Long-term real-world safety of ozanimod – A post-authorisation safety study (PASS) in patients diagnosed with ulcerative colitis

First published: 08/03/2024 Last updated: 15/01/2025



### Administrative details

#### **EU PAS number**

EUPAS100000034

#### **Study ID**

100000034

#### DARWIN EU® study

No

#### **Study countries**

Denmark

France

Germany

Netherlands



#### **Study description**

This post-authorization safety study (PASS) will collect data in participants diagnosed with ulcerative colitis initiating therapy with ozanimod or advanced therapies. Data will be collected from different databases and registries in European countries and in the UK (Denmark, Germany, Netherlands, Norway, England, Scotland, France).

**Study status** 

Ongoing

## Research institutions and networks

### Institutions

### Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023



### University of Dundee



Denmark

First published: 01/02/2024

Last updated: 27/03/2024

Institution

Educational Institution

# Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

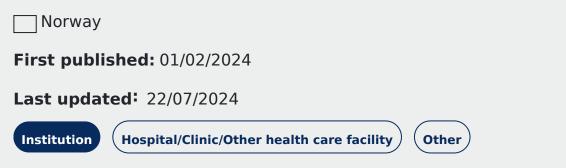


The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

| Netherlands   |
|---|
| First published: 07/01/2022                                     |
| Last updated: 24/07/2024  |
| Institution Laboratory/Research/Testing facility ENCePP partner |

| RTI Health Solutions (RTI-HS)             |
|---|
| France                                    |
| Spain                                     |
| Sweden                                    |
| United Kingdom                            |
| United Kingdom (Northern Ireland)         |
| United States                             |
| First published: 21/04/2010               |
| Last updated: 13/03/2025                  |
| Institution Not-for-profit ENCePP partner |
|   |

## The Norwegian Institute of Public Health



### Networks

| The SIGMA Consortium (SIGMA) |
|------------------------------|
| Denmark                      |
| European Union               |
| France                       |
| Germany                      |
| Italy                        |
| Netherlands                  |
| Norway                       |
| Spain                        |
| Sweden                       |
| United Kingdom               |
| First published: 10/02/2013  |
| Last updated: 16/12/2024     |
| Network ENCePP partner       |

# Contact details

#### Study institution contact

Transparency and Disclosure Lead ctt.group@bms.com

Study contact

ctt.group@bms.com

Primary lead investigator

Primary lead investigator

## Study timelines

**Date when funding contract was signed** Actual: 25/08/2022

Study start date Actual: 01/01/2023

Data analysis start date Planned: 30/12/2025

Date of interim report, if expected Planned: 30/09/2026

**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 (BMS) 100%

Study protocol

IM047-1037\_Redacted Protocol.pdf(10.66 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)

# Other study registration identification numbers and links

IM047-1037

### Methodological aspects

## Study type

## Study type list

#### Study type:

Non-interventional study

# Scope of the study:

Other

#### If 'other', further details on the scope of the study

Evaluate real world safety

#### Data collection methods:

Secondary use of data

#### Main study objective:

To evaluate the risk of developing adverse events of interest in a real-world European population of adults with moderately to severely active ulcerative colitis (UC) in ozanimod-exposed participants versus those treated with advanced therapy.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine

ZEPOSIA

#### Anatomical Therapeutic Chemical (ATC) code

(L04AA38) ozanimod

ozanimod

#### Additional medical condition(s)

Ulcerative colitis

### Population studied

#### Age groups

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

#### Estimated number of subjects

7500

# Study design details

#### Outcomes

- To evaluate the risk of developing malignancies, serious opportunistic infections (SOIs), major adverse cardiovascular events (MACE), venous thromboembolism, including pulmonary embolism (VTE) and severe liver injury in ozanimod-exposed participants versus those treated with advanced therapy

- To evaluate the risk of developing outcomes of interest by subgroups (age, disease history, previous outcome history) in ozanimod-exposed participants versus those treated with advanced therapy

 Frequency, baseline and clinical characteristics of participants experiencing [Macular oedema, Posterior reversible encephalopathy syndrome (PRES),
Progressive multifocal leukoencephalopathy (PML)] in ozanimod-exposed participants and those treated with advanced therapy

- To evaluate the risk of macular oedema, PRES and PML in ozanimod-exposed participants versus those treated with advanced therapy

- To evaluate the risk of cancer, by subtype Solid tumors excluding nonmelanoma skin cancer (NMSC), NMSC, Colorectal cancer, Advanced colonic neoplasia, i.e., composite endpoint including colorectal cancer and high-grade dysplasia, Lymphoma] in ozanimod-exposed participants versus those treated with advanced therapy

- To evaluate the risk of Major Adverse Cardiovascular Events (MACE) [Acute nonfatal myocardial infarction, Acute nonfatal stroke, Cardiovascular (CV) mortality] in ozanimod-exposed participants versus those treated with advanced therapy

#### Data analysis plan

Data management will be conducted by each data source independently. Analyses will be executed independently by each data source provider. The unit of observation will be the treatment episode.

Clinical and demographic variables will be reported by treatment cohorts before and after the application of Inverse probability of treatment weighting (IPTW). Crude incidence rates (IRs) and 95% CIs will be calculated for each outcome by treatment cohort, before and after IPTW. Hazard ratios and associated 95% CIs will be estimated using the Cox proportional hazards model.

For secondary analyses incidence rates, time-to-event and HRs will be computed before and after IPTW with their corresponding 95% CI. Aggregated results including summary estimates resulting from the main analysis of the primary objective of each data source will be pooled for meta-analysis.

### Data management

### Data sources

#### Data source(s)

German Pharmacoepidemiological Research Database Danish registries (access/analysis) PHARMO Data Network Norwegian Health Registers Clinical Practice Research Datalink Système National des Données de Santé (French national health system main database)

#### Data source(s), other

Scottish Prescribing Information 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

Unknown