A Non Interventional Long term safety Study of Ruxolitinib in Myelofibrosis (JAKAVI)

First published: 07/01/2013

Last updated: 18/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3296

Study ID

29298

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] France
- [ ] Germany
- [ ] Italy

- [ ] Netherlands
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is a Post Authorization Safety Study according to the EU Volume 9a of the Rules Governing Medicinal Products in the European Union and is planned as a prospective, multicenter,Multi-national disease registry for patients diagnosed with myelofibrosis. The study is planned to recruit patients diagnosed with MF exposed and non-exposed to Ruxolitinib with the objective of enrolling at least 300 patients exposed to ruxolitinib within 2 years. It is expected that about 150 patients not exposed to Ruxolitinib will be recruited during the enrolment period. A minimum follow-up of at least 3 years will be allowed for all patients enrolled.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Boehringer Ingelheim Pharma GmbH&Co.KG

Multiple centres: 53 centers are involved in the study

Contact details

Study institution contact

Novartis Clinical Disclosure Office
trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/09/2012

Actual: 24/09/2012

Study start date

Planned: 31/01/2013

Actual: 03/06/2013

Data analysis start date

Planned: 01/07/2018

Actual: 05/07/2018

Date of final study report

Planned: 10/12/2018

Actual: 19/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

CINC424AIC01T-v01-nis-protocol_Redacted.pdf (1.75 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)

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this Post Authorization Safety Study is to document long-term safety of Ruxolitinib in patients with myelofibrosis in a real-world setting according to the current prescribing information of the European label.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post Authorization Safety Study, Prospective multicenter multi-national disease registry

Study drug and medical condition

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

RUXOLITINIB PHOSPHATE

Medical condition to be studied

Myelofibrosis

Population studied

Short description of the study population

Adult patients with a diagnosis of primary or secondary Myelofibrosis.

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

450

Study design details

Outcomes

To document the incidence and outcome of events of special interestincluding the following:• bleeding events• serious & opportunistic infections• secondary malignancies• ADRs/ SAEs after discontinuation of Ruxolitinib treatment• pregnancies• deaths of any cause

Data analysis plan

Sponsor personnel or a designated representative will review the data entered by investigational staff for completeness and accuracy. When the data collection process is complete for a patient or at specified time points and the data have been validated, the data are de-identified and moved from the database maintainer to the analysis database of the sponsor. Concomitant medications entered into the database will be coded using the World Health Organization (WHO) Drug Reference List, which employs the Anatomical Therapeutic Chemical (ATC) classification system. Medical history/current medical conditions and adverse events will be coded using the Medical dictionary for regulatory activities (MedDRA) terminology.At the completion of entering data for a patient, the investigator must “electronically certify” or validate that the data for this patient are complete and accurate. At this point, the system will require the investigator to re-enter his password.

Documents

Study results

INC424AIC01T_CSR for redaction_Redacted 4Apr2019.pdf (1.52 MB)

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)

Disease 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