Kyverna Therapeutics Announces Publication of Registrational Miv-cel Data in Patients with Stiff Person Syndrome in JAMA Neurology

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Publication reinforces miv-cel's potential to deliver durable clinical benefit with a single dose, enabled by miv-cel's unique construct, and become the first approved therapy in SPS and first approved CAR T-cell therapy for autoimmune disease

Initially presented at AAN, the primary analysis measured at 16 weeks demonstrated statistically significant improvements across all primary and secondary endpoints, including mobility and disability, with patients no longer requiring chronic immunotherapies

Consistent, well-tolerated safety profile with no high-grade CRS or ICANS, and no cases of IEC-HS

EMERYVILLE, Calif., Nov. 09, 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 publication of the primary analysis of KYSA-8, its registrational trial of miv-cel (mivocabtagene autoleucel, KYV-101) in patients with stiff person syndrome (SPS) in the *Journal of the American Medical Association (JAMA) Neurology.* These published data were presented in a late-breaking oral presentation at the American Academy of Neurology (AAN) Annual Meeting in April 2026. Kyverna also recently shared its one-year durability data from the KYSA-8 trial at MS Toronto, the joint ACTRIMS-ECTRIMS meeting.

"The publication of the KYSA-8 registrational data in *JAMA Neurology* underscores the unique potential of miv-cel to liberate patients with stiff person syndrome from life-long disease burden and chronic immunotherapy use," said Marinos C. Dalakas, MD, PhD, Professor of Neurology, Thomas Jefferson University, senior author and lead study investigator of the clinical trial. "Importantly, for patients and the field, miv-cel showed a well-tolerated safety profile with no high-grade CRS or ICANS, and no cases of IEC-HS. Having cared for patients with SPS for more than 30 years and witnessed the debilitating impact of this progressive disease, I believe miv-cel can change the therapeutic landscape for SPS by offering the potential to reverse patient disability. It's truly remarkable to see some of my patients who, for years, required assistive devices to now walking independently, in some cases even running."

In KYSA-8, a single dose of miv-cel delivered statistically significant improvements across all primary and secondary endpoints at 16 weeks with all patients discontinuing chronic immunotherapies. In addition, of the 12 patients who required walking aid assistance at baseline, 67% no longer needed walking assistance at 16 weeks. Miv-cel also demonstrated a consistent and well-tolerated safety profile.

"The publication of our registrational KYSA-8 trial data in *JAMA Neurology* marks an important milestone for both the miv-cel SPS program and Kyverna," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "These unprecedented results demonstrate clinical outcomes not previously seen in SPS, including patients regaining mobility after a single dose of miv-cel. The data further support miv-cel's potential to redefine treatment in SPS by reversing the course of this debilitating and progressive disease while maintaining a well-tolerated safety profile. With no approved therapies for SPS and a significant unmet need, we are working urgently to bring miv-cel to patients as quickly as possible. We believe these findings further support the potential of miv-cel across a range of neurological autoimmune diseases."

The full publication, "Mivocabtagene Autoleucel CD19 Chimeric Antigen Receptor T-Cell Therapy in Stiff Person Syndrome: A Nonrandomized Clinical Trial," appears in the Nov. 9 th issue of *JAMA Neurology*.

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 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.

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 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 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 transformative and durable clinical benefit of a single dose of miv-cel, including its ability to reverse the course of SPS and redefine treatment for SPS while maintaining a well-tolerated safety profile; Kyverna's regulatory path for SPS and the potential for FDA approval of miv-cel in SPS; Kyverna's efforts to bring miv-cel to patients as quickly as possible; the potential that miv-cel will be the first approved therapy for SPS and the first approved CAR T-cell therapy for autoimmune disease; the potential for miv-cel to liberate patients with SPS from life-long disease burden and chronic immunotherapy use, to reverse disability and change the therapeutic landscape for SPS, or to fundamentally change the treatment paradigm across multiple B-cell-driven and neurological autoimmune diseases; miv-cel's potential to deliver durable, drug-free, disease-free remission in autoimmune diseases; any potential benefits of RMAT designations for miv-cel in SPS, gMG and naSPMS by the FDA; and Kyverna's expected upcoming pipeline milestones, including for SPS, gMG, PMS and additional pipeline opportunities. 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, or may delay or decline approval of miv-cel; risks related to intellectual property rights; and other factors discussed in the "Risk Factors" section of Kyverna's previously filed Annual Report on Form 10-K for the year ended December 31, 2025 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026. 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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