Kyverna Therapeutics Highlights Updated Miv-cel Data at EULAR Demonstrating Substantial Reduction in Disease Activity in ACPA-Positive, Treatment Refractory Rheumatoid Arthritis

June 3, 2026

Majority of patients met the American College of Rheumatology improvement criteria (ACR70) response by Week 36

Single-dose of miv-cel delivered deep B-cell depletion with evidence of immune reset

Miv-cel continues to demonstrate a well-tolerated safety profile, consistent with observations from over 100 patients treated to date[1]

Data reinforce miv-cel's differentiated clinical profile and opportunity to change the treatment paradigm across a variety of autoimmune diseases

EMERYVILLE, Calif., June 03, 2026 (GLOBE NEWSWIRE) -- Kyverna Therapeutics, Inc. (Nasdaq: KYTX), a late-stage clinical biopharmaceutical company developing cell therapies for patients with autoimmune diseases, today announced the presentation of updated data from the Phase 1 portion of COMPARE, a Phase 1/2 investigator-initiated trial (IIT) evaluating miv-cel (mivocabtagene autoleucel, KYV-101) in patients with active anti-citrullinated protein antibody (ACPA)-positive, treatment-refractory rheumatoid arthritis (RA). The data will be presented today in an oral presentation by Charité - University of Berlin at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress in London.

Building on the safety and efficacy results reported at ACR Convergence 2025, the updated data showed a single dose of miv-cel resulted in deep B-cell depletion with subsequent reconstitution with a naïve B-cell phenotype in ACPA-positive RA patients. These findings demonstrate the potential of an immune reset and translate into meaningful clinical improvement.

"We're very pleased to see this updated data add to the growing body of evidence underscoring miv-cel's profound clinical activity across multiple autoimmune indications," said Naji Gehchan, Chief Medical and Development Officer of Kyverna Therapeutics. "In this heavily pre-treated patient population with difficult-to-treat ACPA-positive rheumatoid arthritis, miv-cel demonstrated deep B-cell depletion and substantial reduction in disease activity and disease-associated autoantibodies, highlighting its promising potential to redefine how we treat this debilitating disease."

Charité – University of Berlin Oral Presentation

The COMPARE trial is an open-label, randomized, controlled Phase 1/2 study evaluating miv-cel against the anti-CD20 monoclonal antibody rituximab in patients with active 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 median of 6.5 prior biologic and targeted synthetic disease-modifying anti-rheumatic drugs (DMARDs) before entering the study. Patients received a single infusion of 1×10^8 miv-cel CAR T cells following lymphodepletion with follow-up ranging up to 52 weeks. The primary endpoint for the Phase 1 study was safety and tolerability with patients additionally evaluated for efficacy and key biomarkers of RA.

Key findings are summarized as follows:

- **Deep depletion of autoreactive CD19+ B cells and plasmablasts** in periphery and tissues.
- **Rapid and substantial reduction in disease-associated autoantibodies,** including ACPA, rheumatoid factor immunoglobulin A (IgA) and M (IgM), for up to 52 weeks, while preserving long-term protective vaccine immunity.
- **Substantial reduction in disease activity** in all six patients who showed fewer tender and swollen joints and less joint inflammation following a single dose of miv-cel. In addition, the majority of patients (66.6%) met the ACR70 response by Week 36.
- **Evidence of immune reset with repopulated B-cells** returning as predominantly naïve and transitional cells.
- **Well-tolerated safety profile** with no high-grade cytokine release syndrome (CRS) and no immune effector cell-associated neurotoxicity syndrome (ICANS).

"Miv-cel is delivering a depth of B-cell depletion that we have not seen with existing therapies in patients with difficult-to-treat rheumatoid arthritis," said David Simon, M.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. "Notably, miv-cel clears disease-driving B cells from key tissues, such as bone marrow and inflamed joints. When peripheral B cells return, they predominantly show a naïve and transitional phenotype, and ACPA titers continue to decline in a majority of patients, supporting the potential for a durable immune reset following a single dose of miv-cel."

Based on the Phase 1 findings, the Phase 2 portion of the COMPARE trial has been initiated and is fully enrolled. This trial compares B-cell depletion with miv-cel versus rituximab in patients with active ACPA-positive, treatment refractory RA with moderate to high disease activity.

EULAR Presentation Details

- **Title:** CD19 CAR T-Cell Therapy in Active ACPA-Positive, Treatment-Refractory Rheumatoid Arthritis - Data from the Phase 1 of the Prospective, Interventional COMPARE Trial
- **Presenter:** Dr. Fredrik Albach, Charité, University of Berlin, on behalf of the COMPARE trial investigators
- **Session:** Abstract Plenary Session
- **Date and Time:** Wednesday, June 3, 2026, 12:40-12:50 PM EST

About Rheumatoid Arthritis
Rheumatoid arthritis (RA) 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 anti-citrullinated protein antibodies (ACPAs) and rheumatoid factor (RF), 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 miv-cel (mivocabtagene autoleucel, KYV-101)
Miv-cel is a fully human, autologous, CD19-targeting 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, miv-cel 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 late-stage clinical biopharmaceutical company focused on liberating autoimmune patients through the curative potential of cell therapy. Kyverna's lead autologous CD19-targeting CAR T-cell therapy candidate, miv-cel (mivocabtagene autoleucel, KYV-101), has demonstrated the potential to fundamentally change the treatment paradigm across multiple B-cell-driven autoimmune diseases. Kyverna is advancing its potentially first-in-class neuroimmunology franchise with its recently completed registrational trial in stiff person syndrome (SPS) and an ongoing registrational trial for generalized myasthenia gravis. The Company has initiated its rolling BLA submission for SPS with the FDA. It is also harnessing other KYSA trials and investigator-initiated trials, including in multiple sclerosis and rheumatoid arthritis, to inform the next priority indications. Additionally, its next generation pipeline includes CAR T-cell therapies deploying novel innovations to improve patient access and experience. 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: miv-cel's profound clinical activity across multiple autoimmune indications; miv-cel's potential to change the treatment paradigm across a variety of autoimmune diseases, including its potential to provide a durable immune reset with a single dose and its promising potential to redefine how ACPA-positive RA is treated, and to achieve deep B-cell depletion and immune system reset to deliver durable drug-free, disease-free remission in autoimmune diseases; Kyverna's expected timing for reporting data from the Phase 2 portion of COMPARE; Kyverna's pipeline opportunities; Kyverna's rolling BLA SPS submission; and Kyverna's potentially first-in-class neuroimmunology franchise. 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; 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 miv-cel (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.