Post-authorisation safety study to evaluate the utilisation and safety of atogepant in patients with migraine and significant cardiovascular or cerebrovascular disease in Europe

First published: 08/08/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000648

Study ID

1000000648

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Netherlands

☐ Spain

☐ Sweden

Study status

Ongoing

Research institutions and networks

Institutions

AbbVie

Contact details

Study institution contact

AbbVie Inc CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

AbbVie Inc

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/11/2023

Actual: 18/12/2024

Study start date
Planned: 30/06/2025

Actual: 05/01/2026

Date of final study report
Planned: 31/12/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie Inc.

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)

Other study registration identification numbers and links

P24-433

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Study drug and medical condition

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

ATOGEPANT

Anatomical Therapeutic Chemical (ATC) code

(N02CD07) atogepant

atogepant

Population studied

Short description of the study population

Patients with migraine and significant cardiovascular or cerebrovascular disease in Europe

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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