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

Last Update: Mar 26, 2025

A Non-interventional multiCenter Observational Study to Evaluate tHe Effectiveness and Patient-Reported Outcomes of Ofatumumab (Kesimpta®) in patieNts With Relapsing Multiple sclerOsis Treated in Routine Care Settings in Greece (CHRONOS)

ClinicalTrials.gov Identifier:
NCT06486779

Novartis Reference Number:COMB157GGR01

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 is a single-country, non-interventional, multicenter, observational study, mainly based on primary data collection to assess the effect of ofatumumab on clinical parameters of Multiple Sclerosis (MS) in a routine medical care setting, as compared to the standard of care (SoC) arm of a closely monitored phase-IIIb study (STHENOS, which includes glatiramer acetate, interferons, teriflunomide, or dimethyl fumarate) Primary data from MS adult patients who initiate ofatumumab early in their disease course will be collected over a period of two years, and will be compared to the ofatumumab and Standard of Care (SoC) arms of the STHENOS trial, a closely monitored phase-IIIb trial. Eligible patients are those with Relapsing Multiple Sclerosis (RMS) diagnosis, with 1st MS symptom within 5 years prior to ofatumumab's initiation and on treatment with ofatumumab for at least 3 months, but not longer than 6 months prior to inclusion in the study. The overall study duration is expected to be 48 months, including a recruitment period and a per-patient observation period of 24 months each. Follow-up visit frequency will be determined by the treating physician, however study-related data will be collected at study enrollment and at 6-, 12-, 18-, and 24-month data collection timepoints post with an allowable time window of ±1 month for all data collection timepoints. NEDA-3 status, MS Relapse, EDSS, MRI, PROs questionnaires, MSIS-29, SDMT, Adherence and persistence, AEs will be assessed during the study.

Condition
Relapsing Multiple Sclerosis (RMS)
Overall Status
Recruiting
Number of Participants
160
Start Date
Dec 10, 2024
Completion Date
Dec 30, 2028
Gender

All
Age(s)
18 Years - 55 Years (Adult)

Interventions

Other

Ofatumumab

This is an observational study. There is no treatment allocation. The decision to initiate ofatumumab will be based solely on clinical judgement.

Eligibility Criteria

Inclusion Criteria:

1. Written IC must be obtained before participating in the study.
2. Patients with diagnosis of RMS per McDonald Criteria (2017) and \<5 years since first MS symptom prior to initiation of ofatumumab.
3. Patients who have been on treatment with ofatumumab for at least 3 months, but not longer than 6 months prior to inclusion in the study.
4. Ofatumumab treatment in line with the European Product Information of Kesimpta (i.e., adult patients with relapsing forms of MS with active disease defined by clinical or imaging features).
5. Patients with at least one available brain MRI scan performed at least 3 months after ofatumumab initiation OR for whom the physician (as per her/his routine practice and independently of his/her decision to include the patient in the current study) plans to perform such scanning within 31 days after patient's inclusion in the study.

Notes: This MRI scan can be either brain gadolinium enhanced (Gd+) or not. In case it is not gadolinium enhanced, the most recent MRI prior to ofatumumab treatment should be brain gadolinium enhanced, for relevant comparison and identification of new lesions. This MRI scan will serve as the index reference assessment for the evaluation of NEDA-3 radiological component and shall not have been performed within 30 days after the termination of steroid therapy.
6. Patients willing and able to complete the assessments, including PRO questionnaires, as per physicians' clinical practice and as outlined in this study.

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. Currently pregnant (or intention to become pregnant within the study period), breastfeeding or lactating women.

Greece

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