Kyverna Therapeutics Granted FDA Fast Track Designation for KYV-101 in the Treatment of Patients With Refractory Progressive Multiple Sclerosis

January 19, 2024

The announcement follows the recent IND clearance for KYV-101 to be used in Kyverna's KYSA-7 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., January 19, 2024 – 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 multiple sclerosis (MS).

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

"We appreciate the FDA's support to accelerate the development of potentially life-changing CAR T-cell therapies that could greatly benefit patients living with severe and debilitating neurological autoimmune diseases." said Peter Maag, Ph.D., chief executive officer of Kyverna. "This marks another important milestone in our endeavor to change the treatment paradigm with KYV-101."

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 Multiple sclerosis (MS)

Multiple sclerosis is a chronic neurodegenerative autoimmune disease affecting over 2.8 million individuals worldwide1. 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 Medicine2.

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.

Kyverna Media Contact:

Consort Partners for Kyverna
kyvernatx@consortpartners.com

# # #

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