EUROPEAN NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY RELATED TO ADHERENCE TO THE RISK MINIMIZATION MEASURES 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/37813

EU PAS number
EUPAS35956

Study ID
37813

DARWIN EU® study
No

Study countries
Denmark
France
Germany
Italy
Netherlands
Spain
United Kingdom

Study description
To study the adherence to the risk minimization measures in the product information by estimating the compliance with contraindications and target indication amongst incident romosozumab users, and analyzing the utilization patterns.

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:
30/09/2026

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

op0005-protocol-final-Redacted.pdf(1.18 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:
To study the adherence to the risk minimization measures in the product information by estimating the compliance with contraindications and target indication amongst incident romosozumab users, and analyzing the utilization patterns.

Study drug and medical condition

Name of medicine
Evenity

Medical condition to be studied
Osteoporosis postmenopausal

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
1000

Study design details

Outcomes
Prevalence of contraindications amongst new romosozumab users, - Prevalence of documented indication amongst new romosozumab users- Monthly prevalence of use for each osteoporosis drug- Monthly incidence of use for each osteoporosis drug- Overall duration of treatment/persistence- Proportion persistent at 6, 12, 18, and 24 months- number and percentage of patients who switch to another osteoporosis medication

Data analysis plan
All measures of primary and secondary outcomes will be calculated for each of the contributing databases separately. Estimates will be provided overall (for the whole source population) and stratified by sex (except for use in men), age (5-year bands) and calendar year. Baseline characteristics of all users of romosozumab and of other osteoporosis medications, as well as of romosozumab users in each of the contraindication and restriction of indication groups, will be described.

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