Kyverna Therapeutics Announces FDA Clearance of Phase 2 IND for KYV-101, a Fully Human CD19 CAR T-Cell Therapy to Treat Myasthenia Gravis

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The investigational therapy will be used in Kyverna's KYSA-6 Phase 2 open-label, multicenter study to evaluate KYV-101 in adult patients with myasthenia gravis

This is the fifth IND clearance for KYV-101, a fully human CD19 CAR T-cell therapy designed for use in patients with B cell-driven autoimmune diseases.

EMERYVILLE, Calif. Nov. 13, 2023 – Kyverna Therapeutics, Inc. ("Kyverna"), a patient-centered clinical-stage biopharmaceutical company focus on developing cell therapies for patients suffering from autoimmune diseases, today announced the clearance of its fifth Investigational New Drug (IND) application for KYV-101 by the U.S. Food and Drug Administration (FDA). This will allow Kyverna to initiate a Phase 2 open-label, multicenter study of KYV-101, an autologous, fully human CD19 chimeric antigen receptor (CAR) T cell product candidate for the treatment of myasthenia gravis (MG).

The trial, named KYSA-6, expands Kyverna's current pipeline, which includes the ongoing Phase 1 KYSA-1 trial in the U.S. and the ongoing Phase 1/2 KYSA-3 trial in Germany, where KYV-101 is currently investigated in adults with active lupus nephritis, and the ongoing Phase 1/2 KYSA-5 trial in adults with diffuse cutaneous systemic sclerosis in the U.S. Kyverna also obtained clearance of two additional INDs for investigator-initiated trials of KYV-101 in the U.S.

"We have seen firsthand the transformative effects of KYV-101 in MG patients treated with the investigational therapy in our clinic," said Prof. Aiden Haghikia, Director, Department of Neurology, Medical Faculty, Otto-von-Guericke University, Magdeburg, Germany. "I welcome the FDA's decision and look forward to more clinical data to further our knowledge about CAR T-cell therapy in patients with severe neurological autoimmune diseases."

"We are grateful that the FDA's decision to clear the IND for our Phase 2 KYSA-6 trial will allow Kyverna to offer this potentially paradigm shifting investigational treatment to patients that may benefit from a deep B cell depletion and possibly durable reset of their immune system," said Peter Maag, Ph.D., chief executive officer of Kyverna.

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 is 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 Myasthenia gravis (MG)

Myasthenia gravis is an autoimmune disorder associated with muscle weakness in tissues throughout the body, potentially manifesting in partial paralysis of eye movements, problems in chewing and swallowing, respiratory problems, speech difficulties and weakness in skeletal muscles. MG patients develop antibodies that lead to an immunological attack on critical signaling proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. The symptoms of the disease can be transient and in the early stages of the disease can remit spontaneously. However, as the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months. Disease symptoms reach their maximum levels within two to three years in approximately 80% of patients. Up to 20% of MG patients experience respiratory crisis at least once in their lives.

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[1].

Kyverna is currently conducting two 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. Additional clinical trials of KYV-101 in systemic sclerosis, myasthenia gravis, and multiple sclerosis are in preparation. We believe that the differentiated properties of KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.

About Kyverna Therapeutics

Kyverna is a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases. As our lead product candidate, KYV-101 is advancing through clinical development across two broad areas of autoimmune disease: rheumatology and neurology, including two ongoing multi-center, open-label Phase 1 trials of KYV-101 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. For more information, please visit https://kyvernatx.com.

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