Real World Utilization and Effectiveness of Romosozumab Among Osteoporosis Patients in Hong Kong (20250006)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000724

Study ID

1000000724

DARWIN EU® study

No

Study countries

China

Study status

Ongoing

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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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: 29/08/2025

Study start date

Planned: 15/11/2025

Actual: 03/11/2025

Data analysis start date

Planned: 19/12/2025

Actual: 18/12/2025

Date of final study report

Planned: 15/12/2026

Study protocol

Protocol-Published Original romosozumab 20250006 .pdf (1.56 MB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a retrospective cohort study of participants who initiated Romosozumab in Hong Kong.

Main study objective:

The main objectives of the study are:

• To describe characteristics of participants initiating Romosozumab and use of osteoporosis therapies

• To describe change of bone mineral density among participants initiating Romosozumab

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

Population studied

Short description of the study population

Participants who received at least 1 injection of Romosozumab between 2 July 2020 and 31 December 2024

in Hong Kong

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)

- Adults (85 years and over)

Estimated number of subjects

1.000

Study design details

Outcomes

Primary outcomes:

• The following will be described for participants initiating Romosozumab:

o Demographics.

o Clinical characteristics.

o Romosozumab utilization:

 Dose and dosing schedule.

 Total number of injections and duration of treatment.

o Use of osteoporosis therapies after Romosozumab.

• Percentage change of bone mineral density (BMD) from baseline of Romosozumab initiation to follow-up BMD.

Data analysis plan

• Objective 1: Describe characteristics of participants initiating Romosozumab and use of osteoporosis therapies.

o Descriptive analysis will be conducted to describe the disease and medication history, lab values, treatment pattern of Romosozumab users, and use of other osteoporosis therapies after initiating Romosozumab.

• Objective 2: Describe change of bone mineral density among participants initiating Romosozumab.

o For participants in Hong Kong West cluster, their BMD records can be manually extracted from Clinical Management System (CMS) / Electronic Patient

Records (EPR) system. The change in baseline BMD (available BMD records up to 90 days before/at Romosozumab initiation) and BMD at 6 and 12 months after initiating Romosozumab will be described among participants with both BMD values at baseline and 6 months, or both BMD values at baseline and 12 months, respectively.

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 data source

Data source(s), other

Hong Kong Clinical Data Analysis and Reporting System (CDARS)

Data sources (types)

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