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

First published: 08/03/2024
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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000034

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 institution 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

Networks

The SIGMA Consortium (SIGMA)

Denmark
European Union
France
Germany
Italy
Netherlands
Norway
Spain
Sweden
United Kingdom
First published: 10/02/2013
Last updated
20/03/2024

Network | ENCePP partner

Contact details

Study institution contact

Transparency and Disclosure Lead
Study contact

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Primary lead investigator
Christopher Bond
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:
31/03/2033

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 data collection

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

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, ie, 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