

A Study of CC-97540 (BMS-986353 or Zola-cel), CD19-Targeted NEX-T CAR T Cells, in Participants With Active SLE Despite Immunosuppressants (Breakfree-SLE)

NCT07015983

Status	RECRUITING
Phase	Phase 2
Sponsor	Juno Therapeutics, Inc., a Bristol-Myers Squibb Company
Enrollment	89 participants

Key Eligibility Criteria

Inclusion (3)

- Participants must meet EULAR/ACR 2019 criteria for SLE.
- Participants must have an inadequate response to appropriate doses of glucocorticoids and e 2 immunosuppressant therapies, used for at least 3 months.
- Participants must have active disease when signing ICF.

Exclusion (6)

- Participants must not have other diseases, conditions, or treatments that may confound interpretation of the effects of CC-97540 in SLE.
 - Uncontrolled or clinically significant cardiovascular conditions or CNS pathology participants must not have prior history of malignancies or lymphoproliferative disease, unless the participant has been free of the disease for e 2 years, except for some non-invasive malignancies.
 - IOCBP who are pregnant, nursing, or breastfeeding, or who intend to become pregnant during participation in the study.
 - Participants must not have prior treatment with CAR T cell therapy, genetically modified T cell therapy, stem cell transplant or organ transplant.
 - Participants must not have received live vaccines within 6 weeks before LDC (lymphodepleting chemotherapy) administration.
- ... and 1 more (see full listing online)

Locations (102 total)

Local Institution - 0009, Birmingham, Alabama, United States
Local Institution - 0080, Scottsdale, Arizona, United States
Local Institution - 0106, Scottsdale, Arizona, United States
... and 99 more locations