Ozanimod Real-World Safety - A Post-Authorisation Multi-National Long-term Non-Interventional Study (ORION)

First published: 14/12/2021

Last updated: 14/08/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS44615

Study ID

48378

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] United States

Study description

This is a long-term observational study including patients exposed to ozanimod or other medications used to treat MS. The primary endpoints of interest are MACE (composite and the individual components of MACE), SOI, SALI, macular edema, and malignancy.
The study will estimate the incidence rates of these events in one exposed (ozanimod) cohort, and two comparator cohorts, defined by DMTs for MS. Hazards ratios will be considered the main measure of effect.
The study will use existing multinational distributed data sources, such as administrative healthcare data, electronic health records, and potentially disease registries, which will not be collected primarily for this research but do reflect care in usual clinical practice.
Exposure in the automated datasets will be based on prescription or dispensing data. As in usual practice, patients may switch between study drugs, and thus the analysis will be episode-of-use level, rather than patient-level. Propensity scores based on relevant baseline demographics, clinical characteristics, and number of prior treatments at the start of each new treatment episode will be used to adjust for potential confounding in comparative analyses.

Study status

Ongoing

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

Deutsche Multiple Sklerose Gesellschaft, Germany

Contact details

Study institution contact

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Study contact

ctt.group@bms.com

Primary lead investigator

Nicole Baker

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/06/2020

Actual: 02/09/2021

Study start date
Planned: 30/06/2022

Actual: 30/06/2022

Data analysis start date
Planned: 30/06/2023

Actual: 30/06/2023

Date of interim report, if expected
Planned: 31/12/2024

Date of final study report
Planned: 31/12/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol Myers Squibb

Study protocol

IM047-009 Protocol_redacted_v3.pdf (7.64 MB)

im047009-protamend01_Redacted.pdf (4.53 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To assess the rate of adverse events in those taking Zeposia compared to two comparator groups.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ZEPOSIA

Study drug International non-proprietary name (INN) or common name

OZANIMOD HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(L04AE02) ozanimod

ozanimod

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

9000

Study design details

Outcomes

The primary endpoints of interest are major acute cardiovascular events (MACE) (composite and the individual components of MACE), serious opportunistic infections, serious acute liver injury, macular edema, and malignancy. The secondary outcomes are PRES, PML and symptomatic bradycardia.

Data analysis plan

Incidence rates of MACE, SOI, SALI, macular edema, and malignancy for eligible new users of ozanimod and comparator agents will be estimated and compared at the treatment episode level.

Incidence rates will be reported as point estimates (in cases per 1,000 person-years) and 95% CI.

Incidence rates and hazard ratios of the “other DMT” cohort will also be reported stratified by route of administration (i.e.: oral, intravenous infusion and self-injectables).

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Ambulatory EMR - OMOP

MS-Register of the National MS-Society of Germany (DMSG, Bundesverband e.V.)

Data source(s), other

Gesellschaft fur Versorgungsforschung mbH (GMSR)

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Spontaneous reports of suspected adverse drug reactions

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No