MT2024-07:A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Subjects with Active Systemic Lupus Erythematosus (RESET-SLE)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 18 to 65 years old - diagnosis of Systemic Lupus Erythematosus (SLE) - positive antinuclear antibody (ANA) titer or anti-dsDNA antibody

Exclusion Criteria:

- active infection requiring medical intervention - presence of kidney disease other than active lupus nephritis - prior solid organ (heart, liver, kidney, lung) transplant or hematopoietic cell transplant. - additional medical conditions (study staff will review)

Conditions & Interventions

Conditions:
Immune Diseases
Keywords:
Clinics and Surgery Center (CSC), Lupus, Lupus Nephritis, SLE, Systemic Lupus Erythematosus

More Information

Description: The purpose of this study is to find out what dose of CABA-201 can be safely administered to patients with SLE, including those with lupus nephritis (LN). SLE is thought to involve B cells that cause the body to attack different tissues in the body including your skin, joints, kidneys, heart, lungs, brain, and blood cells. LN is a type of kidney disease caused by SLE. CABA-201 is a chimeric antigen receptor T cell (CAR T) therapy. In this study, we will take some of your T cells, a type of white blood cell, and genetically modify them (put in a “code”) so that they may find and remove the B cells in your body, including the B cells that are involved in causing your disease. Once your cells are modified, CABA-201 cells will be re-infused into your body intravenously (through the vein).
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