Post-authorisation Safety Study of Rimegepant in Patients with Migraine and History of Cardiovascular Disease in European Countries

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/104168

EU PAS number
EUPAS103990

Study ID
104168

DARWIN EU® study
No

Study countries
Denmark
Netherlands
Spain
United Kingdom

Study description
As part of the risk management plan for rimegepant in Europe, this post-authorisation safety study (PASS) is being conducted to evaluate whether there is an increased risk of major adverse cardiovascular events (MACE) among patients with migraine and history of cardiovascular disease (CVD) initiating treatment with rimegepant compared with that among patients with migraine, with history of CVD, and being treated with other treatments

for migraine, either continuing the current treatment or initiating a new one, other than rimegepant. The study will also describe the use of rimegepant in the initial years after approval in the same population.

Study status
Planned

Research institution and networks

Institutions

Pfizer
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Institution

Networks

RTI

Contact details

Study institution contact
Bertoia Monica
Study contact

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Primary lead investigator
Monica Bertoia
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:

01/03/2023
Actual:
01/03/2023

Study start date
Planned:
01/10/2025

Date of final study report
Planned:
01/04/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

C4951017_bhv3000-408 protocol v2_17 Nov 2022.pdf(1.29 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

Main study objective:
Does the use of rimegepant increase the risk of major adverse cardiovascular event (MACE) compared with other treatments for migraine in patients with migraine and history of cardiovascular disease (CVD) who have been recently treated for migraine?

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
Vydura

Medical condition to be studied
Migraine

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
1

Study design details

Outcomes
Major adverse cardiovascular event (MACE), Individual components of major adverse cardiovascular event (MACE) including acute myocardial infarction, stroke, coronary heart disease death, cerebrovascular death, coronary bypass surgery, and coronary revascularization.

Data analysis plan
Each research partner will conduct analyses separately within each data source, and results will be pooled via meta-analytic methods, if appropriate. The analysis will comprise 4 different steps: select the study population, assign exposure and define follow-up, describe the study cohorts and patterns of rimegepant use, and estimate exposure propensity scores. Stabilised propensity score weights will be used in the comparative analyses. Crude and adjusted incidence rates of MACE with their 95% CIs will be estimated using a Poisson regression model with robust estimation of variance. Cumulative incidence of MACE will be estimated using the Kaplan-Meier estimator for each of the 4 exposure groups. Finally, for each comparison, crude and adjusted RRs and risk differences will be estimated using the Kaplan-Meier estimator, and 95% CIs will be derived using bootstrap methods. Adjusted HRs will be estimated with a Cox model.

Data management

Data sources

Data source(s)
The Information System for Research in Primary Care (SIDIAP)
Danish registries (access/analysis)
Clinical Practice Research Datalink
PHARMO Data Network

Data sources (types)
Administrative data (e.g. claims)
Drug dispensing/prescription data
Electronic healthcare records (EHR)
Other

Data sources (types), other
Prescription event monitoring

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