A Research Study to Evaluate the Effects of a New Oral Medicine Called Cenerimod in Adults With Systemic Lupus Erythematosus

NCT05648500

Status	RECRUITING
Phase	Phase 3
Sponsor	Viatris Innovation GmbH
Enrollment	420 participants

Key Eligibility Criteria

Inclusion (36)

- Signed Informed Consent Form (ICF) prior to any study-mandated procedure.
- Diagnosis of Systemic Lupus Erythematosus (SLE) made at least 6 months prior to Screening, according to 2019 European League Against Rheumatism / American College of Rheumatology Criteria.
- A modified Systemic Lupus Erythematosus Disease Activity Index-2000 (mSLEDAI-2K) score e 6 and clinical mSLEDAI-2K score e 4 with at least 2 points for musculoskeletal or mucocutaneous manifestations (i.e., myositis, arthritis, rash, alopecia, mucosal ulcers). The mSLEDAI-2K score does not include "leukopenia".
- British Isles Lupus Assessment Group-2004 (BILAG) Grade B in e 2 organ systems or a BILAG Grade A in e 1 organ system.
- Physician's Global Assessment (PGA) score e 1.0 on a 0 to 3 visual analog scale.

... and 31 more (see full listing online)

Exclusion (42)

- Pregnant, planning to be become pregnant up to Final Study Visit, or lactating women.
- Severe active central nervous system lupus or active severe or unstable neuropsychiatric SLE including but not limited to: aseptic meningitis; cerebral vasculitis; myelopathy; demyelination syndromes (ascending, transverse, acute inflammatory demyelinating polyradiculopathy); acute confusional state; impaired level of consciousness; psychosis; acute stroke or stroke syndrome; cranial neuropathy; status epilepticus; cerebellar ataxia; or mononeuritis multiplex:
- That would make the subject unable to fully understand the ICF; OR
- Where, in the opinion of the investigator/delegate, protocol-specified standard of care is insufficient and the use of a more aggressive therapeutic approach, such as adding i.v. cyclophosphamide and/or high dose i.v. pulse corticosteroid (CS) therapy or other treatments not permitted in the protocol is indicated.
- A diagnosis of mixed connective tissue disease or any history of overlap syndromes of SLE with psoriasis, rheumatoid arthritis, erosive arthritis, scleroderma, autoimmune hepatitis or uncontrolled autoimmune thyroid disease.

... and 37 more (see full listing online)

Locations (216 total)

Providence Medical Foundation, Fullerton, California, United States
California Research Institute, Huntington Park, California, United States
University of Colorado Denver, Aurora, Colorado, United States
... and 213 more locations