ForPatients
by Roche

Lúpus Eritematoso SistêmicoNefrite Lúpica

A Study to Evaluate Mosunetuzumab in Participants With Systemic Lupus Erythematosus With or Without Active Lupus Nephritis

Trial Status	Trial Runs In	Trial Identifier
Recrutando	5 Countries	NCT07598396 2024-519930-22-00 GA45799

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

A Phase II Open-Label Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Mosunetuzumab in Patients With Systemic Lupus Erythematosus With or Without Active Lupus Nephritis

Trial Summary:

This study will assess how mosunetuzumab works in people who have systemic lupus erythematosus (SLE) who may or may not also have active lupus nephritis (LN).

Hoffmann-La Roche	Phase 2
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Diagnosis of SLE for # 6 months as assessed using the 2019 European League Against Rheumatism/ American College of Rheumatology (EULAR/ACR) Classification Criteria at screening

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant during the study or within the time frame in which contraception is required

- Treatment with investigational therapy within 30 days or 5 drug-elimination half-lives (whichever is longer) prior to initiation of study treatment and during the study
- 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
- Any major episode of infection as defined by the protocol
- History of serious recurrent or chronic infection
- History of progressive multifocal leukoencephalopathy (PML)
- Tuberculosis (TB) infection
- History of cancer, including solid tumors, hematological malignancies, and carcinoma in situ, within the past 5 years
- 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. Antiphospholipid syndrome adequately controlled by anticoagulant therapy for at least 2 months prior to screening is acceptable
- 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 or where, in the opinion of the investigator, it is likely to require treatment with protocol-disallowed therapies. Examples of neuropsychiatric SLE manifestations include, but are not limited to the following: meningitis, retinitis, cerebral vasculitis, myelopathy, demyelination syndromes, acute confusional state, psychosis, acute stroke or stroke syndrome, cranial neuropathy, status epilepticus or seizures, cerebellar ataxia, and mononeuritis multiplex
- History of any non-SLE disease treated with oral, intravenous, or intramuscular corticosteroids for more than 14 days in total during the one year prior to Day 1
- History of treatment with any T cell-engaging bispecific antibodies or CAR-T therapy within the past 2 years
- Receipt of any live or attenuated vaccine in the 28 days prior to or during screening