# Efficacy and Safety of Remibrutinib After Switching From Ocrelizumab in Participants Living With Relapsing Multiple Sclerosis.

Last Update: Sep 11, 2025
A Randomized, Open-label, Parallel-group, Non-inferiority Study Comparing Efficacy, Safety, and Tolerability of Remibrutinib After Switching From Ocrelizumab in Participants Living With Relapsing Multiple Sclerosis, Followed by Open-label Treatment With Remibrutinib
ClinicalTrials.gov Identifier:
NCT06846281
Novartis Reference Number:CLOU064C12306
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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 Phase 3b study is to assess the efficacy, safety and tolerability of remibrutinib after switching from ocrelizumab and compared to continuous ocrelizumab treatment, in patients living with relapsing multiple sclerosis (plwRMS). The study is a randomized, open-label, non-inferiority multi-center, Phase 3b study to provide efficacy, safety, and tolerability data for remibrutinib after switching from ocrelizumab and in comparison to continuous ocrelizumab in plwRMS.

This study consists of an initial Core Part (CP) (maximum duration per participant of up to 24 months), followed by an Extension Part (EP) (of up to 24 months duration) for eligible participants.

All participants completing the 24-month treatment of the Core Part of the study may be eligible to continue in the Extension Part, an open-label, single-arm, fixed-dose design in which participants are treated with remibrutinib for up to 24 months.

The study will be conducted in the USA among other countries globally.

Condition
Relapsing Multiple Sclerosis
Phase
Phase3
Overall Status
Recruiting
Number of Participants
360
Start Date
Jul 23, 2025
Completion Date

Jan 08, 2032
Gender
All
Age(s)
40 Years - 70 Years (Adult, Older Adult)

# Interventions

Drug

### Ocrelizumab

Ocrelizumab 600mg infusion or 920mg injection
Drug

### Remibrutinib oral treatment

Remibrutinib tablet taken daily

# Eligibility Criteria

Key Inclusion Criteria:

* Male or female aged 40 to 70 years (inclusive)
* Diagnosis of RMS according to the 2017 McDonald diagnostic criteria
* Treated with ocrelizumab according to routine clinical practice and at standard dose
* Neurologically stable within 30 days
* Suitable to be switched to remibrutinib based on physician judgement or patient preference

Key Exclusion Criteria:

* Diagnosis of primary progressive multiple sclerosis (PPMS) according to the revised 2017 McDonald criteria
* History of clinically significant Central Nervous System disease or neurological disorders
* History of confirmed Progressive Multifocal Leukoencephalopathy or neurological symptoms consistent
* Active clinically significant systemic bacterial, viral, parasitic or fungal infections
* Active, chronic disease of the immune system other than MS
* Severe cardiac disease or significant findings on the ECG
* Participant who is unable to undergo MRI scans
* History of life-threatening infusion or injection reaction related to ocrelizumab

Other inclusion and exclusion criteria may apply

**Australia**

**Novartis Investigative Site**

Recruiting

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**Novartis Investigative Site**

Recruiting

Liverpool,2170,Australia

**Novartis Investigative Site**

Recruiting

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**Novartis Investigative Site**

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**South Africa**

**Novartis Investigative Site**

Recruiting

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# Worldwide Contacts

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