Kyverna Presents Registrational Trial Primary Analysis for Miv-cel in Stiff Person Syndrome Demonstrating Statistically Significant, Durable Clinical Benefit Across All Endpoints in an Oral, Late-Breaker Session at AAN Annual Meeting

April 21, 2026

Single-dose of miv-cel achieved robust and durable improvements in mobility, reversed disability scores, and eliminated the need for chronic immunotherapies – outcomes not previously observed in SPS

Data underscore potential for miv-cel to become the first and only approved treatment for SPS, fundamentally changing the treatment paradigm for patients and caregivers

Company to host conference call on Wednesday, April 22, 2026, at 7:00 am ET

EMERYVILLE, Calif., April 21, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, today announced positive primary analysis results from its registrational trial, KYSA-8, of miv-cel (mivocabtagene autoleucel, KYV-101) in stiff person syndrome (SPS). The data will be presented today in a late-breaking oral presentation at the American Academy of Neurology (AAN) Annual Meeting in Chicago.

In KYSA-8, a single dose of miv-cel delivered rapid, statistically significant and clinically meaningful improvements across all primary and secondary endpoints at 16 weeks, with the majority of patients regaining function, and all patients discontinuing chronic immunotherapies – outcomes not previously observed in SPS. Further, miv-cel was well-tolerated.

“The results from our KYSA-8 registrational trial mark a defining moment for Kyverna, and more importantly, for patients living with stiff person syndrome,” said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. “We see compelling evidence that a one-time therapy can reset the immune system, reverse the course of disease, and free patients from lifelong treatment burden. With no approved therapies, we believe miv-cel could redefine the treatment paradigm for this debilitating, progressive disease. We are preparing our BLA submission for this initial indication, and the data strengthen our confidence in miv-cel’s therapeutic potential in myasthenia gravis, as well as other neurologic autoimmune diseases.”

KYSA-8 Clinical Trial Summary and Highlights from Primary Analysis
KYSA-8 is a single-arm registrational Phase 2 trial evaluating miv-cel in patients with SPS. The primary endpoints are the change from baseline in the Timed 25-Foot Walk (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. Both DSI and HSS are SPS-specific clinical outcome measures designed to assess the extent of muscle stiffness and sensitivity to triggers of muscle spasms, respectively.

A total of 26 patients who had an inadequate response to off-label immunomodulatory treatment options received a single dose of 1×10^8 miv-cel CAR T cells. The data cut-off for the primary analysis was November 26, 2025, with a median follow-up of 6.5 months after miv-cel infusion (range, 4.4-12.2 months).

“The majority of patients with SPS suffer from a progressive condition that often results in loss of independence, reduced quality of life, and a high-risk of permanent disability,” 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. “For decades, patients with SPS have had no approved therapies capable of altering the course of their disease. The ability of miv-cel to significantly decrease disability, stiffness, and hypersensitivity, and improve mobility – the key drivers of SPS morbidity – is unprecedented and highly promising for this underserved patient population.”

Efficacy highlights from the primary analysis following a single dose of miv-cel are as follows:

- The trial met its primary endpoint, demonstrating a statistically significant improvement in the T25FW at Week 16 ($p=0.0003$), with a median improvement of 46% from baseline, regardless of baseline patient- and disease-related characteristics:
  - 81% of patients achieved clinically meaningful improvement (≥20% reduction from baseline), with nearly 1/3 of all patients walking at the speed of healthy adults by Week 16.
  - Of the 12 patients requiring a walking aid at baseline, 67% no longer needed walking assistance at Week 16, reflecting meaningful functional independence.
  - All 26 patients remained free of chronic immunotherapies at Week 16 and through last follow-up.
- The trial met all secondary endpoints with significant ($p<0.0001$) mean improvements in mRS, HAI, DSI, and HSS of -0.8 (SD, 0.86), -1.6 (1.13), -1.5 (1.75), and -3.2 (2.01) points, respectively.

Exploratory endpoints including additional efficacy measures, further supported the differentiated clinical profile of miv-cel:

- Sustained clinical benefit associated with deep, transient B-cell depletion and broad immune reset.
- Significant reductions in GAD65-autoantibody titers associated with SPS, consistent with clinical results and miv-cel's mechanism of action.
- Improvements in physical and mental functioning, including a more than 4-fold improvement over the minimal clinically important change in the 6-Minute Walk Test (6-MWT), and normalization toward healthy population benchmarks across the 36-Item Short Form Health Survey (SF-36) domains.

Miv-cel demonstrated a well-tolerated safety profile consistent with its potential for outpatient administration:

- No high-grade cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) was observed.
- Grade 3/4 neutropenia, a known AE associated with lymphodepletion and CAR T-cell therapy, was observed in four patients and was manageable.
- Serious treatment-related AEs occurred in three patients, all of which resolved fully without sequalae.

"For neurologic autoimmune diseases such as stiff person syndrome, miv-cel is designed to achieve deep B-cell depletion, with the potential to impact immune activity within the central nervous system to enable a broad immune reset," said Naji Gehchan, M.D., Chief Medical and Development Officer of Kyverna Therapeutics. "The findings from our primary analysis of miv-cel highlight its differentiated therapeutic profile, with the potential to deliver durable disease-free remission with just a single dose, without need for any immunotherapies for SPS. We believe the consistency of results across all primary, secondary and exploratory endpoints provide clinical evidence that miv-cel has the potential to transform patient care in SPS."

Natural History Study Results Reinforce Significant Unmet Need in Patients with SPS
Outcomes from a large, multicenter, retrospective natural history study examining the impact of SPS on walking speed, were also presented at AAN.

The study included 153 patients treated with off-label immunomodulators or symptomatic medications and with longitudinal T25FW assessments available. The majority of patients showed minimal (<20%) or no improvement in T25FW and required increasing reliance on walking aids over time. Changes in T25FW correlated with changes in disability assessed by mRS over time.

This analysis supports the use of T25FW as a valid longitudinal measure of mobility and confirms its association with disability in patients with SPS. These findings further highlight the limited impact of current treatment approaches and reinforce the potential for miv-cel to change the treatment paradigm in SPS.

Investor Conference Call Details
Kyverna will host a conference call tomorrow, April 22, at 7:00 a.m. ET to review these results, as well as updated Phase 2 generalized myasthenia gravis (gMG) data from the KYSA-6 trial, which were also presented at AAN. The conference call and live webcast details and presentation materials will be available on the "Events & Presentations" section of Kyverna's Investor Relations webpage at ir.kyvernatx.com. An archived replay will also be available.

Dial-In Registration Link:
Conference Call Registration

Webcast Link:
Kyverna AAN Conference Call

About KYSA-8 Trial Design
The registrational Phase 2 KYSA-8 trial is an open-label, single-arm, multicenter study evaluating the safety and efficacy of miv-cel in patients with SPS. A total of 26 adult patients with SPS were dosed in the trial. Key inclusion criteria included a confirmed SPS diagnosis, stiffness index ≥2, and inadequate response to prior immunomodulatory therapies.

Patients received lymphodepletion with low-dose cyclophosphamide and fludarabine followed by a single infusion of miv-cel at a target dose of 1×10^8 CAR T cells. The primary endpoints were the change from baseline in the T25FW at Week 16 and safety. Secondary endpoints included the change from baseline in mRS, DSI, HAI, and HSS. Patients will be followed for one year.

Primary Endpoints	
Timed 25-Foot Walk (T25FW)	Validated tool capturing improvement in walking ability
Safety	Incidence and severity of AEs
Secondary Endpoints	
Modified Rankin Score (mRS)	Change in degree of disability
Hauser Ambulation Index (HAI)	Change in time and degree of assistance to complete timed 25-foot walk
Distribution of Stiffness Index (DSI)	Change in muscle stiffness across body regions
Heightened Sensitivity Scale (HSS)	Change in muscle spasms

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 use[1-3]. SPS has been shown to lead to permanent disability and increased risk of mortality[3]. 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 States[4-5].

About miv-cel (mivocabtagene autoleucel, KYV-101)
Miv-cel is a fully human, autologous, CD19-targeting CAR T-cell therapy with CD28 co-stimulation, designed for potency and tolerability, which is under investigation for B-cell-driven autoimmune diseases. With a single administration, miv-cel has potential to achieve deep B-cell depletion and immune system reset to deliver durable drug-free, disease-free remission in autoimmune diseases.

About Kyverna Therapeutics
Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a late-stage clinical biopharmaceutical company focused on liberating autoimmune patients through the curative potential of cell therapy. The Company'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 initial indications in stiff person syndrome and generalized myasthenia gravis. The Company is also advancing additional clinical and investigator-sponsored studies, including in multiple sclerosis and rheumatoid arthritis, to inform future priority indications and develop next-generation CAR T platforms to improve access and patient experience. 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: miv-cel's potential in SPS, including the ability of miv-cel to demonstrate statistically significant, durable clinical benefit, to achieve robust and durable improvements in mobility, to reduce or reverse disability scores, stiffness or hypersensitivity, and to eliminate the need for chronic immunotherapies; the potential for miv-cel to impact immune activity within the central nervous system to enable a broad immune reset, to deliver durable disease-free remission with just a single dose without need for any immunotherapies for SPS, to become the first and only approved treatment for SPS, to transform care or fundamentally change the treatment paradigm for SPS patients and caregivers or for other B-cell-driven autoimmune diseases and to strengthen confidence in miv-cel's therapeutic potential in myasthenia gravis and other neurologic autoimmune diseases; miv-cel's potential outpatient administration; Kyverna's BLA submission; the potential impact of the results from the KYSA-8 registrational trial on Kyverna and SPS patients; Kyverna's advancement of its potentially first-in-class neuroimmunology franchise with its initial indications in SPS and gMG and of additional clinical and investigator-sponsored studies, and the potential for such advancement to improve access and patient experience; and the anticipated timing for Kyverna's conference call and webcast and presentations at the AAN Annual Meeting and the topics expected to be discussed during such conference call and webcast and presentations. . 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, the possibility that results from prior clinical trials, named-patient access activities and preclinical studies may not necessarily be predictive of future results; the possibility that the FDA or other regulatory agencies may require additional trials or studies to support its intended BLA submission; intellectual property rights; 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.

Contacts:
Investors: InvestorRelations@kyvernatx.com
Media: media@kyvernatx.com

---

[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.