A Phase 1 Study of GS101 Injection

NCT07411755

Status	RECRUITING
Phase	Phase 1
Sponsor	Jiangsu Genscend Biopharmaceutical Co., Ltd
Enrollment	294 participants

Key Eligibility Criteria

Inclusion (3)

- No clinically significant abnormalities detected in physical examination, vital signs, chest X-ray (posteroanterior \[PA\] view), 12-lead ECG, or laboratory tests prior to investigational product administration.
- Body mass index (BMI) between 19 and 26 kg/m² (inclusive) and body weight between 55 and 85 kg (inclusive).
- Participants and their partner agree to use medically accepted contraceptive methods from the signing of the informed consent form until three months after dosing of the investigational product. In addition, participants have no plans to donate sperm, and their partner has no plans for pregnancy.

Exclusion (3)

- History or presence at screening of neurological/psychiatric, respiratory, cardiovascular, gastrointestinal, hematologic/lymphatic, endocrine, musculoskeletal, or any other disease judged by the investigator to interfere with study assessments.
- History of drug or food allergy (e2 types) or history of specific allergic diseases (e.g., asthma, urticaria, eczematous dermatitis), or known hypersensitivity to monoclonal antibodies targeting the same pathway or to investigational product components.
- Positive result for any infectious disease screening, including human immunodeficiency virus (HIV) antibody and p24 antigen, hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) IgG antibody, or Treponema pallidum (syphilis) antibody.

Locations (1 total)

The Second Affiliated Hospital of Soochow University, Suzhou, Jiangsu, China