ForPatients
by Roche

Systemic Lupus Erythematosus

A Study to Evaluate the Safety, Tolerability, Cellular Kinetics, Pharmacodynamics, and Efficacy of P-CD19CD20-ALLO1 in Participants With Severe, Treatment-refractory Systemic Lupus Erythematosus (SLE)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT06984341 GA45767

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase I, Multicenter, Open-label Study to Evaluate the Safety, Tolerability, Cellular Kinetics, Pharmacodynamics, and Efficacy of P-CD19CD20-ALLO1 in Patients With Severe, Treatment-refractory Systemic Lupus Erythematosus

Trial Summary:

The purpose of this study is to evaluate the safety and tolerability of P-CD19CD20-ALLO1 in participants with highly active, severe, refractory SLE with or without lupus nephritis (LN). This study includes a dose-escalation stage followed by an expansion stage. It will also evaluate the cellular kinetics (CK), pharmacodynamics (PD), and efficacy of P-CD19CD20-ALLO1.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT06984341 GA45767
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

Inclusion Criteria:

18-75 years old

SLE diagnosis per 2019 EULAR/ACR classification criteria # 24 weeks

Autoantibody positive and low complement at screening

Treatment refractory: Failed # 2 treatments for at least 3 months

Highly active disease:

SLEDAI-2K # 8 (excluding alopecia, headache, and fever; additional protocol-specified requirements to enhance specificity of findings)

BILAG-2004 cat A in # 1 organ system and/or cat B in # 2 organ systems (excluding constitutional, musculoskeletal, and/or mucocutaneous organ systems for category B)

PGA score # 1.0 on a 0 to 3 VAS

For patients with lupus nephritis:

Biopsy-proven Class III or IV (± Class V) active LN per 2018 ISN/RPS criteria within 12 months of screening

Modified NIH activity index # 1/24

UPCR # 1g/g

Exclusion Criteria:

Participants who are pregnant, breastfeeding, or intend to become pregnant within the timeframe in which contraception is required

Prior treatment with CAR T-cell therapy, B-cell-targeting T-cell-dependent bispecific antibody, gene therapy product, total body irradiation, allograft organ transplant, or hematopoietic stem cell transplant

Significant organ impairment (renal, hepatic, cardiac, or pulmonary) or uncontrolled medical disease which, in the investigator's opinion would preclude patient participation or that may require treatment with systemic corticosteroids or immunosuppressants during the study

Active severe or unstable neuropsychiatric disease

Protocol-specified active or chronic infections, recent major episode of infection

High-risk medical conditions (e.g. high bleeding risk, history of cancer, recent major surgery, history of HLH/MAS, substance abuse within the previous year)

Other protocol-defined inclusion/exclusion criteria apply