EUROPEAN NON-INTERVENTIONAL POST AUTHORIZATION SAFETY STUDY RELATED TO SERIOUS INFECTIONS FOR ROMOSOZUMAB BY THE EU ADR ALLIANCE

First published: 24/09/2020
Last updated: 05/03/2024

Study | Ongoing

Administrative details

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

PURI
https://redirect.ema.europa.eu/resource/37816

EU PAS number
EUPAS36005

Study ID
37816

DARWIN EU® study
No

Study countries
Denmark
France
Germany
Italy
Netherlands
Spain
United Kingdom

Study description
The overarching objective of this study is to monitor the potential risk of serious infection associated with the use of romosozumab in comparison with other available osteoporosis medications in routine clinical practice in Europe

Study status
Ongoing

Research institution and networks

Institutions

UCB Biosciences
First published: 01/02/2024
Last updated 01/02/2024
Institution

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

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark
First published: 20/07/2021
Last updated
02/04/2024

Institution

Educational Institution

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

Bordeaux PharmacoEpi, University of Bordeaux

France
First published: 07/02/2023
Last updated
08/02/2023

Institution
Educational Institution
Hospital/Clinic/Other health care facility
Not-for-profit
ENCePP partner

Networks

EU-ADR Alliance

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

Network

Study timelines

Date when funding contract was signed
Planned:
30/09/2020
Actual:
30/09/2020

Data collection
Planned:
01/10/2020
Actual:
01/10/2020

Start date of data analysis
Planned:
30/09/2024

Date of final study report
Planned:
31/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma SRL

Study protocol

op0006-protocol-final-Redacted.pdf(1.36 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

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 monitor the potential risk of serious infection (SI) associated with the use of romosozumab in comparison with other available osteoporosis (OP) medications in routine clinical practice in Europe.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Evenity

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
328256

Study design details

Outcomes
Serious infection (SI) leading to hospitalization, Death due to Serious infection (SI), operationalized as either of:- In-hospital death with a diagnosis of infection during the same admission/episode- Recorded diagnosis of any infection followed by death in the subsequent month

Data analysis plan
Incidence rates and 95 % confidence intervals (CIs) for Serious Infection (SI) events 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 key SI risk factors. 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 (SI leading to hospitalization and SI leading to death) 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

Data sources

Data source(s)
Clinical Practice Research Datalink
Danish registries (access/analysis)
IPCI
The Information System for Research in Primary Care
German Pharmacoepidemiological Research Database

Data source(s), other
CPRD, Danish Registries (access/analysis), IPCI, SIDIAP, GePaRD

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