ForPatients
by Roche

Systemic Lupus Erythematosus

To Evaluate the Effects of Cevostamab in Participants With Systemic Lupus Erythematosus With or Without Active Lupus Nephritis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07629583 2025-522904-26-00 2025 GA46280

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:

An Open-Label, Multicenter, Phase Ib Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Cevostamab in Patients With Systemic Lupus Erythematosus With or Without Active Lupus Nephritis

Trial Summary:

The study will evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of cevostamab in participants with systemic lupus erythematosus (SLE) with or without active lupus nephritis (LN).

Genentech, Inc.	Phase 1
Sponsor	Phase

NCT07629583 2025-522904-26-00 2025 GA46280
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Diagnosis of SLE according to the 2019 European League Against Rheumatism (EULAR)/American College of Rheumatology (ACR) Classification Criteria at least 6 months prior to the first screening visit
- Active biopsy-proven LN established within 9 months of screening, demonstrating LN per 2018 Revised International Society of Nephrology/Renal Pathology Society (ISN/RPS) criteria
- Diagnosis of active SLE disease, as demonstrated by the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score

© 2022 F. Hoffmann-La Roche Ltd

- Inadequate response or intolerance to, in the investigator's judgement, standard of care regimens for active SLE with or without LN

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within the timeframe in which contraception is required
- Treatment with investigational or non-investigational biologic therapies that directly deplete B cells (e.g., anti-CD20 or anti-CD19 monoclonal antibodies) (or blinded comparators) is prohibited within 6 months or 5 drug elimination half-lives, whichever is longer, prior to screening and during the study
- Treatment with investigational biologic therapies that do not directly deplete B cells (or blinded comparators) is prohibited within 90 days or 5 drug elimination half-lives, whichever is longer, prior to initiation of study drug and during the study
- Treatment of SLE/LN with non-investigational biologic therapies that do not directly deplete B cells (e.g., belimumab, anifrolumab) is prohibited within 4 weeks prior to screening and during the study
- Treatment with CYC within 3 months prior to screening or during the study
- History of known or suspected allergic reaction or anaphylactic reaction to cevostamab or its excipients
- Major surgery requiring hospitalization during the 4 weeks prior to screening or during screening, or any planned surgery or procedure requiring hospitalization during the 12 weeks following study drug administration
- Alcohol or substance abuse within the 12 months prior to screening
- Active infection of any kind, excluding fungal infection of the nail beds
- History of serious recurrent or chronic infection
- Tuberculosis (TB) infection
- Active overlap syndrome with mixed connective tissue disease or systemic sclerosis within the 12 months prior to screening or during screening
- Catastrophic or severe antiphospholipid syndrome within the 12 months prior to screening or during screening
- High risk for clinically significant bleeding or any condition requiring plasmapheresis, IV immunoglobulin, or acute blood product transfusions
- Active severe or unstable lupus-associated neuropsychiatric disease, which, in the opinion of the investigator, is likely to require treatment with protocol-prohibited therapies
- Non-SLE related CNS disease such as stroke, epilepsy, CNS vasculitis, or neurodegenerative disease

© 2022 F. Hoffmann-La Roche Ltd