A Prospective, Multicentre, Non-interventional, Observational, Post-authorisation Safety Study of Ropeginterferon alfa-2b in Polycythaemia Vera Patients (Besremi-PASS)

First published: 24/04/2019

Last updated: 21/02/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS29462

Study ID

42880

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Germany

Romania

Study description

The objective of the study is to provide further data to characterize the safety and tolerability of ropeginterferon alfa-2b by monitoring the hepatic and cardiovascular safety in patients with polycythaemia vera treated with ropeginterferon alfa-2b in routine post-authorisation use.

Study status

Ongoing

Research institutions and networks

Institutions

AOP Orphan Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trial Disclosure AOP Orphan Pharmaceuticals GmbH

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2019

Study start date

Planned: 31/12/2019

Actual: 17/12/2019

Data analysis start date

Planned: 30/06/2025

Date of interim report, if expected

Planned: 31/12/2024

Actual: 17/12/2024

Date of final study report

Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AOP Orphan Pharmaceuticals GmbH

Study protocol

190913_Ropeg PASS_Protocol_2.0_Redacted.pdf(328.29 KB)

Ropeg PASS_Protocol_2.3_26Apr2022_clean_Redacted.pdf(348.94 KB)

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:

Assessment of risk minimisation measure implementation or effectiveness
Safety study (incl. comparative)

Main study objective:
To assess the incidence rate of the important, identified risk “hepatotoxicity” in PV patients newly treated with ropeginterferon alfa-2b in routine post-authorization use.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
ROPEGINTERFERON ALFA-2B

Anatomical Therapeutic Chemical (ATC) code
(L03AB15) ropeginterferon alfa-2b
ropeginterferon alfa-2b

Medical condition to be studied
Polycythaemia vera

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

228

Study design details

Outcomes

Incidence of significant elevations of liver enzymes and/or bilirubin, and treatment-emergent hepatobiliary adverse drug reactions during the observational phase (i.e. first 6 months of treatment). Incidence of significant elevations of liver enzymes and/or bilirubin, and treatment-emergent hepatobiliary adverse drug reactions over the entire study period.Incidence of cardiovascular adverse events (i.e. thromboembolic adverse events and Major Adverse Cardiac Events) during the observation phase and over the entire study period.

Data analysis plan

Absolute and relative frequencies of patients with treatment emergent adverse events, count and incidence rate (including two-sided 95% CIs) of events overall and by MedDRA primary System Organ Class and Preferred Term will be calculated.

Documents

Study, other information

Besremi-PASS_Protocol Redacted_V2.2_16Jun2020.pdf(335.13 KB)

Data management

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