

# A retrospective analysis of pre-existing and acquired major adverse cardiovascular events (MACE) in a real world cohort of multiple myeloma (MM) patients treated with proteasome inhibitors

**First published:** 30/11/2016

**Last updated:** 02/06/2020

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/35617>

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### **EU PAS number**

EUPAS16302

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### **Study ID**

35617

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### **DARWIN EU® study**

No

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## Study countries

United States

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## Study description

The primary objectives are observational and descriptive. The purpose of the study is to estimate the incidence of CV outcomes for bortezomib- and carfilzomib- treated patients. For the exploratory objective, Kaplan Meier curves will compare time to CV event rate between the two groups- bortezomib- and carfilzomib- treated patients.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Amgen

United States

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

**Last updated:** 21/02/2024

**Institution**

Brigham & Women's Hospital Boston USA, Dana

Farber Institute Boston USA, Massachusetts

General Hospital Boston USA

## 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: 31/05/2016

Actual: 11/07/2016

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### Study start date

Planned: 30/11/2016

Actual: 30/11/2016

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### Data analysis start date

Planned: 30/06/2019

Actual: 05/06/2019

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### Date of final study report

Planned: 01/06/2020

Actual: 02/06/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[01.20.01 Protocol Ver 1.0 2016-08-26 English.pdf](#)(414.07 KB)

## 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)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The aim of this observational study is to describe the differences in the incidence of CV outcomes for bortezomib- and carfilzomib- treated patients.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective analysis

## Study drug and medical condition

**Name of medicine**

KYPROLIS

VELCADE

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## **Medical condition to be studied**

Plasma cell myeloma

## **Population studied**

### **Short description of the study population**

Patients with multiple myeloma (MM) treated with proteasome inhibitors.

Patients eligible for this study will have received treatment for MM at one of the following institutions: Brigham & Women's Hospital, Dana Farber Cancer Institute, or Massachusetts General Hospital, Boston. Patient cohorts will include:

a) 400 consecutive patients treated with bortezomib with MM who have received  $\geq 1$  prior treatments, and

a) 250 consecutive patients with relapsed and/or refractory MM treated with carfilzomib, who have received  $\geq 1$  prior treatments prior to initiating carfilzomib.

### **Inclusion Criteria**

1. Patients with a diagnosis of MM who have received  $\geq 1$  prior treatments prior to treatment with carfilzomib or bortezomib
2. Treatment for at least 1 cycle with bortezomib (21 day cycle) or carfilzomib (28 day cycle)
3. Age  $\geq 18$  years

### **Exclusion Criteria**

1. Use of bortezomib or carfilzomib as first line treatment for MM (i.e. no prior treatment).
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### **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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### **Special population of interest**

Other

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### **Special population of interest, other**

Multiple myeloma patients

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### **Estimated number of subjects**

650

## Study design details

### **Outcomes**

- Incidence of MACE and extended MACE in bortezomib and carfilzomib- treated patients with MM
- Pre-treatment cardiovascular risk profile and overall comorbidities in bortezomib and carfilzomib-treated patients with MM, Risk factors for MACE and extended MACE in MM patients: overall, bortezomib-treated, and carfilzomib- treated

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### **Data analysis plan**

For the primary endpoint, the incidence of MACE and extended MACE will be calculated separately for bortezomib- and carfilzomib- treated patients.

Incidence of MACE and extended MACE will be calculated by counting incident events in the carfilzomib-treated cohort or bortezomib-treated cohort. For the secondary objective, pre-treatment cardiovascular risk profile and overall comorbidities in bortezomib- and carfilzomib-treated patients will be compared using the Fisher Exact Test for categorical data and the Student t-test for

continuous data. For the exploratory objective, risk factors for MACE and extended MACE in MM patients will be analyzed overall and for bortezomib-treated and carfilzomib-treated cohorts, separately. A generalized logistic regression model will be used to identify predictors of MACE and extended MACE.

## Documents

### Study results

[20160154 ORS20May2020\\_Redacted.pdf](#)(77.33 KB)

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## Data management

### Data sources

#### Data sources (types)

[Other](#)

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#### Data sources (types), other

Retrospective cohort based on combination of EMR review, Patient Data Registry, and the National Death index

## 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