NOVARTIS

An Open-label Study to Assess the Safety, Efficacy, and Cellular Kinetics of YTB323 in Relapsing Multiple Sclerosis

Last Update: May 06, 2025

An Open-label, Multi-center, Phase 1/2 Study to Assess Safety, Efficacy, and Cellular Kinetics of YTB323 in Participants With Relapsing Multiple Sclerosis With Breakthrough Disease Activity During Previous Treatment With a Highly Efficacious Therapy

ClinicalTrials.gov Identifier:

NCT06617793

Novartis Reference Number:CYTB323N12101

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

This is an open-label, multi-center, non-confirmatory study to assess the safety, efficacy, and cellular kinetics of YTB323 in approximately 28 participants with Relapsing Multiple Sclerosis (RMS) with breakthrough disease activity during previous treatment with a highly efficacious therapy (BD-HET). The study design utilizes an ascending single dose design consisting of 3 sentinel cohorts followed by an expansion cohort. All participants in this study will receive YTB323. Both the participant and the study doctor will know the participant is getting YTB323. Participants will be given one dose of YTB323. Different groups of participants may receive a higher dose of YTB323, if proven to be safe for every participant at the lower dose. Participants are in this study for 2 years and will be followed for an additional 13 years in a long-term follow up study. The main question this trial is designed to answer: Is YTB323 treatment safe for participants with relapsing MS?

Condition

Relapsing Multiple Sclerosis

Phase

Phase1, Phase2

Overall Status

Recruiting

Number of Participants

28

Start Date

Feb 24, 2025

Completion Date

Oct 01, 2030

Gender

All

Age(s)

18 Years - 60 Years (Adult)

Interventions

Biological

rapcabtagene autoleucel (YTB323)

CAR-T cell suspension for intravenous infusion

Eligibility Criteria

Inclusion Criteria:

* Signed informed consent, and able to communicate well with the investigator and comply with the requirements of the study
* Adequate renal, hepatic, cardiac, hematological, and pulmonary function
* Male or female participants, ≥18 years to ≤60 years at screening, with diagnosis of RMS according to the 2017 McDonald diagnostic criteria Evidence of recent (i.e. within 1 year) breakthrough disease activity while at least 6 months on a highly efficacious therapy (any of the following): rituximab (Rituxan®), ocrelizumab (Ocrevus®), natalizumab (Tysabri®), ofatumumab (Kesimpta®), ublituximab (Briumvi®) or evidence of breakthrough disease activity within 2 years after the latest alemtuzumab infusion (Lemtrada®).

Evidence of breakthrough disease activity is defined as one or more of the following:

1. Confirmed Clinical MS relapse
2. Persistent radiological activity defined by one of the following:

* ≥2 T1 gadolinium-enhancing lesions on a single MRI scan
* ≥1 T1 gadolinium-enhancing lesions on two or more separate MRI scans
* ≥2 new T2 lesions compared to a previous scan within a period ≤1 year

* Ambulatory patients (EDSS of 3 to 6 points, inclusive assessed outside of relapse)
* Disease duration less than 15 years

Exclusion Criteria:

* Diagnosis of primary progressive multiple sclerosis (PPMS) according to the 2017 revision of the McDonald diagnostic criteria at screening
* History of or current clinically significant CNS disease (e.g. stroke, traumatic brain or spinal injury, history or presence of myelopathy) or neurological disorders which may mimic MS or ICANS at screening
* Evidence of clinically significant cardiovascular (such as but not limited to myocardial infarction, unstable ischemic heart disease, New York Heart Association (NYHA) Class III/IV left ventricular failure, arrhythmia and uncontrolled hypertension within 6 months prior to screening), neurological disorders other than MS (including seizure disorders even when well controlled), psychiatric, pulmonary (including, history of or active severe respiratory disease, including Chronic Obstructive Pulmonary Disease, interstitial lung disease or pulmonary fibrosis), renal, hepatic, endocrine, metabolic (e.g. severe hypoproteinemia due to nephrotic syndrome), hematological disorders or gastrointestinal disease that, in the investigator's opinion, would compromise the safety of the participant, interfere with the interpretation of the study results or otherwise preclude participation or protocol adherence of the participant, prior to screening

* Have donated blood or experienced a loss of blood \> 400 mL within 3 months prior screening, or longer if required by local regulations
* Any prior stem cell therapy or organ transplantation or gene therapy
* Any contraindications to LP, including but not limited to:

* Known or suspected structural abnormality of the lumbar spine that, in the opinion of the Investigator, may interfere with the performance of the LP, or increase the risk of the procedure for the participant
* Presence of risk for increased or uncontrolled bleeding including, but not limited to, vascular abnormalities or neoplasms at or near the LP site, disorders of the coagulation cascade, platelet function, or platelet count
* Participants on anticoagulants (e.g., warfarin) or antiplatelets \[except for low-dose aspirin (100 mg/day or lower) and low-dose ibuprofen (600 mg/day or lower) which are allowable\], are not eligible to participate
* Participants not willing or able to take MRI scans as per protocol. Unable to undergo MRI due to for example claustrophobia, or presents absolute contraindications to MRI (e.g., metallic implants, metallic foreign bodies, pacemaker, defibrillator)

Other protocol-defined inclusion/exclusion criteria may apply

Australia

Novartis Investigative Site

Recruiting

Darlinghurst,New South Wales,2010,Australia

Novartis Investigative Site

Recruiting

Melbourne,Victoria,3004,Australia

Germany

Novartis Investigative Site

Recruiting

Essen,45147,Germany

Novartis Investigative Site

Recruiting

Bochum,44791,Germany

Spain

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Recruiting

Valencia,46026,Spain

Switzerland

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Recruiting

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Worldwide Contacts

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

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06617793*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06617793
2. #trial-eligibility
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