Kyverna Therapeutics and Stanford University Agree to Evaluate KYV-101 in Patients with Non-Relapsing and Progressive Forms of Multiple Sclerosis

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The Investigator-Initiated Trial will assess the safety, tolerability, and clinical activity of KYV-101, a fully human anti CD19 CAR T-cell therapy in up to 12 study participants

The clinical study will be supported by cutting edge correlative studies funded through a parallel research collaboration between Kyverna and Stanford University

The agreements further expand the scale of ongoing clinical studies assessing the potential therapeutic effects of KYV-101 in multiple diseases and locations around the world

EMERYVILLE, Calif., March 7, 2024 /PRNewswire/ -- Kyverna Therapeutics, Inc. (Kyverna), a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, today announced the signature of a collaboration agreement with Stanford University to allow the use of KYV-101, an investigational, anti-CD19 CAR T-cell therapy in an open label, phase 1 investigator-initiated trial (IIT) in nine to twelve adult subjects with non-relapsing and progressive forms of multiple sclerosis. Each participant will receive a single dose of KYV-101.

A parallel agreement will support the development of correlative studies thoroughly investigating disease biology upon KYV-101 infusion in MS patients, including the definition of predictors of response and the potential for immune reset.

The investigator-initiated trial adds to the Kyverna-sponsored KYSA-7 Phase 2 study in MS and other sponsored KYSA trials in other rheumatological and neurological autoimmune disorders.

"We foresee great therapeutic potential for CAR T-cell therapy for immune-mediated disease of the nervous system. This phase 1 trial is a first-in-human study that will assess safety, feasibility, and tolerance in patients with non-relapsing multiple sclerosis for which there is no proven treatment," said Jeffrey Dunn, M.D., the Lily Sarafan director of Neuroimmunology and clinical professor and chief of Neuroimmunology within the Department of Neurology and Neurological Sciences at Stanford University in Palo Alto, California. "We are grateful for the opportunity to join forces with Kyverna to explore what may prove to be paradigm-changing immunotherapy.".

"As CAR T-cell therapies are entering the field of B cell-driven autoimmunity, leveraging on our knowledge and expertise in oncology will provide a faster option to address an unmet medical need and make these potentially life-changing therapies available to non-cancer patients," said Robert Lowsky, M.D., professor of medicine, Division of Blood and Marrow Transplantation and Cellular Therapy at Stanford University in Palo Alto, California.

"We are excited about the interest shown by world-class institutions like Stanford to evaluate the clinical performance of KYV-101 in patients suffering from multiple sclerosis," said Peter Maag, Ph.D., chief executive officer of Kyverna. "We look forward to enriching our collective knowledge about the potential paradigm-shifting value of CAR T-cell therapy through these dedicated collaborations between Industry and Academia."

CAR T-cell therapy involves modifying a patient's T cells to recognize and remove B cells in the patient's body. Kyverna's CD19 CAR T-cell therapy, KYV-101, specifically targets CD19, a protein expressed on the surface of B cells, which are involved in various types of autoimmune diseases. Kyverna plans to continue to explore additional indications for KYV-101 and develop a robust pipeline of promising product candidate immunotherapies aimed at addressing unmet medical needs in autoimmune diseases.

About Multiple sclerosis (MS)

Multiple sclerosis is a chronic neurodegenerative autoimmune disease affecting over 2.8 million individuals worldwide[1]. It affects more frequently women, people of Northern European descent, and is also associated with certain environmental and genetic factors. Patients with MS can experience a range of symptoms including blurred vision, slurred speech, tremors, numbness, extreme fatigue, problems with memory and concentration, and, in severe cases, the inability to walk or stand.
Current disease-modifying treatments for MS aim to reduce the frequency of disease relapses and delay progression of disability, but the disease remains a chronic condition that will progressively worsen for most patients.

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*[2].

KYV-101 is currently being evaluated in sponsored, open-label trials of KYV-101 in patients with lupus nephritis, an autoimmune disease in which more than half of patients do not achieve a complete response to current therapies and are at risk of developing kidney failure. Additionally, FDA's IND clearance has been obtained for Phase 2 trials of KYV-101 for multiple sclerosis and myasthenia gravis, and a Phase 1/2 trial for systemic sclerosis.

We believe that the differentiated properties of KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.

KYV-101 is also being evaluated in investigator-initiated trials for multiple indications in multiple geographies.

About Kyverna Therapeutics

Kyverna Therapeutics (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 multiple sclerosis and myasthenia gravis, a Phase 1/2 trial for systemic

sclerosis, and two ongoing multi-center, open-label Phase 1 trials in the United States and Germany for patients with lupus nephritis.

Kyverna's pipeline includes next-generation chimeric antigen receptor (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.

By advancing more than one mechanism for taming autoimmunity, Kyverna is positioned to act on its mission of transforming how autoimmune diseases are treated.

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. 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 the final prospectus. 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.

For more information, please visit https://kyvernatx.com.

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1. Walton C, et al. Mult Scler. 2020; 26:1816-1821.
2. Brudno et al., Nature Medicine 2020; 26:270-280.

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