Kyverna Therapeutics Announces FDA Clearance of IND for KYV-101, a Novel Fully Human CD19 CAR T-Cell Therapy to Treat Scleroderma

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The investigational therapy will be used in Kyverna's KYSA-5 Phase 1/2 open-label, multicenter study to evaluate KYV-101 in adult patients with diffuse cutaneous systemic sclerosis (scleroderma)

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

EMERYVILLE, Calif. October 11, 2023 – Kyverna Therapeutics ("Kyverna"), a clinical-stage cell therapy company with the mission of engineering a new class of therapies for serious autoimmune diseases, today announced the clearance of their third 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 1/2 open-label, multicenter study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor (CAR) T cell therapy for the treatment of diffuse cutaneous systemic sclerosis (scleroderma).

The trial, named KYSA-5, adds to the ongoing Phase 1 KYSA-1 trial in the U.S. and the Phase 1/2 KYSA-3 trial in Germany where KYV-101 is currently investigated in adults with active lupus nephritis.

"We welcome Kyverna's enthusiasm and interest to push forward with their CAR T approach in scleroderma patients with the KYSA-5 trial," said Luke Evnin, chairman of the Scleroderma Research Foundation, "We await the results with optimism that CAR-T driven B cell ablation may ultimately deliver efficacy with adequate safety for a broader range of our patients than immune-ablative chemotherapy alone."

"We are immensely proud of being able to bring KYV-101 to patients suffering from scleroderma," said Peter Maag, Ph.D., chief executive officer of Kyverna Therapeutics." We are keen to initiate our KYSA-5 trial in this new patient population and generate data to support our KYV-101 design goals. With the deep B cell depletion from KYV-101 treatment, patients with scleroderma may have a full reset of their immune system to stop the vicious cycle of their overactive immune system."

About KYV-101

KYV-101 is an autologous version of a novel, fully human clinical-stage anti-CD19 chimeric antigen receptor (CAR) T cell construct with properties well suited for use in B cell-driven autoimmune diseases such as lupus nephritis, scleroderma, and other B cell-driven autoimmune diseases. In a 20-patient Phase 1/2 study in oncology, expected anti-lymphoma activity was associated with a significant reduction of cytokines released that translated into a strong reduction of cytokine-driven side effects such as the rate of immune effector cell-associated neurotoxicity syndrome (ICANS).[1] The fully human anti-CD19 CAR also translated into reduced immunogenicity that favorably impacted cell persistence at one month. Kyverna recognized that these properties singled out KYV-101 as a product ideally poised for use in patients with autoimmune diseases, and the company obtained exclusive, worldwide licenses from the National Institutes of Health (NIH) to use this CD19 construct in both autologous and allogeneic CAR T-cell therapies.

About Systemic Sclerosis

Systemic sclerosis (scleroderma) is a rare, chronic autoimmune disorder that affects the skin and internal organs and can have life-threatening complications.[2, 3] Severe scleroderma is associated with widespread pain, discomfort, and stiffness due to skin and joint involvement. Organ involvement may include interstitial lung disease, pulmonary hypertension, heart complications, kidney dysfunction, and gastrointestinal issues and may significantly reduce life expectancy. Managing severe scleroderma is complex and often requires a combination of medications, including immunosuppressants and disease-modifying drugs, as well as specialized care.

About Kyverna Therapeutics

Kyverna Therapeutics is a clinical-stage cell therapy company with the mission of engineering a new class of therapies for autoimmune and inflammatory diseases. The Kyverna therapeutic platform combines advanced T-cell engineering and synthetic biology technologies to suppress and eliminate the autoreactive immune cells at the origin of autoimmune and inflammatory diseases. Kyverna's pipeline includes next-generation chimeric antigen receptor (CAR) T-cell therapies in both autologous and allogeneic formats with properties well suited for use in B cell-driven autoimmune diseases. By offering 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.

[2]Bergamasco et al., *Clin Epidemiol* 2019; 11:257-273

[3]Adigun et al., Systemic Sclerosis. [Updated 2022 May 8].
https://www.ncbi.nlm.nih.gov/books/NBK430875/