ForPatients
*by Roche*

Multiple Sclerosis (MS)

# A Study To Investigate The Pharmacokinetics, Safety, And Tolerability Of Subcutaneous Ocrelizumab Administration In Patients With Multiple Sclerosis

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 1 Country | NCT03972306 CN41144 |

*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 Ib, Open-Label, Multicenter Study To Investigate The Pharmacokinetics, Safety, And Tolerability Of Subcutaneous Ocrelizumab Administration In Patients With Multiple Sclerosis

## *Trial Summary:*

This study will evaluate the pharmacokinetics, safety and tolerability, and immunogenicity of ocrelizumab administered subcutaneously to participants with multiple sclerosis (MS).

**Hoffmann-La Roche**
Sponsor

**Phase 1**
Phase

**NCT03972306 CN41144**
Trial Identifiers

## *Eligibility Criteria:*

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

## *Inclusion Criteria:*

- 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
- Absence of relapses for 30 days prior to the screening visit
- For the dose escalation phase for participants pretreated with ocrelizumab (Group A):

treatment with IV ocrelizumab for at least 1 year prior to screening (i.e., at least two 600-mg doses of ocrelizumab separated by 24 weeks)

- For women of childbearing potential: agreement to remain abstinent or use acceptable contraceptive methods during the treatment period and for 6 months after the final dose of ocrelizumab.
- For female perticipants without reproductive potential:

Women may be enrolled if post-menopausal unless the participant is receiving a hormonal therapy for her menopause or if surgically sterile (i.e., hysterectomy, complete bilateral oophorectomy).

## *Exclusion Criteria:*

- MS disease duration of more than 15 years for participants with an Expanded Disability Status Scale (EDSS) score <2.0 at screening.
- Known presence of other neurologic disorders that may mimic MS, including, but not limited to, the following:
- History of ischemic cerebrovascular disorders (e.g., stroke, transient ischemic attack) or ischemia of the spinal cord
- History or known presence of Central Nervous System (CNS) or spinal cord tumor (e.g., meningioma,glioma)
- History or known presence of potential metabolic causes of myelopathy (e.g., untreated vitamin B12 deficiency)
- History or known presence of infectious causes of myelopathy (e.g., syphilis, Lyme disease, human T-lymphotropic virus 1, herpes zoster and myelopathy.
- History of genetically inherited progressive CNS degenerative disorder (e.g., hereditary paraparesis and mitochondrial myopathy, encephalopathy, lactic acidosis, and stroke syndrome)
- Neuromyelitis optica
- History or known presence of systemic autoimmune disorders potentially causing progressive neurologic disease (e.g., lupus, anti-phospholipid antibody syndrome, Sjögren syndrome, Behçet disease, sarcoidosis).
- History of severe, clinically significant brain or spinal cord trauma (e.g., cerebral contusion, spinal cord compression