Post-marketing Study Assessing the Serious Cardiovascular Events Among Osteoporotic Patients Initiating Romosozumab in Japan Using the Medical Information Database Network (MID-NET) (20190206)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000308

EU PAS number

EUPAS1000000308

Study ID

1000000308

DARWIN EU® study

No

Study countries

Japan

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

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Institution

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: 07/06/2024

Actual: 07/06/2024

Study start date
Planned: 01/11/2024

Actual: 23/12/2024

Data analysis start date
Planned: 01/04/2026

Date of final study report
Planned: 01/12/2026

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Protocol-Published Original romosozumab 20190206.pdf(848.25 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main study objective is to assess the serious cardiovascular events of romosozumab and other osteoporosis medications among osteoporotic patients overall and with/without renal dysfunction in Japan.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

EVENITY

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

ROMOSOZUMAB

Anatomical Therapeutic Chemical (ATC) code

(M05BX06) romosozumab

romosozumab

Medical condition to be studied

Osteoporosis

Population studied

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

3850

Study design details

Outcomes

Primary outcome:

• Composite endpoint of hospitalized acute myocardial infarction, cerebral hemorrhage and cerebral infarction

Secondary outcome:

• Composite endpoint of hospitalized acute myocardial infarction, cerebral hemorrhage and cerebral infarction

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Data analysis plan

[Approach to primary objective]

Propensity scores will be calculated for each patient using multiple logistic regression modelling based on baseline demographic characteristics and clinical characteristics. Inverse probability of treatment weights (IPTW) will be created using propensity scores to minimize the measured confounding in the comparison of patients initiating romosozumab relative to patients initiating other specific osteoporosis therapies. Standardized mean differences (SMD) will be used to assess the differences in baseline patient characteristics between the treatment groups. Negative control outcome analyses will be used to detect presence of unmeasured confounding. COX proportional hazards model in the weighted sample will be used to estimate hazard ratio.

[Approach to secondary objective]

The same approach will be performed by the level of renal insufficiency.

Data management

Data sources

Data source(s), other

MID-NET database

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes