Panobinostat Post Authorization Safety Study, a non-interventional study of panobinostat in combination with bortezomib and dexamethasone in patients with Relapsed and/or Refractory Multiple Myeloma (RRMM)

First published: 01/05/2017

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS18261

Study ID

34837

DARWIN EU® study

No

Study countries

Germany

Greece

Study description

This Post Authorization Safety Study is a non interventional study conducted in Europe, of panobinostat in combination with bortezomib and dexamethasone in patients with Relapsed and/or Refractory Multiple Myeloma.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Multiple centres: 46 centres are involved in the study

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/04/2015

Actual: 09/01/2016

Study start date

Planned: 20/04/2017

Actual: 02/05/2017

Data analysis start date

Planned: 14/11/2022

Actual: 31/03/2019

Date of final study report

Planned: 14/05/2023

Actual: 29/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

CLBH589D2408-v00--protocol_Redacted.pdf (2.88 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CLBH589D2408

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:

Primary objective 1:collect safety data in patients with relapsed and/or refractory multiple myeloma treated with panobinostat in combination with bortezomib and dexamethasone in a realworldsetting, according to the current EU prescribing information 2: Document the adherence to the dosing regimen (including the dosing card, blister pack)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional Post Authorization Safety Study

Study drug and medical condition

Medicinal product name

FARYDAK

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

The target population includes adult patients with a diagnosis of Relapsed and/or Refractory Multiple Myeloma.
Any patients irrespective of age, previous treatment, ECOG status, living in one of the EEA countries can be entered in the protocol as soon as they have received at least one dose of panobinostat and treated according to the EU SmPC.
Patients were eligible if they meet the following criteria:
Inclusion criteria
1. Patients diagnosed with Relapsed and/or Refractory Multiple Myeloma
2. Patients have a new or ongoing treatment with a regimen of PAN+BTZ+DEX according to the EU approved SmPC.
3. Patients were eligible to enter the study at any time during the first 12 cycles and no later than day 1 of cycle 13.
Exclusion criteria
1. Patients not providing informed consent
2. Patients participating concurrently in an investigational study involving panobinostat or another anti-myeloma drug.

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

Renal impaired

Estimated number of subjects

425

Study design details

Outcomes

The proportions of patients with AEs/SAEs, discontinuation due to AE, and on-treatment deaths will be provided.Counts, and proportions of patients with medication errors (i.e. dose omission and improper dose (underdose, overdose, and extradose) will be provided

Data analysis plan

No statistical hypotheses will be tested in this study.

Documents

Study results

lbh589d2408--legacy-clinical-study-report_Redacted.1 minus appendix 16.pdf (1.19 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

No