

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

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Study

Ongoing

## Administrative details

### PURI

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

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### EU PAS number

EUPAS103648

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### Study ID

104100

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### DARWIN EU® study

No

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### Study countries

United States

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## 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.

Study contact

[medinfo@amgen.com](mailto: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

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**Study start date**

Planned: 01/03/2023

Actual: 01/03/2023

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**Data analysis start date**

Planned: 20/03/2023

Actual: 20/03/2023

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**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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### Study type:

Non-interventional study

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#### 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

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## **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

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

CARFILZOMIB

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## **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)

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## **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.
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## **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

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No