Safety and Efficacy Study of CC312 for Moderate to Severe SLE

NCT07177911

Status	RECRUITING
Phase	Phase 1
Sponsor	CytoCares Inc
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (8)

- Fully understand the trial's purpose, nature, methodology, and potential adverse reactions, voluntarily participate as a subject, and sign the informed consent form.
- Aged 18 to 65 years (inclusive, based on the date of signing the informed consent form), regardless of gender.
- Diagnosed with systemic lupus erythematosus (SLE) according to the 2019 EULAR/ACR classification criteria.
- SLEDAI-2000 score e7 with at least one BILAG A or two BILAG B domains, despite standard therapy.
- Meet at least one of the following criteria: positive antinuclear antibody (ANA) e1:80 at screening, positive anti-dsDNA antibody at screening, or positive anti-Sm antibody at screening.

... and 3 more (see full listing online)

Exclusion (23)

- Severe lupus nephritis within 8 weeks prior to screening (defined as urinary protein \>6 g/24 h, or serum creatinine \>2.5 mg/dL or 221 μmol/L, or requiring prohibited medications for active nephritis per protocol, or needing hemodialysis, or receiving prednisone e100 mg/d or equivalent glucocorticoids for e14 days).
- Central nervous system disorders (including but not limited to epilepsy, psychosis, interstitial encephalopathy syndrome, cerebrovascular accident, encephalitis, CNS vasculitis) within 8 weeks prior to screening, whether SLE-related or not.
- History of major organ transplantation (e.g., heart, lung, kidney, liver) or hematopoietic stem cell/bone marrow transplantation.
- Other concurrent autoimmune diseases requiring systemic therapy, except for Sjögren's syndrome.
- IgA deficiency (serum IgA level \<10 mg/dL).

... and 18 more (see full listing online)

Locations (1 total)

West China Hospital, Sichuan University, Chengdu, Sichuan, China