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

First published: 14/12/2021
Last updated: 05/03/2024

Contact details

Study institution contact
Christopher Bond

ctt.group@bms.com

Primary lead investigator
Christopher Bond

PURI

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 institution and networks

Institutions

Bristol-Myers Squibb (BMS)
First published: 01/02/2024
Last updated: 01/02/2024

Optum
Germany
First published: 03/01/2012
Last updated: 07/02/2014

ENCePP partner
Other
Study timelines

Date when funding contract was signed
Planned: 30/06/2020
Actual: 02/09/2021

Data collection
Planned: 30/06/2022
Actual: 30/06/2022

Start date of data analysis
Planned: 30/06/2023

Date of interim report, if expected
Planned: 30/06/2023

Date of final study report
Planned: 30/06/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol Myers Squibb

Study protocol
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 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

Name of medicine
Zeposia

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

Data sources

Data source(s)
Ambulatory EMR - OMOP
MS-Register of the National MS-Society of Germany (DMSG, Bundesverband e.V.)

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Spontaneous reporting system

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