A Study of CLN-978, a Subcutaneously Administered CD19-directed T Cell Engager, in Subjects With Systemic Lupus Erythematosus

NCT06613360

Status	RECRUITING
Phase	Phase 1
Sponsor	Cullinan Therapeutics Inc.
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (15)

- Diagnosis of SLE at least 24 weeks prior to Screening and meet 2019 EULAR / ACR Classification Criteria at screening.
- Presence of one or more of the following autoantibodies documented during screening or in the previous 12 months before screening: positive anti-nuclear antibody (ANA) test (e1:80); anti dsDNA above the upper limit of normal (ULN); anti-Sm above the ULN.
- Active SLE disease, as demonstrated by a SLEDAI total score e6 at screening.
- Inadequate response to at least 2 of the following treatments: oral corticosteroid, antimalarials, conventional immunosuppressants, or biologics. At least one of the failed treatments should be an immunosuppressive or biologic standard-of care agent.
- If on corticosteroid and/or antimalarial, the dose must be stable prior to day 1.

... and 10 more (see full listing online)

Exclusion (16)

- Active inflammatory disease other than SLE. Thyroiditis or secondary Sjogren's syndrome is allowed.
- Considered at high risk for thrombosis.
- Rapidly progressive glomerulonephritis, and/or urine protein/creatinine \>3 mg/mg (339 mg/mmol).
- Active severe neuropsychiatric/CNS manifestations of SLE.
- Evidence of hepatitis B, hepatitis C (HCV) infection, human immunodeficiency virus (HIV), Epstein-Barr virus (EBV), or cytomegalovirus (CMV) infection.

... and 11 more (see full listing online)

Locations (15 total)

Cullinan Investigative Site, Avondale, Arizona, United States
Cullinan Investigative Site, Tucson, Arizona, United States
Cullinan Investigative Site, Orlando, Florida, United States
... and 12 more locations