ForPatients
by Roche

Multiple Sclerosis (MS)

A Study to Evaluate the Safety of Administering Ocrelizumab Per a Shorter Infusion Protocol in Participants With Primary Progressive Multiple Sclerosis (PPMS) and Relapsing Multiple Sclerosis (RMS).

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03606460 ML40638

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 IIIb, Open-Label Study To Evaluate The Safety And Tolerability Of Shorter Infusions Of Ocrelizumab In Patients With Primary Progressive And Relapsing Multiple Sclerosis

Trial Summary:

This study is an open-label, non-randomized study to evaluate rate and severity of infusion-related reactions (IRRs) of ocrelizumab infused over a shorter time period than the approved administration rate in participants with PPMS or RMS in the United States (U.S.). Participants will be enrolled into two cohorts. Cohort 1 will examine the effect of administering ocrelizumab per a shorter infusion protocol for Dose 2 or Dose 3. This cohort will consist of patients who have already received one or two doses of ocrelizumab according to the approved infusion protocol (i.e., per the currently U.S. label) and have reported no serious IRRs and who will then receive the next infusion of ocrelizumab at a higher rate in order to deliver 600 mg over the course of approximately 2 hours. Cohort 2 will examine the effect of administering ocrelizumab per a shorter infusion protocol for the second infusion of Dose 1. This cohort will consist of ocrelizumab naïve patients who, after receiving Infusion 1/Dose 1 of ocrelizumab at the approved rate (300 mg over approximately 2.5 hours or longer) have no reported serious IRRs, will then receive the second 300-mg shorter infusion over approximately 1.5 hours.

Genentech, Inc.	Phase 3
Sponsor	Phase

NCT03606460 ML40638
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Eligible to receive ocrelizumab per the United States Package Insert (USPI)
- Able to comply with the study protocol, in the investigator's judgment
- Age 18-55 years, inclusive
- Have a diagnosis of PPMS or RMS, confirmed per the revised 2017 McDonald criteria
- Expanded Disability Status Scale (EDSS) score of 0 to 6.5, inclusive
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and for at least 6 months after the last dose of study treatment (per the USPI)

Exclusion Criteria:

- Experienced serious IRR(s)
- History of life-threatening infusion reaction to ocrelizumab
- Known presence of other neurological disorders
- Pregnancy or lactation, or intention to become pregnant during the study
- 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, and gastrointestinal or any other significant disease that may preclude patient from participating in the study
- Congestive heart failure
- Known active bacterial, viral, fungal, mycobacterial infection or other infection or any severe episode of infection requiring hospitalization or treatment with IV antibiotics within 4 weeks prior to baseline visit or oral antibiotics within 2 weeks prior to baseline visit
- History of or currently active primary or secondary immunodeficiency
- History or known presence of recurrent or chronic infection (e.g., HIV, syphilis, tuberculosis)
- History of recurrent aspiration pneumonia requiring antibiotic therapy
- History of malignancy, including solid tumors and hematological malignancies,except basal cell, in situ squamous cell carcinoma of the skin, and in situ carcinoma of the cervix of the uterus that have been excised with clear margins
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies
- History of alcohol or drug abuse within 24 weeks prior to enrollment
- Receipt of a live vaccine within 6 weeks prior to enrollment
- Systemic corticosteroid therapy within 4 weeks prior to enrollment
- Contraindications to or intolerance of oral or IV corticosteroids, including IV methylprednisolone (or equivalent steroid) administered according to the country label
- Treatment with alemtuzumab
- Treatment with a B-cell targeted therapies other than ocrelizumab
- Treatment with a drug that is experimental
- Abnormal laboratory results per local laboratory standards and investigator assessment