

A Study in Participants With Active Systemic Lupus Erythematosus With Inadequate Response to Glucocorticoids and 2 Immunosuppressants

NCT07175285

Status RECRUITING
Sponsor Bristol-Myers Squibb
Enrollment 223 participants

Key Eligibility Criteria

Inclusion (8)

- Participants must have signed and dated an Institutional Review Board/ Independent Ethics Committee (IRB/IEC)-approved written informed consent form (ICF) in accordance with regulatory, local, and institutional guidelines
- Participants must be ≥16 years of age at the time of signing the ICF
- Meet the European League Against Rheumatism (EULAR) / American College of Rheumatology (ACR) 2019 classification criteria for systemic lupus erythematosus (SLE)
- Have an inadequate response to glucocorticoids and ≥2 immunosuppressant therapies such as cyclophosphamide, mycophenolic acid and its derivatives, belimumab, anifrolumab, rituximab, methotrexate, azathioprine, obinutuzumab, cyclosporine, tacrolimus, or voclosporin, used for at least 3 months each. Eligibility is regardless of prior hydroxychloroquine or any anti-malarial treatment. Inadequate response is defined as a lack of response, insufficient response, or lack of sustained response after at least 3-month treatment with appropriate doses of a standard of care agent. Intolerance or contraindication may be considered as inadequate response provided it is documented and confirmed acceptable by the Adjudication Committee
- Have active disease at study entry when signing ICF, defined as:
... and 3 more (see full listing online)

Exclusion (3)

- Pregnant women
- Participants enrolled in concurrent interventional clinical trials involving investigational therapies or any other clinical trial
- Participant is unwilling and unable to adhere to the study visit schedule and other protocol requirements

Locations (49 total)

Local Institution - 0062, Mesa, Arizona, United States
Local Institution - 0054, La Jolla, California, United States
Local Institution - 0001, La Palma, California, United States
... and 46 more locations