Non-interventional, post-authorization prospective safety study of filgotinib in patients with moderately to severely active ulcerative colitis: a European multi registry-based study

First published: 08/11/2023

Last updated: 05/09/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/108231

EU PAS number

EUPAS106566

Study ID

108231

DARWIN EU® study

No

Study countries

- ☐ Netherlands
- ☐ Spain
- ☐ Sweden

Study description

This study aims to further evaluate the long-term safety (LTS) of filgotinib in the treatment of patients with moderately to severely active ulcerative colitis (UC) under real-world conditions, specifically with respect to important identified and potential risks listed in the Jyseleca® risk management plan (RMP). This non-interventional, post-authorization, prospective, multi-country registry-based safety cohort study is being conducted based on real-word data derived from 3 inflammatory bowel disease (IBD) registries, namely the Nationwide Study on Genetic and Environmental Determinants of Inflammatory Bowel Disease (ENEIDA) Register from Spain (ES), the Initiative on Crohn's and Colitis (ICC) Register from the Netherlands (NL), and the Swedish National Quality Registry for Inflammatory Bowel Disease (SWIBREG).

Study status

Ongoing

Research institutions and networks

Institutions

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**

Alfasigma

☐ Italy

First published: 30/08/2024

Last updated: 30/08/2024

Institution **Pharmaceutical company**

Networks

ENEIDA (ES), ICC (NL), SWIBREG (SE)

Contact details

Study institution contact

Joan Fortuny

Study contact

jfortuny@rti.org

Primary lead investigator

Joan Fortuny

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/01/2023

Study start date
Actual: 01/05/2023

Date of interim report, if expected
Planned: 30/06/2028

Date of final study report
Planned: 09/04/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alfasigma S.p.A

Study protocol

glpg0634-cl-413-protocol-redacted.pdf(6.07 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

GLPG0634-CL-413

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

This study aims to further evaluate the LTS of filgotinib in the treatment of patients with moderately to severely active UC under real-world conditions, specifically with respect to important identified and potential risks listed in the

Jyseleca® risk management plan (RMP).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

JYSELECA

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

FILGOTINIB MALEATE

Anatomical Therapeutic Chemical (ATC) code

(L04AA45) filgotinib

filgotinib

Additional medical condition(s)

Moderately to severely active ulcerative colitis

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

1200

Study design details

Outcomes

Estimate incidence rates (IRs) following RMP-listed risks: serious and opportunistic infections, herpes zoster, and primary varicella infection, major adverse cardiovascular events (MACE), venous thromboembolism (VTE), pulmonary embolism PE), hyperlipidemia, malignancy, nonmelanoma skin cancer (NMSC), gastrointestinal (GI) perforation, fractures and all-cause mortality. Describe patients' baseline characteristics. Estimate IRs of the endpoints in comparator cohorts provided by each registry Estimate the hazard ratios (HRs) of the identified and potential risks listed above between patients treated with filgotinib (Cohort 1) and comparator Cohort 2, and Cohort 3 assuming sufficient statistical power.

Data analysis plan

All statistical analyses will be performed by each registry or its local contracted scientific partner. Regular reports adhering to a predefined format will be provided by each registry to the marketing authorization holder (MAH) at 24-month intervals after enrolment is opened to filgotinib-treated patients in the 3 participating countries. The progress reports will be provided as part of the PSUR. The final analysis will be conducted after reaching the end of study period and will summarize descriptive statistics for patients initiating filgotinib as well as for patients in the other cohorts. Depending on adequate statistical

power and comparability between the filgotinib cohort and the advanced therapy Cohort 2 and the immunosuppressant/immunomodulator therapy Cohort 3 in relation to their underlying risk of outcome development, comparative analysis between patients exposed to filgotinib and patients in the advanced therapy Cohort 2 and Cohort 3 will be performed in the final analy

Data management

Data sources

Data source(s), other

- Estudio Nacional en Enfermedad Inflamatoria intestinal sobre Determinantes genéticos y Ambientales (Nationwide study on genetic and environmental determinants of inflammatory bowel disease) (ENEIDA), Spain;
- Initiative on Crohn’s and Colitis (ICC), Netherlands;
- Swedish National Quality Registry for Inflammatory Bowel Disease (SWIBREG), Sweden.

Data sources (types)

Disease registry

Other

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