Kyverna Therapeutics Announces Regulatory Approval of Phase 1/2 Clinical Trial for KYV-101 in Germany

July 6, 2023

Approval of the Phase 1/2 open-label clinical trial in lupus nephritis by the Paul Ehrlich Institute in Germany follows KYV-101 Fast Track Designation by the U.S. Food and Drug Administration earlier this year

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

EMERYVILLE, Calif., July 6, 2023 – Kyverna Therapeutics ("Kyverna"), a cell therapy company with the mission of engineering a new class of therapies for serious autoimmune diseases, today announced the approval of its first Clinical Trial Application (CTA) by the Paul-Ehrlich-Institut (PEI) in Germany for KYV101, a novel therapy for the treatment of lupus nephritis (LN). KYV 101 is a novel, fully human anti-CD19 chimeric antigen receptor (CAR) T-cell therapy for use in B cell-driven autoimmune diseases such as LN and represents an innovative approach to fighting autoimmune diseases by harnessing the power of the body's immune system.

"This approval recognizes the potential impact novel CD19 CAR T-cell therapies may bring to patients living with aggressive autoimmune diseases and reflects the global potential for KYV 101. We believe in changing the treatment paradigm by generating rigorous clinical data, and the PEI's approval paves the way to generate additional insights." said Peter Maag, Ph.D., chief executive officer of Kyverna Therapeutics.

CAR T-cell therapy involves modifying a patient's immune T cells to recognize and remove B cells in the patient's body. Kyverna's anti-CD19 CAR T-cell therapy, KYV 101, specifically targets CD19, a protein expressed on the surface of B cells, which are involved in various types of autoimmune diseases. This experimental treatment may offer new hope to patients who have exhausted conventional treatment options. As more patients commence their journey with KYV 101, Kyverna continues to explore additional indications for this therapy, as well as develop a robust pipeline of promising immunotherapies aimed at addressing unmet medical needs.

About Lupus Nephritis (LN)

Lupus nephritis (LN) is a serious complication of systemic lupus erythematosus (SLE), more commonly known as lupus. Approximately 40 percent of adults diagnosed with lupus eventually develop LN and 60 percent of LN patients will fail standard of care and approved treatments[1]. Aside from modest efficacy, current treatments expose these young adults to the well-demonstrated detrimental consequences of chronic treatment with corticosteroids and other powerful immunosuppressants. Up to 10 percent of patients with LN and 40 percent with diffuse LN (class IV) will ultimately develop kidney failure, requiring dialysis or a kidney transplant to stay alive[2].

About KYV-101

KYV 101 is an autologous version of a novel, fully human clinical-stage anti-CD19 chimeric antigen receptor T-cell (CAR T) construct with properties well suited for use in B cell-driven autoimmune diseases such as lupus nephritis 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 cells-associated neurotoxicity syndrome (ICANS)[3]. 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 autoimmune disease patients, 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 Kyverna Therapeutics

Kyverna Therapeutics is a 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 T-cell (CAR T) 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.

Media Contacts:

Kathy Vincent
Greig Communications, Inc.
kathy@greigcommunications.com

1. E. Carter et al., Nature Reviews Rheumatology, 12, Oct. 2016, 605-620.
2. Adv Chronic Kidney Dis. 2019;26(5):313.
3. Brudno et al., Nature Medicine 2020; 26:270-280.