

# Safety, Efficacy and Cellular Metabolic Dynamics of CT1195E in Patients With Refractory / Progressive SSC

NCT07355972

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<b>Status</b>	RECRUITING
<b>Phase</b>	Early Phase 1
<b>Sponsor</b>	Union Hospital, Tongji Medical College, Huazhong University of Science and Technology
<b>Enrollment</b>	12 participants

## Key Eligibility Criteria

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### Inclusion (19)

- voluntarily sign the informed consent form (ICF): I fully understand and know this study and sign the informed consent form. I am willing to follow and be able to complete all research procedures;
- when signing ICF, the age is between 18 and 60 years old (including 18 and 60 years old), regardless of gender;
- no systemic active infection (such as infectious pneumonia and tuberculosis) within 2 weeks before screening;
- women with fertility (defined as all women who are physically able to conceive) must agree to use efficient contraceptive methods from at least 28 days before the start of gonorrhea to 1 year after ct1195e infusion, and it is absolutely prohibited to donate eggs within 1 year after receiving study treatment infusion during the study period. Men whose partners are fertile must agree to use effective barrier contraception from the beginning of gonorrhea to 1 year after ct1195e infusion, and should not donate semen or sperm during the entire study period;
- women with fertility must be tested negative for serum  $\beta$ human chorionic gonadotropin ( $\beta$  hcg) at the time of screening and within 48 hours before gonorrhea treatment.

... and 14 more (see full listing online)

### Exclusion (20)

- FVC  $\leq$  30% predicted value or DLCO (corrected by hemoglobin)  $\leq$  30% predicted value;
- study participants with severe kidney disease or signs of renal crisis;
- there is active tuberculosis risk during screening: there are signs or symptoms of active tuberculosis judged by the investigator (such as fever, cough, night sweat and weight loss); Records of chest imaging (e.g., chest X-ray, chest CT scan) performed at screening or any time within 6 months before screening showed active tuberculosis.
- have previously received car-t cell or other gene modified T cell therapy, or have a history of major organ transplantation (such as heart, lung, kidney, liver) or hematopoietic stem cell / bone marrow transplantation;
- have used drugs targeting B cells (such as rituximab) within 3 months before screening;

... and 15 more (see full listing online)

## Locations (1 total)

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Wuhan Union Hospita, Wuhan, Hubei, China

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<https://clinicaltrials.gov/study/NCT07355972>

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