Kyverna Therapeutics Announces Positive Interim Phase 2 Data from KYSA-6 Study of KYV-101 in Generalized Myasthenia Gravis at AANEM 2025

October 29, 2025

Compelling results set new clinical standard in generalized myasthenia gravis (gMG), increasing confidence in the Company's registrational KYSA-6 Phase 3 MG trial

100% of patients achieved clinically meaningful responses in MG-ADL and QMG -- the co-primary endpoints of the Phase 3 trial -- with mean reductions of -8.0 pts and -7.7 points at 24 weeks

KYV-101 was well-tolerated with no high-grade CRS and no ICANS observed, further supporting the consistent and manageable safety profile of KYV-101

Unprecedented results further reinforce KYV-101's potential to deliver durable, drug-free, disease-free remission with a single dose

Company to host conference call today, October 29, 2025, at 8:00 am ET

EMERYVILLE, Calif., Oct. 29, 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 positive interim data from the Phase 2 portion of the registrational KYSA-6 clinical trial of KYV-101 in generalized myasthenia gravis (gMG). The data will be shared in an oral presentation today by Srikanth Muppidi, M.D., Clinical Professor, Adult Neurology, Stanford Medicine, at the Myasthenia Gravis Foundation of America (MGFA) Scientific Session during the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting in San Francisco, CA.

"With today's results, we are setting a new standard across key clinical outcome measures for gMG, particularly in the depth and durability of response achieved with just a single dose of KYV-101," said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. "Patients experienced rapid and unprecedented symptom improvement without the need for ongoing background therapy. These compelling data build upon our previously reported compassionate use[1] experience, further advancing our goal to deliver durable, drug-free, disease-free remission, and importantly, reinforce our confidence in the KYSA-6 Phase 3 trial design. With the growing body of evidence supporting KYV-101's promising potential in gMG and across multiple autoimmune indications, we believe we are well-positioned to deliver on a first-in-class neuroimmunology franchise, while expanding our future growth opportunities."

KYSA-6 Phase 2/3 Clinical Trial Summary and Data Highlights

The Phase 2 portion of the registrational KYSA-6 clinical trial is a single-arm, open-label, multicenter study of KYV-101 in gMG. The primary endpoints were Myasthenia Gravis Activities of Daily Living (MG-ADL) score at 24 weeks and the incidence and severity of adverse events (AEs). Secondary endpoints included Quantitative Myasthenia Gravis (QMG) and Myasthenia Gravis Composite (MGC) scores.

As of the October 3, 2025 data cut-off, six patients with moderate to severe gMG (mean MG-ADL 11.2, QMG 17.3, MGC 21.8), and an average disease duration of 5.3 years (1.7-13.3) were treated with a single dose of 1×10^8 KYV-101 CAR+T cells. All patients had failed prior immunosuppressant therapies such as FcRns and complement inhibitors. At data cut-off, duration of follow-up after KYV-101 infusion was up to 36 weeks.

"Interim results showed that KYV-101 has the potential to deliver rapid, substantial and clinically meaningful improvements in MG-ADL, QMG, and MGC scores for 100% of patients with a single dose, while also offering the potential for patients to become symptom-free," said Naji Gehchan, M.D., Chief Medical and Development Officer of Kyverna Therapeutics. "With all patients exceeding the thresholds for our Phase 3 co-primary endpoints, we believe the data further validate the powering and overall design of our Phase 3 superiority trial. We look forward to initiating enrollment for the Phase 3 portion of the trial by the end of this year, as well as sharing updated data from the Phase 2 portion of the trial next year."

Highlights from the interim Phase 2 trial to be featured in the oral presentation at AANEM include:

Efficacy:

- 100% (6/6) of patients achieved clinically meaningful[2], robust, rapid, and sustained reductions in MG-ADL and QMG scores from baseline regardless of prior biologic exposure.
  - The mean reductions of MG-ADL and QMG scores were -8.0 points and -7.7 points at 24 weeks, respectively, with deep responses seen as early as two weeks.
  - 100% (6/6) of patients responded, achieving a ≥3-point reduction in both MG-ADL and QMG.
  - Of the three patients with at least 24 weeks of follow-up, two achieved minimal symptom expression (MSE), defined as an MG-ADL score of 0 or 1.
  - 100% (6/6) of patients achieved clinically meaningful response by MGC[3] with a mean reduction of -12 points at 24 weeks.
- KYV-101 also significantly reduced treatment burden up to 24 weeks after a single dose, with

100% of patients free of nonsteroidal immunosuppressants, high-dose steroids (>10mg), and FcRn and complement inhibitors.

Safety:

- KYV-101 was well-tolerated with no new safety signals observed.
- No high-grade (Grade ≥3) cytokine release syndrome (CRS) and no immune effector cell-associated neurotoxicity syndrome (ICANS) events were observed.
- One patient experienced a serious adverse event of Grade 4 neutropenia, an expected adverse event, which improved with standard supportive care to Grade 1 at data cut off.

“Despite available treatment options, many patients living with gMG continue to experience ongoing disease burden. Even recently approved novel therapies require frequent and chronic dosing and fail to provide a symptom-free state desired by all patients. Today’s results are very promising, as we are seeing that KYV-101 can target gMG upstream at the disease source, through deep, tissue-based B-cell depletion. This is likely a prerequisite to an immune reset, representing a potentially significant treatment advance in gMG,” said Professor Srikanth Muppidi, M.D., Clinical Professor, Adult Neurology, Stanford Medicine.

The KYSA-6 Phase 2 study was amended into a registrational Phase 2/3 study following an end-of-Phase 2 meeting with the FDA earlier this year.

Investor Conference Call Details
Kyverna management will host a conference call today, Wednesday, October 29, 2025, at 8:00 am ET to review these results. The conference call and live webcast details and supporting 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.

AANEM 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., Clinical Professor, Adult Neurology, Stanford Medicine
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 Myasthenia Gravis
Myasthenia gravis is a B-cell and antibody-mediated neuromuscular autoimmune disease that causes muscle weakness and fatigue, potentially manifesting in trouble speaking, difficulty chewing and swallowing, shortness of breath, and, most severely, respiratory failure, which can be life-threatening. 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 symptoms of the disease can be transient and in the early stages of the disease can remit spontaneously. However, as the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months. Disease symptoms reach their maximum levels within two to three years of diagnosis in approximately 80% of patients. Up to 20% of MG patients experience respiratory crisis at least once in their lives[4].

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 potential for KYV-101 to deliver rapid, substantial and clinically meaningful improvements while also offering the potential for patients to become symptom free; Kyverna’s potential to deliver on a first-in-class neuroimmunology franchise; the potential for the interim data to further validate the powering and overall design of Kyverna’s Phase 3 superiority trial; 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 updated 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 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] Similar to expanded access or compassionate use in the United States, IH or “Individueller Heilversuch,” also known as “named-patient basis access,” 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.

[2] Clinically meaningful improvements in MG-ADL and QMG are defined as a ≥2-point reduction in MG-ADL from baseline and a ≥3-point reduction in QMG from baseline.

[3] A clinically meaningful improvement in MGC is defined as ≥3-point reduction from baseline.

[4] Claytor B, et al. Muscle Nerve. 2023;68(1):8-19.