[redacted]

For Health Care Professionals

About the [redacted] Clinical Trials

Trial purpose

The [redacted] Clinical Trials in Rheumatology are evaluating the efficacy and safety of an investigational CD19-targeted [redacted] autologous CAR T cell product in participants with a range of autoimmune diseases including systemic lupus erythematosus (SLE), systemic sclerosis (SSc), idiopathic inflammatory myopathies (IIM), and (RA) rheumatoid arthritis.[1]

Current [redacted] Clinical Trials in rheumatology

Below are select inclusion and exclusion criteria.

	Phase 2: [redacted][2]	Phase 1: [redacted][3]		
	SLE	SSc	IIM	RA
Inclusion Criteria	• Active disease • Failed steroids + ≥ 2 immunosuppressants	• Diffuse or limited cutaneous SSc with progressive ILD • Failed ≥ 1 immunosuppressant or IVIG	• Active disease: skin, muscle, CK > 3 × ULN, biopsy, or progressive ILD • Failed steroids + ≥ 2 immunosuppressants	• Active disease: ≥ 3 SJC + ≥ 3 TJC • Inadequate response to SoC (e.g., DMARDs, biologics, JAKi)
Exclusion Criteria	• Participants must not have other diseases, conditions, or treatments that may confound interpretation of the effects of [redacted] in SLE	• Other systemic autoimmune diseases (e.g., multiple sclerosis, psoriasis, inflammatory bowel disease, etc.)		
	Primary endpoint: DORIS drug-free remission at 6 months	**Primary endpoint:** Safety and tolerability as determined by the number of participants with SAEs, AEs, and dose-limiting toxicities and recommended phase 2 dose (RP2D)		

CK: creatine kinase, DMARDs: disease-modifying antirheumatic drugs, ILD: interstitial lung disease, IVIG: intravenous immunoglobulin, JAKi: Janus kinase inhibitor, SJC: swollen joint count, SoC: standard of care, TJC: tender joint count, ULN: upper limit of normal

What is the investigational therapy?

These studies are evaluating an investigational immunotherapy called autologous **chimeric antigen receptor (CAR) T cell therapy**.

- A **CAR** is a special receptor (a structure that receives a message to act a certain way in the body) created by scientists. CARs are made to recognize and bind with certain proteins (i.e., antigens) on other target cells.
- **T cells** are a kind of white blood cell, which attack foreign invaders in the body.

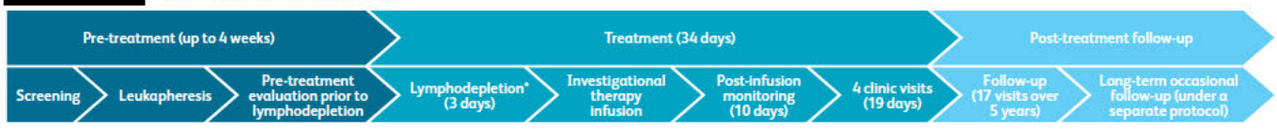
In autologous CAR T cell therapy, T cells are removed from the patient's blood, then, at a laboratory, the CAR sequence is introduced to T cells that may enable them to target and attack the potential cause of disease symptoms. Next, these T cells, now called autologous CAR T cells, are multiplied in the laboratory and then returned to the same person's bloodstream through an infusion at a later time.

Autologous CAR T cell therapy is being evaluated for use in many autoimmune conditions. It has been an innovative option for several types of blood cancers and is FDA approved as a therapy for leukemia, lymphoma, and multiple myeloma.[4]

Researchers are studying autologous CAR T cell therapy to see if it improves autoimmune diseases by helping the body destroy malfunctioning immune cells.

How long will the patient be in the trial?

[redacted] Schematic of Treatment



*Lymphodepletion for up to 3 consecutive days, starting approximately 5 days before the infusion of the study treatment, followed by a 2-day rest period

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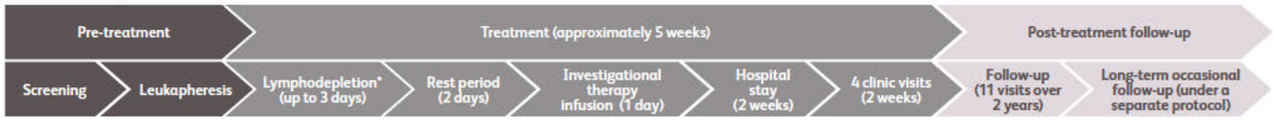

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Key discussion points with your patients considering autologous CAR T cell treatment

Study period details

- **Pre-study treatment period:** At screening, certain tests and procedures may be done to make sure you are eligible to participate in the study. To partake in the study, you will need to stop receiving your current treatment(s) – the study doctor will go over this process with you in detail.
  - In preparation for the investigational therapy, you will complete a procedure called **leukapheresis**. You will be connected to a machine that circulates your blood to collect the T cells that will then be genetically modified at a [redacted] laboratory before they are returned to your bloodstream at a later time. This procedure may take a few hours.
- **Study treatment period:** Following a single infusion of the investigational therapy, you will remain in the hospital for up to 2 weeks to be monitored. After this, you will be asked to remain within a 60-minute drive of your clinical study site for at least an additional 14 days* as you will attend clinic visits and undergo procedures such as vital sign measurements, physical exams, blood and urine sample collections, and questionnaires.
  - Before receiving the investigational therapy, you will undergo a treatment known as **lymphodepletion**. This treatment reduces certain white blood cells in the body so that they do not attack the autologous CAR T cells that are introduced during the investigational therapy infusion.
  - You will be contacted by an experienced autologous CAR T health care provider via phone call every day that you are not in the hospital or visiting the study site until the end of the first 4 weeks.
- **Study follow-up period:** The study team will check on your health after you have completed the full treatment period and are sent home. These visits will include procedures such as physical exams, blood and urine sample collections, and questionnaires. Some of these visits will be held in person, while others will be over the phone.
- **Long-term follow-up period:** After the study has been completed, you may enter a long-term follow-up if you choose. This will include occasional check-ins to monitor your health after receiving the investigational therapy and will mostly be conducted by phone.

[redacted] may be able to cover appropriate expenses for your stay once you are released from the hospital, including travel, meal expenses, and other costs. Please ask about patient caregiver support and other reimbursements.

What are the risks and benefits?

Each person's experience in this study will be different. You may face side effects, privacy risks, reproductive risks, and unknown risks associated with the investigational therapy.

It is not known whether a patient's disease will or will not improve from participating in this study. However, information gathered from it may help researchers learn more about the investigational autologous CAR T cell therapy that could benefit individuals with autoimmune disease.

Please ask the study team any questions you may have about study participation.

Is there a cost to participate?

All study-related tests and procedures will be provided at no cost. You may be reimbursed for travel and out-of-pocket expenses.

Can I withdraw from the study?

You can withdraw from the study at any time. Participation is completely voluntary, and you can change your mind about participation. Withdrawing from the study will not affect your future medical care or any other benefits you may otherwise be entitled to.

To discuss a potential patient referral, please contact the trial team from contact information on ClinicalTrials.gov or at [redacted].com.

[redacted] **For information about these trials ([redacted] and [redacted]) and a full list of site locations and contacts, visit [redacted].com.**

Disclaimer: Autologous CAR T cell therapy is not approved for the treatment of any autoimmune disease(s). It is available only to people with certain autoimmune diseases in clinical trials.

References: 1. CARTAutoimmune.com. Accessed October 2025. cartautoimmune.com/cart-t-in-autoimmune-diseases.html **2.** ClinicalTrials.gov. Accessed October 2025. clinicaltrials.gov/study/NCT[redacted] **3.** ClinicalTrials.gov. Accessed October 2025. clinicaltrials.gov/study/NCT[redacted] **4.** PennMedicine.org. Accessed October 2025. pennmedicine.org/cancer/navigating-cancer-care/treatment-types/immunotherapy/what-is-car-t-therapy

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