Post-Authorization Long Term Safety Surveillance Study of Fostamatinib in Adult Patients with Chronic Immune Thrombocytopenia (cITP) who are Refractory to Previous Treatments

First published: 22/07/2021

Last updated: 11/01/2022

Study Planned

Administrative details

EU PAS number

EUPAS42043

Study ID

45096

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

This post-marketing observational study is a multi-centre, prospective, non-interventional, active surveillance study with intensive monitoring in adult patients with refractory cITP who are planned to start receiving new treatment with fostamatinib. This study is intended to provide additional long-term safety data of fostamatinib in patients with cITP according to the current prescribing information of the European label in a real-world setting.

Study status

Planned

Research institutions and networks

Institutions

Instituto Grifols

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

To be confirmed To be confirmed

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 17/04/2020

Study start date
Planned: 28/02/2022

Date of final study report
Planned: 01/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Grifols Bioscience Industrial Group

Regulatory

Was the study required by a regulatory body?

Yes

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:

Safety study (incl. comparative)

Main study objective:

The primary objective of this PASS is to document the long-term safety and tolerability of fostamatinib in adult patients with cITP who are refractory to other treatments when used according to the current approved prescribing information per the European Summary of Product Characteristics (SmPC) in a real-world setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, non-interventional, active surveillance study

Study drug and medical condition

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

FOSTAMATINIB

Medical condition to be studied

Immune thrombocytopenia

Additional medical condition(s)

Chronic Immune Thrombocytopenia (cITP)

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

67

Study design details

Outcomes

All adverse event (AE), serious AE (SAE), suspected adverse drug reaction (ADR), complete blood count, and liver function test data will be collected, and the incidence of AEs of special interest, namely hypertension, hepatotoxicity, neutropenia and infections (including serious and opportunistic infections), osteoporosis, bone fractures and fracture healing, and diarrhoea will be calculated.

Data analysis plan

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor. The SAP may modify the plans outlined in the protocol, any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment. For the purpose of this study, the safety analysis population will consist of all patients treated with at least 1 dose of fostamatinib. Analyses will generally be descriptive in nature and will be conducted using SAS statistical software (version 9.3 or higher). All variables will be summarized descriptively through tabular displays of number of non-missing observations, mean, median, ranges and standard deviations of continuous variables, and frequency and percentages of categorical variables. No formal hypothesis testing or comparisons is planned.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

All clinical and treatment data for the study will be collected from each subject’s medical records by the designated site personnel and entered into the electronic data capture (EDC) system.

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