A prospective, non-interventional study in female patients with moderate to severe active rheumatoid arthritis in France receiving filgotinib for 2 years (PARROTFISH)

First published: 05/04/2022

Last updated: 01/10/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS46020

Study ID

49028

DARWIN EU® study

No

Study countries

France

Study description

To describe the effectiveness, safety, and patient-reported outcomes in female patients with moderate to severe active rheumatoid arthritis in France receiving filgotinib in real-world setting.

Study status

Ongoing

Research institutions and networks

Institutions

Alfasigma

Italy

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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: 30/12/2021

Study start date
Actual: 03/05/2022

Date of final study report
Planned: 30/06/2027

Sources of funding

- Other

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

Other study registration identification numbers and links

ClinicalTrials.gov Identifier: https://clinicaltrials.gov/ct2/show/NCT05323591

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 treatment persistence rate at 24 months per routine practice, defined as the rate of patients continuing to receive filgotinib for approximately 24 months from treatment initiation.

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

150

Study design details

Outcomes

Treatment persistence rates at 24 months, Throughout the study: disease activity (DAS28CRP and/or CDAI), rates of AE and SAE during 24 months, patients' assessment of pain (Pain VAS), patients' assessment of fatigue (FACIT-F score), patients' assessment of work productivity (WPAI-RA), patients' assessment of Rheumatoid Arthritis Impact of Disease (RAID).

Data analysis plan

In general, for continuous variables, descriptive summary statistics will be provided including number of patients (N), mean, standard deviation (SD), minimum, median, and maximum, together with the number of missing values. Categorical variables will be summarized with counts and percentages, with missing values as separate category. Incidence rates and 95% confidence intervals (CIs) will be provided. Demographics and baseline characteristics will be summarized using descriptive statistics.

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