

## MT2025-20: A Phase II, multi-part, five-year, randomized, open-label, assessor-blinded, active-controlled, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucl versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 18 years and over

This study is NOT accepting healthy volunteers

**Inclusion Criteria:**

- 18 to 70 years old - diagnosis of systemic sclerosis and meet the criteria for diffuse cutaneous (dcSSc) - Disease onset from the first symptoms attributable to SSc (e.g., puffy hands, scleroderma, digital ulcers, arthralgia, dyspnea) within past 7 years - severe, progressive systemic sclerosis disease - see link to [clinicaltrials.gov](http://clinicaltrials.gov) for complete Inclusion criteria

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**Exclusion Criteria:**

- Rheumatic disease other than dcSSc - pulmonary hypertension - significant kidney disease - uncontrolled hypertension - see link to [clinicaltrials.gov](http://clinicaltrials.gov) for complete Exclusion criteria

### Conditions & Interventions

**Interventions:**

Biological: rapcabtagene autoleucl, Biological: rituximab

**Conditions:**

Rare Diseases, Immune Diseases

**Keywords:**

Clinics and Surgery Center (CSC), Scleroderma

### More Information

**Description:** The goal of this study is to find out if the experimental drug rapcabtagene autoleucl (herein referred to as YTB323), an investigational new therapy, is safe and effective (can help) for people who have severe refractory diffuse cutaneous systemic sclerosis (dcSSc). YTB323 is a chimeric antigen receptor T cell (CAR-T cell) therapy, which is a type of gene therapy or immunotherapy. CAR-T involves collecting and using a patient's own immune cells, specifically their T cells, to treat their condition.

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**Phase:** PHASE2

**IRB Number:** STUDY00025182

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