# 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

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**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

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**Study start date**

Planned: 20/04/2017

Actual: 02/05/2017

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**Data analysis start date**

Planned: 14/11/2022

Actual: 31/03/2019

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**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

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**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