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

First published: 30/06/2017

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46780

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

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Institution

Multiple centres: 40 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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

Study start date

Planned: 01/01/2018

Actual: 26/12/2017

Data analysis start date

Planned: 21/02/2023

Actual: 21/02/2023

Date of interim report, if expected

Planned: 30/03/2022

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

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

Non-interventional study design, other

Prospective observational study

Study drug and medical condition

Name of medicine

KYPROLIS

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.

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

Multiple Myeloma patients

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

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