

NOW ENROLLING

Phase 1/2 Trial in People With Lupus Nephritis

KYSA-1: A Phase 1/2, Open-Label, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell Therapy, in People With Refractory Lupus Nephritis



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 1/2 clinical trial, doctors want to understand if a treatment has a clinical benefit and is safe and well tolerated in humans.



About the trial

The KYSA-1 trial is designed to evaluate if Chimeric Antigen Receptor (CAR) T-cell therapy is effective and safe in people who have active lupus nephritis and do not get better with standard therapies.



What is lupus nephritis?

Lupus nephritis is a serious kidney manifestation of Systemic Lupus Erythematosus (SLE), which, if not treated, can lead to kidney failure over time.

SLE is a condition where the immune system is abnormally active and causes inflammation in various parts of the body, such as skin, joints, and internal organs such as the kidney.



What are the possible treatments?

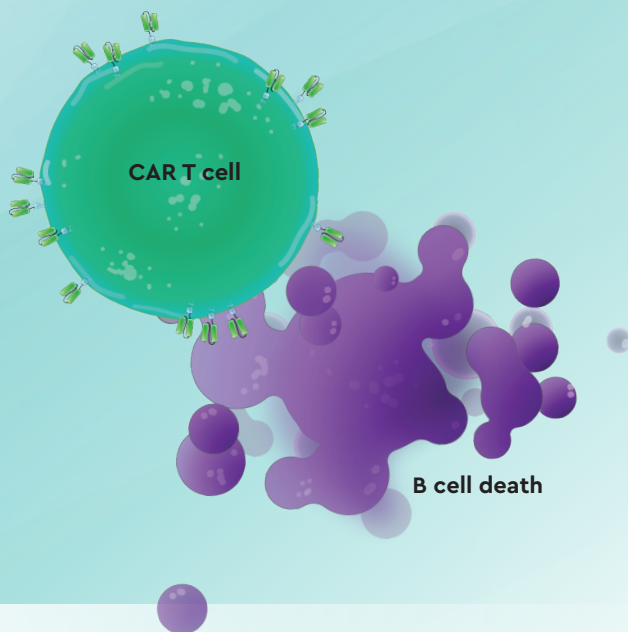
Lupus nephritis is typically treated with various medications, such as corticosteroids and other immune suppressive therapies. Your doctor can discuss with you the variety of treatment options for lupus nephritis, including the benefits and risks of such options.



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 lupus nephritis.

This is the first study using KYV-101 in humans with lupus nephritis, but another investigational CAR T-cell therapy has been used to treat people with lupus nephritis in Germany.



KYV-101 is an investigational therapy.



To learn more about this trial:

Visit: lupusnephritistrials.com

Email: ClinicalTrialsInfo@kyvernatx.com



What will the **KYSA-1** study involve?



SCREENING

You will undergo various study eligibility assessments and provide written consent to participate, if eligible.



APHERESIS

Apheresis is a procedure lasting approximately 2–3 hours in which your white blood cells, including T cells, will be collected from your blood.



PREPARATION OF CAR T CELLS

The collected T cells are altered into CAR T cells to recognize, attack and destroy B cells.



PREPARATION FOR TREATMENT

About 1 week before KYV-101 infusion, you will receive a short course of pre-dosing lymphodepletion therapy to prepare your body for the new CAR T cells.



KYV-101 INFUSION

The KYV-101 CAR T cells are returned to your body via infusion, delivered directly into your vein.



HOSPITAL MONITORING

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 high blood pressure and high fever, shock and potentially organ failure.
- Symptoms of ICANS include fatigue, uncontrolled movements (tremors), impairment in thinking, loss of speech, muscle weakness, seizures, and swelling in the brain.



FOLLOW-UP PERIOD

You will need to return to the trial site periodically for follow-up visits to have your health monitored for up to 24 months after KYV-101 infusion.

KYV-101 is an investigational therapy.

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To learn more about this trial:

Visit: lupusnephritis.trials.com

Email: ClinicalTrialsInfo@kyvernatx.com

