Real World Use, Effectiveness and Safety of Romosozumab among Osteoporosis Patients in Guangdong China (20250009)

First published: 16/10/2025

Last updated: 09/04/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000758

Study ID

1000000758

DARWIN EU® study

No

Study countries

☐ China

Study status

Planned

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: 28/02/2026

Actual: 01/04/2026

Study start date

Planned: 30/04/2026

Data analysis start date

Planned: 30/05/2026

Date of interim report, if expected

Planned: 30/08/2026

Date of final study report

Planned: 01/12/2026

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Protocol Original romosozumab 20250009 .pdf (1.64 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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a retrospective cohort study of participants who initiated Romosozumab in Guangdong, China.

Main study objective:

The main objectives of this study are:

• To describe characteristics of participants initiating Romosozumab and its utilization.

• To describe change of available bone mineral density, bone turnover markers, and participant reported pain scores.

• To characterize the safety profile of 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 initiated Romosozumab in Guangdong province hospitals where Romosozumab is available through special medical zone policy since October 2024.

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

100

Study design details

Setting

The study population is patients with osteoporosis that have received Romosozumab treatment in Guangdong province of China through special medical zone policy.

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.

• Changes in bone mineral density (BMD) from baseline at the lumbar spine, total hip and femur neck at 6 and 12 months.

• Changes in bone resorption and formation markers (e.g., C-terminal Telopeptide [CTX], Procollagen Type 1 N-terminal Propetied [P1NP]) at 1, 3, 6 and 12 months.

• Changes in pain score at available time points.

• Number of recorded adverse events and serious adverse events since the first dose injection in the data source.

Data analysis plan

Descriptive analysis will describe the number of Romosozumab participants by participant history, disease characteristics, and the duration of Romosozumab use.

The number of recorded safety events will be estimated during study follow-up. For BMD analysis, percentage change from baseline at 6 and 12 months will be calculated. A minimum dosage is required for BMD analysis, 5 doses for the 6-month analysis or 10 doses for the 12-month analysis. Compared to baseline levels, the values of bone turnover biomarkers will be described at 1, 3, 6 and 12 months.

Pain score will not be available in all study sites and change from baseline will be described at available timepoints. Pain score will also be analyzed according to whether a participant had recent orthopedic surgery.

A stratified analysis of effectiveness outcomes will be conducted by types of osteoporosis medication used before Romosozumab initiation and by study sites.

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

The data source is the electronic health records in each participating hospital site in GBA Guangdong province. This includes a pre-specified hospital department tracking form designed for Romosozumab. An existing common analytic platform (CAP) of de-identified Romosozumab data will be used for analysis across hospital

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown