Kyverna's KYV-101 Receives U.S. FDA IND Clearance for Treatment of Patients With Treatment-Refractory Stiff-Person Syndrome in the KYSA-8 Phase 2 Trial

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This IND clearance expands the use of KYV-101 CAR T-cell therapy in a Phase 2, open-label KYSA-8 clinical trial targeting a devastating neuroimmunological autoimmune disease

KYV-101 is a fully human anti-CD19 CAR T-cell therapy designed for use in patients with B cell-driven autoimmune diseases

EMERYVILLE, Calif., June 20, 2024 /PRNewswire/ -- Kyverna Therapeutics, Inc. (Kyverna), a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, announced today the clearance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) for its autologous, fully human anti-CD19 chimeric antigen receptor (CAR) T-cell product candidate, KYV-101, to be used for the treatment of stiff-person syndrome (SPS) in Kyverna's trial, named KYSA-8.

"CAR T-cell therapy has already shown preliminary but promising results in patients with SPS treated outside of the US," said Marinos Dalakas, M.D., FAAN, Professor of Neurology, Director of the Neuromuscular Division at Thomas Jefferson University School of Medicine in Philadelphia, PA, and a leading physician and researcher on SPS. "I find the KYSA-8 trial of extraordinary importance as a promising novel therapy for patients with stiff person syndrome who do not respond to current therapies, with implications in providing potentially long-lasting benefits."

"The IND clearance gives us confidence in our dedication to bringing a potential paradigm shift in the treatment of patients suffering from SPS and reaffirms a target dose of 100 million cells for KYV-101," said Sham Dholakia, M.D., business unit head rare diseases at Kyverna. "We are also very grateful to the FDA for the collaborative approach and timely vetting of our clinical trial design."

About Stiff Person Syndrome (SPS)
SPS is a rare, progressive neurological autoimmune disorder causing debilitating muscle stiffness in the torso, arms, and legs, impacting the ability to walk or move. Patients typically present with muscle spasms and stiffness, resulting in difficulty turning and bending. When stiffness is severe, the patient's walking resembles a statue. Muscle spasms and stiffness can be precipitated by unexpected stimuli, including sounds, like a phone ring or a siren, sudden touches or conditions triggering anxiety and emotional upset which, when severe, are misdiagnosed as a primary anxiety disorder[1].

There is no cure for SPS, but only treatments focused on treating the symptoms.

About KYV-101
KYV-101 is an autologous, fully human anti-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, Phase 1/2 and Phase 2 trials of KYV-101 in the United States and Germany across two broad areas of autoimmune disease: rheumatology and neurology.

With 50 patients treated so far with the CAR in KYV-101 in both oncological and autoimmune conditions at more than 15 locations in Europe and the U.S., 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, 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, open-label 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.

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 efficacy of KYV-101 in patients with SPS, the potential that the results of the KYSA-8 trial could usher in a transformational event in the treatment of SPS patients; Kyverna's goals to develop certain paradigm-shifting treatment options; Kyverna's beliefs about the differentiated properties of KYV-101; and Kyverna's clinical trials. 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.

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

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[1] Dalakas, M.C., Neurotherapeutics 2022; 19, 832–847.
[2] Brudno et al., Nature Medicine 2020; 26:270-280.

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