ForPatients
by Roche

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

A Study of the Efficacy and Safety of Ocrelizumab in Patients With Relapsing-Remitting Multiple Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Completed	18 Countries	NCT00676715 2007-006338-32 WA21493 ACT4422g

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:

Phase II, Multicenter, Randomized, Parallel-Group, Partially Blinded, Placebo and Avonex Controlled Dose Finding Study to Evaluate the Efficacy As Measured by Brain MRI Lesions, and Safety of 2 Dose Regimens of Ocrelizumab in Patients With RRMS

Trial Summary:

This is a phase II, multicenter, randomized, parallel-group, partially blinded, placebo and Avonex (interferon beta-1a) controlled dose finding study to evaluate the efficacy as measured by brain MRI lesions, and safety of 2 dose regimens of ocrelizumab in participants with Relapsing Remitting Multiple Sclerosis (RRMS).

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT00676715 2007-006338-32 WA21493 ACT4422g
Trial Identifiers

Eligibility Criteria:

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

Inclusion Criteria:

- Ability to provide written informed consent and to be compliant with the schedule of protocol assessments
- Relapsing-remitting multiple sclerosis (MS)
- Ages 18-55 years inclusive

- For sexually active female and male participants of reproductive potential, use of reliable means of contraception

Exclusion Criteria:

- Secondary or primary progressive multiple sclerosis at screening
- Incompatibility with MRI
- Contra-indications to or intolerance of oral or IV corticosteroids
- Known presence of other neurologic disorders
- Pregnancy or lactation
- Lack of peripheral venous access
- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies
- Significant, uncontrolled disease, such as cardiovascular, pulmonary, renal, hepatic, endocrine or gastrointestinal
- Congestive heart failure
- Known active bacterial, viral, fungal, mycobacterial infection or other infection or any major episode of infection requiring hospitalization or treatment with IV antibiotics within 4 weeks prior to screening or oral antibiotics within 2 weeks prior to screening
- History or known presence of recurrent or chronic infection
- History of cancer, including solid tumors and hematological malignancies (except basal cell, in situ squamous cell carcinomas of the skin, and in situ carcinoma of the cervix of the uterus that have been excised and resolved)
- History of alcohol or drug abuse within 24 weeks prior to randomization
- History of or currently active primary or secondary immunodeficiency
- History of coagulation disorders
- Treatment with any investigational agent within 4 weeks of screening
- Receipt of a live vaccine within 6 weeks prior to randomization
- Incompatibility with Avonex use
- Previous treatment with rituximab
- Previous treatment with lymphocyte-depleting therapies except mitoxantrone
- Treatment with lymphocyte trafficking blockers within 24 weeks prior to randomization
- Treatment with beta interferons, glatiramer acetate, IV immunoglobulin, plasmapheresis, or immunosuppressive therapies within 12 weeks prior to randomization
- Systemic corticosteroid therapy within 4 weeks prior to randomization