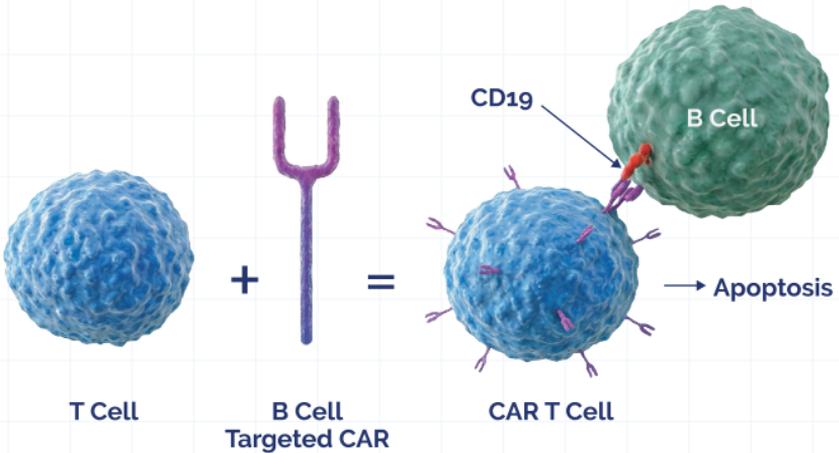


# CAR-T IN SLE: POINT-OF-CARE POCKET GUIDE



## 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

- ✓  $\geq 16$  y/o
- ✓ SLE dx (EULAR/ACR 2019 criteria)
- ✓ Failed glucocorticoids and  $\geq 2$  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 w/in 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

- ✓  $\geq 18$  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
  - $\geq 1$  major organ system with a BILAG A score (excluding musculoskeletal, mucocutaneous, and/or constitutional organ system)
- ✓ Failed glucocorticoids and  $\geq 2$  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 2K  $\geq$ 8 despite standard of care therapy (nonrenal cohort)
- ✓ Active, biopsy-confirmed class III or IV  $\pm$  V LN despite SOC (LN cohort)

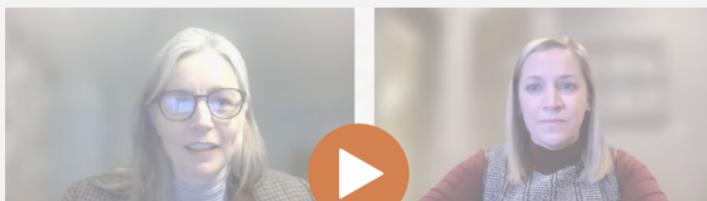
### Key SLE Exclusion Criteria

- ✗ 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

### 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  
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**LIVE**  
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