

A Study of Nipocalimab in Adults With Moderate to Severe Systemic Lupus Erythematosus

NCT07438496

Status	RECRUITING
Phase	Phase 3
Sponsor	Janssen Research & Development, LLC
Enrollment	600 participants

Key Eligibility Criteria

Inclusion (5)

- Medically stable on the basis of physical examination, medical history, vital signs and 12-lead electrocardiogram (ECG) performed at screening
- Clinical diagnosis of systemic lupus erythematosus (SLE) for more than or equal to (\geq) 24 weeks prior to screening according to european league against rheumatism/american college of rheumatology (EULAR/ACR) classification criteria
- Must have a systemic lupus erythematosus disease activity index 2000 (SLEDAI-2K) score \geq 6 and a clinical SLEDAI-2K \geq 4 at screening, AND a clinical SLEDAI-2K score \geq 4 points at Week 0, excluding points attributed to "lupus headache," "alopecia," and "organic brain syndrome"
- Participants of childbearing potential must have a negative serum beta human chorionic gonadotropin (β hCG) test at screening and a negative urine (β -hCG) test at Week 0 prior to randomization
- Has at least 1 BILAG-2004 A score or 2 BILAG-2004 B scores observed at screening

Exclusion (5)

- History of severe, progressive and/or uncontrolled hepatic, gastrointestinal, renal, pulmonary, cardiovascular, psychiatric, neurological or musculoskeletal disorder, hypertension, and/or any other medical or uncontrolled autoimmune disorder (s) or clinically significant abnormalities in screening laboratory
- Any unstable or progressive manifestation of SLE that is likely to warrant escalation in therapy beyond permitted background medications
- Confirmed or suspected clinical immunodeficiency syndrome not related to treatment of SLE or has a family history of congenital or hereditary immunodeficiency unless confirmed absent in the participant
- Has shown a previous severe immediate hypersensitivity reaction, such as anaphylaxis, to therapeutic proteins
- Suspected or known allergies, hypersensitivity, or intolerance to nipocalimab or its excipients, or excipients used in the placebo formulation

Locations (5 total)

Advanced Medical Research, La Palma, California, United States
Clinical Research of West Florida, Tampa, Florida, United States
Joint and Muscle Research Institute, Charlotte, North Carolina, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT07438496>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.