Kyverna Therapeutics Granted FDA Fast Track Designation for KYV-101 in the Treatment of Patients With Refractory Myasthenia Gravis

December 13, 2023

The announcement follows the recent IND clearance for KYV-101 to be used in Kyverna's KYSA-6 Phase 2 open-label, multicenter study

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

EMERYVILLE, Calif., December 13, 2023 – Kyverna Therapeutics, Inc. ("Kyverna"), a patient-centered clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, today announced it received fast track designation by the U.S. Food and Drug Administration (FDA) for its autologous, fully human CD19 chimeric antigen receptor (CAR) T-cell product candidate, KYV-101, to be used for the treatment of myasthenia gravis (MG).

Fast track designation is a program intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition.

"We are very happy to receive this important designation for KYV-101 in the KYSA-6 trial and remain committed to improving the lives of patients living with severe and debilitating neurological autoimmune diseases.", said Peter Maag, Ph.D., chief executive officer of Kyverna. "This is the second time KYV-101 has received such designation, after obtaining the first one for lupus nephritis earlier this year."

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(MG)

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(MG)

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.