Early Experience with Etrasimod in Ulcerative Colitis Patients: an Observational Study in the United States

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Study Planned

Administrative details

EU PAS number

EUPAS1000000587

Study ID

1000000587

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a population-based retrospective cohort study of adults (ages ≥ 18 years of age) with ulcerative colitis (UC) initiating treatment with etrasimod since its marketing authorization, using claims data from a large United States (US) database.
Primary endpoint is baseline characteristics of patients. Secondary endpoints are adherence, measured by proportion of days covered method, persistence (delay until etrasimod discontinuation), the use of corticosteroids and change in level of fecal calprotectin, within 12 months of etrasimod initiation.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Planned: 27/05/2025

Study start date
Planned: 08/09/2025

Data analysis start date
Planned: 08/09/2025

Date of final study report
Planned: 30/10/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C5041059_NIS Protocol_Etrasimod tt patterns_V1.0_22AUG2025.pdf (1.84 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

C5041059

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

The study cohort will be defined as UC patients initiating etrasimod from its marketing authorization. For the secondary objectives, patients with closed claims will be followed for up to 12 months after the index date or to the end of their continuous enrollment, whichever comes first.

Main study objective:

Primary Objective

1. To describe the baseline demographic characteristics, comorbidities, disease and treatment characteristics of patients with UC who initiated treatment with etrasimod.

Secondary Objectives

1. To describe the treatment patterns of etrasimod (adherence and persistence) among patients with UC within 12 months of etrasimod initiation.
2. To describe corticosteroid use among patients with UC within 12 months of etrasimod initiation.
3. To describe the change in level of fecal calprotectin in patients with UC, from baseline through 12 months of etrasimod initiation.

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

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

The population under study will be US patients diagnosed with UC and initiating etrasimod from its marketing authorization on October, 13, 2023, to the end of study period.

Inclusion criteria:

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:

1. Patients who have initiated etrasimod, defined by a filled pharmacy claim

2. Patients with at least ≥1 inpatient or outpatient claim with evidence of UC diagnosis in medical claims using ICD-10-CM codes: K51.x on or prior to index date
3. Patients aged ≥ 18 years at index date
4. Data availability ≥ 12 months prior to index date

Exclusion Criteria
Patients meeting any of the following criteria will not be included in the study:
1. Patients with medical claims with diagnosis code(s) corresponding to Crohn's disease (CD) during pre-index period or index date
2. Patients with medical claims with procedure code(s) corresponding to colectomy during pre-index period or index date
3. Any co-prescription with select immunomodulators (methotrexate, tacrolimus, cyclosporin, thiopurine) or advanced therapies for UC (biologics, anti-TNFs, interleukin 12 and 23, anti-integrin, small molecules such as Janus kinase inhibitors [JAKi], or with any other S1P receptor modulator) on index date

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Age groups

- **Adult and elderly population (≥18 years)**

Estimated number of subjects
800

Study design details

Setting
The population under study will be US patients diagnosed with UC and initiating etrasimod from its marketing authorization on October, 13, 2023 to the end of study period.

This study will use existing data from large US claims database, which captures claims data from 300 million US people sufficiently representative of the US population with insurance coverage. Data from the eligible patients available in the datasource, i.e from 2015 to latest date of data availability will be used in the study, to document baseline characteristics and assess endpoints of interest.
The US UC population will be identified from the database, by considering all patients with an ICD-10 diagnosis code equal to K51.x (UC) between 2015 to the end of study period.

Comparators

No comparison

Outcomes

Primary endpoint is baseline characteristics of patients.
Secondary endpoints are adherence, measured by proportion of days covered method, persistence (delay until etrasimod discontinuation), the use of corticosteroids and change in level of fecal calprotectin, within 12 months of etrasimod initiation.

Data analysis plan

All analyses defined in detail in the statistical anlaytical plan (SAP), which will be the reference document.
Primary objective (baseline characteristics) will be analyzed among patients who have met the selection criteria (eligible population). For the analysis of secondary objectives, analyses will be performed on patients with closed index etrasimod claim and continuous enrollment after the index date. Specific windows of minimal continuous enrollment will be defined in the SAP for each analysis.

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), other

Panalgo-MMIT (NorstellaLinQ)

Data sources (types)

Administrative healthcare records (e.g., claims)

Laboratory tests and analyses

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