ForPatients
*by Roche*

Multiple Sclerosis (MS)

# A Study to Investigate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Pharmacodynamics of a New Subcutaneous Formulation of Ocrelizumab in Participants With Multiple Sclerosis

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Recruiting | 4 Countries | NCT07667322 2024-513639-26-00 WN45319 |

*The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.*

## *Official Title:*

A Phase 1b Multicenter, Non-randomized, Open-label Study to Investigate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Pharmacodynamics of Single Ascending Doses of a New Subcutaneous Formulation of Ocrelizumab in Patients With Multiple Sclerosis

## *Trial Summary:*

The main purpose of this study is to evaluate the safety and tolerability of the ocrelizumab subcutaneous (SC) test formulation in participants with multiple sclerosis (MS). The study consists of two treatment phases: a dose-escalation and dose-continuation phase. Participants will receive single ascending doses of ocrelizumab SC during an initial dose-escalation phase, with the option to continue treatment with the selected dose of ocrelizumab SC in the dose-continuation phase.

| Hoffmann-La Roche | Phase 1 |
|---|---|
| Sponsor | Phase |

**NCT07667322 2024-513639-26-00 WN45319**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years & # 65 Years | No |

## *Inclusion Criteria:*

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- Diagnosis of Primary Progressive Multiple Sclerosis (PPMS) or Relapsing Multiple Sclerosis (RMS) according to the revised McDonald 2017 criteria (Thompson et al. 2018)
- Expanded Disability Status Scale (EDSS) score, 0-6.5, inclusive, at screening

## *Exclusion Criteria:*

- Participants who have previously received anti-cluster of differentiation 20 (CD20s) (including ocrelizumab) less than 2 years before screening
- Any known or suspected active infection at screening or baseline (except nailbed infections), or any major episode of infection requiring hospitalization or treatment with intravenous (IV) antimicrobials within 8 weeks prior to and during screening or treatment with oral antimicrobials within 2 weeks prior to and during screening
- History of confirmed or suspected progressive multifocal leukoencephalopathy (PML)
- History of cancer, including hematologic malignancy and solid tumors, within 10 years of screening
- Immunocompromised state
- Any concomitant disease that may require chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study
- Significant, uncontrolled disease, such as cardiovascular (including cardiac arrhythmia), pulmonary (including obstructive pulmonary disease), renal, hepatic, endocrine or gastrointestinal, or any other significant disease that may preclude participation in the study
- Lack of peripheral venous access
- Previous treatment with cladribine, atacicept, and alemtuzumab
- Previous treatment with fingolimod, siponimod, ponesimod, or ozanimod within 6 weeks of baseline
- Any previous treatment with bone marrow transplantation and hematopoietic stem cell transplantation
- Any previous history of transplantation or anti-rejection therapy
- Positive screening tests for active, latent, or inadequately treated hepatitis B
- Sensitivity or intolerance to any ingredient (including excipients) of ocrelizumab

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