JOIN US

in our work to advance the care for Autoimmune Diseases

CALiPSO-1 will be enrolling patients with several different autoimmune diseases

Talk to your doctor today to determine whether you or someone you know may be eligible to receive CNTY-101 through the CALiPSO-1 clinical trial.

CALIPSO-1: A Phase 1 Study of CNTY-101, a CD19-targeted CAR-iNK Cell Product, in Participants with Refractory B cell-mediated Autoimmune Diseases

Clinical Trials.gov identifier: NCT06255028



CALiPSO-1 is a clinical trial to see how safe the treatment with CNTY-101 is. Another purpose is to see if the study treatment can improve your condition. The study treatment is an investigational study because it has not been approved by the US Food and Drug Administration (FDA) for use outside of a clinical study, including treatment of Systemic Lupus Erythematosus (SLE), Lupus Nephritis (LN), Idiopathic Inflammatory Myopathy (IIM), and Diffuse Cutaneous Systemic Sclerosis (DcSSc).

CNTY-101 is a type of cell therapy because it uses immune cells to treat autoimmune diseases including SLE, LN, IIM, and DcSSc. CNTY-101 is not made from your own cells; it is available to treat you if you and your doctor decide it is the right treatment for you and you qualify for participation. Therapies like CNTY-101 can potentially overcome many of the challenges of current available treatment. These challenges include

- Disease activity: In many patients, current treatments haven't made a significant difference in frequency or severity of symptoms, and it's rare for patients to get fully better long-term.
- Treatment toxicity and durability: Current treatments must be taken over long periods of time and have side effects, and symptoms may still return.

The duration of treatment will be two 29-day treatment cycles, consisting of three doses of CNTY-101 administered intravenously (IV) on days 1, 8 and 15 (Cycle 1), and three doses of CNTY-101 administered IV on days 1, 8 and 15, starting up to three weeks after Cycle 1 (Cycle 2). There will be administration of chemotherapy drugs before CNTY-101 to prepare your system and to allow the possibility for CNTY-101 to work better.

Century provides the following at NO COST to the patient:

A service for booking and prepaying for hotels and transportation.

Funds for meals for the patient and their significant other.

Additional stipend for lost wages or childcare can be provided as well depending on the location and your doctor's practices. Please talk with your doctor about the trial and the help you may be able to receive.





KEY INCLUSION CRITERIA

- Age ≥ 17 years
- Moderate to severe SLE, LN, IIM, or DcSSc
- Received at least two standard immunosuppressive therapies, but they did not work

KEY EXCLUSION CRITERIA

- Certain medications need to be decreased or stopped before treatment in this study. Ask your doctor for details.
- · Currently on hemodialysis
- Other health conditions may make you ineligible. Ask your doctor for details.

For a full list of inclusion/exclusion criteria, please visit: https://clinicaltrials.gov/study/NCT06255028.

For more information, please reach out to: ClinicalTeamCNTY@centurytx.com



What to Expect in the CALIPSO-1 Clinical Trial



SCREENING

You will be required to provide written consent to participate in the clinical trial. Within a month before treatment, you will go through various assessments to determine if you're eligible to participate in the clinical trial.

LYMPHODEPLETION

A treatment cycle will include Lymphodepleting Chemotherapy (LDC) for 3 days. For LDC, you will be treated with 2 agents: Fludarabine IV and Cyclophosphamide IV.

CNTY-101 INFUSION

You will be treated with CNTY-101 IV infusion on Days 1, 8 and 15 of Cycle 1 and Cycle 2.

INPATIENT MONITORING

After the first infusion, you will be required to stay in the hospital at the trial site for at least 3 days. This is to monitor your response to treatment.

PATIENT FOLLOW-UP

After leaving the hospital, you will need to stay within 1 hour of the trial site for 30 days following your first CNTY-101 treatment. After that, you will continue to be followed for a total of a year on this study.

FREQUENTLY ASKED QUESTIONS

What are clinical trials?

Clinical trials are research studies that test a new therapeutic in humans with the goal of finding better ways to prevent, diagnose or treat disease. A Phase I clinical trial determines if a treatment is safe and well tolerated.

What are Autoimmune Diseases?

Autoimmune diseases occur when the immune system starts attacking its own tissues and organs. Abnormal B-cell function and auto antibody production are central to how autoimmune diseases develop. B-cells play an important role in the immune system by producing antibodies to fight off infections and disease. In SLE, LN, IIM, and DcSSc, B-cells become overactive and produce auto antibodies that contribute to inflammation and tissue damage.

What are CD19-targeted therapies?

CNTY-101 is a CAR-iNK cell therapy targeting CD19. CD19 is a protein found only on B-cells. It's not present in other types of cells. Therefore, CD19 may be a good target for therapies that aim to remove B-cells from the body.

CNTY-101 is designed to:

- Specifically recognize and target CD19-expressing B-cells.
- Improve functionality and persistence of cells for potentially deeper and more durable responses via repeat dosing.
- Provide the option to eliminate the drug product if ever necessary.

