An observational study - Evaluation of efficacy and safety of Bosulif® under real life conditions of use (BOSEVAL)

First published: 07/01/2015

Last updated: 05/06/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/8232

EU PAS number

EUPAS8231

Study ID

8232

DARWIN EU® study

No

Study countries

☐ France

Study description

This trial is a national, observational, descriptive, prospective study conducted in France on adult patients treated for Philadelphia positive (Ph+) CML in the chronic, accelerated or blast phase, previously treated with one or more TKIs and for whom imatinib, dasatinib or nilotinib are not considered as appropriate treatments. CML is a rare disease, a minimum number of patients is not expected but a total of about one hundred (100) patients included in the study appears to be a reasonable objective. This non-interventional study is designed to evaluate the safety and efficacy, and the methods of use of Bosulif®, under real life conditions.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Multiple centres: 23 centres are involved in the study

Contact details

Study institution contact

Delphine BERZIN

Study contact

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Primary lead investigator

Philippe Rousselot

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/02/2015

Study start date

Planned: 01/04/2015

Actual: 24/10/2015

Date of final study report

Planned: 31/01/2024

Actual: 31/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B1871047_Protocole v1.1 _16032015-EN .pdf(4.12 MB)

B1871047_Protocole v2 _Amendment 1_ 15022019_Clean_English.pdf(1.03 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Study design:

Non-interventional observational multicentric prospective study not affecting the patient’s medical care.

Main study objective:

To determine the percentage of patients with Ph+ CML in chronic, accelerated or blast phase presenting with AEs considering related to bosutinib by the investigator,

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BOSULIF

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

BOSUTINIB MONOHYDRATE

Additional medical condition(s)

Chronic Myeloid Leukemia (CML)

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

100

Study design details

Outcomes

To evaluate the percentage of patients who permanently discontinued bosutinib following an AE considered as related to bosutinib by the investigator.

- Safety profile of bosutinib
- Evaluate patient compliance
- Evaluate quality of life
- Describe the methods of treatment of bosutinib under real-life conditions of use
- Evaluate the efficacy of treatment
- Describe the haematological, cytogenetic and molecular responses
- Describe the characteristics of patients
- Evaluate cross-intolerance between bosutinib and previously prescribe TKI

Data analysis plan

The descriptive analysis of qualitative and ordinal variables will consist of the sample size and frequency of each modality with its 95% confidence interval (CI), as well as the number of missing data. Quantitative variables will be

described in terms of sample size, mean, median, standard deviation, confidence interval, as well as number of missing data. Data on overall survival and progression-free survival will be described with Kaplan Meier curves. Median survival will be estimated and presented with its 95% CI. The data will be evaluated separately for patients with Ph + CML in PC, PA or CB and depending on the processing line. Interim analyzes will be carried out once a year.

Documents

Study report

B1871047_BOSEVAL_Study report_V1.0_30MAY2024.pdf(16.28 MB)

B1871047_BOSEVAL_Study report abstract_V1.0_30MAY2024.pdf(180.12 KB)

2024-48327 CIOMS_1.pdf(1.28 MB)

2024-48327 CIOMS_2.pdf(991.98 KB)

2024-48327 CIOMS_3.pdf(884.19 KB)

2024-48327 CIOMS_4.pdf(902.98 KB)

2024-48327 CIOMS_5.pdf(884.9 KB)

2024-48327 CIOMS_6.pdf(740.13 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