Postmarketing Surveillance Study of EVENITY (Romosozumab) in South Korea (20170753)

First published: 19/07/2019

Last updated: 16/01/2026

Study Finalised

Administrative details

EU PAS number

EUPAS30346

Study ID

39019

DARWIN EU® study

No

Study countries

Korea, Republic of

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

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

Planned: 30/06/2019

Study start date
Planned: 25/01/2021

Actual: 30/12/2020

Data analysis start date
Planned: 31/01/2025

Actual: 17/01/2025

Date of interim report, if expected
Planned: 31/01/2020

Actual: 29/01/2020

Date of final study report
Planned: 21/08/2025

Actual: 21/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Superseding romosozumab 20170753 2 .pdf (4.25 MB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Safety Reporting

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to estimate the incidence rates of adverse events, serious adverse events, and adverse drug reactions among patients receiving EVENITY on label in the post-marketing setting in South Korea as required by the MFDS.

Study Design

Non-interventional study design

Cohort

Non-interventional study design, other

Prospective, observational study

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

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)

Estimated number of subjects

300

Study design details

Outcomes

Incidence of adverse events, serious adverse events, and adverse drug reactions, Treatment response as determined by percent change from baseline in BMD (measured by DXA) of the lumbar spine and/or total hip and/or femoral neck at 12 months (or as close as possible to the last dose of EVENITY) per local standard of care.

Data analysis plan

Given the observational nature of the study, data will be summarized descriptively. The Safety Analysis Set will include all patients who received at least 1 dose of EVENITY and have at least 1 follow-up.
The incidence of adverse events will be summarized to include all treatment-emergent adverse events recorded from the start of EVENITY on this study or any worsening of medical conditions initially experienced before initiation of this study.
This summary for adverse events will be performed for the following categories:
• All adverse events and adverse drug reactions

• Serious adverse events and serious adverse drug reactions
• Adverse events leading to EVENITY discontinuation
• Fatal events

Documents

Study results

20170753 redacted ORSR Abstract_ final _25Nov2025.pdf (250.48 KB)

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 sources (types)

Spontaneous reports of suspected adverse drug reactions

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