VALIDATION STUDY PROTOCOL (OP0007) FOR THE 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 (OP0004) AND EUROPEAN NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY RELATED TO SERIOUS INFECTIONS FOR ROMOSOZUMAB BY THE EU-ADR ALLIANCE (OP0006)

First published: 08/10/2020

Last updated: 19/06/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/37819

EU PAS number
EUPAS36734

Study ID
37819

DARWIN EU® study
No

Study countries
Germany
Italy
Netherlands
Spain

Study description
The objective of this study is to determine the completeness and diagnostic validity of the following outcomes, which will be evaluated in the 2 European non-interventional post-authorisation safety studies (PASS) of romosozumab: 1. cardiovascular death, 2. myocardial infarction, 3. Stroke, 4. serious infection. Outcomes will be identified based on predefined code lists, which were adapted according to the relevant coding system for the respective database. Validation algorithms are defined individually for each specific outcome. In addition, the validation procedures, e.g. manual free text evaluation, will depend on the specific characteristics of the individual databases (primary care and claims databases). Validation of the outcomes of interest will be conducted for databases where previous validation demonstrated insufficient positive predictive values (PPVs) <75% (all-case validation), or where validation has not yet been performed (sample validation of 250 cases).

Study status
Ongoing

Research institution and networks

Institutions

UCB Biopharma SRL

Health Search, Italian College of General Practicioners
Italy
First published: 02/03/2010
Last updated
25/06/2014

Institution
Educational Institution
Other
ENCePP partner

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany
First published: 29/03/2010
Last updated 26/02/2024

Institution | Not-for-profit | ENCePP partner

Clinical Practice Research Datalink (CPRD)

United Kingdom
First published: 15/03/2010
Last updated 02/07/2019

Institution | Laboratory/Research/Testing facility | ENCePP partner

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands
First published: 03/11/2022
Last updated 02/05/2024

Institution | Educational Institution | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
First published: 05/10/2012
Last updated 23/02/2024

Institution

Educational Institution
Laboratory/Research/Testing facility
Not-for-profit
ENCePP partner

Teamit Institute

Spain
First published: 12/03/2024
Last updated 12/03/2024

Institution
ENCePP partner
Other

Networks

EU-ADR Alliance

First published: 01/02/2024
Last updated 01/02/2024

Network

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.

Study contact

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
Planned:
30/09/2020
Actual:
30/09/2020

Study start date
Planned:
01/10/2020
Actual:
01/10/2020

Data analysis start date
Planned:
30/09/2026

Date of final study report
Planned:
31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma SRL

Study protocol

op0007-protocol-final-Redacted.pdf(2.5 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 type:
Not applicable

If ‘other’, further details on the scope of the study
Validation of real-world data

Main study objective:
The objective of this study is to determine the completeness and diagnostic validity of the following outcomes, which will be evaluated in the 2 European non-interventional PASS of romosozumab: 1. cardiovascular death, 2. myocardial infarction, 3. Stroke, 4. serious infection.

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
(M05BX) Other drugs affecting bone structure and mineralization

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)

Estimated number of subjects
250

Study design details

Outcomes
Validation of 4 main outcomes in 2 PASS studies

Data analysis plan
In patients eligible for each of 2 PASS studies, outcomes will be identified based on predefined code lists, which were adapted according to the relevant coding system for the respective databases. All validations (either sample or all-case validations) will be based on free text review of the individual cases. Primary care charts and any related documents (e.g. specialist letters, referrals) will be reviewed by clinically trained validators blinded to exposure. The algorithms for the validation of each of 4 outcomes is provided. Adaptations and specifications to the algorithm may be required to adapt the algorithm to database-specific needs.

Data management

Data sources

Data source(s)
IPCI
The Information System for Research in Primary Care (SIDIAP)
German Pharmacoepidemiological Research Database

Data sources (types)
Administrative data (e.g. claims)
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
No