Phase 2 Study Evaluating Rapcabtagene Autoleucel in Participants With Severe Active GPA or MPA

Last Update: Jun 29, 2025
A Phase 2, Randomized, Open-label, Controlled Study to Evaluate the Efficacy and Safety of Rapcabtagene Autoleucel Versus Comparator in Participants With Severe Active Granulomatosis With Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)
ClinicalTrials.gov Identifier:
NCT06868290
Novartis Reference Number:CYTB323I12201
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

The purpose of this study is to evaluate the efficacy and safety of rapcabtagene autoleucel versus comparator in participants with severe active Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)
This is a Phase 2, 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 comparator.

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
ANCA Associated Vasculitis (AAV)
Phase
Phase2
Overall Status
Recruiting
Number of Participants
126
Start Date
Mar 13, 2025
Completion Date
May 24, 2030
Gender
All
Age(s)

18 Years - 75 Years (Adult, Older Adult)

Interventions

Other

Active Comparator

Active comparator option as per protocol
Drug

Glucocorticoids

Concomitant glucocorticoids as per protocol
Biological

Rapcabtagene autoleucel

Single infusion of rapcabtagene autoleucel

Eligibility Criteria

Key inclusion criteria:

1. Men and women, aged ≥18 and ≤ 75 years with a diagnosis of GPA or MPA according to the American College of Rheumatology/ European League Against Rheumatism 2022 (ACR/EULAR 2022) classification criteria
2. Positive test for ANCA-autoantibodies
3. GPA and MPA participants with severe active disease

Key exclusion criteria:

1. Any condition 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. Hypersensitivity and/or contraindications to any product to be given to the participant as part of the study protocol
3. Other systemic autoimmune diseases requiring therapy
4. Any medical conditions that are not related to GPA/MPA that would jeopardize the ability of the participant to tolerate CD19 CAR-T cell therapy
5. Inadequate organ function

Israel

Novartis Investigative Site

Recruiting

Ramat Gan,5265601,Israel

Novartis Investigative Site

Recruiting

Haifa,3109601,Israel

Japan

Novartis Investigative Site

Recruiting

Kobe,Hyogo,650-0047,Japan

Novartis Investigative Site

Recruiting

Chiba,2608677,Japan

Novartis Investigative Site

Recruiting

Kanazawa,Ishikawa,920 8641,Japan

Novartis Investigative Site

Recruiting

Sendai city,Miyagi,980 8574,Japan

Novartis Investigative Site

Recruiting

Suita,Osaka,565 0871,Japan

Novartis Investigative Site

Recruiting

Kyoto,606 8507,Japan

Novartis Investigative Site

Recruiting

Sapporo city,Hokkaido,060 8648,Japan

Saudi Arabia

Novartis Investigative Site

Recruiting

Riyadh,11211,Saudi Arabia

Singapore

Novartis Investigative Site

Recruiting

Singapore,119074,Singapore

Novartis Investigative Site

Recruiting

Singapore,S308433,Singapore

Switzerland

Novartis Investigative Site

Recruiting

Basel,4031,Switzerland

Novartis Investigative Site

Recruiting

Bern,3010,Switzerland

United States

Oregon Health Sciences University

Recruiting

Portland,Oregon,97239,United States

Atul Deodhar

Yuki Harry

Email: harryy@ohsu.edu

Northwestern Memorial Hospital

Recruiting

Evanston,Illinois,60611,United States

Anisha Dua

John Seagrist

Email: john.seagrist@northwestern.edu

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

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06868290*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06868290
2. #trial-eligibility
3. mailto:harryy@ohsu.edu
4. mailto:john.seagrist@northwestern.edu
5. tel:+41613241111
6. mailto:novartis.email@novartis.com
7. tel:1-888-669-6682
8. mailto:novartis.email@novartis.com