Kyverna Therapeutics Announces New Patient Data Highlighting Potential of KYV-101 for Treatment of Lupus Nephritis in Symposium at ACR Convergence 2024

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Positive Sustained Efficacy and Durability at >6-month Follow-Up Observed in Patients With Severe Lupus Nephritis (LN) Treated With KYV-101 Target Dose

KYV-101 Treatment Continues to Demonstrate Robust Safety and Tolerability With No High-Grade CRS or ICANS Observed

EMERYVILLE, Calif., Nov. 14, 2024 /PRNewswire/ -- Kyverna Therapeutics, Inc. (Kyverna), a clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases, announces today that it will present updated clinical data from LN patients treated with KYV-101 in ongoing Kyverna-sponsored KYSA-1 and KYSA-3 Phase 1/2 studies and named patient treatments. Kyverna, alongside leading academic collaborators, will highlight all six patients treated with the target dose of 1×10^8 CD19 CAR T cells, four of which have at least six months of follow-up. All patients at six months of follow-up after treatment at the target dose continue to display sustained efficacy and durability across numerous key clinical measures.

These updates will be presented at a company symposium titled, "*KYV-101 Anti-CD19 CAR T-Cell Therapy: The Future of Autoimmune Disease Treatment*," to be held at 5:45 pm ET on November 18, 2024. Slides from the presentation will be posted to the company website following the symposium.

"Lupus nephritis patients encounter a tremendous burden of disease associated with high morbidity and mortality, with up to 30% of patients ultimately experiencing end-stage renal disease that requires dialysis or kidney transplant," said Prof. Georg Schett, M.D. from the Friedrich-Alexander-University in Erlangen, Germany, and one of the presenters. "The data reinforce that treatment with KYV-101 drives deep B cell depletion in patients with LN, and appears to reset the immune system, stabilize eGFR, preserve kidney function and enable clinical improvement in SLE activity. Notably, this clinical benefit is occurring while also eliminating immunosuppressants and reducing glucocorticoids to physiologic levels with a manageable safety profile."

"As our KYV-101 clinical datasets mature, we are increasingly able to focus on the right patients, treated at the right dose, with the right protocol. We are excited to share these new data, which continue to reinforce KYV-101's potential for durable and life-changing outcomes in lupus nephritis patients, including those with high chronicity and disease severity," said Warner Biddle, Chief Executive Officer at Kyverna.

Additional Updates:

Also at ACR Convergence 2024, Kyverna will present data on next-generation approaches, most notably with a poster on Ingenui-T, the Company's preclinical 3-day manufacturing process using autologous whole blood as starting material. Ingenui-T is designed to improve the patient experience by eliminating apheresis, leading to a potential for improved convenience, access and overall cost reduction. As the poster highlights, drug product from the Ingenui-T process manufactured with whole blood from patients with SLE or healthy donors displayed product characteristics similar to KYV-101.

In addition, results from collaborative work on the molecular mechanisms underlying immune reset through deep B-cell depletion with CD19 CAR T-cell therapy performed in collaboration with Verily Life Sciences, an Alphabet precision health company, and the University of Erlangen will be shared as an oral presentation.

The posters and slides from the oral presentation at ACR Convergence 2024 will be available on the publications page of Kyverna's website.

About Lupus Nephritis (LN)
Lupus nephritis (LN) is a serious complication of systemic lupus erythematosus (SLE), more commonly known as lupus. Approximately 40 percent of adults diagnosed with lupus eventually develop LN and 60 percent or more of LN patients will fail standard of care and approved treatments[1,2]. Aside from modest efficacy, current treatments expose these young adults to the well-demonstrated detrimental consequences of chronic treatment with corticosteroids and other powerful immunosuppressants. Up to 30 percent of patients with LN will develop kidney failure, requiring dialysis or a kidney transplant to stay alive[3].

About KYV-101
KYV-101 is an autologous, fully human CD19 CAR T-cell product candidate for use in B cell-driven autoimmune diseases. The CAR in KYV-101 was

designed by the National Institutes of Health (NIH) to improve tolerability and tested in a 20-patient Phase 1 trial in oncology. Results were published by the NIH in Nature Medicine[4]. KYV-101 is currently being evaluated in sponsored, open-label, Phase 1/2 and Phase 2 trials in the United States and Germany across two broad areas of autoimmune diseases, rheumatologic and neuroinflammatory, as well as in investigator-initiated trials for multiple indications in multiple geographies. The clinical experience to date with KYV-101 in both oncological and autoimmune diseases highlights the differentiated properties of KYV-101 and the potential to treat autoimmune patients.

About Kyverna Therapeutics
Kyverna Therapeutics, Inc. (Nasdaq: KYTX) is a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases. Our lead CAR T-cell therapy candidate, KYV-101 is advancing through clinical development with sponsored clinical trials across two broad areas of autoimmune disease: rheumatology and neurology, including Phase 2 trials for stiff-person syndrome, multiple sclerosis and myasthenia gravis, a Phase 1/2 trial for systemic sclerosis, and two ongoing multi-center Phase 1/2 trials in the United States and Germany for patients with lupus nephritis. Kyverna's pipeline includes next-generation CAR T-cell therapies in both autologous and allogeneic formats with properties intended to be well suited for use in B cell-driven autoimmune diseases.

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 potential impact of the clinical outcomes from the ongoing clinical programs; the potential impact of the new data on the treatment efficacy and safety profile of KYV-101; the potential that the results of the ongoing trials could drastically change the treatment landscape for the targeted autoimmune diseases; Kyverna's goals to develop certain paradigm-shifting treatment options; the potential for KYV-101 to provide durable, immunosuppressant-free remission for autoimmune disease patients; Kyverna's beliefs about the differentiated properties of KYV-101; and Kyverna's clinical trials and named-patient activities. 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, 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.

Contact:
Consort Partners for Kyverna: kyvernatx@consortpartners.com
Investors: InvestorRelations@kyvernatx.com
Media: media@kyvernatx.com

[1]Anders et al., *Nat Rev Dis Primers*. 2020; 6:7.
[2]Parodis et al., *Autoimmun Rev*. 2024; 23:103418.
[3]Lateef and Petri, *Arthritis Res & Ther.* 2012; 14(Suppl 4):S4.
[4]Brudno et al., *Nature Medicine.* 2020; 26:270-280.