Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of a New Maintenance Dosing Regimen of Ofatumumab

Last Update: Apr 24, 2025

An Open-label, Randomized, Parallel Group, Non-inferiority Study to Investigate the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of a New Maintenance Dosing Regimen of Ofatumumab, Followed by Extended Treatment in Participants With Relapsing Multiple Sclerosis

ClinicalTrials.gov Identifier:

NCT06869785

Novartis Reference Number:COMB157Q12301

See if you Pre-qualify

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This study will evaluate the pharmacokinetics, pharmacodynamics, safety and tolerability of a new dosage of ofatumumab compared to the approved dosage of ofatumumab followed by extended treatment in participants with relapsing multiple sclerosis. This is a Phase 3, open label, parallel-group, multicenter study in participants with relapsing multiple sclerosis

Condition

Relapsing Multiple Sclerosis (RMS)

Phase

Phase3

Overall Status

Recruiting

Number of Participants

180

Start Date

Mar 13, 2025

Completion Date

May 26, 2031

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

Interventions

Biological

Ofatumumab approved dose

Approved dosage
Biological

Ofatumumab new dose

New dosage

Eligibility Criteria

Inclusion Criteria:

* Signed informed consent must be obtained prior to participation in the study.
* Male or female study participants aged 18 to 60 years (inclusive) at screening.
* Diagnosis of multiple sclerosis (MS) according to the 2017 Revised McDonald criteria (Thompson et al 2018). Relapsing forms of MS: relapsing-remitting MS (RRMS), or active secondary progressive MS (SPMS).

Exclusion Criteria:

* Participants suspected of not being able or willing to cooperate or comply with study protocol requirements in the opinion of the Investigator or emergence of any clinically significant condition/disease (e.g. active systemic bacterial, viral or fungal infections) during screening prior to Day 1 which might result in safety risk for participants.
* Participants with history of confirmed progressive multifocal leukoencephalopathy (PML) or neurological symptoms consistent with PML.
* Participants at risk of developing or having reactivation of hepatitis
* Emergence of active chronic disease (or stable but treated with immune therapy) prior to Day 1 of the immune system other than MS (e.g. rheumatoid arthritis, scleroderma, Sjögren's syndrome, Crohn's disease, ulcerative colitis, etc.) or with immunodeficiency syndrome (hereditary immune deficiency, drug-induced immune deficiency).
* Pregnant or nursing (lactating) women
* History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system (except for basal cell carcinoma, or squamous cell carcinomas of the skin that have been treated with no evidence of recurrence in the past 3 months).
* Participants taking prohibited therapies, including B cell targeted therapies (e.g. such as ocrelizumab, rituximab, ofatumumab, ublituximab, and inebilizumab)

Other protocol-defined inclusion/exclusion criteria may apply

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