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

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## Administrative details

<b>EU PAS number</b> EUPAS103648	
Study ID	
104100	
DARWIN EU® study	
No	
Study countries	
United States	

## **Study status**

Ongoing

Research institutions and networks

## **Institutions**

## **Amgen**

☐ United States

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Institution

## Contact details

#### **Study institution contact**

Global Development Leader Amgen Inc. medinfo@amgen.com

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 typo

#### 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

#### **Medicinal product name**

**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

## **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

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