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

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000034

Study ID

1000000034

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ France
- ☐ Germany
- ☐ Netherlands

Norway

United Kingdom

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

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **Not-for-profit** | **ENCePP partner**

University of Dundee

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

University of Southern Denmark (SDU)

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

Institution | Not-for-profit | ENCePP partner

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

☐ Norway

First published: 01/02/2024

Last updated: 22/07/2024

Institution | Hospital/Clinic/Other health care facility | Other

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

Nicole Baker

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 non-melanoma 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

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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