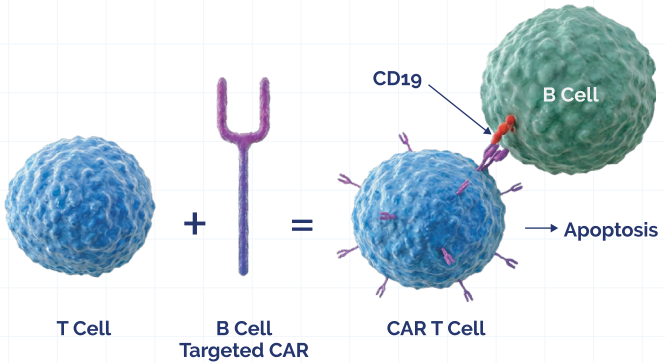


CAR-T IN SLE: POINT-OF-CARE POCKET GUIDE



CAR T Cell Mechanism of Action

- Chimeric antigen receptor (CAR) T cell therapy is an immunotherapy that reprograms T cells
- Gene transfer technology is used to express CARs on T cells. These T cells express a CAR that binds to a specific antigen on target cells, leading to T cell activation, expansion, and cytotoxicity.
- CAR T-cell therapy combines the specificity of an antibody with the cytotoxic capabilities of a T cell

Rationale for Use in Autoimmune Diseases (AID)

- B cells frequently play a central role in AID pathogenesis
- CAR T cells targeting B cells via their CD19 antigen result in extensive B cell death
- B cell depletion results in rapid and sustained breakdown of B cell-mediated immune response, which may "reboot" the immune system in AID

Patient Journey Through the CAR T Cell Therapy Process



Patient Identification and Referral

- Patient identification begins with the referring rheumatology provider
- Early collaboration is essential to facilitate timely referral



Consultation at CAR T treatment center

- Patients are evaluated by a multidisciplinary CAR T team for eligibility and are co-managed at the CAR T center by both the CAR T hematologist and a rheumatology provider from the center



Washout Period

- Washout Periods (holding certain SLE medications) may be needed after prior therapy and/or bridging therapy



Apheresis

- Peripheral blood mononuclear cells (PBMCs) are collected via leukapheresis and transported to a manufacturing facility
- There, they are genetically engineered to express CARs



Bridging Therapy

- Bridging therapy used to maintain disease control during CAR T-cell manufacturing should be coordinated jointly between the referring rheumatology provider and the CAR T treatment team



Lymphodepleting Chemotherapy (LDC) and CAR T Infusion

- Patients receive LDC prior to CAR T-cell infusion for most trials at a certified center to reduce endogenous T cells and support CAR T expansion
- They are monitored for adverse effects for at least 4 weeks, after which care transitions back to the referring rheumatology provider



Long-term Follow-Up

- Patients require ongoing monitoring and management of post-treatment complications
- Continued communication between the CAR T treatment center and referring rheumatology provider to support long-term care is key

Patient-Referral Checklist :

- **Appropriate Patient Profile**
 - B-cell-driven autoimmune disease
 - Refractory or recurrent despite conventional/biologic therapy or intolerant to standard options
 - Concern for organ damage or opportunity for meaningful reversal
- **Practical Eligibility Signals**
 - Functional status suitable for multi-step CAR-T process
 - Has caregiver support
 - Able to stay within proximity for 4 weeks post-infusion (financial/logistical assistance may be available)
- **Send This With the Referral**
 - Recent rheum notes + course of disease
 - Treatment history
 - Key labs: CBC, CMP, inflammatory markers, immunoglobulins, viral serologies
 - Relevant imaging/ organ involvement documentation

Breakfree-SLE (Phase 2)

Key Inclusion Criteria

- ✓ ≥ 16 y/o
- ✓ SLE dx (EULAR/ACR 2019 criteria)
- ✓ Failed glucocorticoids and ≥ 2 immunosuppressant therapies, used for at least 3 months
- ✓ Active disease when signing ICF

Key Exclusion Criteria

- ✗ Other diseases, conditions, or treatments that may confound interpretation of the effects of CC-97540 in SLE (MS, IBD, RA, HIV, TB, viral hepatitis, malignancy)
- ✗ Significant Cardiovascular conditions or CNS pathology
- ✗ Prior history of malignancies or lymphoproliferative disease within 2 years
- ✗ Pregnant, nursing, breastfeeding, or who intend to become pregnant
- ✗ Prior treatment with CAR T cell therapy, genetically modified T cell therapy, or stem cell transplant
- ✗ Live vaccines within 6 weeks before CC-97540 administration

Breakfree-1 (Phase 1)

Key SLE Inclusion Criteria

- ✓ ≥ 18 y/o
- ✓ SLE dx (EULAR/ACR 2019 criteria AND anti-dsDNA, anti-histone, anti-chromatin, anti-Ro (anti-SS-A), anti-La (anti-SS-B), or anti-Sm antibodies)
- ✓ Active disease at screening
 ≥ 1 major organ system with a BILAG A score (excluding musculo-skeletal, mucocutaneous, and/or constitutional organ system)
- ✓ Failed glucocorticoids and ≥ 2 immunosuppressant therapies, used for at least 3 months

Key SLE Exclusion Criteria

- ✗ Diagnosis of drug-induced SLE rather than idiopathic SLE
- ✗ Other systemic autoimmune diseases (multiple sclerosis, psoriasis, inflammatory bowel disease, etc)

RESET-SLE (Phase 1/2)

Key SLE Inclusion Criteria

- ✓ 18-65 y/o
- ✓ SLE dx
- ✓ ANA+ or anti-dsDNA+
- ✓ SLEDAI $\geq 2K \geq 8$ despite standard of care therapy (nonrenal cohort)
- ✓ Active, biopsy-confirmed class III or IV \pm V LN despite SOC (LN cohort)

RESET-SLE (Phase 1/2)

Key SLE Exclusion Criteria

- ✗ Contraindications to leukapheresis or specific trial drugs (fludarabine, cyclophosphamide)
- ✗ Active infections requiring intervention
- ✗ Severe uncontrolled renal, hepatic, cardiac dysfunction
- ✗ Previous CAR T-cell therapy or organ transplants

AUTOGRAPH - SLE/LN (Phase 2)

Key SLE Inclusion Criteria

- ✓ Age 18–75 years
- ✓ SLE diagnosis meeting 2019 EULAR/ACR classification criteria
- ✓ Positive ANA ($\geq 1:80$), anti-dsDNA, or anti-Sm antibody
- ✓ Active refractory SLE (SLEDAI-2K ≥ 6) **or** active lupus nephritis without significant chronic damage

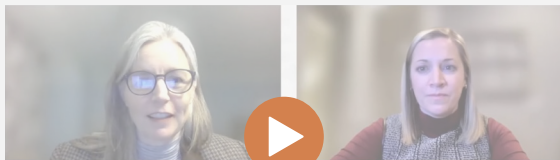
Key SLE Exclusion Criteria

- ✗ Significant organ dysfunction or clinically significant cardiac abnormalities
- ✗ Active HIV, hepatitis B, or hepatitis C infection
- ✗ Grade ≥ 2 thromboembolic event within 4 weeks of screening
- ✗ Other medical conditions that would increase risk or interfere with CAR-T therapy evaluation

Learn More About CAR-T in Lupus

Watch the full expert discussion from
RhAPP's Live Virtual Presentation:

CAR-T in Lupus: A New Era in Treatment and Trial Engagement.



Elizabeth Kirchner, DNP

Melissa Griffith, MD, RhMSUS

CAR-T in Lupus:
A New Era in Treatment
and Trial Engagement

LIVE
Elizabeth Kirchner, DNP & Melissa Griffith, MD, RhMSUS

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