Kesimpta® (Ofatumumab) in Swiss Multiple Sclerosis Patients - an Observational Study

Last Update: Jan 14, 2025
Kesimpta® (Ofatumumab) in Swiss Multiple Sclerosis Patients - an Observational Study (KOSMOS)
ClinicalTrials.gov Identifier:
NCT05285904
Novartis Reference Number:COMB157GCH01
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 is a multi-center, observational study carried out in Switzerland that aims to describe the effects of Ofatumumab in a setting of routine medical care. This non-interventional study will observe the effect of Ofatumumab treatment compared to the standard of care (SoC) arm of a closely monitored phase-IIIb study (STHENOS-COMB157G3301) in MS patients in a real-world setting in Switzerland over an observational period of 12 month.

Condition
Multiple Sclerosis
Overall Status
Recruiting
Number of Participants
149
Start Date
May 12, 2022
Completion Date
Jun 30, 2026
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

Ofatumumab

Prospective observational cohort study. There is no treatment allocation. Patients administered Ofatumumab, that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Written informed consent must be obtained before participating in the study.
2. Diagnosis of RMS per McDonald Criteria (2017) occurred within 3 years prior to initiation of Ofatumumab.
3. Adult patients who have been on treatment with Ofatumumab for at least 3 months, but not longer than 12 months prior to inclusion in the study.
4. Ofatumumab treatment in line with the Swiss Kesimpta® label (i.e. adult patients with active, relapsing forms of MS)
5. Patient is willing and able to complete patient diary during course of the study, as well as to complete PRO questionnaires.

Exclusion Criteria:

1. Use of investigational drugs during the study, OR between Ofatumumab initiation and inclusion into the study, OR within 3 months before Ofatumumab initiation, OR within 5 half-lives of investigational drug before Ofatumumab initiation, OR until the expected pharmacodynamic effect has returned to baseline, whichever is longer.
2. Subjects who are not able to provide consent due to incapable judgement

Switzerland

Novartis Investigative Site

Recruiting

Basel,4001,Switzerland

Novartis Investigative Site

Recruiting

Zuerich,CHE,8001,Switzerland

Novartis Investigative Site

Recruiting

Zuerich,8091,Switzerland

Novartis Investigative Site

Recruiting

Bern,3010,Switzerland

Novartis Investigative Site

Recruiting

Luzern,LU,6006,Switzerland

Novartis Investigative Site

Recruiting

Lausanne,1011,Switzerland

Novartis Investigative Site

Recruiting

Sargans,Saint Gallen,7320,Switzerland

Novartis Investigative Site

Recruiting

Lugano,6900,Switzerland

Novartis Investigative Site

Recruiting

Gland,Vaud,1196,Switzerland

Novartis Investigative Site

Recruiting

Luzern,6000,Switzerland

Novartis Investigative Site

Recruiting

Zug,ZG,6300,Switzerland

Novartis Investigative Site

Recruiting

Luzern,6004,Switzerland

Novartis Investigative Site

Recruiting

Zurich,ZH,8006,Switzerland

Novartis Investigative Site

Recruiting

Baden,Aargau,5405,Switzerland

Novartis Investigative Site

Recruiting

Sion,1950,Switzerland

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: +41613241111
Email: novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05285904*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT05285904
2. #trial-eligibility
3. tel:+41613241111
4. mailto:novartis.email@novartis.com