Who Qualifies for the RESOLUTION Trial?

Key Inclusion Criteria:

- **Age:** 18 to <70 years.
- **Confirmed Active Autoimmune Disease:**
  - **Lupus (SLE):** Active disease (e.g., SLEDAI-2K ≥6, and specific organ involvement despite ≥3 months of standard-of-care immunosuppression (in addition to HCQ).
  - **Myositis (IIM):** Active muscle, skin, OR lung involvement despite ≥3 months of standard-of-care immunosuppression (in addition to HCQ).
  - **Scleroderma (SSc):** Active disease (e.g., mRSS >10, or specific organ involvement) despite ≥3 months of standard-of-care immunosuppression.
- **Adequate Organ Function:** Hematologic, liver, cardiac, pulmonary.
- **Study Compliance & Safety:**
  - Willingness and ability to comply with all scheduled visits, study procedures, and long-term safety monitoring (up to 15 years).
  - Willingness to use a highly effective method of contraception for the specified duration (12 months for females, 6 months for males, post-LD or ALLO-329 administration, whichever is later).
- **Geographic Proximity:** Able to remain within 2 hours driving distance of a study site for at least 35 days post-treatment.

Key Exclusion Criteria:

- Active systemic bacterial, fungal, or viral infection requiring systemic treatment.
- Any known active to prior malignancy within 5 years (excluding adequately treated non-melanoma skin cancer or low-risk prostate cancer).
- Prior treatment with CD19 or CD70 targeted therapy, or other engineered cell therapy.
- **Significant Uncontrolled Chronic Disease:** Cardiac (recent intervention, or symptomatic ECG abnormality), Liver (Child-Pugh Class B or C cirrhosis), Pulmonary (recent intervention, , or pulmonary embolism requiring anticoagulation).
- **Immunological Issues:** Primary, inherited immunodeficiency. Participants known to be refractory to platelet or red blood cell transfusions.
- History or presence of documented, clinically significant CNS
- **Pregnancy/Lactation:** Pregnant, breastfeeding, or planning to become pregnant.
- **Unwillingness to Comply:** Refusal to participate in extended safety monitoring.

Disease-Specific Exclusions:

- **Lupus (SLE):** Any CNS disease or severe/ advanced renal chronicity
- **Myositis (IIM):** Non-assessable myositis or dermatomyositis with anti-TIF1 gamma antibody.
- **Scleroderma (SSc):** Pulmonary arterial hypertension requiring treatment, severe GI involvement, or prior renal crisis.

Request a Consult or Refer Your Patient Today

For more information or to refer or enroll a patient, visit https://allogene.com/ or contact clinicaltrials@allogene.com.

Allogene THERAPEUTICS

Updated September 2025

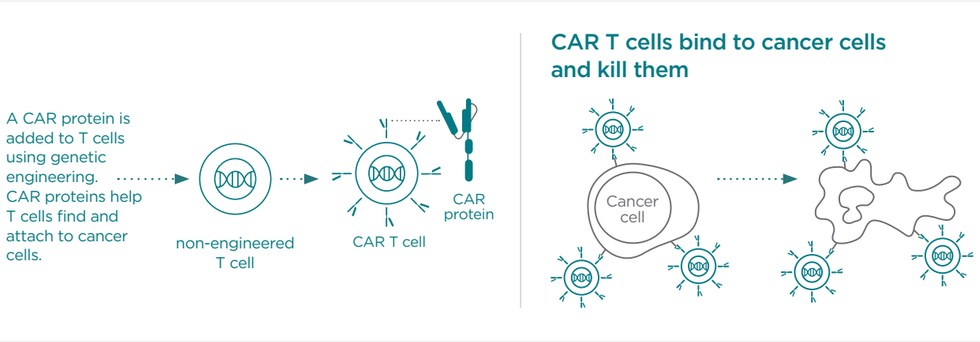
ALLO-329: Pioneering CAR T Therapy for Autoimmune Diseases (AID)

An Investigational, “Off-the-Shelf” Approach to Immune System Reset

Allogene THERAPEUTICS

What is CAR T-Cell Therapy?

Chimeric Antigen Receptor (CAR) T-cell therapy is a cutting-edge cellular immunotherapy that reprograms T cells to target and eliminate B cells and a subset of T cells that show signs of activation.



Autologous vs. Allogeneic CAR T: What's the Difference?

While CAR T cell therapy is established in oncology, its potential application in autoimmune diseases (AID) like lupus (SLE), Myositis (IIM) or Scleroderma (SSc) introduces unique considerations, particularly regarding cell sourcing. Here's how autologous and allogeneic CAR T differ:

Autologous CAR T

- Utilizes the patient's own T cells, requiring cell collection (apheresis) and a complex, sometimes lengthy, manufacturing process. Logistical challenges include potential manufacturing failures and delays, which may be critical for patients with rapidly progressing conditions or compromised T-cell health.

Allogeneic CAR T Candidates

- Uses T cells derived from healthy human donors, manufactured in advance and stored to be used as an "off-the-shelf" product.
- Clinical advantages in autoimmune diseases include:
  - **Immediate Availability:** Eliminates apheresis and manufacturing wait times, enabling rapid treatment initiation.
  - **Consistent Product Quality & Control:** Derived from healthy volunteer donors, potentially ensuring a standardized and reliable therapeutic.
  - **Broader Accessibility:** Lack of need for apheresis and lengthy wait times could reduce barriers for some patients whose T cells are depleted or who cannot wait 1-2 months for product availability. .
  - **Scalability:** Offers a more efficient and scalable manufacturing model.

Allogene® THERAPEUTICS

Introducing ALLO-329 and the RESOLUTION Trial

ALLO-329: A Dual-Targeted CD19/CD70 "Off-the-Shelf" CAR T Therapy

ALLO-329 is an investigational, allogeneic CAR T product designed to reset the immune system by targeting two key drivers of autoimmune diseases:

- **Dual Targeted:** Depletes both CD19+ B cells and CD70+ T cells, which play a role in autoimmune disease pathogenesis.
- **Prevent Rejection:** Proprietary Dagger® Technology enhances CAR T expansion and persistence while minimizing host immune rejection, and may eliminate the need for intensive lymphodepletion regimens.
- **Single Dose:** ALLO-329 is administered as a one-time intravenous infusion.

The RESOLUTION Trial

A Phase 1, first-in-human, single-arm, open-label study designed to evaluate the safety, tolerability, and preliminary efficacy of ALLO-329 in adults with moderate-severe, treatment-resistant autoimmune diseases.

- **Study Population:** Adults aged 18 to <70 years with confirmed active, moderate-severe Lupus (SLE), Idiopathic Inflammatory Myopathies (IIM), or Systemic Sclerosis (SSc) despite prior treatment with standard-of-care immunosuppression.

Study Design:

Modified 3+3 dose escalation design, systematically evaluating different dose levels of ALLO-329, with or without lymphodepletion (LD).

Screening (up to 28 days): Comprehensive evaluation to confirm diagnosis, disease activity, and eligibility.

Lymphodepletion (LD): For cohorts requiring LD, participants will receive a brief regimen of cyclophosphamide (Cy) alone, or fludarabine and cyclophosphamide (FC), typically 3-5 days prior to ALLO-329 infusion. The study is exploring reduced or potentially no lymphodepletion regimens to enhance safety and patient experience.

ALLO-329 Infusion (Day 0): A single, one-time intravenous infusion of ALLO-329, typically administered over approximately 5 minutes.

Initial Monitoring (Post-Infusion): Participants will be closely monitored for at least 35 days post-treatment, including a minimum 4-day inpatient stay. During this critical period, patients must remain within 2 hours driving distance of the study site.

Follow-up: Regular study visits will occur for 60 months post-treatment, with an additional extended safety monitoring period of up to 15 years. This long-term follow-up is mandated by FDA and other health authorities for all CAR T therapies and is crucial for assessing durable remission and potential late-onset side effects.

Safety Oversight: An independent Safety Review Team (SRT) continuously monitors safety data and guides dose escalation and study conduct.