Kyverna Therapeutics Highlights Potential of KYV-101 in Multiple Sclerosis with Data from Phase 1 Investigator-Initiated Trials to be Presented at ECTRIMS

September 24, 2025

KYV-101 IIT data demonstrate promising clinical activity, including robust CAR T penetration into the central nervous system (CNS) and improved expanded disability status scale scores (EDSS)

KYV-101 continues to demonstrate a tolerable safety profile, consistent with observations from the first 100 patients treated with KYV-101[1]

Encouraging early data of KYV-101 in multiple sclerosis highlights broader potential within neuroimmunology autoimmune diseases

EMERYVILLE, Calif., Sept. 24, 2025 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, today announced updated data from Phase 1 investigator-initiated trials (IITs) of KYV-101 in the treatment of progressive multiple sclerosis (MS) to be presented at the 2025 European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Congress, taking place in Barcelona, Spain from September 24-26, 2025. Data presented will include an oral presentation from Stanford Medicine (Stanford), Department of Neurology & Neurological Sciences and a poster presentation from the University of California, San Francisco (UCSF), Weill Institute for Neurosciences.

“Encouraging KYV-101 IIT data in multiple sclerosis underscores the therapy’s broad potential within neuroimmunology autoimmune diseases, including stiff person syndrome and myasthenia gravis,” said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. “We are grateful to our partners at Stanford and UCSF for leading these important studies exploring the potential of CAR T-cell therapy in treating a disease that affects millions of people and carries significant unmet need. As data continue to mature, we look forward to using these insights to inform our path forward.”

“In progressive multiple sclerosis, where patients face a steady progression of disability, halting or reversing disease progression is key to addressing a significant unmet medical need,” said Naji Gehchan, M.D., Chief Medical and Development Officer of Kyverna Therapeutics. “Longer follow-up data of KYV-101 across these IITs continue to show promise, with patients demonstrating disease stabilization, or even more encouragingly, an improvement in their disability status – potentially reflecting an immune reset. Notably, KYV-101 was also well-tolerated with no high-grade CRS or ICANS. We are pleased to see these results further reinforce the consistent clinical profile of KYV-101 observed to date across multiple autoimmune indications.”

Phase 1 IIT data for KYV-101 in MS were previously presented by Stanford and UCSF at the 2025 Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum and the American Academy of Neurology (AAN) Annual Meeting.

Stanford Oral Presentation

Title: Chimeric Antigen Receptor T Cell (CAR-T) Immunotherapy for Progressive Phenotypes of Multiple Sclerosis: Early Results from a Phase 1, Open-Label, Single Center Study of an Autologous Fully Human Anti-CD19 CAR-T
Presenter: Kristin Galleta, M.D., Clinical Assistant Professor, Adult Neurology, Stanford Medicine
Presentation ID: O027
Date and Time: Wednesday, September 24, 2025, 15:05 CEST

Stanford is conducting an open-label, Phase 1, single-center study of KYV-101 in patients with non-relapsing progressive multiple sclerosis, either secondary progressive MS (SPMS) or primary progressive MS (PPMS). Six patients were enrolled in the study and four have been infused. The oral presentation features data from the four patients who received either 33M (n=3) or 100M CAR+T (n=1) cells dose levels using a bendamustine lymphodepleting regimen, with up to 12 months of follow-up. Key highlights are outlined below:

Safety: KYV-101 was well-tolerated with no serious adverse events (SAEs) or high-grade Cytokine Release Syndrome (CRS) or Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS).

Biological Activity: Data demonstrated robust CAR T-cell expansion in blood and penetration into the CNS, where expansion was detected in the cerebrospinal fluid (CSF) by Day 14 post infusion. Further, the reconstitution of B-cells to a naive phenotype in three patients with six months of follow-up supports a CAR T-induced immune reset (4th patient follow-up data pending).

Efficacy: Stable to improved EDSS was observed in all four patients with six-month follow-up. Clinically meaningful improvement in fatigue scores was observed at the last follow-up (3-12 months) in all patients, with three achieving a substantial clinical improvement in fatigue scores.

UCSF Poster Presentation

Title: An Investigator Initiated Study of KYV-101, a CD19 CAR T Cell Therapy, in Participants with Treatment Refractory Progressive Multiple Sclerosis
Presenter: Sasha Gupta, M.D., Assistant Professor, Neurology, UCSF Weill Institute for Neurosciences
Poster ID: P792
Date and Time: Thursday, September 25, 2025, 16:30-18:30 CEST

UCSF is conducting an open-label, Phase 1, single-center study of KYV-101 in patients with treatment refractory progressive multiple sclerosis. The poster presentation features data from two patients who have been enrolled in the study and received 33M CAR+T cells with up to 48 weeks of follow-up. Key highlights are outlined below:

Safety: KYV-101 demonstrated a tolerable safety profile with no high-grade CRS or ICANS.

Biological Activity: Data demonstrated successful penetration into the CNS compartment, with CAR T cells observed in the CSF by day 14 based on available data for one patient. In addition, B-cell reconstitution was observed in both patients by 24 weeks. Data available for one patient showed the reconstitution of B-cells to a naive phenotype by 24 weeks of follow-up, supportive of a CAR T-induced immune reset.

Efficacy: Stable to improved EDSS scores were observed for both patients – one at 24 weeks of follow-up and another at 48-weeks of follow-up.

About Multiple Sclerosis

Multiple sclerosis is a chronic autoimmune disease causing neurodegeneration, in which patients can experience a range of symptoms including blurred vision, slurred speech, tremors, numbness, extreme fatigue, problems with memory and concentration, and, in severe cases, the inability to walk or stand. B cells play a significant role in MS by producing autoantibodies that attack the protective sheath around nerves, activating T cells, and increasing inflammation. Current disease-modifying treatments for MS aim to reduce the frequency of disease relapses and delay progression of disability, but the disease remains a chronic condition that will progressively worsen for most patients.

About KYV-101

KYV-101 is a fully human, autologous, CD19 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, KYV-101 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 clinical-stage biopharmaceutical company focused on liberating patients through the curative potential of cell therapy. Kyverna's lead CAR T-cell therapy candidate, KYV-101, is advancing through late-stage clinical development with registrational trials for stiff person syndrome and myasthenia gravis, and two ongoing multi-center Phase 1/2 trials for patients with lupus nephritis. The Company is also harnessing other KYSA trials and investigator-initiated trials, including in multiple sclerosis and rheumatoid arthritis, to inform the next priority indications for the Company to advance into late-stage development. Additionally, its pipeline includes next-generation CAR T-cell therapies in both autologous and allogeneic formats, including efficiently expanding into broader autoimmune indications and the potential to increase patient reach with KYV-102 using its proprietary whole blood rapid manufacturing process. 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 topics to be presented at the ECTRIMS Congress; KYV-101's potential within neuroimmunology-related autoimmune diseases; KYV-101's potential to deliver durable drug-free, disease-free remission with a single dose; Kyverna's engagement with regulators; and Kyverna's clinical trials, investigator initiated trials and named-patient access data. 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; 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.

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[1] Includes patients treated in KYSA clinical trials, investigator-initiated trials, and "IH" or "Individueller Heilversuch," also known as "named-patient basis access". Similar to expanded access or compassionate use in the United States, IH is a regulatory mechanism in Germany that allows for the supply of a treatment that has not received marketing authorization for an individual patient in response to a request by the treating physician on behalf of the named patient. This option can be pursued for the expected benefit of a patient who has exhausted all available treatment options, under the discretion of the treating physician with the patient's consent. The use of KYV-101 in the IH setting is not a substitute for, nor intended to replace, Kyverna's clinical trials. The goal is not to assess the effectiveness of a potential therapy, but rather to provide an individual patient with a possible efficacious approach when all other treatment options have failed, as determined by the patient's physician.