Phase 2 Study Evaluating Rapcabtagene Autoleucel in Participants With Diffuse Cutaneous Systemic Sclerosis

Last Update: Jan 27, 2025
A Phase 2, Multi-part, Randomized, Open-label, Assessor-blinded, Active-controlled, Study to Evaluate the Efficacy and Safety of Rapcabtagene Autoleucel Versus Rituximab Treatment in Participants With Severe Refractory Diffuse Cutaneous Systemic Sclerosis
ClinicalTrials.gov Identifier:
NCT06655896
Novartis Reference Number:CYTB323K12201
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to evaluate the efficacy, safety and tolerability of rapcabtagene autoleucel (administered once following lymphodepletion) in participants with severe refractory diffuse cutaneous systemic sclerosis relative to rituximab. This is a phase 2, multi-part, three-year, randomized, open-label, assessor-blinded, multicenter study to evaluate the efficacy and safety of rapcabtagene autoleucel versus rituximab in participants with severe refractory diffuse cutaneous systemic sclerosis (dcSSc) . This study comprises two cohorts:

* A Lead-in Cohort enrolling participants to receive rapcabtagene autoleucel.
* A Randomized Cohort enrolling participants to receive rapcabtagene autoleucel or rituximab.

After end of study, participants who received rapcabtagene autoleucel infusion will enter a long-term follow-up (LTFU) period lasting up to 15 years after rapcabtagene autoleucel infusion. This LTFU will be described in a separate study protocol.

Condition
Scleroderma, Diffuse
Phase
Phase2
Overall Status
Recruiting
Number of Participants
86
Start Date
Oct 29, 2024
Completion Date

Dec 17, 2030
Gender
All
Age(s)
18 Years - 65 Years (Adult, Older Adult)

Interventions

Biological

rapcabtagene autoleucel

single infusion of rapcabtagene autoleucel
Biological

rituximab

rituximab intravenous infusion (i.v.) as per protocol

Eligibility Criteria

Inclusion Criteria:

1. Participant must fulfill the 2013 American College of Rheumatology/ European League Against Rheumatism classification criteria for systemic sclerosis and meet the diffuse cutaneous SSc (dcSSc) subset classification according to LeRoy.
2. Disease onset from the first non-Raynaud symptoms attributable to SSc (e.g., puffy hands, scleroderma, digital ulcers, arthralgia, dyspnea) within 7 years prior to the Screening visit.
3. Severe, progressive systemic sclerosis disease defined by at least one of the following:

* Progressive systemic sclerosis-associated interstitial lung disease
* Severe, progressive systemic sclerosis skin disease
* Clinically significant systemic sclerosis-associated cardiac involvement at Screening

Exclusion Criteria:

1. Any condition during Screening that could prevent a complete washout of medications as required per protocol or could otherwise make the participant ineligible for anti-CD19 CAR-T therapy and further participation in the study, as judged by the Investigator.
2. Participants with history of hypersensitivity to excipients in rapcabtagene autoleucel or to rituximab.
3. Any participant for whom treatment with rituximab is clinically inappropriate in the opinion of the investigator.
4. Any medical conditions that are not related to SSc that, in the opinion of the Investigator, would jeopardize the ability of the participant to tolerate lymphodepletion and anti-CD19 CAR-T cell therapy.
5. Rheumatic disease other than dcSSc, (except secondary Sjogren's syndrome or scleroderma myopathy), limited cutaneous systemic sclerosis (lcSSc) or sine scleroderma at Screening.
6. Participants with pre-existing pulmonary hypertension.
7. Significant renal pathology at Screening, including:

* Active SSc renal crisis
* Confirmed diagnosis of glomerulonephritis

8. Participants with uncontrolled stage II hypertension at Screening.
9. Vaccination with live attenuated vaccines within 6 weeks prior to randomization.

Other protocol-defined inclusion/exclusion criteria may apply.

Australia

Novartis Investigative Site

Recruiting

Darlinghurst,New South Wales,2010,Australia

France

Novartis Investigative Site

Recruiting

Bordeaux Cedex,33076,France

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Recruiting

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Germany

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