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

**First published:** 01/03/2023

**Last updated:** 23/04/2024





# Administrative details

#### **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 requiatory is	s the study required by a regu	ulatory 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