First-in-Disease Use of Kyverna Therapeutics' KYV-101 in Patient With Severe Stiff-Person Syndrome Published in Proceedings of the National Academy of Sciences (PNAS)

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Patient received KYV-101, a fully human anti-CD19 CAR T-cell product candidate, as part of a named-patient treatment option after failure to respond to conventional therapies

Significant improvement in walking distance and 40% reduction in GABAergic medications were among the reported results

Well-tolerated treatment with low-grade CRS and no ICANS supports continued exploration of KYV-101 in neuroimmunological disease

EMERYVILLE, Calif., June 17, 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 publication in Proceedings of the National Academy of Sciences (PNAS)[1] of a report describing the first use of KYV-101, a fully human anti-CD19 chimeric antigen receptor (CAR) T-cell product candidate, in a 69-year-old patient suffering from treatment-refractory stiff-person syndrome (SPS) as part of a named-patient use in Germany for critically ill individuals who fail conventional therapies.

"It is extremely encouraging to see this patient improving the self-reported, uninterrupted walking distance from less than 50 meters to several kilometers within three months after treatment," said Simon Faissner, M.D., professor for translational neuroimmunology at the Department of Neurology, Ruhr University Bochum, St. Josef Hospital, in Germany, and lead co-author. "These dramatic improvements – if confirmed by further studies – may eventually provide renewed hope for a much-needed paradigm shift in the treatment of debilitating autoimmune diseases."

"It is remarkable to observe the transformational effects in a patient deemed refractory to available standard treatments. With the disease progressing over several years despite the best medical treatment, I recommended the CAR T-cell therapy approach," said Ralf Gold, M.D., professor of Medicine, chair of Neurology at Ruhr University Bochum, St. Josef Hospital, in Germany, and senior co-author. "The absence of observed neurotoxicity and the measured impact on the pathogenic anti-GAD65 autoantibodies pave the way for additional studies to confirm the initial, promising findings."

"On the heels of recent case reports of the use of KYV-101 in multiple sclerosis and myasthenia gravis, we are excited to see positive outcomes of KYV-101 in a patient suffering from SPS," said Peter Maag, Ph.D., chief executive officer of Kyverna. "These data underscore the dedication of the Kyverna village to patient care and scientific advancement."

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[2]. There is no cure for SPS, but only treatments focused on the symptoms.

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[3].

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 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, or that the results of any named patient activities may be repeated in any clinical trials; the potential impact of named-patient case reports; 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.

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

[1] Faissner S, et al. *PNAS*. 2024;121: e2403227121. doi.org/10.1073/pnas.2403227121

[2] Dalakas, M.C., *Neurotherapeutics* 2022; 19, 832–847.

[3] Brudno et al., *Nature Medicine* 2020; 26:270-280.

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