Non-interventional post-authorization cohort safety study evaluating the effectiveness of the additional risk minimization measures for filgotinib (Jyseleca®) use in patients with moderate to severe active rheumatoid arthritis within European registries

First published: 29/06/2022

Last updated: 10/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48898

EU PAS number

EUPAS46852

Study ID

48898

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Germany
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

Study description

Additional risk minimization measures (aRMMs) are in place to mitigate important identified and potential risks associated with the use of filgotinib. These include a healthcare professional (HCP) guide designed to increase awareness among HCPs by delivering specific information on contraindications and warnings, and a patient alert card to enhance awareness of risks and early signs and symptoms relating to specific adverse drug reactions and the best course of action to take.

To evaluate the effectiveness of aRMMs and to describe filgotinib use in real-world clinical settings, a drug utilization study will be implemented using a non-interventional follow-up (cohort) design with secondary use of data collected from 5 European rheumatoid arthritis (RA) registries from Sweden (ARTIS), Spain (BIOBADASER), the UK (BSRBR-RA), Denmark (DANBIO), 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

Raymond Schlienger

Study contact

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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: 30/06/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alfasigma S.p.A

Study protocol

glpg0634-cl-408-protocol-redacted.pdf(5.29 MB)

glpg0634-cl-408-protocol-amend1-v2.1-redacted.pdf(1.72 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-408

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Additional Risk Management Measures assessment

Study design:

DUS using a non-interventional follow-up (cohort) design with secondary use of data
collected from 5 European rheumatology registries (from DK, GE, ES, SW, and the UK). The study was requested by the PRAC and fulfills the criteria of a non-interventional PASS.

Main study objective:

The purpose of this non-interventional PASS requested by the PRAC, is to examine the characteristics of patients under filgotinib treatment in terms of prevalence of risk factors for MACE, malignancy, VTE, and serious and opportunistic infections, to evaluate whether the appropriate initial dose of filgotinib is being prescribed (e.g., 100 mg/day in patients aged over 65-years-of-age and older), whether contraindications are adhered to (e.g., no administration in pregnant women and discontinuation in women who become pregnant during the treatment
administration), and to evaluate treatment changes following an event of concern (e.g., discontinuation following a VTE episode).

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

500

Study design details

Data analysis plan

Data from this non-interventional study will be summarized using univariate descriptive statistical methods. The number and proportion of users of filgotinib will be estimated among several subgroups of relevance at treatment initiation

and follow up, as per the objectives of the study.
Categorical variables will be summarized by number and percentage of patients in each categorical definition and include 95% CIs. Counts for missing values will be also tabulated but missing values will not be considered in the percentages.
Continuous variables will be summarized descriptively (mean, standard deviation, and median, lower quartile, upper quartile, minimum, maximum, 95% CIs).
Detailed methodology for the analyses of data included in this study will be documented in the statistical analysis plan, which will be created by the investigators from the 5 registries, dated, filed, and archived by the MAH.

Data management

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