Kyverna Therapeutics Highlights Neuroimmunology CAR T Franchise and Registrational Phase 3 Trial Design in Myasthenia Gravis at Virtual KOL Event

August 28, 2025

KYV-101 has the potential to deliver durable, drug-free, disease-free remission in myasthenia gravis and set a new treatment standard for stiff person syndrome

Innovative FDA-aligned KYSA-6 Phase 3 trial design for myasthenia gravis supports clear and rapid path to BLA

Webcast today August 28th, at 11 am ET

EMERYVILLE, Calif., Aug. 28, 2025 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, will host a virtual KOL event today to highlight its neuroimmunology CAR T franchise in stiff person syndrome (SPS) and myasthenia gravis (MG).

As part of this event, the Company will share details of its Phase 3 clinical trial design in MG; positive longer-term follow-up data from MG and SPS compassionate use patients[1] treated with KYV-101; key insights from leading KOLs highlighting the potential of CD19 CAR T-cell therapy in autoimmune diseases; and the initial framework of its neuroimmunology commercial strategy.

“We are proud to highlight our potential first-in-class CAR T-cell therapy that can address the significant unmet needs of patients with autoimmune diseases, beginning with SPS and MG,” said Warner Biddle, Chief Executive Officer of Kyverna. “As part of our efforts to accelerate our neuroimmunology franchise, we’re pleased to share today the details of our innovative, FDA-aligned Phase 3 trial in MG, which we believe offers an efficient and robust design and highlights KYV-101's differentiated clinical profile. Additionally, as we continue to observe durable treatment outcomes in compassionate use patients treated with KYV-101, we are energized by the potential to bring the first FDA-approved therapy to SPS patients – a progressive and highly debilitating disease with growing prevalence – and to fundamentally change the treatment paradigm in MG by providing durable, drug-free, disease-free remission with a single dose.”

Registrational KYSA-6 Trial Design for MG

Following alignment with the FDA, Kyverna has amended KYSA-6, its Phase 2 trial in MG, into a Phase 2/3 registrational study. The Company expects to initiate patient enrollment in the Phase 3 portion by year-end 2025.

The KYSA-6 Phase 2/3 trial is an open-label, randomized, controlled study in adults with generalized myasthenia gravis seeking to demonstrate the superiority of KYV-101, a fully human autologous CD19-directed CAR T-cell therapy, compared to standard-of-care (SOC), which could include traditional agents or complement pathway inhibitors.

The Phase 3 portion of the trial will include approximately 60 patients randomized 1:1 to receive either a single infusion of KYV-101 or continue SOC therapy. Highlights of the trial design include:

- The co-primary endpoints are a change from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores at 24 weeks compared to the SOC treatment arm.
- A key secondary endpoint is the change from baseline in Myasthenia Gravis Composite (MGC) score at 24 weeks compared to the SOC treatment arm.
- Other endpoints will further seek to measure the magnitude of the anticipated clinical impact, reporting the proportion of patients demonstrating a ≥3-point reduction in MG-ADL score, achieving Minimum Symptom Expression (MSE), and remaining off immunosuppressant therapy following treatment.
- Patients initially randomized to the SOC treatment arm will ultimately have the option to crossover and receive KYV-101.

Based on the substantial clinical effect size that has been observed in MG patients treated with KYV-101[2], the Company believes the Phase 3 portion of the study is efficient and well-powered, enabling a clear and rapid path to BLA. In addition, distinct from most MG trials, KYSA-6 is designed to assess the impact of KYV-101 as a standalone treatment in the absence of concurrently maintained background immunosuppressive therapy, thereby enabling evaluation of its potential to deliver durable drug-free, disease-free remission after a single dose.

Kyverna has completed enrollment of the Phase 2 portion of the KYSA-6 study and expects to report interim data in the fourth quarter of 2025.

Event Details

The virtual KOL event will take place today, Thursday, August 28, 2025, from 11 am to 1:30 pm ET, and can be accessed **here**. Following formal presentations, management will host a Q&A session with featured KOLs.

The live webcast 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.

About the KOLs

Ricardo Grieshaber-Bouyer, M.D., Ph.D. is a rheumatologist and immunologist and leads the Clinical Trial Unit at the Department of Internal Medicine, Division of Rheumatology and Immunology at Erlangen University Hospital.

His research spans basic, translational and clinical studies. He focuses on uncovering the mechanisms that drive immune cell heterogeneity in tissues and inflammatory conditions and how these variations contribute to disease diversity among individuals. He also currently serves as Professor of Clinical Systems Immunology at Friedrich-Alexander University (FAU) Erlangen-Nuremberg.

Previously, Dr. Grieshaber-Bouyer was a resident-fellow in internal medicine and rheumatology at Heidelberg University Hospital and group leader at the Division of Rheumatology and Institute for Immunology and also served as a physician scientist fellow on medical faculty and as a visiting researcher at the European Molecular Biology Laboratory (EMBL). Earlier, he held a postdoctoral fellowship with the Immunological Genome Project and trained in immunology research at the Brigham and Women's Hospital of Harvard Medical School.

Dr. Grieshaber-Bouyer has won numerous awards, including Forbes 30 under 30 and various research prizes, and holds an M.D. and Ph.D. in Immunology from Heidelberg University, as well as a Master of Health Business Administration (M.H.B.A.) from FAU Erlangen-Nuremberg.

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Aiden Haghikia, M.D. is a neurologist and Professor of Neurology, currently serving as Chair of the Department of Neurology and Director of the Department of Neurology and Clinical Neurophysiology at Hannover Medical School.

Dr. Haghikia's research centers on the pathogenesis and treatment of neuroimmunological and neurodegenerative disorders, including multiple sclerosis and Parkinson's disease, with a particular emphasis on the role of the gut. He also has been appointed a peer reviewer for numerous leading journals and international research councils and has supported the development of treatment guidelines for neurologimmunological conditions including multiple sclerosis.

Previously, Dr. Haghikia was Professor and Director of the Department of Neurology at Otto-von-Guericke University. He began his academic career at Ruhr-Universität Bochum, where he completed clinical fellowships in neurology and psychology and later held a professorship in Translational Neuroimmunology. He also completed a postdoctoral fellowship at the Weatherall Institute of Molecular Medicine at the University of Oxford.

Dr. Haghikia earned his medical degree from Ruhr-Universität Bochum.

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Srikanth Muppidi, M.D., M.S.C.S. is a neurologist specializing in neuromuscular and autonomic disorders and serves as Clinical Professor of Neurology in the Department of Neurology and Neurological Sciences at Stanford University School of Medicine. He is also the Neurodiagnostic Lab Director, overseeing the EMG and Autonomic sections.

Dr. Muppidi's research bridges clinical, translational, and outcomes-based studies, with a focus on myasthenia gravis, autonomic dysfunction, and neuromuscular junction disorders. He has developed and validated outcome measures, such as the MG-ADL scale, that are widely used in clinical trials for MG. Dr. Muppidi has participated in numerous pivotal Phase 3 trials and currently leads efforts in advancing novel therapies for autoimmune neuromuscular diseases, including CAR-T cell therapy and subcutaneous FcRn inhibitors.

Previously, Dr. Muppidi was Assistant Professor at UT Southwestern Medical Center, where he also completed his neuromuscular fellowship. He trained in neurology at Thomas Jefferson University Hospital, where he served as Chief Resident, and completed his internal medicine internship at the Medical College of Wisconsin.

Dr. Muppidi has received multiple teaching awards at Stanford, including the Lysia Forno Award for Teaching Excellence, and serves on editorial boards and review panels for leading neurology journals and conferences. He earned his medical degree from Osmania Medical College in India and holds a Master's in Clinical Sciences from UT Southwestern.

About Myasthenia Gravis (MG)
Myasthenia gravis is a 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 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. Symptoms can be transient; however, as the disease progresses, symptom-free periods become less frequent, and exacerbations can last for months. Symptoms reach their maximum levels within two to three years of diagnosis in approximately 80% of patients. Up to 20% of MG patients experience a respiratory crisis at least once in their lives[3].

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[4-6]. SPS can lead to permanent disability and increased risk of mortality[6]. 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 physical, speech, occupational therapy, supportive care, and psychiatric therapy; however, the majority of patients have inadequate or no response to these treatment options.

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 KOL event; KYV-101's differentiated profile and its potential to be the first FDA-approved therapy for SPS; the potential for the observed clinical effect size to support a BLA and provide a well-defined and rapid regulatory pathway towards potential approval of a BLA; the expected timing for enrolling the first patient in the Phase 3 portion of the registrational MG trial and the expected number of patients to be enrolled; the trial design for the registrational MG trial; the potential for Kyverna to have a first-in-class CAR T-cell therapy; the potential for KYV-101 to achieve deep B-cell depletion and immune system reset and its potential to provide durable, drug free, disease-free remission in MG and set a new treatment standard for SPS; 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.

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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] Clinical effect size as measured through the Individueller Heilversuch (IH) pathway.

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

[4] Rakocevic G, et al. BMC Neurol. 2019;19:1.

[5] Dalakas MC. Nat Rev Neurol. 2024;20(10):587-601.

[6] Duddy ME, Baker MR. Front Neurol Neurosci. 2009;26:147-165.