Non-interventional post-authorization safety study of filgotinib in the treatment of patients with moderate to severe active rheumatoid arthritis within European registries

First published: 12/07/2022

Last updated: 05/09/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS46856

Study ID

48895

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Germany

☐ Spain

☐ Sweden

☐ United Kingdom

Study description

Filgotinib is a JAK1 preferential inhibitor for the treatment of moderate/severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs (DMARD). Randomized clinical trials (RCTs) have provided information on filgotinib's efficacy and safety. However, for assessing safety RCT designs have limitations, e.g. restrictive eligibility criteria, sample sizes and follow-up. Long term safety data are thus needed in patients treated with filgotinib in real world clinical settings. European RA registries have been established to evaluate the safety profiles of numerous DMARDs and used to address post-authorization safety requirements. This non-interventional postauthorization safety study aims to evaluate the long-term safety of filgotinib in RA by making secondary use of data collected by registries from Sweden (ARTIS), Spain (BIOBADASER), UK (BSRBRRA), Denmark (DANBIO) and Germany (RABBIT).

Study status

Ongoing

Research institutions and networks

Institutions

Alfasigma

☐ Italy

First published: 30/08/2024

Last updated: 30/08/2024

Institution | Pharmaceutical company

Epidemiology Unit, Deutsches Rheuma-Forschungszentrum Berlin (DRFZ)

Germany

First published: 02/05/2010

Last updated: 20/08/2024

Institution | Educational Institution

British Society for Rheumatology Biologics Registers (BSRBR)

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Other

Karolinska Institutet

Sweden

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

BSRBR - Rheumatic and Musculoskeletal Conditions Manchester, UK

DANBIO – Dansk Reumatologisk Database Glostrup, Denmark

BIOBADASER Madrid, Spain

Networks

Registro Español de Acontecimientos Adversos de Terapias Biológicas en Pacientes Reumáticos (BIOBADASER)

Spain

First published: 06/07/2010

Last updated: 20/08/2024

Network

ARTIS, BSRBR, DANBIO, RABBIT

Contact details

Study institution contact

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Study contact

Raymond.Schlienger@alfasigma.com

Primary lead investigator

Raymond Schlienger

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/12/2021

Study start date

Actual: 29/12/2021

Date of final study report

Planned: 01/07/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alfasigma S.p.A

Study protocol

glpg0634-cl-403-protocol-redacted.pdf(7.2 MB)

glpg0634-cl-403-protocol V2_Redacted.pdf(8.43 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-403

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To estimate incidence rates of the risks listed in the risk management plan, including: serious and opportunistic infections, Herpes zoster and primary Varicella infection, MACE, VTE, hyperlipidemia, malignancy, non-melanoma skin cancer, gastrointestinal perforation and fractures and all-cause mortality in RA patients in Denmark, Germany, Sweden, Spain, and the UK who initiate filgotinib treatment.

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

Rheumatoid arthritis

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

2500

Study design details

Outcomes

Serious and opportunistic infections, Herpes zoster and primary Varicella infection, major adverse cardiovascular events (MACE), venous thromboembolism -VTE- (including deep venous thromboembolism DVT, pulmonary embolism PE), hyperlipidemia, malignancy, nonmelanoma skin cancer (NMSC), gastrointestinal (GI) perforation and fractures and all-cause mortality.

Data analysis plan

All statistical analyses will be performed by each registry and described in detail in the statistical analysis plan. Regular reports adhering to a predefined format will be provided by each registry to the marketing authorization holder at 6 or 12 month intervals after enrolment is opened to filgotinib-treated patients in participating countries. At the end of the study period the final analysis will summarize descriptive statistics for patients initiating filgotinib (overall and in subgroups) and for patients in the other treatment-defined cohorts. Event counts and crude incidence rates derived from registry linkages will be tabulated for each cohort and safety event. Depending on adequate statistical power and comparability between the filgotinib and other exposure cohorts in relation to their underlying risk of outcome development, comparative analysis

will be performed between filgotinib-exposed and comparator-exposed cohorts, adjusted for potential confounders.

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)

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

Rheumatoid Arthritis - Observation of Biologic Therapies

Data source(s), other

ARTIS Sweden, BIOBADASER Spain, DANBIO Denmark

Data sources (types)

Disease registry

Other

Data sources (types), other

Exposure registry

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