Real-World Observational Study Using US Pharmacy Claims Data to Assess Safety Outcomes and Treatment Patterns in the US Among Migraine Patients Treated with REYVOW (Lasmiditan) Long Term (H8H-MC-B010)

First published: 17/04/2023

Last updated: 22/11/2024

Study Planned

Administrative details

EU PAS number

EUPAS104191

Study ID

104192

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Nicole Kellier-Steele kellier_nicole_a@lilly.com

Study contact

kellier_nicole_a@lilly.com

Primary lead investigator

Nicole Kellier-Steele

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/10/2022

Study start date
Planned: 31/12/2023

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly &amp, Co

Study protocol

LY573144 H8H-MC-B010 Non_interventional PASS Protocol_Redacted.pdf
(350.47 KB)

Regulatory

Was the study required by a regulatory body?
No

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

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Assess utilization and safety outcomes among patients treated with lasmiditan long term, and describe patient demographics and clinical characteristics and treatment patterns of lasmiditan treated patients treated long term

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LASMIDITAN

Anatomical Therapeutic Chemical (ATC) code

(N02CC08) lasmiditan

lasmiditan

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

100

Study design details

Outcomes

Cardiovascular adverse events, malignancy, serotonin syndrome, and all other diagnoses identified utilizing AHRQ CCSR groupings

---

Data analysis plan

All patients who fulfil the study selection criteria will be included. Study findings will be described as well as a summary of the literature to provide context. A flow diagram illustrating the selection of the study population will be presented. Analyses for safety outcomes will include all data up to the end of insurance

coverage, end of study period, or death, upon which patients will be censored. Analyses for utilization will go through final treatment episode, end of insurance coverage, end of study period, or death, whichever occurs first.

Data management

Data sources

Data source(s), other

IBM® MarketScan United States

Data sources (types)

Administrative healthcare records (e.g., claims)

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