

# European non-interventional post-authorization safety study related to serious cardiovascular events of myocardial infarction and stroke, and all-cause mortality for romosozumab by the EU-ADR Alliance

**First published:** 24/09/2020

**Last updated:** 06/02/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS35881

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### Study ID

37810

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### DARWIN EU® study

No

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### Study countries

-  Denmark
  -  France
  -  Germany
  -  Italy
  -  Netherlands
  -  Spain
  -  United Kingdom
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### **Study description**

The main objective is to evaluate potential differences in terms of serious cardiovascular adverse events between romosozumab and currently available therapies used in comparable patients in real-world conditions.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

[UCB Biopharma SRL](#)

## Contact details

### **Study institution contact**

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent

required for disclosure according to applicable data protection laws is not available. [clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

**Study contact**

[clinicaltrials@ucb.com](mailto:clinicaltrials@ucb.com)

### **Primary lead investigator**

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Actual: 30/09/2020

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### **Study start date**

Actual: 01/10/2020

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### **Date of final study report**

Planned: 31/03/2027

## Sources of funding

## More details on funding

UCB Biopharma SRL

## Study protocol

[op0004-protocol-final-Redacted.pdf](#) (1.62 MB)

[OP0004-protocol-Substantial Amendment-4\\_Redacted.pdf](#) (1.71 MB)

[OP0004-protocol-Substantial Amendment-4\\_Redacted.pdf](#) (1.71 MB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

OP0004

## Methodological aspects

Study type

Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

The overarching objective of this study is to characterize the risk of serious cardiovascular events of myocardial infarction and stroke, and all-cause mortality including cardiovascular death associated with the use of romosozumab, in comparison with other available osteoporosis medications in routine clinical practice in Europe

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

[EVENTY](#)

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**Study drug International non-proprietary name (INN) or common name**

ROMOSOZUMAB

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## **Anatomical Therapeutic Chemical (ATC) code**

(M05BX) Other drugs affecting bone structure and mineralization

Other drugs affecting bone structure and mineralization

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## **Medical condition to be studied**

Osteoporosis postmenopausal

## Population studied

### **Age groups**

- 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**

337200

## Study design details

### **Outcomes**

MACE-2 (first occurrence of death all cause including cardiovascular (CV) death, Myocardial Infarction (MI), or stroke), - Myocardial Infarction (MI)- Stroke- Death due to cardiovascular (CV) causes, ie, MI or stroke- All-cause mortality- First occurrence of death (CV causes), MI, or stroke (MACE-1)

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### **Data analysis plan**

Incidence rates and 95 % confidence intervals for each outcome will be calculated for each study drug cohort using a Poisson model. These will be

reported for prespecified intervals of 6, 12, 18, and 24 months after treatment indexes, and will be stratified by several factors including age, prior use of osteoporosis medication, and previous history of cardiovascular event. For comparative safety studies, propensity score matching will be used to match patients using romosozumab to up to 3 users of alendronate. Cox regression models stratified by matched sets will be used to calculate hazard ratios and 95 % CIs for each of the safety endpoints (MI, stroke, MACE-1, and MACE-2) according to drug exposure in the propensity-matched cohorts. The pooled estimates of the incidence rate for the databases will be calculated using the random or fixed effects meta-analysis depending on heterogeneity detected using an  $I^2$  threshold of  $>40\%$ .

## 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)**

Clinical Practice Research Datalink

Danish registries (access/analysis)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

German Pharmacoepidemiological Research Database

Système National des Données de Santé (French national health system main database)

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**Data source(s), other**

Health Search Database (HSD), Italy

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**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**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

No