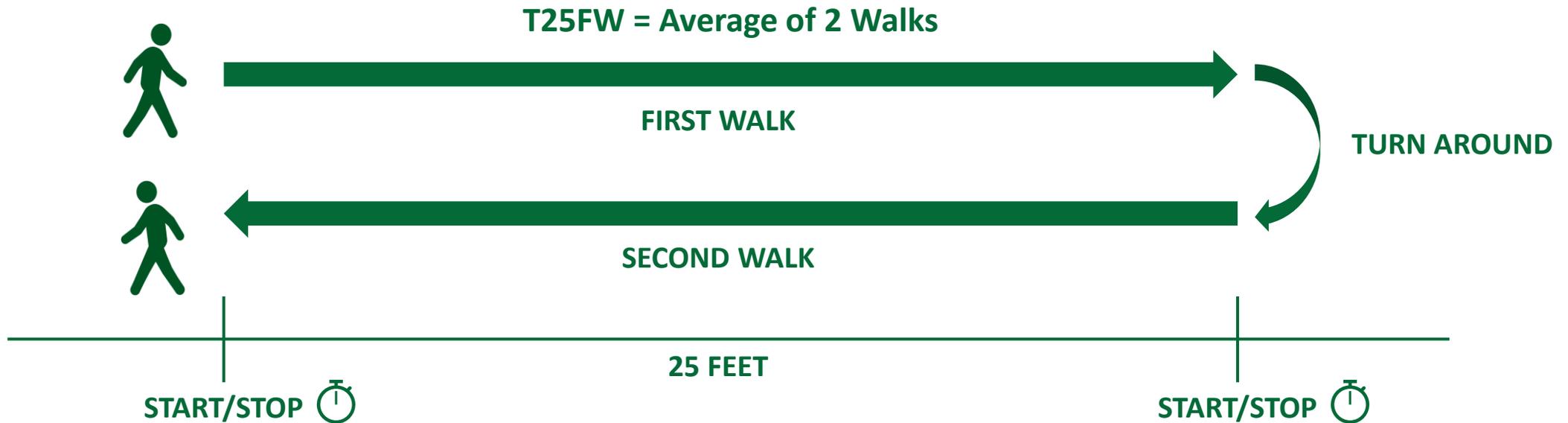
Data cutoff: 26Nov2025

# Primary Endpoint Assesses Impact of SPS on Walking Ability

## Timed 25-Foot Walk (T25FW)

- Validated tool to assess walking ability<sup>1</sup>
- Used to evaluate stiffness and loss of mobility in SPS<sup>2</sup>
- Healthy adults can perform the T25FW in ~4-5 seconds<sup>3</sup>

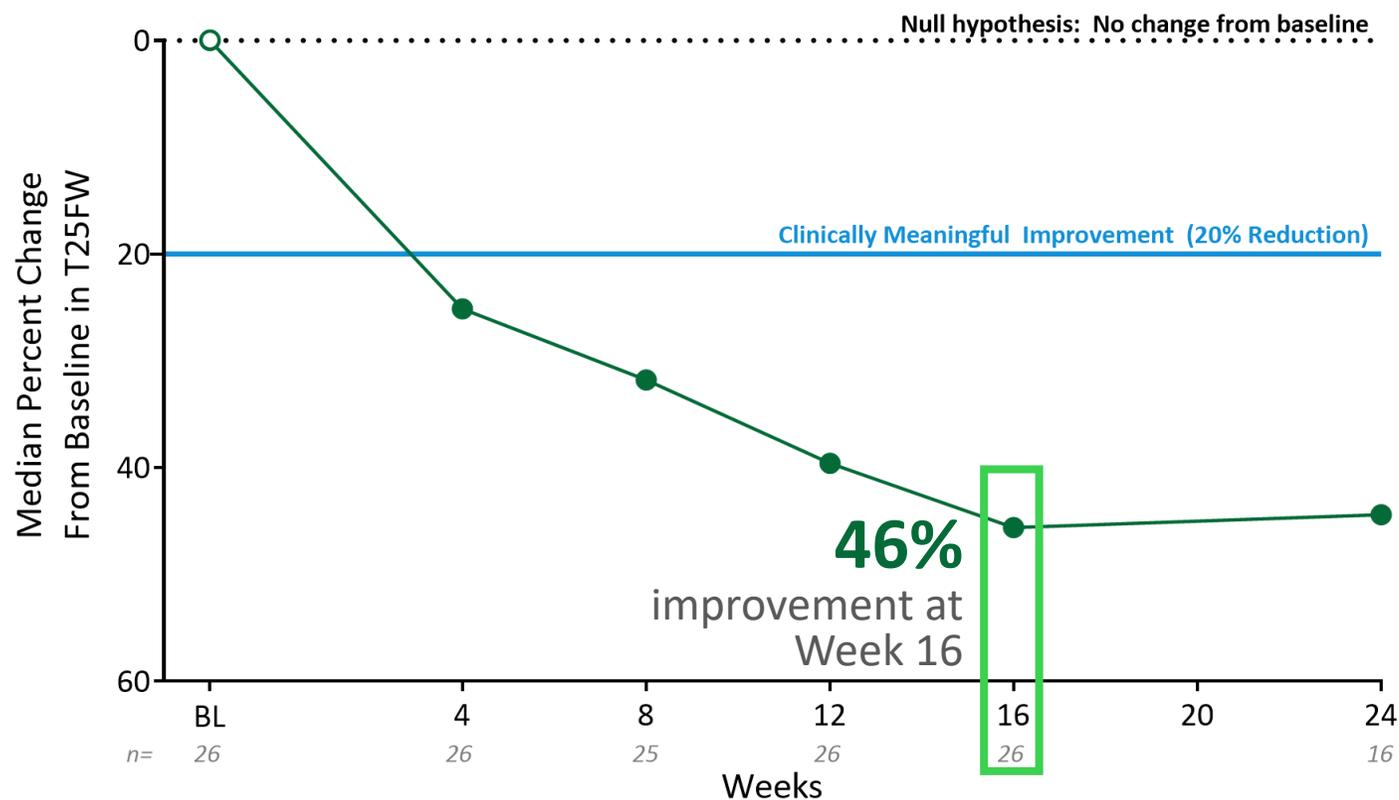
**20% improvement  
considered clinically  
meaningful<sup>1</sup>**



# Primary Endpoint Met: Robust and Sustained Improvement in Mobility

*All Patients Remained Free of Immunotherapies Through Last Follow Up*

## Significant Improvement in Timed 25-Foot Walk



- **Statistically significant** improvement in T25FW ( $P=0.0003$ )
- **81% of patients** achieved clinically meaningful improvement

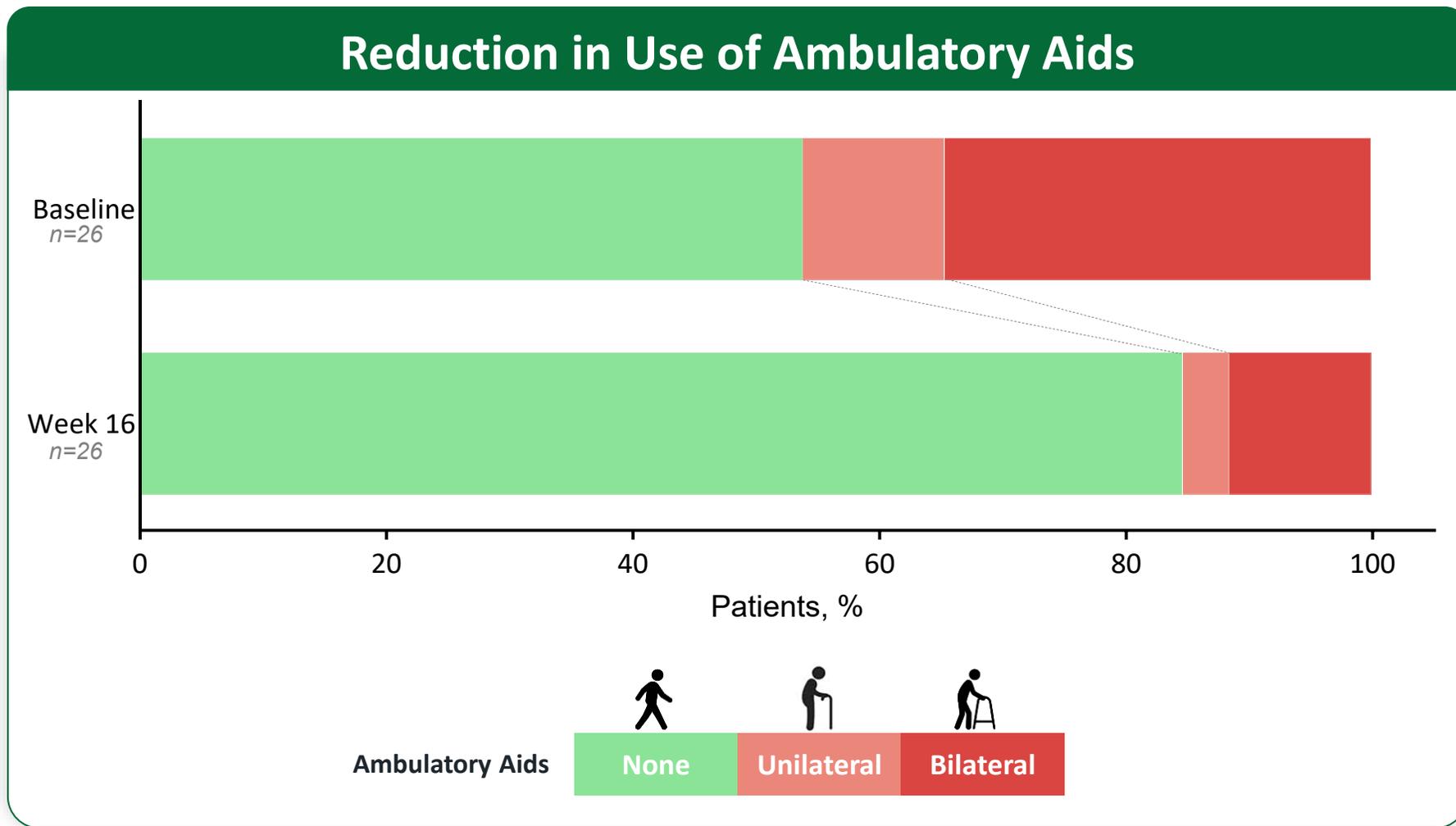
Data cutoff: 26Nov2025

T25FW, timed 25-foot walk.  
Immunotherapy defined as off-label immunosuppressants (e.g., prednisone), rituximab and/or IVIg.

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# Many Patients Eliminated Ambulatory Aids After a Single Dose of Miv-cel



- Of 12 patients who required a walking aid-device prior to treatment, **67% (8/12)** no longer needed assistance to walk

Data cutoff: 26Nov2025

# Secondary Endpoints Assess Extent of Disability and SPS-Specific Symptoms

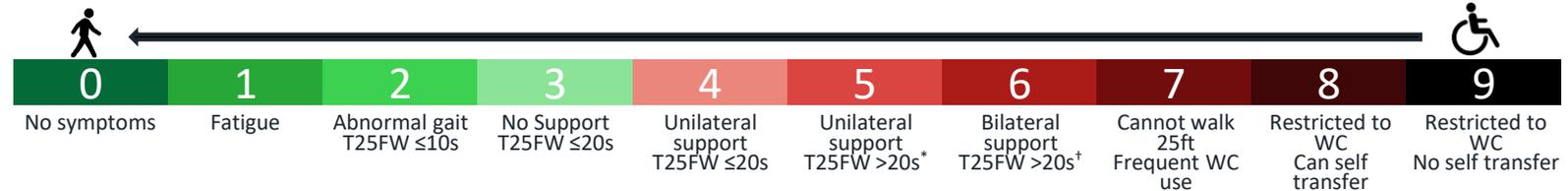
## Modified Rankin Scale (mRS)

Degree of disability<sup>1</sup>



## Hauser Ambulation Index (HAI)

Time and degree of assistance to complete T25FW<sup>2</sup>



## Distribution-of-Stiffness Index (DSI)

Muscle stiffness across body regions<sup>3,4</sup>

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



## Heightened Sensitivity Scale (HSS)

Number of triggers of muscle spasms<sup>3,4</sup>

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



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# Well-Tolerated and Manageable Safety Profile

Safety	N=26
CRS (any Grade), n (%)	24 (92)
Grade 1	10 (38)
Grade 2	14 (54)
ICANS (any Grade), n (%)	3 (12)
Grade 1	3 (12)
Grade 3/4 neutropenia, n (%)	16 (62)

- No high-grade CRS or ICANS
- 16 patients had Grade 3/4 neutropenia, a known AE associated with CAR T treatments
  - All events were manageable with the majority resolved within 28 days of infusion

Data cutoff: 26Nov2025

AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy; CTCAE, Common Terminology Criteria for Adverse Events; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome. CRS and ICANS graded using ASTCT criteria; other AEs graded using CTCAE criteria.

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# Patient Case Study: Miv-cel in KYSA-8 Patient With Severe Disease and Long-History of Other Symptomatic Treatments

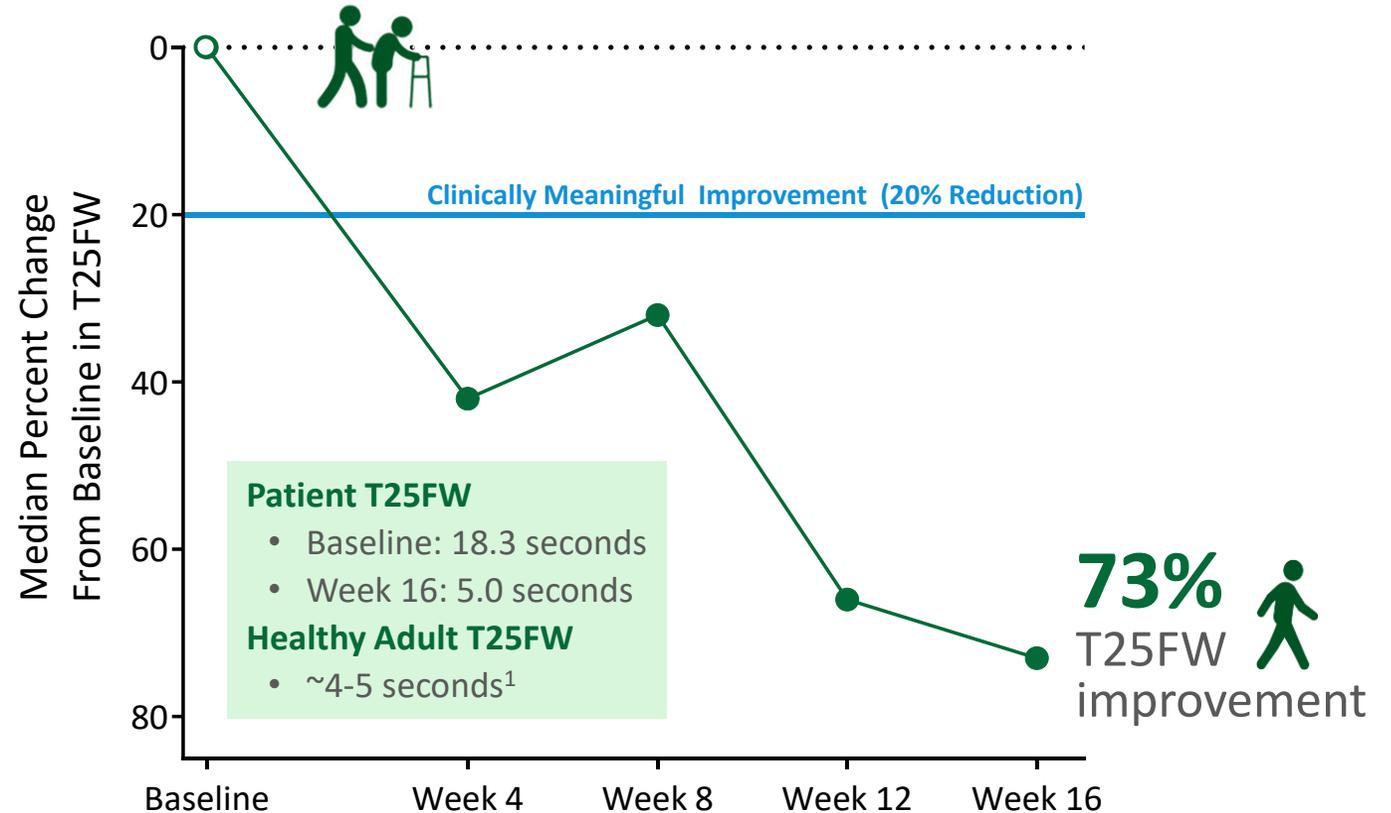
## Patient History

- **Age:** 52-year-old man
- **Time from diagnosis:** 8.5 years
- **Antibody status:** anti-GAD65+
- **Treatment:** Over 8 years of IVIg plus valium, baclofen, and botulinum toxin
- **Symptoms:** Back and neck pain, headaches, stiffness, and spasms leading to decreased mobility

## Miv-cel Safety

- Grade 2 CRS and Grade 3 neutropenia, resolved

## Miv-cel Efficacy



Improvement across all secondary efficacy endpoints: mRS, DSI, HAI, and HSS

# Patient Video

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KYSA-8 Clinical Trial

# Today's Results Represent a Breakthrough in SPS

## *Potentially the First and Only Approved Therapy in SPS and CAR T for Autoimmune*



First completed registration-enabling trial **in autoimmune CAR T**



Miv-cel achieved **highly statistically significant benefit** on primary and all secondary efficacy endpoints, durable clinical **improvement** and **reversed disability scores**



**100% elimination** of off-label **immunotherapies** with a **single dose**



**Well-tolerated** and manageable **safety profile**



Data supports expected **SPS BLA submission** for miv-cel in **1H 2026**



# Expanding Our Leadership in Autoimmune CAR T

Warner Biddle – Chief Executive Officer

# SPS Data Solidifies Kyverna's Leadership in Autoimmune CAR T



Could pave the way for potentially **FIRST** approved therapy in SPS, **designed to help patients reverse their disease**



Miv-cel to potentially be the **FIRST** approved **CAR T-cell therapy for autoimmune disease**



**FIRST mover advantage** for Kyverna, laying groundwork for broader indications

# Miv-cel: Potential to Be First and Only Approved Therapy in SPS with Addressable Patient Population Ready for Better Options



**~6k**

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



**Miv-cel  
Addressable Market<sup>2,3</sup>**

**Initial  
Priority**

**~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*

IVIg, intravenous immunoglobulin.

\*Immunotherapy defined as off-label immunosuppressants (e.g., prednisone), rituximab and/or IVIg.

1. Crane PD, et al. *Neurology*. 2024;103(12):e210078. 2. Analysis of 2024 Komodo U.S. Claims Data.

3. Kyverna Patient Journey and Demand Study (data on file).

# Our Conviction in Delivering on a Valuable Commercial Opportunity in SPS

## Attractive SPS Market Dynamics

- ✓ High unmet need
- ✓ No approved therapies
- ✓ ~6,000 patients in U.S.<sup>1,2</sup> - larger than previously reported
- ✓ Growth in disease awareness
- ✓ Diagnostic and treatment guidelines under development



## Focused Commercialization Strategy

- ✓ First-mover advantage
- ✓ Scalable CDMO model
- ✓ Targeting academic centers where patients are concentrated<sup>2</sup>
- ✓ Experienced CAR T leadership team

**Leveraging existing CAR T ecosystem for patients with autoimmune disease**

# Promising Path to Achieving First-in-Class Neuroimmunology CAR T Franchise

## NEUROIMMUNOLOGY

**SPS:** Positive topline data, valuable commercial opportunity; BLA on track for 1H 2026

**MG:** Positive Phase 2 interim data; ongoing Phase 3; large indication

## INNOVATION & PIPELINE

**MS & RA:** Early IIT data reinforce miv-cel's potential across autoimmune diseases

**KYV-102:** Rapid whole-blood manufacturing process; IND filed in Q4 2025

Current financial position expected to support SPS BLA filing, MG Phase 3 trial and pre-launch activities

# Patient Video

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KYSA-8 Clinical Trial



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# Q&A



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