ForPatients
by Roche

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

A Study of Ocrelizumab in Participants With Primary Progressive Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Completed	29 Countries	NCT01194570 2010-020338-25 WA25046

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 III, Multicentre, Randomized, Parallel-group, Double-blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ocrelizumab in Adults With Primary Progressive Multiple Sclerosis

Trial Summary:

This randomized, parallel group, double-blind, placebo controlled study will evaluate the efficacy and safety of ocrelizumab in participants with primary progressive multiple sclerosis. Eligible participants will be randomized 2 : 1 to receive either ocrelizumab or placebo.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT01194570 2010-020338-25 WA25046
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Diagnosis of primary progressive multiple sclerosis (according to revised McDonald criteria)
- EDSS at screening from 3 to 6.5 points
- Disease duration from onset of MS symptoms less than (<) 15 years if EDSS greater than (>) 5.0; <10 years if EDSS greater than or equal to (>/=) 5.0

- Sexually active male and female participants of reproductive potential must use two methods of contraception throughout the study treatment phase and for 48 weeks after the last dose

Exclusion Criteria:

- History of relapsing remitting MS, secondary progressive, or progressive relapsing MS at screening
- Inability to complete an MRI (contraindications for MRI)
- Known presence of other neurologic disorders
- Known active infection or history of or presence of recurrent or chronic infection
- History of cancer, including solid tumors and hematological malignancies (except for basal cell, in situ squamous cell carcinomas of the skin and in situ carcinoma of the cervix that have been excised and resolved)
- Previous treatment with B-cell targeted therapies (e.g. rituximab, ocrelizumab, atacicept, belimumab, or ofatumumab)
- Any previous treatment with lymphocyte trafficking blockers, with alemtuzumab, anti-cluster of differentiation 4 (CD4), cladribine, cyclophosphamide, mitoxantrone, azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, total body irradiation, or bone marrow transplantation
- Any concomitant disease that may require chronic treatment with systemic corticosteroids or immunosuppressants during the course of the study