

Multiple Sclerosis (MS)

An Extension Study to Assess Impact of Multiple Sclerosis (MS) on Physical Function and Provide Continued Ocrelizumab Treatment

Trial Status
Recruiting

Trial Runs In
3 Countries

Trial Identifier
NCT06675955 2023-507633-21-01
MN45053

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, Multicenter Extension Study Evaluating the Patient Perspective of the Physical Impact of Multiple Sclerosis and Providing Continued Access to Ocrelizumab in Patients With Multiple Sclerosis Previously Enrolled in a Genentech and/or F. Hoffmann-La Roche Ltd Sponsored Study and Without Access to a Post-Trial Access Program

Trial Summary:

The study will evaluate the physical impact of MS from participant's perspective, provide continued access to ocrelizumab and assess the safety and tolerability of ocrelizumab.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Participants who were on ongoing ocrelizumab treatment on one of the following parent-studies [Studies MN39159/CONSONANCE (NCT03523858), BN42082/MUSETTE (NCT04544436), BN42083/GAVOTTE (NCT04548999), BN44083/GLOBEAM, MN43978/CONSONANCE Ext., WA40404/O'HAND (NCT04035005), MN43964/OLERO (NCT05269004), GN41791/FENTREPID (NCT04544449), BP46016/MINTAKA, CN41144/OCARINA I-SC (NCT03972306), CN42097/OCARINA II-SC

ForPatients

by Roche

(NCT05232825)] at the time of roll-over and who do not have access to the ocrelizumab treatment locally.

- The first dose of study treatment in this extension study will be received no earlier than 5 months after the last treatment in the parent study.
- Negative urine pregnancy test within 24 hours to first dose administered on MN45053 study treatment in participants of childbearing potential.

Exclusion Criteria:

- Study treatment is commercially marketed in the participant's country for the participant specific disease and is reasonably accessible to the participant.
- Study treatment is available via Post Trial Access Program (PTAP) in the participant's country and is accessible to the participant.
- Permanent premature discontinuation of study treatment for any reason during the parent study or during the time between last treatment in the parent study and the first dose of study treatment in this extension study (if applicable).
- Any condition that, in the opinion of the investigator, would interfere with the interpretation of participant safety or place the participant at high risk for treatment-related complications.
- Concurrent participation in any therapeutic clinical trial (other than the parent study).
- Immunocompromised state
- Known active malignancy or are being actively monitored for recurrence of malignancy.
- Known presence of other neurological disorders.