

# To Evaluate the Efficacy and Safety of SG301 SC Injection in Systemic Lupus Erythematosus

NCT07447986

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Hangzhou Sumgen Biotech Co., Ltd.
<b>Enrollment</b>	120 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Voluntarily participate in the clinical study and sign a written informed consent form.
- Participants must be diagnosed with SLE in accordance with the 2019 European League Against Rheumatism (EULAR)/American College of Rheumatism (ACR) SLE classification criteria and have inadequate response to standard treatment, intolerance to standard treatment, or recurrent disease.
- SLEDAI-2K score  $\leq$  8 points, with clinical features corresponding to a SLEDAI-2K score  $\leq$  4 points.
- Positive serological test results for autoantibodies, defined as antinuclear antibody (ANA) positivity and/or anti-double-stranded DNA (anti-dsDNA) antibody positivity.
- Body weight  $\geq$  35 kg.
- ... and 2 more (see full listing online)

### Exclusion (15)

- Previous use of CD38 or monoclonal antibodies targeting CD38.
- Active central nervous system (CNS) disease within 2 months before the first dose, or CNS disease that the investigator believes may require treatment with prohibited therapies specified in the protocol.
- Diagnosis of mixed connective tissue disease or a history of any overlap syndrome between SLE and systemic sclerosis.
- Laboratory abnormalities.
- Current acute or chronic infection meeting any of the following criteria.
- ... and 10 more (see full listing online)

## Locations (1 total)

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Peking University People's Hospital, Beijing, Beijing Municipality, China