ForPatients
by Roche

Relapsing-Remitting Multiple Sclerosis (RRMS)Multiple Sclerosis (MS)

Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Participants With Early Stage Relapsing Remitting Multiple Sclerosis (RRMS)

Trial Status	Trial Runs In	Trial Identifier
Terminated	29 Countries	NCT03085810 2016-002937-31 MA30143

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:

An Open-Label, Single-Arm Study to Evaluate the Effectiveness and Safety of Ocrelizumab in Patients With Early Stage Relapsing Remitting Multiple Sclerosis

Trial Summary:

This is a prospective, multicenter, open-label, single-arm, phase 3b study which evaluates effectiveness and safety of ocrelizumab in participants with early stage RRMS. The study will consist of an open-label treatment period of 192 weeks and follow-up period of at least 48 weeks. The optional shorter infusion substudy will evaluate the safety of a shorter infusion of ocrelizumab in a subgroup of participants with early stage RRMS enrolled in the main MA30143 study. Approximately 700 patients will be enrolled in the substudy, and will receive additional 600 mg ocrelizumab administered in a shorter time frame.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03085810 2016-002937-31 MA30143
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Have a definite diagnosis of RRMS, as per the revised McDonald 2010 criteria
- Have a length of disease duration, from first documented clinical attack consistent with MS disease of less than or equal to (</=) 3 years
- Within the last 12 months one or more clinically reported relapse(s) or one or more signs of MRI activity
- EDSS of 0.0 to 3.5 inclusive, at screening
- An agreement to use an acceptable birth control method for women of childbearing potential, during the treatment period and for at least 6 months or longer after the last dose of study drug

Exclusion Criteria:

- Secondary progressive multiple sclerosis or history of primary progressive or progressive relapsing MS
- Inability to complete an MRI
- Known presence of other neurological disorders

Exclusions Related to General Health:

- Pregnancy or lactation
- Participants intending to become pregnant during the study or within 6 months after the last dose of the study drug
- 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
- Lack of peripheral venous access
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies
- Significant or uncontrolled somatic disease or any other significant disease that may preclude participant from participating in the study
- Congestive heart failure (New York Heart Association III or IV functional severity)
- Known active bacterial, viral, fungal, mycobacterial infection or other infection, (excluding fungal infection of nail beds) or any major episode of infection requiring hospitalization or treatment with IV antibiotics within 4 weeks prior to screening or oral antibiotics 2 weeks prior to screening
- History of malignancy, major opportunistic infections, alcohol or drug abuse, recurrent or chronic infection, and/or coagulation disorders

Exclusions Related to Medications:

- Received any prior approved disease modifying treatment (DMT) with a label for MS, for example, interferons, glatiramer acetate, natalizumab, alemtuzumab, daclizumab, fingolimod, teiflunomide and dimethylfumarate
- Receipt of a live vaccine or attenuated live vaccine within 6 weeks prior to the baseline visit
- Previous treatment with B-cell targeted therapies (i.e., rituximab, ocrelizumab, atacicept, belimumab, or ofatumumab)
- Any previous treatment with immunosuppressants/ immunomodulators/ antineoplastic therapies (cyclophosphamide, azathioprine, mycophenolate mofetil, cyclosporine, methotrexate, cladribine, mitoxantrone, laquinimod, total body irradiation, or bone marrow transplantation)
- Treatment with investigational DMT
- Treatment with fampridine/dalfamipridine unless on stable dose for >/=30 days prior to screening

Exclusion related to Shorter Infusion Substudy:

- Any previous serious IRRs experienced with ocrelizumab treatment