# Postmarketing Surveillance Study for Kyprolis® (carfilzomib) in Korea (20160117)

**First published:** 30/06/2017

**Last updated:** 27/03/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS18108

**Study ID**

46780

**DARWIN EU® study**

No

**Study countries**

Korea, Republic of

**Study description**

To assess safety and effectiveness of Kyprolis® in post-marketing real-life setting

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Amgen

United States

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

**Last updated:** 27/03/2026

**Institution**

### Multiple centres: 40 centres are involved in the study

## Contact details

**Study institution contact**

Global Development Leader Amgen Inc.
medinfo@amgen.com

**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: 29/03/2016

Actual: 29/03/2016

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**Study start date**
Planned: 01/01/2018

Actual: 26/12/2017

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**Data analysis start date**
Planned: 21/02/2023

Actual: 21/02/2023

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**Date of interim report, if expected**
Planned: 30/03/2022

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**Date of final study report**
Planned: 30/06/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

# Study protocol

01 20 01 Protocol Ver 1 0 2016-03-29 English (002).pdf (717.33 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

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

Non-EU RMP only

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of this study is to determine the incidence of adverse events (AEs), serious AEs and adverse drug reactions (ADRs) among patients receiving Kyprolis® in reallife setting in its registered indication(s) as required by MFDS.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective observational study

## Study drug and medical condition

**Medicinal product name**

KYPROLIS

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**Medical condition to be studied**

Plasma cell myeloma

## Population studied

**Short description of the study population**

Patients with multiple myeloma who were prescribed treatment of Kyprolis®.

Inclusion Criteria:

1. Signed and dated informed consent
2. Patients diagnosed with multiple myeloma who have received at least one prior therapy
3. Patients who are prescribed with Kyprolis® (in combination with lenalidomide and dexamethasone or in combination with dexamethasone) for the first time

Exclusion Criteria:

All contraindications specified in the local product information have to be considered. In addition, patients treated with any regimens not specified in the approved prescribing information of Kyprolis® in Korea should be excluded from the study.

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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**

700

# Study design details

**Outcomes**

Number of patients, subject incidence with adverse events, adverse drug reactions and serious adverse events during the observational period will be calculated and summarized, Overall response rate for disease assessment - Patients with confirmed sCR, CR, VGPR, or PR will be considered to have achieved an overall response

**Data analysis plan**

Patient demographics, baseline characteristics, medical history and concomitant drug use will be summarized. For the safety analysis, adverse event will be presented using the number of treated patients, incidence proportion and number of patients with events. For the effectiveness analysis, overall response rate at 12 and 24 weeks after drug administration will be analysed

# Documents

**Study results**

20160117 abstract ORSR_Redacted.pdf (172.51 KB)

# Data management

# ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Prospective patient-based data collection

## 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