Phase 2 Study of Rapcabtagene Autoleucel in Myositis

Last Update: Apr 06, 2025
A Phase 2, Randomized, Open-label, Controlled Study to Evaluate the Efficacy and Safety of Rapcabtagene Autoleucel Versus Comparator in Participants With Severe Refractory Idiopathic Inflammatory Myopathies (IIM)
ClinicalTrials.gov Identifier:
NCT06665256
Novartis Reference Number:CYTB323L12201
See if you Pre-qualify
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

A Phase 2, randomized, open-label, controlled study to evaluate the efficacy and safety of rapcabtagene autoleucel versus comparator in participants with severe refractory idiopathic inflammatory myopathies (IIM) This is a Phase 2, two-year, randomized, assessor- blinded, active-controlled study. This study comprises two cohorts:

* A lead-in cohort enrolling participants to receive rapcabtagene autoleucel
* A randomized cohort with participants receiving either rapcabtagene autoleucel or a comparator option.

After end of study (EOS), 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
Idiopathic Inflammatory Myopathies
Phase
Phase2
Overall Status
Recruiting
Number of Participants
123
Start Date
Dec 17, 2024
Completion Date
Jul 20, 2030
Gender
All
Age(s)

18 Years - 65 Years (Adult, Older Adult)

Interventions

Other

Active Comparator Option

Investigator choice of treatment as per protocol
Biological

Rapcabtagene autoleucel

Single infusion of rapcabtagene autoleucel

Eligibility Criteria

Key Inclusion Criteria:

1. Men and women, aged \>18 and ≤65 years, with a diagnosis of probable or definite myositis according to American College of Rheumatology/European League Against Rheumatism 2017 (ACR/EULAR 2017) criteria
2. Participants who had inadequate response to prior therapy
3. Diagnosed with active disease
4. Participant must meet criteria for severe myositis

Key Exclusion Criteria:

1. Any condition during Screening that could prevent a complete washout of medications or could otherwise make the participant ineligible for anti-CD19 CAR-T therapy and further participation in the study
2. BMI at Screening of ≤18.5 or ≥35 kg/m2
3. Severe muscle damage at Screening
4. Inadequate organ function
5. Hypersensitivity and/or contraindications to any product (including its ingredients) to be given to the participant as per the study protocol
6. Other inflammatory and non-inflammatory myopathies
7. Any medical conditions that are not related to IIM that would jeopardize the ability of the participant to tolerate CD19 CAR-T cell therapy

Other protocol-defined inclusion/exclusion criteria may apply.

France

Novartis Investigative Site

Recruiting

Paris,75013,France

Novartis Investigative Site

Recruiting

Rennes,35043,France

Novartis Investigative Site

Recruiting

Lyon,69003,France

Germany

Novartis Investigative Site

Recruiting

Jena,07740,Germany

Novartis Investigative Site

Recruiting

Leipzig,Sachsen,04103,Germany

Israel

Novartis Investigative Site

Recruiting

Haifa,3109601,Israel

Novartis Investigative Site

Recruiting

Ramat Gan,52621,Israel

Novartis Investigative Site

Recruiting

Tel Aviv,6423906,Israel

Italy

Novartis Investigative Site

Recruiting

Milano,MI,20122,Italy

Japan

Novartis Investigative Site

Recruiting

Kanazawa,Ishikawa,920 8641,Japan

Novartis Investigative Site

Recruiting

Kyoto,606 8507,Japan

Novartis Investigative Site

Recruiting

Sapporo city,Hokkaido,060 8648,Japan

Novartis Investigative Site

Recruiting

Bunkyo-ku,Tokyo,113-8519,Japan

Singapore

Novartis Investigative Site

Recruiting

Singapore,119074,Singapore

Novartis Investigative Site

Recruiting

Singapore,169608,Singapore

Novartis Investigative Site

Recruiting

Singapore,S308433,Singapore

Taiwan

Novartis Investigative Site

Recruiting

Taichung,407219,Taiwan

United States

University Of Iowa

Recruiting

Iowa City,Iowa,52242,United States

Ashley Pieper

Phone: 319-356-2197
Email: ashley-pieper@uiowa.edu

Hanna Zembrzuska

Northwestern University

Recruiting

Chicago,Illinois,60611,United States

George Georges

Matthew Selle

Email: autoimmunesct@nm.org

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111
Email: novartis.email@novartis.com

Novartis Pharmaceuticals

Phone: 1-888-669-6682
Email: novartis.email@novartis.com

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