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

**First published:** 19/07/2019

**Last updated:** 05/02/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS30346

**Study ID**

39019

**DARWIN EU® study**

No

**Study countries**

☐ Korea, Republic of

**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Amgen

United States

**First published:** 01/02/2024

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**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

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**Data analysis start date**
Planned: 31/01/2025

Actual: 17/01/2025

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

Actual: 29/01/2020

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**Date of final study report**
Planned: 28/07/2025

## 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

**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**

Other

**Non-interventional study design, other**

Prospective, observational study

## 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 (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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**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.

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**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

# 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)**

Other

Spontaneous reports of suspected adverse drug reactions

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**Data sources (types), other**

Prospective patient-based data collection

## 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