

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

**First published:** 14/12/2021

**Last updated:** 05/07/2024

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, SALL, 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

Other

ENCEPP partner

Deutsche Multiple Sklerose Gesellschaft, Germany

## Contact details

### Study institution contact

Nicole Baker [ctt.group@bms.com](mailto:ctt.group@bms.com)

Study contact

[ctt.group@bms.com](mailto: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 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

---

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

OZANIMOD HYDROCHLORIDE

---

**Anatomical Therapeutic Chemical (ATC) code**

(L04AA38) 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 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