A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2a Study With an Open-Label Extension Evaluating the Efficacy and Safety of VENT-03 in Adult Participants With Active Cutaneous Lupus Erythematosus With or Without Systemic Lupus Erythematosus

NCT07260877

Status	RECRUITING
Phase	Phase 2
Sponsor	Ventus Therapeutics U.S., Inc.
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (7)

- Cutaneous lupus:
- CLASI-A score e8;
- At least 1 active discoid lupus erythematosus (DLE) lesion, OR at least 1 active subacute CLE lesion
- If participant has previous SLE diagnosis:
- Positive antinuclear antibody test at Screening by immunofluorescent assay at the central laboratory with titer e 1:80;

... and 2 more (see full listing online)

Exclusion (12)

- Meet protocol-specified infection or lab criteria; any other laboratory test results that, in the investigator's opinion, might place participant at unacceptable risk for participating in this study;
- Moderate or severe liver impairment as classified by the Child-Pugh criteria (categories B and C);
- Has drug-induced lupus, rather than 'idiopathic' lupus;
- History of, or current, inflammatory joint or skin disease other than SLE and cutaneous lupus;
- Diagnosis of select potentially confounding autoimmune disorders

... and 7 more (see full listing online)

Locations (27 total)

Investigative Site, Beverly Hills, California, United States
Investigative Site, Clearwater, Florida, United States
Investigative Site, DeBary, Florida, United States
... and 24 more locations