Post-authorisation Safety Study (PASS): Retrospective Medical Chart Review of Patients with PAH Newly Treated With Either Uptravi® (selexipag) or any Other PAH-specific Therapy (EXTRACT)

First published: 06/10/2022

Last updated: 15/08/2024

Study Finalised

Administrative details

EU PAS number

EUPAS49227

Study ID

103768

DARWIN EU® study

No

Study countries

- ☐ Lithuania
- ☐ Netherlands

- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Actelion Pharmaceuticals

First published: 01/02/2024

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Institution

University of Calgary Calgary, Canada, Saint Jopseph Healthcare Hamilton, Canada, Vancouver General Hospital Vancouver, Canada, PAH Center VFN Prague General University Hospital Prague, Czeck Republic, CHU Nice Hopital Pasteur Nice, France, Ospedale San Bortolo Vicenza, Italy,

Vilnius University Hospital - Santaros Klinikos Vilnius, Lithuania, Uniwersyteckie Centrum Kliniczne Gdansk, Poland, Europejskie Centrum Zdrowia Otwock, Poland, Vychodoslovensky ustav srdcovych a cievnych chorob (VUSCH) Kosice. Slovakia

Contact details

Study institution contact

Fabrice Kiefer fkiefer@its.jnj.com

Study contact

fkiefer@its.jnj.com

Primary lead investigator

Audrey Muller

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/10/2021

Actual: 20/10/2021

Study start date
Planned: 28/02/2023

Actual: 10/02/2023

Date of final study report
Planned: 29/03/2024

Actual: 07/03/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Actelion Pharmaceuticals Ltd, a Janssen pharmaceutical company of Johnson and Johnson

Study protocol

15Aug2024-REDACTED_Protocol-FD-67896049PAH0002-588005_1363699.pdf (1009.78 KB)

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

67896049PAH0002

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

This retrospective medical chart review study aims to further characterise the safety profile of Uptravi when used in clinical practice, and to describe clinical characteristics and outcomes of patients newly treated with Uptravi or newly treated with any other PAH-specific therapy who were never treated with Uptravi in the international post-marketing setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective Medical Chart Review

Study drug and medical condition

Name of medicine

UPTRAVI

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

910

Study design details

Outcomes

Primary outcome: MACE and all-cause death

Secondary outcomes: important identified or potential risks of Uptravi

Data analysis plan

a) Summary statistics of demographics, disease characteristics and clinical course in Uptravi exposed patients and patients initiating other PAH-specific therapies. b) Occurrence and incidence rate during Uptravi exposure period of all-cause death and the important identified and potential risks of Uptravi, including MACE, in the Uptravi exposed patients. c) Occurrence and incidence rates of MACE and all-cause death in the Uptravi cohort and the Other PAH-specific cohort.

Documents

Study results

15Aug2024-REDACTED_Interim CSR #7-Body-67896049PAH0002_AC-065A401-1119952_1363698.pdf(2.52 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective patient chart review

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