Topological Analysis of the baseline characteristics of relapsed and/or refractory multiple myeloma (R/R MM) patients treated with carfilzomib in clinical trials to identify cohorts that represent levels of risk of select cardiovascular adverse events (CV AEs) in that patient population (20190506)

First published: 01/05/2020

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43766

EU PAS number

EUPAS35042

Study ID

43766

DARWIN EU® study

No

Study countries

United States

Study description

Develop and characterize risk profiles for select cardiovascular adverse events in patients with relapsed and/or refractory (R/R) multiple myeloma (MM) treated with carfilzomib across four clinical trials through an analysis of baseline characteristics

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/04/2020

Actual: 23/04/2020

Study start date

Planned: 24/01/2020

Actual: 24/01/2020

Data analysis start date

Planned: 06/07/2020

Actual: 29/09/2020

Date of final study report

Planned: 31/01/2021

Actual: 29/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS35042-43764.pdf(1.98 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Develop and characterize risk profiles for select cardiovascular adverse events in patients with relapsed and/or refractory (R/R) multiple myeloma (MM) treated with carfilzomib across four clinical trials through an analysis of baseline characteristics.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective analysis of randomized controlled trial data using machine learning

Study drug and medical condition

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

CARFILZOMIB

Medical condition to be studied

Cardiac failure

Hypertension

Arrhythmia

Pulmonary hypertension

Population studied

Short description of the study population

The study population consists of both (Kyprolis treatment) arms of the ARROW study (Moreau 2018) and the Kyprolis treatment arms of the ASPIRE (Stewart 2015), ENDEAVOR (Dimopoulos 2016) and FOCUS studies (Hajek 2017).

Inclusion Criteria

The subjects in this study are the individuals who participated in the ARROW, ASPIRE, ENDEAVOR and FOCUS studies and were treated with carfilzomib.

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)

Special population of interest

Other

Special population of interest, other

Patients with Cardiac failure, Hypertension, Arrhythmia, Pulmonary hypertension

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Estimated number of subjects

1485

Study design details

Outcomes

Rate of CVAEs in cohorts of patients identified as having high, intermediate or low risks for the select CVAEs

Data analysis plan

The analysis uses three techniques in sequence:Topological data analysis to produce network representations of data,Network clustering known as cold-spot detection to identify coherent sets of non-AE subjects, andMulti-class single-decision-tree learning to discover groups of subjects and conditions on variables that explain them.The sequence may be repeated more than once.

Documents

Study results

20190506_Abstract Observational Research Study Report Published Report.pdf (1.19 MB)

Data management

Data sources

Data source(s), other

ARROW study, ASPIRE study, ENDEAVOR study, FOCUS study

Data sources (types)

Other

Data sources (types), other

Phase 3 randomized clinical trials

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