Prescribing Patterns of Lipegfilgrastim (Lonquex®) in the European Union

First published: 01/09/2016

Last updated: 19/05/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS12984

Study ID

28713

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Croatia
- Germany
- Netherlands

Study description

This is a post-authorisation, multi-national, non-interventional, multicentre, retrospective DUS, to describe the pattern of lipegfilgrastim use, and specifically to quantify the extent of lipegfilgrastim off-label use in routine clinical practice. Data for approx. 500 patients of all ages who were treated with lipegfilgrastim as part of usual clinical practice will be collected at sites in several European countries. Data will be abstracted from medical charts. Data analysis in the study will be descriptive. Initially a pilot study will be conducted in order to assess the feasibility of the data collection, and to modify the protocol if needed.

Study status

Ongoing

Research institutions and networks

Institutions

PRA Health Sciences

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Real World Solutions, PRA Real World Solutions

France

Germany

First published: 19/05/2021

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Lang Nicole Nicole.Lang@ratiopharm.de

Study contact

Nicole.Lang@ratiopharm.de

Primary lead investigator

Bettina Rillmann

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/05/2016

Study start date

Planned: 10/06/2019

Actual: 16/12/2016

Data analysis start date

Planned: 15/04/2020

Date of final study report
Planned: 16/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TEVA

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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The primary objective is to quantify the extent of off-label Lipegfilgrastim use in routine clinical practice in several countries in the European Union (EU).

Study drug and medical condition

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

LIPEGFILGRASTIM

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

The primary endpoint of this study is off-label use of Lipegfilgrastim as documented in the most recent chemotherapy cycle with administration of Lipefilgrastim.

Data analysis plan

There will be descriptive data analysis. Off-label use will be described by type and frequency. Study results will be quantified in terms of incidence of off-label lipegfilgrastim use per 1,000 investigated population. The rates and 95% confidence intervals of off-label use stratified by sex, age-group, center clinical setting, country and possibly, depending on the numbers in the sub-category, type of off-label use will be reported per 1,000 investigated population. Similarly, rates per 1000 and 95% CI will be provided for the authorized lipegfilgrastim use by sex, age-group, center clinical setting, and country.

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)

Drug dispensing/prescription data

Other

Data sources (types), other

Medical records

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