A prospective, non-interventional, multi-country cohort study of the effectiveness and safety of filgotinib in adult patients with moderately to severely active ulcerative colitis (GALOCEAN)

First published: 11/04/2023

Last updated: 05/09/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS50214

Study ID

105477

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium

- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

To describe the effectiveness, treatment patterns, quality of life, and safety of patients with moderately or severely active ulcerative colitis treated with filgotinib in a real-world setting

Study status

Ongoing

Research institutions and networks

Institutions

Alfasigma

- [ ] Italy

First published: 30/08/2024

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Institution | Pharmaceutical company

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Monia Zignani

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/05/2022

Study start date

Actual: 12/06/2023

Date of final study report

Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alfasigma S.p.A

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To describe the real-world clinical treatment persistence in adult patients with moderately or severely active UC treated with filgotinib for approximately 52 weeks in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

FILGOTINIB MALEATE

Medical condition to be studied

Colitis ulcerative

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

600

Study design details

Outcomes

Treatment persistence rate at week 52, Treatment persistence rate at weeks 10 and 24, Clinical response rate, Clinical remission rate, change from baseline in Health-Related Quality of Life (HRQoL) as measured by the Short Inflammatory Bowel Disease Questionnaire (SIBDQ), Urgency Numeric Rating Scale (NRS), and Functional Assessment of Chronic Illness Therapy-Fatigue score (FACIT-F), rate of AE and SAE during 52 weeks

Data analysis plan

In general, data analysis will be descriptive and use summary statistics. Continuous variables will include the number of patients (N), mean, standard deviation (SD), median, interquartile range (IQR), minimum, and maximum, together with the number of missing values. Categorical variables will include numbers and percentages, with missing values as separate category. Descriptive summary statistics will be conducted for all effectiveness measurements, as well as baseline characteristics, demographics, medical and treatment histories, HRU, AEs, and HRQoL. More advanced analysis (e.g. time-to-event, change from baseline) may also be conducted.

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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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