ForPatients
by Roche

Multiple Sclerosis (MS)

A Study of Ocrelizumab in Participants With Relapsing Remitting Multiple Sclerosis (RRMS) Who Have Had a Suboptimal Response to an Adequate Course of Disease-Modifying Treatment (DMT)

Trial Status	Trial Runs In	Trial Identifier
Completed	17 Countries	NCT02861014 2015-005597-38 MA30005

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

An Open-Label Study To Evaluate the Efficacy and Safety of Ocrelizumab in Patients With Relapsing Multiple Sclerosis Who Have A Suboptimal Response to an Adequate Course of Disease-Modifying Treatment

Trial Summary:

The purpose of this prospective, multicenter, open-label, efficacy, and safety study is to assess the efficacy and safety of ocrelizumab in participants with Relapsing Remitting Multiple Sclerosis (RRMS) who have had a suboptimal response to an adequate course of a Disease-Modifying Treatment (DMT). The study will consist of a Screening period (up to 4 weeks), an Open-label treatment period (96 weeks; with last dose administered at Week 72), and a Follow-up period of at least 2 years.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT02861014 2015-005597-38 MA30005
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

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- Have a definite diagnosis of RRMS, confirmed as per the revised McDonald 2010 criteria
- Have a length of disease duration, from first symptom, of less than (<) 10 years
- Have received no more than two prior DMTs, and the discontinuation of the most recent DMT was due to lack of efficacy
- Suboptimal disease control while on a DMT
- Expanded Disability Status Scale (EDSS) of 0.0 to 4.0, inclusive, at Screening
- For women of childbearing potential: agreement to use an acceptable birth control method during the treatment period and for at least 6 months after the last dose of study drug

Exclusion Criteria:

- Secondary progressive multiple sclerosis (SPMS) or history of primary progressive or progressive relapsing multiple sclerosis (MS)
- Inability to complete an Magnetic Resonance Imaging (MRI) procedure
- Known presence of other neurological disorders
- Any concomitant disease that may require chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study
- History or currently active primary or secondary immunodeficiency
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies
- History of opportunistic infections
- History or known presence of recurrent or chronic infection
- History of malignancy
- Congestive heart failure
- Known active bacterial, viral, fungal, mycobacterial infection or other infection, excluding fungal infection of nail beds

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