Retrospective Analysis of Second Primary Malignancies (SPM) Data From ASPIRE and ENDEAVOR Studies (20220146)

First published: 01/03/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/104100

EU PAS number

EUPAS103648

Study ID

104100

DARWIN EU® study

No

Study countries

☐ United States

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/12/2022

Actual: 01/12/2022

Study start date
Planned: 01/03/2023

Actual: 01/03/2023

Data analysis start date
Planned: 20/03/2023

Actual: 20/03/2023

Date of final study report
Planned: 30/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original carfilzomib 20220146.pdf(807.62 KB)

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:

Other

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

Clinical study databases of ASPIRE and ENDEAVOR.

Main study objective:

The main objective of this study is to describe the incidence rates of SPM in each arm of ASPIRE and ENDEAVOR.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, post hoc analysis of two Phase 3 randomized controlled trials of carfilzomib-based regimen vs non-carfilzomib regimen.

Study drug and medical condition

Name of medicine

KYPROLIS

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

CARFILZOMIB

Medical condition to be studied

Plasma cell myeloma

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

1700

Study design details

Outcomes

• Overall participant incidence of SPM and SPM by categories of solid tumor (skin or non-skin cancer), hematologic malignancies, or other non-specified malignancies.

• Exposure-adjusted incidence rate of SPM and SPM by category.

• Time to onset of SPM.

• Outcome of SPM.

• Baseline demographic and disease characteristics.

Data analysis plan

The descriptive statistics will be provided by treatment arm for participants with SPM & without SPM. Continuous variables are summarized by non-missing sample size, mean, standard deviation, median, interquartile range, minimum, maximum. Categorical variables are summarized by number of participants & percentage in each category.

Malignant tumors standardized MedDRA query (SMQ) & tumors of unspecified malignancy SMQ are used in adverse events data search to identify participants with SPM.

Participant incidence of SPM & SPM by category (solid tumor skin/non-skin cancer, hematologic malignancies, or other non-specified) will be summarized based on the listing. Outcomes of SPMs will be summarized by arms.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Clinical study databases of ASPIRE and ENDEAVOR.

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