A Postmarketing Observational Registry to Evaluate the Incidence of and Risk Factors for Vascular Occlusive Events Associated With ICLUSIG® (ponatinib) in Routine Clinical Practice in the US (OMNI)

First published: 25/03/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45170

EU PAS number

EUPAS9097

Study ID

45170

DARWIN EU® study

No

Study countries

United States

Study description

A Post-marketing Observational Registry to Evaluate the Incidence of and Risk Factors for Vascular Occlusive Events Associated with Iclusig® (Ponatinib) in Routine Clinical Practice in the US (OMNI – Study Number AP24534-14-401)

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Annette Stemhagen

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Annette Stemhagen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/11/2014

Study start date

Planned: 01/12/2016

Actual: 02/03/2018

Data analysis start date

Actual: 19/02/2019

Date of final study report

Planned: 30/11/2021

Actual: 03/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ARIAD Pharmaceuticals, Inc (a wholly-owned subsidiary of Takeda Pharmaceuticals Company Limited)

Study protocol

Redacted AP24534-14-401 OMNI Protocol Amendment 4, v5.0.pdf(2.04 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 type list

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

Data collection methods:

Primary data collection

Main study objective:

The primary objectives of this study are to assess the following for patients with CP-CML AP-CML, BP-CML, or Ph+ ALL treated with Iclusig with or without anticoagulant and/or antiplatelet agents in routine clinical practice in the US: · the incidence of vascular occlusive events (VOEs) · the risk factors for development of VOEs · the outcomes of VOEs

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, observational registry study

Study drug and medical condition

Name of medicine

ICLUSIG

Medical condition to be studied

Vascular occlusion

Population studied

Short description of the study population

The target registry population will include adult patients in the US who are diagnosed with CP-CML, AP-CML, BP-CML, or Ph+ ALL; who are over 18 years of age; and for whom the decision to initiate treatment with commercially available Iclusig has already been made. Inclusion criteria are broad and exclusion criteria are limited so as to include a representative population of patients being treated with Iclusig in routine clinical practice for one of the current approved indications.

Inclusion Criteria

Patients must meet all of the following criteria to be eligible for the registry:

1. Adult patients (age ≥18 years) who are diagnosed with CP-CML, AP-CML, BP-CML, or Ph+ ALL
2. Patients who are initiating Iclusig therapy for the first time, or for whom Iclusig therapy was initiated within 30 days before registry enrollment.
3. The decision to prescribe Iclusig must have been made prior to enrollment in the registry and based upon approved US indications.
4. Patients who have the ability to understand the requirements of the registry, and provide written informed consent to comply with the registry data collection procedures.

Exclusion Criteria

Patients are not eligible for participation in the registry if they meet any of the following exclusion criteria:

1. Patients previously treated with investigational Iclusig.
2. Patients receiving any investigational agent (eg, any drug or biologic agent or medical device that has not received approval in the US) or receiving Iclusig for any indication not currently approved in the US.
3. Concurrent treatment with another TKI.

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

300

Study design details

Outcomes

To evaluate the safety of Iclusig in routine care

Data analysis plan

Analyses will include tabulations of the number of candidate patients identified and the number of eligible patients per the inclusion/exclusion criteria. Baseline demographic and medical history data will be presented using descriptive statistics using number and percent for categorical endpoints, n, mean, SD, SE of the mean, median, minimum (min), and maximum (max) for continuous endpoints. The primary analyses will also present 95% CIs. Exploratory analyses will also be performed to better understand any differences in patients who experience any of the adverse events of special interest (VOEs) versus those who do not. The exploratory analyses will be performed using logistic regression, including factors such as patient demographic characteristics, risk factors, dose and duration of Iclusig treatment, and concomitant medications, including but not limited to prophylactic and/or therapeutic use of anticoagulant and/or antiplatelet agents.

Documents

Study results

AP24534-14-401 Clinical Study Report Synoptic Body_Redacted.pdf(858.25 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