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: 22/04/2024

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 institution and networks

Institutions

Galapagos
First published: 01/02/2024
Last updated 01/02/2024
Institution

Epidemiology Unit, Deutsches Rheuma-Forschungszentrum Berlin (DRFZ)
Germany
First published: 02/05/2010
Last updated 02/08/2013
Institution
Educational Institution
ENCePP partner

British Society for Rheumatology Biologics Registers (BSRBR)
First published: 01/02/2024
Last updated 01/02/2024

Institution

Other

Educational Institution

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
11/11/2013

Network

ENCePP partner

ARTIS, BSRBR, DANBIO, RABBIT

Contact details

Study institution contact

Galapagos NV Study Director

Study contact

medicalinfo@glpg.com

Primary lead investigator

Galapagos NV Study Director

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

Galapagos NV

Study protocol

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

Main study objective:
To assess the Health Care Professional (HCP) adherence with the Summary of Product Characteristics (SmPC) and the HCP Guide (i.e. avoidance of contraindicated populations and use of screening prior to administration of filgotinib) and to estimate the proportion of filgotinib users being at high risk

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