Kyverna Therapeutics Highlights Potential of KYV-101 in Rheumatoid Arthritis with Phase 1 Data from Investigator-Initiated Trial Presented at ACR Convergence 2025

October 25, 2025

KYV-101 resulted in a profound reduction in disease-associated autoantibodies and impact on disease activity in patients with difficult-to-treat rheumatoid arthritis (RA)

KYV-101 continues to demonstrate a well-tolerated profile, consistent with observations from 100 patients treated with KYV-101 to date[1]

Emerging IIT data in RA reinforce broad potential for KYV-101 in rheumatology indications

EMERYVILLE, Calif., Oct. 25, 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 the presentation of data from the Phase 1 portion of an investigator-initiated Phase 1/2 trial (IIT) evaluating KYV-101 in patients with active and treatment-refractory rheumatoid arthritis (RA). The data will be featured in a poster presentation from Charité, University of Berlin, at the American College of Rheumatology (ACR) Convergence 2025, taking place in Chicago, Illinois from October 24-29, 2025.

“We are very encouraged by these results, in which KYV-101 continues to provide robust CAR T cell expansion and B-cell depletion with a well-tolerated profile, driving compelling outcomes in patients with difficult-to-treat autoimmune disease,” said Warner Biddle, Chief Executive Officer of Kyverna Therapeutics. “Alongside IIT data recently presented in multiple sclerosis, these promising results in rheumatoid arthritis reinforce Kyverna’s potential to address serious autoimmune diseases beyond our core neuroimmunology CAR T programs, further demonstrating our leadership in this space.”

Charité – University of Berlin Poster Presentation

The COMPARE trial is an open-label, randomized, controlled Phase 1/2 study evaluating KYV-101 against the anti-CD20 monoclonal antibody rituximab in patients with anti-citrullinated protein antibody (ACPA)-positive, treatment-refractory RA with moderate to high disease activity.

All six patients enrolled in the Phase 1 portion of the study displayed highly refractory disease and had failed a mean of 5.8 prior biologic and targeted synthetic disease-modifying anti-rheumatic drugs (DMARDs) before entering the study and receiving a single infusion of 1×10^8 KYV-101 CD19 CAR T cells with follow-up ranging from 28-175 days. The primary endpoint for the Phase 1 study was safety and tolerability with patients additionally evaluated for efficacy and key biomarkers of RA.

Key highlights are outlined below:

- **Safety:** KYV-101 was well-tolerated with no high-grade Cytokine Release Syndrome (CRS), and no instances of Immune Cell Associated Neurotoxicity Syndrome (ICANS).
- **Biological Activity:** CAR T-cells expanded rapidly, peaking between 14 and 21 days, and B-cell depletion occurred in all patients. Profound reductions in pathogenic ACPA, and in Rheumatoid Factor – Immunoglobulin M (RF-IgM) titers were also observed.
- **Efficacy:** With follow up ranging from 28 to 175 days, four out of six patients met the American College of Rheumatology 20% improvement criteria (ACR20) response, with two of these patients additionally achieving an ACR50 response (meeting 50% improvement thresholds).

“These are encouraging results in patients with long-standing, treatment-resistant rheumatoid arthritis for whom KYV-101 could offer profound relief from this debilitating disease," said David Simon, M.D., Ph.D., Head of the Clinical Trial Unit in the Department of Rheumatology and Clinical Immunology at Charité, University of Berlin and Principal Investigator of the COMPARE trial. “These data highlight the safety and potency of KYV-101, with a rapid decline in key biomarkers and promising clinical response that are especially meaningful since all treated patients had failed multiple prior therapies. We believe these observations warrant further study of KYV-101 in RA as we progress into the Phase 2 portion of the study.”

These results supported the initiation of the randomized Phase 2 portion of the study, which is currently ongoing with patient enrollment completed.

Presentation Details

Title: An Open-label, Randomized, Controlled Phase 1/2 Study to Assess the Safety and Efficacy of KYV-101 Anti-CD19 CAR-T Cell Therapy in Active and Difficult-to-treat Rheumatoid Arthritis: Preliminary Results of the COMPARE Trial
Presenter: Dr. Ioanna Minopoulou, M.D., MSc, Charité, University of Berlin
Session: Rheumatoid Arthritis – Treatment Poster I, Poster Session A
Date and Time: Sunday, October 26, 2025, 10:30 AM - 12:30 PM CT

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 Rheumatoid Arthritis
Rheumatoid arthritis is a chronic and systemic autoimmune disease in which the immune system attacks the lining of the joints, causing persistent inflammation that leads to pain, swelling, disability and stiffness of multiple joints. Over time, ongoing immune activity can erode cartilage and bone, resulting in progressive joint damage and deformity. RA can also cause inflammation in other organs, including blood vessels, the lungs and heart, contributing to fatigue and overall reduced quality of life. Autoantibodies produced by B cells, most notably rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPAs), represent a hallmark of RA and play a key role in driving disease. While current therapies, including biologic and targeted synthetic agents, aim to manage symptoms and slow or prevent joint damage, many patients continue to experience persistent disease activity or lose response over time.

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 ACR Convergence 2025 meeting; KYV-101's potential to deliver durable drug-free, disease-free remission with a single dose; KYV-101's potential to continue to demonstrate a consistent and well-tolerated profile and its potential to offer profound relief from RA; Kyverna's potential to address serious autoimmune diseases beyond its core neuroimmunology CAR T programs; 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.