ForPatients
by Roche

Relapsing Multiple Sclerosis (RMS)Primary Progressive Multiple Sclerosis (PPMS)

A Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Ocrelizumab in Participants With Relapsing Multiple Sclerosis and Primary Progressive Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07483450 YN44938

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 Multicenter, Open-label, Single-arm Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Ocrelizumab in Chinese Patients With Relapsing Multiple Sclerosis and Primary Progressive Multiple Sclerosis

Trial Summary:

The main purpose of this study is to evaluate the efficacy of ocrelizumab in participants with relapsing multiple sclerosis (RMS) and to characterize the ocrelizumab pharmacodynamic (PD) profile in Chinese participants with primary progressive multiple sclerosis (PPMS).

Hoffmann-La Roche
Sponsor

Phase 4
Phase

NCT07483450 YN44938
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 55 Years	No

Inclusion Criteria:

- Diagnosis of RMS/PPMS in accordance with the revised 2017 McDonald Criteria
- EDSS score from 0-5.5 (RMS) or 3.0-6.5 (PPMS), inclusive, at screening and baseline
- Documented MRI of brain with abnormalities consistent with MS before screening

Exclusion Criteria:

- Diagnosis of PPMS or non-active secondary progressive multiple sclerosis (SPMS) (only for RMS cohort)
- History of relapsing remitting multiple sclerosis (RRMS) or SPMS at screening (only for PPMS cohort)
- Disease duration of more than 10 years in participants with an EDSS # 2.0 at screening (only for RMS cohort)
- History of confirmed or suspected progressive multifocal leukoencephalopathy (PML)
- Inability to complete an MRI scan or contraindication to Gd administration
- Contraindications to mandatory pre-medications (i.e., corticosteroids and antihistamines)
- Known presence of other neurologic disorders if they could interfere with the diagnosis of MS or assessments of efficacy and/or safety during the study
- Any concomitant disease that may require chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study
- Known history of human immunodeficiency virus (HIV) infection
- Lack of peripheral venous access
- Previous treatment with B-cell targeted therapies (i.e., rituximab, ocrelizumab, atacicept, belimumab, or ofatumumab), unless the last infusion was at least 6 months prior to screening
- Positive screening tests for hepatitis B virus (HBV) and/or hepatitis C virus (HCV)