



Kyverna Therapeutics Presents Full One-Year Registrational Data Set Demonstrating Sustained Clinical Benefit of Miv-cel in Stiff Person Syndrome at MS Toronto

October 21, 2026

Miv-cel reversed disability and achieved durable efficacy across all primary and secondary endpoints through one year, with nearly all patients remaining off chronic immunotherapies

Deep B-cell depletion demonstrated with a single dose supports the potential for broad immune reset enabled by miv-cel's unique construct

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

Data further strengthens SPS BLA package and supports potential for miv-cel to be the first approved therapy in SPS and first approved CAR T-cell therapy for autoimmune diseases

EMERYVILLE, Calif., Oct. 21, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical immunology company pioneering transformative therapies for people with neurologic autoimmune diseases, today announced the full one-year data set from KYSA-8, its registrational trial of miv-cel (mivocabtagene autoleucel, KYV-101) in patients with stiff person syndrome (SPS). The data will be presented today at MS Toronto 2026, the joint ACTRIMS-ECTRIMS meeting.

"The totality of the one-year durability data from the KYSA-8 trial is very encouraging and suggests miv-cel has the potential to fundamentally change how we treat stiff person syndrome, a progressive, disabling disease with no approved therapies," said Amanda Piquet, M.D., FAAN, Director of Autoimmune Neurology at the University of Colorado Anschutz School of Medicine, Céline Dion Foundation Endowed Chair, and lead investigator of the KYSA-8 trial. "The positive primary endpoint results, together with the secondary and exploratory endpoint data, highlight the full clinical benefit of miv-cel with a single dose. Through one year, patients experienced significant improvements across multiple measures of disease burden, including disability, mobility, stiffness, hypersensitivity, physical functioning and mental health, with a well-tolerated safety profile."

Poster Presentation:

Title: 1-Year Analysis of KYSA-8: the Pivotal, Multicenter, Phase 2 Study of Miv-cel (Mivocabtagene Autoleucel; Formerly KYV-101) CD19 CAR T-Cell Therapy in Stiff Person Syndrome

Presenter: Amanda Piquet, M.D., FAAN, Director of Autoimmune Neurology at the University of Colorado Anschutz School of Medicine

Poster ID: P0364

Date & Time: Wed., October 21, 2026, 4:30 – 6:30 PM ET

As reported at [AAN 2026](#), the primary endpoint and all key secondary endpoints were achieved with statistical significance in KYSA-8. The one-year durability data being presented today further strengthens these positive results.

Efficacy highlights from one-year follow-up data on 26 patients include:

- Significant improvement in the timed 25-Foot Walk (T25FW) sustained at one year ($p < 0.0001$): median improvement from baseline of 46% at week 16 (primary endpoint) and 49% at one year.
- At 16 weeks and one year after receiving miv-cel, 81% (21/26) and 77% (20/26) of patients achieved clinically meaningful improvement ($\geq 20\%$ reduction from baseline) in T25FW, respectively, demonstrating sustained benefit for the vast majority of patients.
- Over one-third of patients completed T25FW in < 5 seconds, comparable to a typical time for healthy adults.
- Of the 12 patients requiring a walking aid prior to treatment, 67% (8/12) continue to not require assistance.
- 92% (24/26) of patients remained free of chronic immunotherapies for SPS.
- At one year, the trial continued to meet all secondary endpoints, with significant mean improvements from baseline in Modified Rankin Scale, Hauser Ambulation Index, Distribution-of-Stiffness and Heightened Sensitivity Scale, of -1.0 ($p = .0003$), -1.7 (1.38; $p < .0001$), -1.6 (1.75; $p < .0001$) and -2.8 (2.11; $p < .0001$), respectively.

Exploratory endpoints, including additional efficacy measures continue to support miv-cel's differentiated clinical profile:

- In the 6-minute walk test, responses deepened over time, with the median improvement in walking distance increasing from 89 meters at the 16-week primary endpoint measurement to

119 meters at one year, a nearly 6-fold improvement over the clinical minimally important change of 20 meters.

- Sustained clinical benefit at one year in physical functioning and mental health, comparable to healthy adults, across the 36-item short form health survey.
- B-cell reconstitution was observed with sustained efficacy and antibody reduction.

Miv-cel continued to demonstrate a well-tolerated safety profile, supporting its potential for outpatient administration:

- No high-grade cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), and no cases of immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS).
- Grade 3/4 neutropenia, an expected adverse event (AE) with lymphodepletion and CAR T-cell therapies, was observed in five patients and was manageable.
- Serious treatment-related AEs occurred in three patients, all of which have fully resolved.

"This is a remarkable data set, demonstrating consistent and durable clinical benefit across primary, secondary, and exploratory endpoints, with a well-tolerated safety profile," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "These results reinforce miv-cel's potential best-in-class clinical profile, which may meaningfully change the trajectory of stiff person syndrome with a single dose, while allowing patients to remain free of chronic immunosuppressive therapies. We look forward to bringing this transformative therapy to patients as quickly as possible."

About KYSA-8 Registrational Clinical Trial

KYSA-8 is a single-arm registrational Phase 2 trial in which 26 adult patients with SPS, who had an inadequate response to at least one immunotherapy treatment, received a single dose of miv-cel. The primary endpoints are the change from baseline in the T25FW at 16 weeks and the incidence and severity of adverse events (AEs). Secondary endpoints measuring disability, stiffness, hypersensitivity, and mobility include the Modified Rankin Scale (mRS), Distribution-of-stiffness Index (DSI), Heightened Sensitivity Scale (HSS), and Hauser Ambulation Index (HAI), respectively.

About miv-cel (mivocabtagene autoleucel, KYV-101)

Miv-cel is a fully human, autologous, CD19-targeting CAR T-cell therapy with CD28 co-stimulation. It is uniquely designed for potency and tolerability with the potential to achieve deep B-cell depletion, reset the immune system, and deliver durable drug-free, disease-free remission in autoimmune diseases with a single dose. Miv-cel is under investigation for B-cell driven autoimmune diseases and is produced using a well-established, validated manufacturing process. To date, more than 100 patients have been treated with miv-cel across a range of autoimmune diseases, and the clinical data demonstrates a consistent and well-tolerated safety profile.

About Stiff Person Syndrome (SPS)

SPS is a rare, progressive neurologic autoimmune disease characterized by muscle stiffness and painful muscle spasms, impacting mobility and gait. Stiffness, rigidity, and spasms in the torso, arms, and legs lead to progressive disability causing up to 80% of patients to lose mobility, requiring walking aid assistance or wheelchair use¹⁻³. SPS has been shown to lead to permanent disability and increased risk of mortality³. Most patients with SPS have antibodies to glutamic acid decarboxylase 65 (GAD65) or the glycine receptor, which disrupt normal inhibitory neurotransmission, contributing to the hallmark symptoms of SPS. There are currently no FDA-approved treatments for SPS. Current treatment options include symptomatic treatments, off-label immunotherapies, such as intravenous immunoglobulin (IVIg), rituximab and plasmapheresis, as well as supportive care and physical, speech, occupational, and psychiatric therapy; however, the majority of patients have inadequate or no response to these treatment options. An estimated 6,000 patients are diagnosed with SPS in the United States⁴⁻⁵.

About Kyverna Therapeutics

Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a late-stage clinical immunology company pioneering differentiated therapies with curative potential for neurologic autoimmune diseases. Kyverna's lead autologous CD19-targeting CAR T-cell therapy candidate, miv-cel (mivocabtagene autoleucel, KYV-101), has demonstrated the potential to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases. Kyverna is advancing its potentially first-in-class neuroimmunology franchise with its recently completed registrational trial in stiff person syndrome (SPS) and an ongoing registrational trial for generalized myasthenia gravis (gMG).

Miv-cel has received three FDA Regenerative Medicine Advanced Therapy (RMAT) designations, in SPS, gMG, and non-active secondary progressive multiple sclerosis (naSPMS) based on compelling clinical data and significant unmet need, further reinforcing the therapy's potential across neuroimmunology. Additionally, the Company continues to advance new innovations that broaden access and choice for patients, expanding its leadership position in the field. For more information, please visit <https://kyvernatx.com>.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements." The words, without limitation, "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Forward-looking statements in this press release include, without limitation, those related to: the potential for a single dose of miv-cel to provide a broad immune reset; miv-cel's potential to fundamentally change how stiff person syndrome is treated; miv-cel's potential outpatient administration; miv-cel's potential best-in-class clinical profile; miv-cel's potential to meaningfully change the trajectory of stiff person syndrome with a single dose while allowing patients to remain free of chronic immunosuppressive therapies; the potential for miv-cel to achieve deep B-cell depletion, reset the immune system, and deliver durable drug-free, disease-free remission in autoimmune diseases with a single dose or to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases; the possibility that miv-cel may be the first approved treatment for patients with SPS or the first approved CAR T-cell therapy for autoimmune diseases; Kyverna's pipeline opportunities; and Kyverna's potentially first-in-class neuroimmunology franchise. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties related to market conditions; risks related to the timing and outcome of regulatory submissions and interactions with the FDA; the ability to enroll

patients in clinical trials on anticipated timelines; the possibility that topline results may change following further analysis or differ from final results; the possibility that results from prior clinical trials, named-patient access activities and preclinical studies may not necessarily be predictive of future results; and other factors discussed in the “Risk Factors” section of Kyverna’s most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q that Kyverna has filed or may subsequently file with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this press release are based on the current expectations of Kyverna’s management team and speak only as of the date hereof, and Kyverna specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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¹ Rakocevic G, et al. *BMC Neurol.* 2019;19:1.

² Dalakas MC. *Nat Rev Neurol.* 2024;20(10):587-601.

³ Duddy ME, Baker MR. *Front Neurol Neurosci.* 2009;26:147-165.

⁴ Crane PD, et al. *Neurology.* 2024;103(12):e210078.

⁵ Analysis of 2024 Komodo U.S. Claims Data.