NOW ENROLLING

Clinical Trial in People With Myasthenia Gravis

A Phase 2, Open-Label, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell Therapy, in People with Refractory Generalized Myasthenia Gravis





What is myasthenia gravis?

Myasthenia gravis is a neuromuscular autoimmune disease that can impact the function of muscles throughout the body. There are two clinically recognized forms of myasthenia gravis: ocular and generalized myasthenia gravis. In ocular myasthenia gravis, muscles that control the movement of the eyes and/or eyelids are impacted. In generalized myasthenia gravis, varying combinations of muscles of the eyes/eyelids, arms, legs, and respiratory system may be impacted.



What are the possible treatments?

Myasthenia gravis can be treated with a variety of therapies including intravenous immunoglobulin (IVIg), plasma exchange, thymectomy, immunosuppressants, as well as newer treatments targeting B cells, complement inhibition, and neonatal Fc receptor inhibition. Your doctor can discuss with you the variety of treatment options for myasthenia gravis, including the benefits and risks of such options.



What is CAR T-cell therapy?

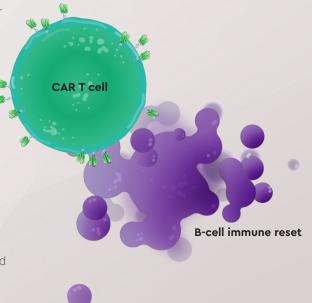
The investigational treatment called KYV-101 is a CAR T-cell therapy. CAR T-cell therapy is a type of treatment called immunotherapy. This means it works with your immune system to target the cells that harm your body. The CAR T cells in KYV-101 target and remove B cells in the body, including unhealthy B cells that drive inflammation and disease activity in myasthenia gravis.

This is the first study using KYV-101 in humans with myasthenia gravis, but KYV-101 has been used to treat individuals with myasthenia gravis under a form of compassionate-use treatment permitted in Germany and it is also being investigated in individuals with lupus nephritis, systemic sclerosis (scleroderma), multiple sclerosis, and stiff-person syndrome.



What is a clinical trial?

Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease. In a Phase 2 clinical trial, doctors want to understand if a treatment has a clinical benefit and is safe and well tolerated in humans.





About KYSA-6

The KYSA-6 trial is designed to evaluate if Chimeric Antigen Receptor (CAR) T-cell therapy is safe and effective in people with generalized myasthenia gravis who do not get better with standard therapies.



To learn more about this trial:

Visit: myastheniagravistrials.com **Email:** ClinicalTrialsInfo@kyvernatx.com



What will the KYSA-6 study involve?







SCREENING

You will undergo assessments and provide consent, if eligible.





APHERESIS

Giving blood to collect your T cells. Lasts 2-3 hours.





PREPARATION OF CAR T CELLS

Your T cells will be made into KYV-101 CAR T cells to recognize and remove B cells.





PREPARATION FOR TREATMENT

About 1 week before KYV-101 infusion, you will receive treatment to help prepare the immune system.



The KYV-101 CAR T cells are returned to your body via infusion.



HOSPITAL MONITORING



FOLLOW-U

Follow-up visits to monitor your health will be performed after KYV-101 infusion.

Beginning with KYV-101 infusion, you will be required to stay in the hospital at the trial site for 10 days so doctors can check how well you are responding to treatment and monitor any potential side effects.

Serious and potentially life-threatening side effects can occur from CAR T-cell therapy, including Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), and typically resolve within the first month after treatment.

- Symptoms of CRS include fever, nausea, feeling tired (fatigue), and body aches and can progress in severity and may include low blood pressure, high fever, shock, and potentially organ failure.
- Symptoms of ICANS include fatigue, uncontrolled movements (tremors), impairment in thinking, loss of speech, muscle weakness, or more severe symptoms such as seizures and swelling in the brain.



To learn more about this trial:

Visit: myastheniagravistrials.com **Email:** ClinicalTrialsInfo@kyvernatx.com

