



Kyverna Therapeutics Announces Publication in The Lancet Neurology of Case Report of Patient with Refractory Myasthenia Gravis Treated with Investigational KYV-101

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No adverse events related to CAR T-cell therapy 60 days post-infusion in patient suffering from severe, treatment-refractory, generalized myasthenia gravis

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

In addition to the use of KYV-101 in investigator-initiated trials and named patient activities, open-label Phase 1 and Phase 1/2 clinical trials for KYV-101 are actively recruiting patients with autoimmune disease at multiple sites in the US and Germany

EMERYVILLE, Calif Nov. 15, 2023 – Kyverna Therapeutics (“Kyverna”), a patient-centered clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases, today announced the publication in *The Lancet Neurology* of a Letter to the Editor by a group of German investigators describing the first case of treatment using KYV-101 in a 33 year-old patient with severe, treatment-refractory, anti-acetylcholine receptor auto-antibody positive, generalized myasthenia gravis (MG), who was treated on a named patient basis outside of a clinical trial setting.

Within the 2-month post-treatment follow-up period, the patient was not observed to experience any adverse events related to chimeric antigen receptor (CAR) T-cell therapy, such as cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS). In this period, the patient experienced improved muscle strength and reduced fatigue, along with elimination of B cells and a 70% reduction in pathogenic anti-acetylcholine receptor autoantibodies.

“We believe this case report provides compelling evidence for the potential of anti-CD19 CAR T-cell-mediated deep B cell depletion in inducing remission and improving symptoms in severe, treatment-refractory MG.”, said Aiden Haghikia, M.D. Director, Department of Neurology, Medical Faculty, Otto-von-Guericke University, Magdeburg, Germany, and lead author of the Letter.

KYV-101 is an autologous, fully human CD19 CAR T-cell product candidate for use in B cell-driven autoimmune diseases such as MG.

“We are extremely happy with the outcome so far, which suggests that a different CAR T-cell approach targeting CD19 with a stably expressed CAR, delivered following a conventional lymphodepleting regimen, has the potential to be safe and effective in severe and refractory MG.”, said Dimitrios Mouggiakakos, M.D., Director, Clinic of Hematology, Oncology, and Stem Cell Transplantation, Otto-von-Guericke University, Magdeburg, Germany, and senior author of the Letter.

“This groundbreaking case report rewards and reinforces our commitment to provide potentially paradigm-shifting therapeutic options to patients suffering from autoimmune diseases.”, said Peter Maag, Ph.D., chief executive officer of Kyverna Therapeutics. “We want to commend patients and their medical care teams that are helping advance the field of treatment options for B cell-driven autoimmune diseases.”

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