Real-world Evidence of the Use of a Carfilzomib Triplet Including an Anti-CD38 Antibody in Patients With Multiple Myeloma who Have Received at Least one Prior Therapy (20200445)

First published: 09/11/2022

Last updated: 11/03/2025

Study Cancelled

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50712

EU PAS number

EUPAS49271

Study ID

50712

DARWIN EU® study

No

Study countries

- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ Greece
- ☐ Italy
- ☐ Portugal
- ☐ Spain

Study status

Cancelled

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

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 27/07/2021

Study start date
Planned: 23/01/2024

Data analysis start date
Planned: 22/01/2026

Date of final study report
Planned: 08/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main objective of this study is to describe overall response rate (ORR) in participants with multiple myeloma (MM) who have received at least one prior treatment and initiated therapy with a carfilzomib triplet including an anti-CD38 antibody.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

KYPROLIS

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

250

Study design details

Outcomes

Overall response: defined as the best proportion of best overall response of complete response or better, very good partial response (VGPR), or partial

response (PR) by investigator assessment recorded in the participant chart. Progression-free survival Overall Survival Response duration Subsequent anti-MM therapy Disease progression Overall Response Dose, schedule, cycles, discontinuation, reason for discontinuation, carfilzomib/anti-CD38 antibody dropping/switching Concomitant medications (antibiotics, anti-hypertensives, anti-myeloma therapy, bone targeting agents) Adverse events excluding exempted events

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Data analysis plan

Categorical data will be summarised by the number and percentage of participants in each category.

Two-sided 95% CIs will be presented, where appropriate. Continuous data will be summarised by mean, standard deviation (StD), median, lower and upper quartiles, and minimum and maximum values.

Time-to-event endpoints will be summarised using Knowledge Management methodology.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Chart review

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