Post-authorisation safety study (PASS): observational cohort study of PAH patients newly treated with either Uptravi (selexipag) or any other PAH-specific therapy, in clinical practice (EXPOSURE)

First published: 12/05/2017

Last updated: 21/11/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48403

EU PAS number

EUPAS19085

Study ID

48403

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Canada
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Lithuania
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Russian Federation
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This prospective observational cohort study is conducted to further characterise the safety profile of Uptravi and to describe clinical characteristics and outcomes of patients newly treated with Uptravi in the post-marketing setting. A cohort of patients newly treated with any other PAH-specific therapy than Uptravi and who were never treated with Uptravi is included in this study for the

purpose of comparing the incidence of major adverse cardiovascular events (MACE) and all-cause death with patients newly treated with Uptravi.

Study status

Ongoing

Research institutions and networks

Institutions

Actelion Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Florence Nave-Shelby

Study contact

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Primary lead investigator

Audrey Muller

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 11/04/2017

Actual: 11/04/2017

Study start date
Planned: 30/09/2017

Actual: 13/09/2017

Date of interim report, if expected
Planned: 31/03/2024

Actual: 21/03/2024

Date of final study report
Planned: 30/06/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Actelion Pharmaceuticals Ltd.

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Safety study (incl. comparative)

Main study objective:

To describe demographics, disease characteristics and clinical course in PAH patients newly treated with either Uptravi, or any other PAH-specific therapy, who were never treated with Uptravi, further characterise the safety profile of Uptravi in clinical practice, compare rates of MACE and all-cause.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

UPTRAVI

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

SELEXIPAG

Anatomical Therapeutic Chemical (ATC) code

(B01AC27) selexipag

selexipag

Medical condition to be studied

Pulmonary arterial hypertension

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

3034

Study design details

Outcomes

- Outcomes related to PAH clinical course. Occurrence of all-cause death

- Outcomes related to the Uptravi safety profile. Occurrence of: 1. the identified or potential risks 2. any other AEs 3. Discontinuation of Uptravi and reason for stopping

- Outcomes to compare rates of MACE and all-cause death. Occurrence of: 1. MACE 2. all-cause death

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Data analysis plan

Exposure to Uptravi will be described in terms of duration, maximum dose received in the titration period, maintenance dose and maintenance dose changes in all exposed patients. Uptravi safety profile will be described with the frequency and incidence rates of important identified and potential risks as described in the Risk Management Plan and all-cause death during the exposure period will be calculated in the Uptravi exposed patients. MACE and all-cause death incidence rates observed in Uptravi exposed patients will be compared with the rates observed in Uptravi unexposed patients using a propensity score weighting analysis.

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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