ForPatients
by Roche

Multiple Sclerosis (MS)

A Study of Ocrelizumab Administered Subcutaneously in Participants With Multiple Sclerosis Who Switch From an Approved Anti-CD20 Therapy

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting	2 Countries	NCT07609719 ML46740

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 Prospective, Multicenter, Single-arm Study of Ocrelizumab Administered Subcutaneously in Patients With Multiple Sclerosis Who Switch From an Approved Anti-CD20 Therapy

Trial Summary:

The purpose of this study is to assess the imaging biomarkers, patient outcomes, safety, tolerability, and treatment satisfaction of ocrelizumab (OCR) combined with recombinant human hyaluronidase (rHuPH20) administered subcutaneously (SC) in participants with relapsing multiple sclerosis (RMS) or primary progressive multiple sclerosis (PPMS) after switching from another anti-cluster of differentiation 20 (aCD20) therapy approved for RMS (ofatumumab SC, ublituximab-xiiy intravenous [IV], ocrelizumab IV) or PPMS (ocrelizumab IV).

Genentech, Inc.
Sponsor

Phase 4
Phase

NCT07609719 ML46740
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Diagnosis of RMS or PPMS according to the revised McDonald 2017 criteria

- Documented Expanded Disability Status Scale (EDSS) score of 0-6.5, inclusive, at screening (or within 6 months of screening)
- Participants discontinuing aCD20 therapy for reasons including, but not limited to, physician/participant preference, access to commercial drug (e.g., insurance coverage issues), or other logistical reasons (such as geographical relocation, travel, etc.) are eligible for this study
- Prior treatment with ofatumumab SC, ublituximab-xiiy IV, or ocrelizumab IV aCD20 therapy

Exclusion Criteria:

- Participants who have demonstrated suboptimal response to aCD20 therapy
- Discontinuing aCD20 therapy because of any of the following treatment emergent adverse events (TEAEs): 1) Grade #3 severe infusion-related reaction (IRRs) or injection reactions (IRs); 2) Recurrent Grade #3 infections, or the need for #2 courses of antibiotics after starting aCD20 therapy, if the investigator believes infection is related to therapy
- Participants with contraindication to Gd+ and participants who for any reason cannot tolerate MRI procedure
- Known presence of active, recurrent, or chronic infection (e.g., human immunodeficiency virus [HIV], syphilis, human papillomavirus [HPV], tuberculosis [TB])
- History of confirmed or suspected progressive multifocal leukoencephalopathy (PML)
- Known presence of neurologic disorders that may interfere with the diagnosis of RMS or PPMS
- Any concomitant disease that may require treatment with systemic corticosteroids (e.g., mineralocorticoids and glucocorticoids) or immunosuppressants during the study
- Known allergy or hypersensitivity to ocrelizumab, rHuPH20, or excipients of the OCR SC formulation
- Any previous treatment with bone marrow transplantation and hematopoietic stem cell transplantation
- Treatment with any live-attenuated vaccine within 6 weeks prior to baseline
- Treatment with any experimental procedures for RMS or PPMS (e.g., treatment for chronic cerebrospinal venous insufficiency)
- Previous treatment with cladribine, atacicept, alemtuzumab or mitoxantrone
- Positive hepatitis B virus (HBV) and hepatitis C virus (HCV) antibody test at screening

Other protocol defined inclusion and exclusion criteria may apply.