



Administration of mivocabtagene autoleucel (miv-cel)

Fall 2026 ICD-10 Coordination and
Maintenance Committee Update

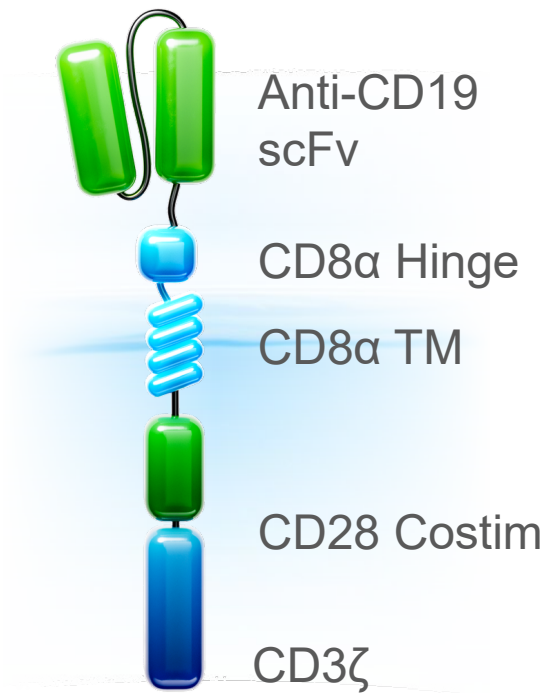
General Description and Clinical Purpose of miv-cel

Miv-cel is an investigational product that has not been approved by the Food and Drug Administration (FDA) for the diagnosis or treatment of any disease state. The safety and efficacy of miv-cel has not been established. There is no guarantee that the product will become commercially available or approved for the uses discussed.

Miv-cel (KYV-101): Unique CAR Designed for Potency & Tolerability in Autoimmune Diseases

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

Fully Human Autologous CD19 CAR T
With CD28 Costim



- **More than 100** patients dosed with miv-cel across multiple indications³
- Observed **deep and broad depletion of peripheral- and tissue-resident B cells**^{4,5}
- First stiff person syndrome (SPS) and gMG patients treated with a single dose of miv-cel achieved **durable efficacy beyond 24 months without the need for background therapies**⁶
- No high-grade CRS or ICANS have been observed³

CAR, chimeric antigen receptor; CRS, cytokine release syndrome; gMG, generalized myasthenia gravis; ICANS, immune effector cell-associated neurotoxicity syndrome; TM, transmembrane.

1. Brudno JN, et al. *Nat Med*. 2020;26:270-280. 2. Alabanza L, et al. *Mol Ther*. 2017;25:2452-2465. 3. Data on file, Kyverna Therapeutics. 4. Minopoulou I, et al. *Ann Rheum Dis*. 2025;84(3):e4-e7. 5. Albach FN, et al. *Rheumatology*. 2025;64(6):4075-4077. 6. Named patient access data, Kyverna Therapeutics.

What miv-cel Is and What It Does

● Autologous CD19-Directed CAR T-Cell Therapy

Mivocabtagene autoleucel (miv-cel) is a fully human, autologous CD19-targeting CAR T-cell therapy with CD28 co-stimulation, engineered from the patient's own T-cells. Collected via leukapheresis, T-cells are genetically modified ex vivo to express a fully human CD19-directed CAR construct, then expanded and returned to the patient.

● Mechanism: Deep B-Cell Depletion & Immune Reset

Upon infusion, miv-cel CAR T-cells recognize CD19 on B-cells driving SPS autoimmune pathology. CD28 co-stimulation enhances T-cell activation and effector function. CD19 binding triggers cytolytic activity resulting in deep B-cell depletion, eliminating pathogenic B-cell clones and autoantibody-producing plasma cell precursors — resetting the dysregulated immune milieu.

● Single-Dose Immune Reset Strategy

Miv-cel is administered as a single intravenous infusion. Modified T-cells proliferate in vivo, with the potential to reset the immune system via deep B-cell depletion leading to reset of the B cell compartment and broad immune effects such as increase in regulatory T-cells. These mechanisms are hypothesized to underly the potential to achieve durable, drug-free remission.

● Distinguishing Therapeutic Characteristics

Miv-cel uses a fully human scFv binding domain — unlike murine-derived or humanized sdAb CAR T constructs — with a CD8α hinge and transmembrane domain associated with improved tolerability. As an autologous cell therapy requiring ex vivo genetic engineering, it is distinct from standard IV drugs, biologics, or conventional immunosuppressives.

1. Idecabtagene vicleucel (Abecma®) Prescribing Information, FDA, 2024. 2. Mishra et al., Vaccines (Basel), 2023 [pmc.ncbi.nlm.nih.gov]

Clinical Indication and Associated Diagnoses

Indication: Stiff Person Syndrome (SPS)

ICD-10-CM: G25.82

SPS is a rare, progressive, severely debilitating autoimmune neurological disease characterized by progressive muscle stiffness, heightened sensitivity to sensory stimuli, and painful episodic muscle spasms. Approximately 80% of patients lose the ability to walk independently. SPS is driven by autoimmune dysfunction — most patients have anti-glutamic acid decarboxylase (GAD65) antibodies — resulting in dysregulation of inhibitory neuronal pathways in the brain.¹

Associated Diagnoses & Epidemiology

- SPS affects an estimated 1–2 per 100,000 people and is challenging to diagnose, with significant underdiagnosis and misdiagnosis thought to occur in clinical practice.^{2,3,4}
- Higher prevalence among women
- Associated diagnoses: anti-GAD65 antibody positivity, autonomic dysfunction, anxiety disorders, functional mobility impairment

1. Dalakas MC. Lancet Neurol. 2009;8(7):647–657. 2. Crane PD, et al. Neurology. 2024;103(12):e210078. 3. Bhatt SP, et al. Curr Treat Options Neurol. 2024;26:1–18. 4. Dalakas MC. Nat Rev Neurol. 2023;19:514–527.

Unmet Medical Need & Trial Analysis

Unmet Medical Need

- No FDA-approved therapies exist for SPS. Current off-label management includes benzodiazepines/muscle relaxants for symptoms, and IVIg, rituximab, and plasmapheresis (PLEX) for immune modulation.¹ These options provide incomplete and non-durable symptomatic relief without addressing underlying sources of immune dysregulation.
- A large multicenter natural history study (n=153) at AAN 2026 confirmed the majority of patients show minimal to no improvement with current therapies and increasing reliance on walking aids over time.

KYSA-8 Primary Analysis — AAN 2026²

46%

Median T25FW improvement

Week 16 vs. baseline (p=0.0003)

81%

Achieved ≥20% T25FW

clinically meaningful threshold

96%

≥1 endpoint improved

25 of 26 patients

All 26 patients discontinued chronic immunosuppressive therapies and remained off through Week 16 or last follow-up — an outcome not previously observed in SPS. Highly significant benefit (all $p < 0.0001$) across all secondary endpoints: mRS, HAI, DSI, and HSS.

1. Dalakas MC, et al. Lancet Neurol. 2009;8(7):647–657. 2. Kyverna Therapeutics. KYSA-8 Primary Analysis. Presented at: American Academy of Neurology (AAN) Annual Meeting; April 2026.

SPS Results Represent a Potential Breakthrough in Care

Miv-cel May Be the First and Only Approved Therapy in SPS and CAR T for Autoimmune Disease



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 **and projected first to market autoimmune CAR T**

BLA, biologics license application; CAR, chimeric antigen receptor.

Immunotherapy defined as off-label immunosuppressants (e.g., prednisone), rituximab and/or intravenous immunoglobulin.

Source: Kyverna Therapeutics. KYSA-8 Primary Analysis. Presented at: American Academy of Neurology (AAN) Annual Meeting; April 2026. Data cut-off: 26 November 2025.

Registrational Trial Designed to Support Rapid Path to BLA *Received Both Orphan Drug Designation (ODD) and Regenerative Medicine Advanced Therapy (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 ≥ 2

Miv-cel

Cy/Flu lymphodepletion
+
Single infusion of
 1×10^8 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

SPS immunotherapies are discontinued

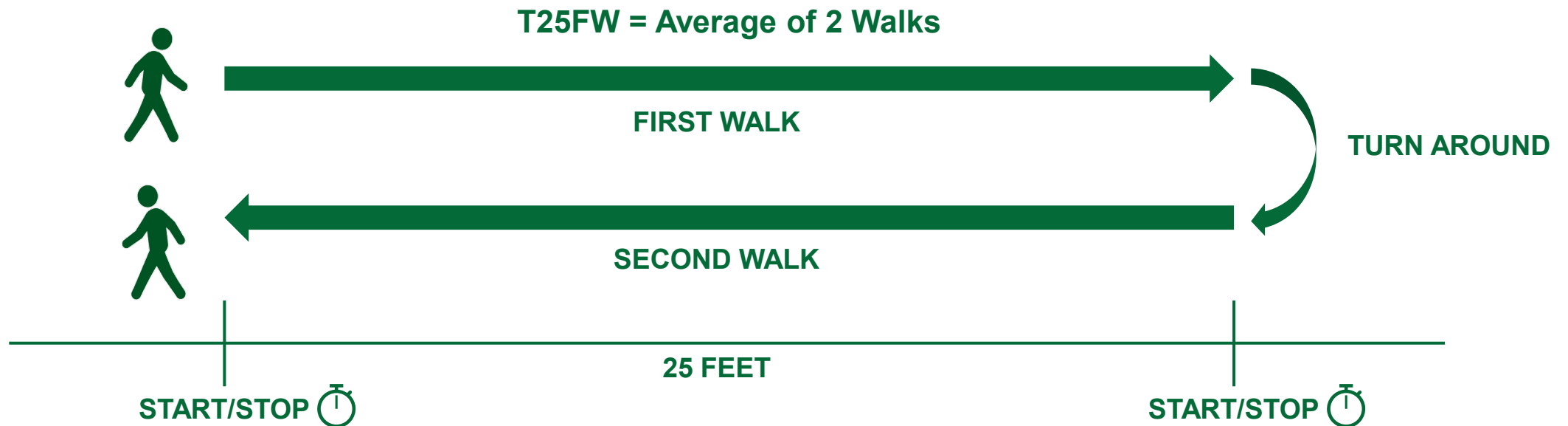
Kyverna Therapeutics. KYSA-8 Primary Analysis. Presented at: American Academy of Neurology (AAN) Annual Meeting; April 2026. Data cut-off: 26 November 2025.

Primary Endpoint 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

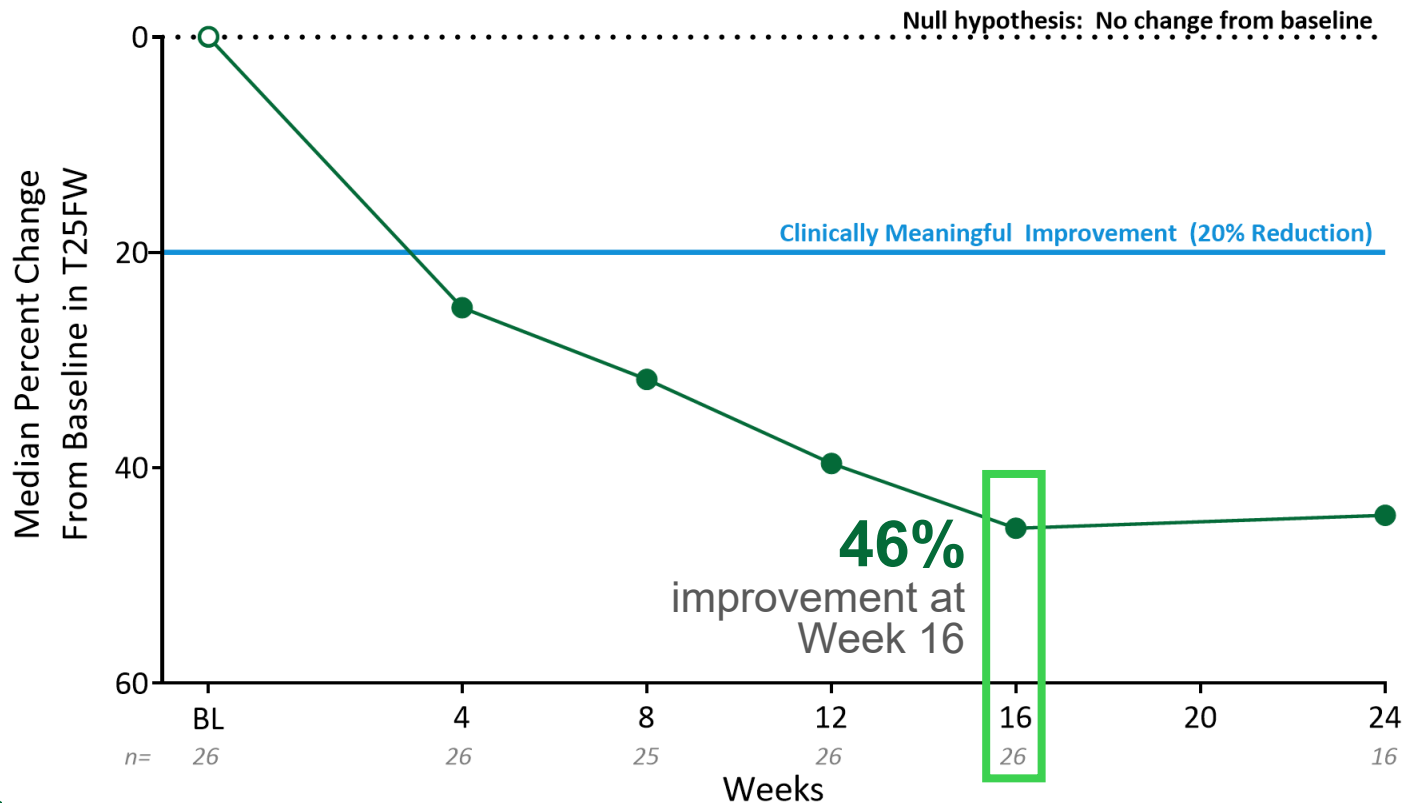
**20% improvement
considered clinically
meaningful¹**



Primary Endpoint: Robust and Sustained Improvement in Mobility

All Patients Remained Free of Immunotherapies Through Last Follow Up

Significant Improvement in Timed 25-Foot Walk (T25FW)



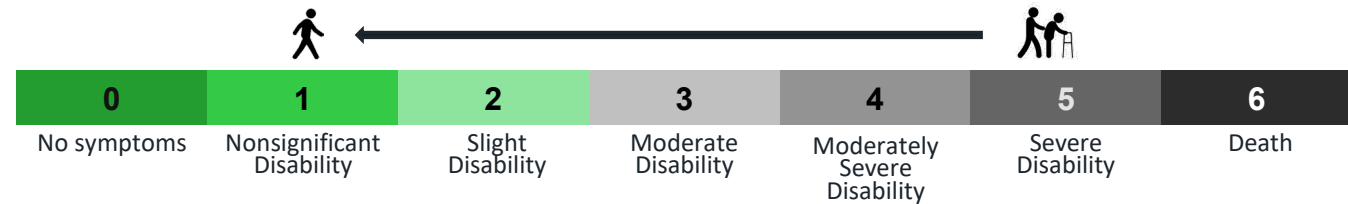
Data cutoff: 26Nov2025

- **Statistically significant** improvement in T25FW ($P=0.0003$)
- **81% of patients** achieved clinically meaningful improvement¹
- 31% completed T25FW in <5 seconds, a **typical time for healthy adults**²

Secondary Endpoints Assess Extent of Disability and SPS-Specific Symptoms

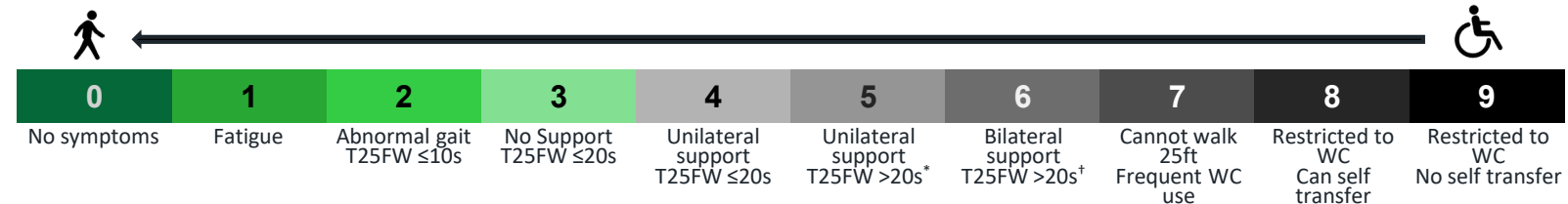
Modified Rankin Scale (mRS)

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)



Procedural Steps Involved in the Development and Administration of miv-cel

Single Procedure Requiring Dedicated Coding for Infusion

Leukapheresis Collection

- Peripheral blood T-lymphocytes are collected from the patient at an authorized treatment center (ATC) via leukapheresis.

Off-Site Manufacturing

- Collected T-cells are shipped to a manufacturing facility for CAR transduction and ex vivo expansion. Cells are genetically modified to express the CD19-targeting CAR construct with CD28 co-stimulation. Once the product passes quality release testing, it is shipped to the ATC.

Lymphodepleting Conditioning

- Patients receive lymphodepletion—typically low-dose cyclophosphamide and fludarabine — to prepare the immune environment for CAR T-cell engraftment and in vivo persistence.

miv-cel Infusion

- Miv-cel is administered as a single IV infusion via peripheral or central vein (percutaneous approach) under physician supervision with continuous monitoring for adverse events, such as CRS and ICANS.
- The infusion is the procedure for which a unique ICD-10-PCS code is requested.

Care Setting and Relationship to Other Procedures

Inpatient Administration

Miv-cel may be administered in an inpatient hospital setting with standard nursing and physician oversight, monitoring for CRS and ICANS, and access to emergency support. The ICD-10-PCS code requested would capture the miv-cel infusion in the inpatient setting.

Outpatient Administration

Miv-cel may also be administered in an outpatient facility, supported by its favorable safety profile — no high-grade (Grade 3+) CRS or ICANS was observed in KYSA-8, supporting the potential for outpatient delivery.¹ The treating physician and institution determine the appropriate care setting.

Relationship to Other Procedures²

Leukapheresis

T-cell collection via apheresis precedes miv-cel infusion

Lymphodepletion

Conditioning chemotherapy is administered in the days before infusion

miv-cel Infusion

The IV infusion of miv-cel is a standalone procedure for ICD-10-PCS coding purposes..

Post-Infusion Monitoring

Assessments for CRS, ICANS, cytopenias, and hypogammaglobulinemia

1. Kyverna Therapeutics. Miv-cel CD19 CAR T: Reimagining Treatment for Neurologic Autoimmune Diseases. Industry Therapeutic Update presented at: American Academy of Neurology Annual Meeting; April 18, 2026; Chicago, IL. 2. CMS. ICD-10-PCS Official Guidelines for Coding and Reporting. FY2026.

Medical Record Locations and Documentation for Identification

Inpatient Progress Notes & Physician Orders

Physician orders for miv-cel infusion, pre-infusion assessment notes, and daily progress notes document the decision to administer, the product name (mivocabtagene autoleucel / miv-cel / KYV-101), route, and infusion date.

Medication Administration Record (MAR)

The MAR captures the cellular product name, dose, route of administration, infusion date and time, and administering nurse.

Infusion Nursing Notes

Nursing infusion records document IV administration details including vascular access route (peripheral or central vein), infusion duration, vital signs, and any acute reactions observed.

Discharge Summary

The discharge summary documents procedures performed during the stay, including miv-cel infusion, lymphodepletion, and leukapheresis.

Pharmacy & Manufacturing Records

Pharmacy records document receipt, preparation, and release of the miv-cel cellular product. cGMP manufacturing release documentation and chain-of-identity records confirm product identity.

Post-Infusion Monitoring Notes

Daily nursing and physician assessments for adverse events, such as CRS, ICANS, cytopenias, and hypogammaglobulinemia. These are separate from the infusion note and documented chronologically.

Documentation standards described are consistent with CMS ICD-10-PCS Official Guidelines for Coding and Reporting and standard hospital coding practices. CMS. ICD-10-PCS Official Guidelines for Coding and Reporting. FY2026.

cGMP, current good manufacturing practice; MAR, medication administration record.

Naming Conventions

Nonproprietary (INN/USAN)	mivocabtagene autoleucel
Abbreviated Name	miv-cel
Investigational Name	KYV-101
Construct Designation	Hu19-CD828Z

INN, International Nonproprietary Name; USAN, United States Adopted Name.

Routes of Administration

Routes of Administration

Intravenous (IV) Delivery Routes

- Peripheral Vein: Administered via a standard peripheral IV catheter using a percutaneous approach (through the skin).
- Central Vein: Administered via a central venous catheter (such as a PICC line or central line), also using a percutaneous approach.

Number of Administrations

Miv-cel is administered as a single infusion per treatment course. One autologous cellular product per patient is manufactured and administered. Routine second infusion is not part of the protocol.

IV, intravenous; PICC, peripherally inserted central catheter.

Miv-cel Demonstrated a Well-Tolerated Safety Profile

Treatment-Related Adverse Events, n (%)	N=26
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	4 (15)
Any treatment-related serious AE	3 (12)

Data cutoff: 26Nov2025

CRS and ICANS graded using ASTCT criteria; other AEs graded using CTCAE criteria.

AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy; CAR, chimeric antigen receptor; CTCAE, Common Terminology Criteria for Adverse Events; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; LD, lymphodepletion.

Source: Kyverna Therapeutics. Miv-cel CD19 CAR T: Reimagining Treatment for Neurologic Autoimmune Diseases. Industry Therapeutic Update presented at: American Academy of Neurology Annual Meeting; April 18, 2026; Chicago, IL.

- **No high-grade CRS or ICANS observed**
- Most common treatment-related AEs were CRS (92%), fatigue (54%), diarrhea (38%), and headache (31%)
- 4 patients had Grade 3/4 neutropenia, an expected AE with lymphodepletion and CAR T-cell therapies
 - All events were manageable with treatment including G-CSF, fully resolved in 3 patients (median duration of 85 days), and was ongoing in 1 patient
 - No serious infections associated with neutropenia
- Serious treatment-related AEs occurred in 3 patients; all fully resolved without sequelae