ForPatients
by Roche

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

Study to Explore the Mechanism of Action of Ocrelizumab and B-Cell Biology in Participants With Relapsing Multiple Sclerosis (RMS) or Primary Progressive Multiple Sclerosis (PPMS)

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT02688985 2015-004616-37 ML29966

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This is an open-label, multicenter, biomarker study designed to be hypothesis-generating in order to better understand the mechanism of action of ocrelizumab and B-cell biology in RMS or PPMS. The study will be conducted in two cohorts i.e. RMS cohort (4 arm group) and PPMS cohort (one arm group). RMS cohort: Ocrelizumab will be administered as two intravenous (IV) infusions of 300 milligrams (mg) on Days 1 and 15. Subsequent doses will be given as single 600-mg infusions at Weeks 24 and 48. Participants will be randomized in 1:1:1 ratio to receive lumbar puncture (LP) post-treatment at Week 12, 24, or 52 following the first dose of ocrelizumab in three arm groups. A fourth RMS arm with delayed treatment start (Arm 4 [control group]) will not be a part of the randomization and will be recruited separately, wherein treatment with ocrelizumab will be delayed for 12 weeks from pre-treatment baseline. PPMS cohort: Ocrelizumab 600 mg will be administered as two 300-mg IV infusions separated by 14 days at a scheduled interval of every 24 weeks. Participants will receive a LP at the start of the study before dosing with ocrelizumab and second LP at Week 52 following the first dose of ocrelizumab. A long-term extension will be conducted for participants that complete the study and continue to receive ocrelizumab. Treatment with ocrelizumab in the entire study will continue for approximately 4.5 years after the first infusion.

Genentech, Inc.	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**>= 18 Years & <= 55 Years**	**No**