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

EU PAS number

EUPAS1000000308

Study ID

1000000308

DARWIN EU® study

No

Study countries

Japan

Study status

Ongoing

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

Actual: 07/06/2024

Study start date

Actual: 23/12/2024

Date of final study report

Planned: 01/12/2026

Study protocol

Protocol-Published Original romosozumab 20190206.pdf (848.25 KB)

Protocol-Published Amendment romosozumab 20190206 2 .pdf (714.32 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:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Retrospective cohort study employing a new user with active comparator design

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

Medicinal product name

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

Myocardial infarction

Cerebral haemorrhage

Cerebral infarction

Population studied

Short description of the study population

Patient Eligibility Criteria

Inclusion criteria

- Three cohorts of patients defined by new initiation of romosozumab, Parathyroid hormone 1 receptor (PTH1R) agonists (teriparatide, abaloparatide) or oral alendronate from 4 March 2019 onwards to one year prior to the end of available data.
- Patients at least 50 years of age at the date of new treatment initiation.

Exclusion criteria

- Patient without an adequate period of records in the data source for assessment of baseline cardiovascular risk.

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

Setting

MID-NET database is a hospital-based setting of 23 hospitals from ten healthcare organizations.

Comparators

patients initiating other specific osteoporosis therapies.

- romosozumab vs. PTH1R agonists
- romosozumab vs. oral alendronate

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

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 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