Kyverna Therapeutics to Highlight Interim Phase 2 Data from KYV-101 KYSA-6 Study in Myasthenia Gravis at AANEM 2025

September 15, 2025

Oral presentation to include topline efficacy and safety data for 6 patients with up to 9 months of follow up

Enrollment for registrational Phase 3 portion of KYSA-6 trial in MG on track to initiate by year-end 2025

EMERYVILLE, Calif., Sept. 15, 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 that interim data from the Phase 2 portion of the KYSA-6 study of KYV-101 in myasthenia gravis (MG), will be presented during an oral presentation at the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting, taking place October 29 – November 1, 2025, in San Francisco, CA.

“We look forward to sharing interim data from our Phase 2 trial in myasthenia gravis, where we aim to continue to build a body of scientific evidence supporting KYV-101’s potential to deliver durable drug-free, disease-free remission with a single dose,” said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. “This data readout marks an important milestone for the Company as we advance our neuroimmunology CAR T franchise – actively preparing for the initiation of the registrational Phase 3 portion of our myasthenia gravis trial this year, as well as the topline pivotal data readout for stiff person syndrome in the first half of next year.”

Following alignment with the FDA, the KYSA-6 Phase 2 open-label, single-arm, multicenter study of KYV-101 in generalized myasthenia gravis (gMG) was amended into a registrational Phase 2/3 study. The interim Phase 2 results that will be presented at AANEM will include top-line efficacy and safety data for six patients with up to nine months of follow-up. At the time the abstract was submitted, five patients had been dosed; the oral presentation will report on these patients as well as early data for a sixth patient who was dosed recently.

Presentation Details

Title: Update on the Phase 2 Part of KYSA-6, an Open-Label, Single-Arm, Multicenter Study of KYV-101, a Fully Human CD19 Chimeric Antigen Receptor T-Cell Therapy in Generalized Myasthenia Gravis
Presenter: Srikanth Muppidi, M.D.
Date and Time: Wednesday, October 29, 2025, 11:00 AM PT

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 discussed at the AANEM annual meeting; KYV-101’s potential to deliver durable drug-free, disease-free remission with a single dose; the expected timing for enrolling the first patient in the Phase 3 portion of the registrational MG trial; the trial design for the registrational MG trial; Kyverna's engagement with regulators; the expected timing for reporting interim data for the Phase 2 portion of the MG trial; 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 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.

Contacts:

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