A Non-Interventional Study of Bosutinib in Patients With Previously Treated Chronic Phase Chronic Myelogenous Leukemia (CML)

First published: 23/12/2013

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5461

Study ID

18483

DARWIN EU® study

No

Study countries

United States

Study description

A Non-Interventional Study of Bosutinib in Patients With Previously Treated Chronic Phase Chronic Myelogenous Leukemia (CML)

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

Multiple centres: 30 centers are involved in the study

Contact details

Study institution contact

Graciela Mabel Woloj mabel.woloj@pfizer.com

Study contact

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Primary lead investigator

Jorge Cortes

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2014

Actual: 28/10/2013

Study start date

Planned: 01/05/2014

Actual: 08/01/2014

Date of final study report

Planned: 23/06/2015

Actual: 23/06/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

FAP B1871042 Protocol 28 October 2013.pdf (996.13 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

This Non-Interventional Study (NIS) will aim to capture real-world treatment related adverse events (AEs) and discontinuation rates and evaluate effective dosing strategies employed in clinical practice when managing these AEs.

Data collection methods:

Primary data collection

Main study objective:

This Non-Interventional Study (NIS) will aim to capture real-world treatment related adverse events (AEs) and discontinuation rates and evaluate effective dosing strategies employed in clinical practice when managing these AEs.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective Non-Interventional

Study drug and medical condition

Medicinal product name

BOSULIF

Medical condition to be studied

Chronic myeloid leukaemia

Population studied

Short description of the study population

Previously treated patients from US with chronic phase chronic myelogenous leukemia (CML) who were prescribed or started with bosutinib.
Patients meeting the following criteria were included:
1. Evidence of a personally signed and dated informed consent document indicating that the patient (or a legally acceptable representative) has been informed of all pertinent aspects of the study
2. Age 18 years or older
3. Philadelphia chromosome positive or BCR-ABL positive CP ML
4. Resistant or intolerant to previous therapy for CP CML
5. Has been prescribed bosutinib for the treatment of previously treated CP CML, who has either not started treatment or has not taken bosutinib for more than 7 days at the time of baseline visit
6. Prior history of malignancy is permitted

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

Renal impaired

Estimated number of subjects

170

Study design details

Outcomes

The primary objectives of this NIS are to:1. Determine the rate of treatment related AEs in CP CML patients treated with bosutinib.2. Observe the discontinuation (DC) rate due to treatment related AEs and compare with theDC rate in patients with chronic phase CML resistant or intolerant to previous treatment(s)observed in the clinical trials. Safetydosing, treatment duration, adherence, reasons for dose reductions/ delay/ discontinuations,timing and tests performed during treatment, concomitant medications).Patient self reported adherence information and quality of lifeResponses (results of hematological, cytogenetic and/or molecular testing)Baseline information to describe the patient population treated with bosutinib

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Data analysis plan

Analysis will be based on the safety population, which includes all enrolled patients whoreceived at least one dose of bosutinib. Patients who signed informed consent but who werenot treated will be reported with a reason(s) why treatment was not received.Analysis will be based on observed data. Incomplete dates will be imputed and details willbe included in the SAP.

Documents

Study report

B1871042 CSR Final 20150623.pdf (7.41 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)

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

Unknown