An Active Surveillance, Post-Authorization Safety Study to Characterize the Safety of Etrasimod in Patients with Ulcerative Colitis Using Real-World Data in the European Union (C5041046)

First published: 09/01/2026

Last updated: 27/01/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000895

Study ID

1000000895

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Netherlands

Sweden

Study description

This multi-country, non-interventional Post-Authorization Safety Study (PASS) aims to characterize the real-world safety of etrasimod (Velsipity®) among patients aged 16 years and older with ulcerative colitis (UC) across Germany, Sweden, and the Netherlands. Using electronic health records, healthcare claims, and registry data, the study follows new users of etrasimod and comparator therapies—including other S1P receptor modulators, biologics, and JAK inhibitors—to estimate incidence rates of key safety outcomes such as macular oedema, serious liver injury, malignancy, serious opportunistic infections, neurologic events including PRES or convulsions, and symptomatic bradycardia. The study describes patient characteristics at treatment initiation, compares incidence rates between etrasimod and comparator cohorts when sample size allows, and evaluates safety in adults aged 65 years and older by assessing rates of eye adverse events, infections, and cardiovascular events.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

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: 19/12/2025

Institution | Non-Pharmaceutical company | ENCePP partner

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing 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: 19/01/2026

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Shahar Shmuel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/01/2024

Actual: 23/01/2024

Study start date

Planned: 15/11/2026

Data analysis start date

Planned: 01/07/2035

Date of interim report, if expected

Planned: 16/05/2028

Date of final study report

Planned: 31/12/2035

Study protocol

C5041046_ETRASIMOD PROTOCOL VERSION 3_07JULY2025_Clean.pdf (1.33 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

C5041046

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Non-interventional, multi-country cohort study using real-world data to follow new users of etrasimod or comparator UC therapies, applying a restricted as-treated approach to estimate safety event incidence across Germany, Sweden, and the Netherlands.

Main study objective:

The study’s main objectives are to describe the characteristics of patients with ulcerative colitis when they initiate etrasimod or comparator therapies, to estimate the incidence rates of key safety events among new users of etrasimod, and to estimate these same rates among patients starting other S1P receptor modulators, biologics, or JAK inhibitors. The study also seeks to compare the incidence of these safety events between etrasimod and each comparator cohort when sample sizes allow. In addition, it aims to evaluate safety in adults aged 65 years and older by estimating the incidence of eye adverse events, infections, and cardiovascular events across all treatment groups.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VELSIPITY

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

ETRASIMOD

Anatomical Therapeutic Chemical (ATC) code

(L04AE05) etrasimod

etrasimod

Population studied

Short description of the study population

The study population includes patients aged 16 years and older with a confirmed diagnosis of ulcerative colitis (UC) who begin treatment with etrasimod or comparator UC therapies (other S1P receptor modulators, biologics, or JAK inhibitors). Patients must have at least one year of prior healthcare data and no prior use of the same cohort-defining medication. Individuals may enter more than one cohort if they switch therapies, and a subgroup analysis focuses on older adults aged 65 years and above.

Study design details

Setting

The study is conducted across three European countries (Germany, Sweden, and the Netherlands) using large, population-based healthcare databases that capture routine clinical care. These data sources include electronic health records, national health and cancer registries, healthcare claims, inpatient and

outpatient hospital data, and pharmacy dispensing records. Together, they provide broad and complementary coverage of diagnoses, treatments, and outcomes for patients with ulcerative colitis. Each country contributes data through an established research institution: GePaRD in Germany, the Swedish National Health Registers and SWIBREG in Sweden, and the PHARMO Data Network in the Netherlands. The setting reflects real-world clinical practice at national scale, enabling assessment of etrasimod and comparator treatments within diverse healthcare systems.

Comparators

The study includes three comparator groups representing alternative advanced therapies for ulcerative colitis. These comparators consist of other S1P receptor modulators such as ozanimod, which share a similar mechanism of action to etrasimod; biologic therapies, including TNF inhibitors, integrin receptor antagonists, and interleukin inhibitors, which are commonly used in moderate to severe UC; and JAK inhibitors, another advanced treatment class used when patients have inadequate response to prior therapies.

Outcomes

The study evaluates several predefined safety outcomes, including macular oedema, serious liver injury, malignancy, serious opportunistic infections, neurologic events such as Posterior Reversible Encephalopathy Syndrome (PRES) or convulsions, and symptomatic bradycardia including conduction disorders. For adults aged 65 and older, it also assesses broader categories of eye adverse events, infections, and cardiovascular events.

Data analysis plan

The data analysis plan uses a distributed common data model so each country can run identical analytic programs locally while preserving data privacy. Analyses begin with describing cohort selection and patient characteristics,

followed by estimating crude and age-sex–standardized incidence rates for all safety outcomes within each treatment cohort. When sample sizes allow, comparative analyses will be conducted using methods such as propensity score–based inverse probability weighting to adjust for confounding. Additional plans include meta-analysis of country-specific effect estimates in the final study report, predefined subgroup analyses in adults aged 65 and older, and multiple sensitivity analyses to assess the impact of alternative risk windows, outcome definitions, and inclusion criteria.

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)

German Pharmacoepidemiological Research Database

PHARMO Data Network

Other data source

Data source(s), other

Swedish National Health Registers, Swedish Inflammatory Bowel Disease Registry

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Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Not applicable