Kyverna Therapeutics Reports Positive One-Year Data Demonstrating Durable Clinical Responses and Favorable Safety Profile for Miv-cel in Stiff Person Syndrome and Generalized Myasthenia Gravis

September 24, 2026

Topline durability data reinforce potential for single-dose miv-cel to free patients from life-long disease burden and chronic immunotherapies, further highlighting miv-cel's differentiated construct

Sustained clinical benefit and reversal of disability through one year support the potential to be the first approved therapy in SPS and first approved CAR T-cell therapy for autoimmune disease; rolling BLA submission on track for completion in Q4 2026

Longer-term Phase 2 follow-up in gMG demonstrate robust and durable effects sustained for up to 1.5 years, with majority of patients maintaining MSE;
Phase 3 enrollment expected to be completed in mid-2027

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

Company to host conference call on September 24, 2026 at 8 am ET

EMERYVILLE, Calif., Sept. 24, 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 positive one-year topline data from KYSA-8, its registrational trial of miv-cel (mivocabtagene autoleucel, KYV-101) in patients with stiff person syndrome (SPS), and positive topline longer-term follow-up data from the Phase 2 portion of KYSA-6, its registrational trial in patients with generalized myasthenia gravis (gMG). Data from both trials will be shared at upcoming medical meetings.

"The durable clinical responses achieved in SPS and gMG, combined with a consistently favorable safety profile, set a new benchmark for autoimmune CAR T and reinforce miv-cel's potential best-in-class profile and ability to transform the treatment landscape across neurologic autoimmune diseases," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "These one-year SPS data further strengthen our rolling BLA submission, which is on track to be completed in the fourth quarter of this year. Miv-cel's differentiated construct and well-established manufacturing process underpin these longer-term results and highlight the opportunity to deliver one-time transformative therapies for people living with serious neurologic autoimmune conditions."

"The results from KYSA-8 are compelling, particularly given the severe burden of SPS and the absence of 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. "After a single dose of miv-cel, the sustained improvements observed in mobility, stiffness and other disease-specific measures, together with a well-tolerated profile, underscore its potential to deliver significant, long-lasting benefit to patients with SPS."

Topline 12-month Data in KYSA-8 SPS Registrational Trial

As reported at AAN 2026, the primary endpoint and all key secondary endpoints were achieved with statistical significance in KYSA-8. The topline one-year durability data further strengthen the positive results.

As of a database lock in July 2026, 12-month follow-up data on 26 patients with SPS include:

- Significant timed 25-Foot Walk (T25FW) improvement sustained at month 12 ($p < 0.0001$): median improvement from baseline of 46% at week 16 and 49% at month 12
- 95% of patients who achieved a clinically meaningful improvement (>20% reduction from baseline) at the primary analysis sustained their benefit
- 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% continue to not require assistance
- Significant improvements in secondary endpoints remained consistent at 12 months (p values between <0.0001 and 0.0003)
- 92% of patients remained free of chronic immunotherapies for SPS
- Miv-cel continued to be well-tolerated with 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).

Kyverna intends to include the one-year data in its rolling Biologics License Application (BLA) submission, which is on track to be completed in Q4

2026. The full data set will be presented at MS Toronto, the joint ACTRIMS-ECTRIMS meeting, taking place October 21–23, 2026, in Toronto, Canada.

"In SPS, we continue to see powerful evidence that a single dose of miv-cel has the potential to reset the immune system, reverse disease progression, and free patients from chronic immunotherapies, delivering sustained clinical benefit and a well-tolerated safety profile," said Naji Gehchan, M.D., Chief Medical and Development Officer of Kyverna Therapeutics. "Similarly, clinically meaningful responses were sustained to at least one year in our Phase 2 gMG trial, with nearly all patients remaining off immunosuppressant therapies. These unprecedented outcomes, combined with miv-cel's differentiated profile as a fully human CD19 CAR T-cell therapy with CD28 co-stimulation, distinguish miv-cel from both approved and investigational treatments, and strongly support our ongoing Phase 3 registrational trial. Most importantly, they bring us closer to our goal of delivering durable, drug-free, disease-free remission for patients living with neurologic autoimmune diseases."

Longer-term Follow-Up Data in KYSA-6 Phase 2 Trial in gMG

As of data cut-off in June 2026 (n=7), follow-up now extends one year and beyond (up to 1.5 years) in five patients, with one patient at 9 months and another at 6 months. Further strengthening the data shared at AAN 2026, a single dose of miv-cel led to deep and durable clinical responses, demonstrating:

- All 7 patients (100%) achieved clinically meaningful improvement in Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG), co-primary endpoints of the ongoing Phase 3 portion, at 24 weeks, with mean reductions of -8.3 and -11.7 points, respectively
    - Clinically meaningful improvements in MG-ADL, QMG and Myasthenia Gravis Composite (MGC) scores maintained through one year or longer in all five patients who have reached this time point
- Minimal symptom expression (MSE; defined as an MG-ADL score of 0 or 1) maintained in 57% of patients as of last follow up
- All 7 patients (100%) remained free of immunotherapies for MG, including nonsteroidal immunosuppressive therapies, high-dose steroids (>10 mg), and FcRn and complement inhibitors at 24 weeks, with 6 of 7 patients (86%) remaining off immunosuppressants as of last follow-up.
- Miv-cel continued to be well-tolerated, with no high-grade CRS, no ICANS, and no cases of IEC-HS.

Additional longer-term follow-up data from the Phase 2 portion of KYSA-6 will be shared in an oral presentation at the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting on September 29, 2026, at 10:15 am EDT in Orlando, Florida.

The Phase 3 portion of the KYSA-6 trial is ongoing, with enrollment expected to be completed in mid-2027.

Investor Conference Call Details

Kyverna will host a conference call on Thursday, September 24, at 8 am ET to review the topline SPS and gMG longer-term follow-up data from KYSA-8 and KYSA-6, respectively. 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 SPS and gMG Longer-Term Follow-Up Data Conference Call

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 KYSA-6 Phase 2/3 Clinical Trial
The Phase 2 portion of the KYSA-6 registrational trial is designed as a single-arm, open-label, multicenter study of miv-cel in patients with gMG. The primary efficacy endpoint is the change from baseline in MG-ADL score at 24 weeks and secondary endpoints include change from baseline in QMG and MGC scores at 24 weeks. Seven patients with moderate to severe gMG, all of whom had failed prior immunosuppressant therapies including FcRn and complement inhibitors, received a single dose of miv-cel.

The Phase 3 portion of the trial is a ~60-patient, global, open-label, randomized controlled trial with crossover design evaluating miv-cel versus standard of care (SOC). The co-primary endpoints are MG-ADL and QMG and the secondary endpoints include MGC change from baseline at 24 weeks compared to SOC, proportion of patients with a ≥3 point improvement from baseline in MG-ADL at 24 week compared to SOC, and the proportion of patients with MSE at 24 weeks compared to SOC. The Phase 3 trial is expected to complete enrollment by mid-2027.

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 Generalized Myasthenia Gravis (gMG)
Myasthenia gravis is a B-cell and antibody-mediated autoimmune neuromuscular disease that causes muscle weakness and fatigue, and patients may experience difficulty speaking, chewing, swallowing, or breathing.[6-7] MG is caused by autoantibodies produced by B-cells that lead to an immunological attack on critical signaling proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. The disease includes gMG, which impacts muscles beyond the eyes and may involve bulbar, limb, and respiratory muscles. Most patients with ocular manifestations, the most common presenting symptoms, develop gMG within two years after MG diagnosis. Although symptoms may initially remit, most patients experience progressive disease requiring chronic immunosuppressive therapy. Up to 20% of MG patients experience respiratory crisis at least once in their lives.[8] An estimated 80,000 patients are diagnosed with gMG in the United States.[9-10]

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 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, 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 free patients from life-long disease burden and chronic immunotherapies, reset the immune system, reverse disease progression and deliver significant, long-lasting or sustained clinical benefit for patients with SPS; miv cel's potential best-in-class profile; the potential for miv-cel to transform the treatment landscape across neurologic 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 disease; the anticipated timing of the completion of the rolling BLA submission for miv-cel in SPS and data expected to be included in such submission; the expected timing of completion of enrollment in the Phase 3 portion of the KYSA-6 trial in gMG; 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.

Contact:
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.
[6] Dresser L, et al. *J Clin Med*. 2021;10(11).
[7] DeHart-McCoyle M, et al. *BMJ Med*. 2023;2(1): e000241.
[8] Claytor B, et al. *Muscle Nerve*. 2023;68(1):8-19.
[9] Rodrigues E, et al. *Muscle Nerve*. 2024;69(2):166-171.
[10] Ye Y, et al. *Front Neurol*. 2024; 15:1339167.