

# 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:** 15/04/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS19085

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### Study ID

48403

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### DARWIN EU® study

No

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### 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
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## **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.

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## **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

Clinical Registry RA-RNDUS-ClnclTrlsEU@its.jnj.com

Study contact

[RA-RNDUS-ClnclTrlsEU@its.jnj.com](mailto:RA-RNDUS-ClnclTrlsEU@its.jnj.com)

#### Primary lead investigator

Audrey Muller

Primary lead investigator

### Study timelines

#### Date when funding contract was signed

Planned: 11/04/2017

Actual: 11/04/2017

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### **Study start date**

Planned: 30/09/2017

Actual: 13/09/2017

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### **Date of interim report, if expected**

Planned: 31/03/2024

Actual: 21/03/2024

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### **Date of final study report**

Planned: 31/01/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Actelion Pharmaceuticals Ltd.

## Study protocol

[REDACTED\\_Protocol-FD-Amend 7-AC-065A401-265931\\_1787970.pdf](#) (939.18 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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## Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

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

### Medicinal product name

UPTRAVI

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### Medicinal product name, other

UPBRAVI

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

SELEXIPAG

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### Anatomical Therapeutic Chemical (ATC) code

(B01AC27) selexipag

selexipag

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### 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)
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## **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

### 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.

## Data sources

### Data source(s)

Comparative, Prospective Registry of Newly Initiated Therapies for Pulmonary Hypertension

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### Data sources (types)

[Disease registry](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No