ForPatients
by Roche

Multiple Sclerosis (MS)

A Study to Evaluate the Long-term Safety and Efficacy of Fenebrutinib in Participants With Multiple Sclerosis (MS)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07937852 2026-526037-26-00 CN45787

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Multicenter, Single Arm, Open-label, Extension, Roll-over Study to Evaluate the Long-term Safety and Efficacy of Fenebrutinib in Participants With Multiple Sclerosis

Trial Summary:

The primary purpose of this study is to evaluate the long-term safety of fenebrutinib in participants with MS who were previously enrolled in one of the eligible Roche-sponsored parent studies, including, but not limited to FENhance I (NCT04586010), FENhance II (NCT04586023), FENtrepid (NCT04544449), and FENopta (NCT05119569).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Previous eligibility and participation in the open-label extension (OLE) phase of an eligible Roche-sponsored parent study, where the participant is receiving fenebrutinib as an investigational medicinal product (IMP)
- Minimum of 24 weeks exposure to open-label fenebrutinib in parent study

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- Ability and willingness to comply with all aspects of the protocol including completion of procedures, interviews, questionnaires, assessments for the duration of the study

Exclusion Criteria:

- Concurrent participation in any clinical trial (other than the parent study). Participants who withdrew from fenebrutinib treatment in their respective parent study should also be excluded
- Pregnant or breastfeeding, or intention of becoming pregnant during the study or within the time frame in which contraception is required
- Chronic liver disease unless considered stable for >6 months
- Acute liver disease
- Cirrhosis (Child-Pugh Class A, B, or C)
- Gilbert's syndrome
- Aspartate aminotransferase (ALT) or alanine aminotransferase (AST) > 1.5 × upper limit of normal (ULN)
- Total bilirubin greater than 1.5 × ULN
- A "yes" on any item of the Suicidal Behavior section of the Columbia-Suicide Severity Rating Scale (C-SSRS) or significant risk of a suicide, in the investigator's judgment

Note: Other protocol-defined inclusion/exclusion criteria may apply

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