

# A post-authorisation safety study (PASS) to evaluate cardiovascular events in adult patients with obstructive sleep apnoea (OSA) treated with solriamfetol (JZP865-401)

**First published:** 05/09/2022

**Last updated:** 22/07/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS45651

---

### Study ID

50596

---

### DARWIN EU® study

No

---

### Study countries

 France

 Germany

---

## Study description

Obstructive sleep apnoea (OSA) is a breathing condition when airways are narrowed due to muscle relaxation and can result in the airway obstruction and apnoea. Solriamfetol is indicated to reduce EDS in adult patients with narcolepsy or obstructive sleep apnea in whom EDS has not been satisfactorily treated by primary OSA therapy. Per EMA requirement, Jazz Pharmaceuticals/Axsome Therapeutics aims to carry out a PASS of solriamfetol in patients with OSA in Europe to assess the safety of the treatment and to evaluate MACE and other potential safety outcomes in adult patients. This study will be a prevalent new user cohort study using secondary data sources (claims/EHR) conducted in Germany and France, where solriamfetol has been marketed. The primary objective of this study is to estimate and compare the incidence rate of incident MACE, as a composite endpoint of: All cardiovascular (CV) mortality, non-fatal acute myocardial infarction, and non-fatal stroke, in adults newly exposed to solriamfetol plus positive airway pressure with patients exposed only to continuous PAP (C-PAP). The study population will be patients diagnosed with OSA at 18 years of age or greater and treated with C-PAP for at least one month with or without pharmacological intervention (solriamfetol or other wake-promoting agents). Main exposure will be solriamfetol and non-pharmacological intervention for airway obstruction (positive airway pressure). Secondary exposures will be the wake-promoting agents. The primary outcome will be a composite measure of MACE including All CV mortality, non-fatal acute MI, non-fatal stroke. Patients treated with solriamfetol plus C-PAP will be compared with patients exposed to C-PAP alone, adjusting for disease severity and known cardiovascular risk factors. Multivariable adjusted hazard ratio (HR) of MACE outcome will be measured comparing those exposed to solriamfetol (plus C-PAP) vs C-PAP only.

---


## Study status

Planned

## Research institutions and networks

# Institutions

**IQVIA**

 United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

Multiple centres: 2 centres are involved in the study

## Contact details

### Study institution contact

Sofia Correia [PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

**Study contact**

[PAS\\_registrations@iqvia.com](mailto:PAS_registrations@iqvia.com)

### Primary lead investigator

Sofia Correia

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 26/05/2022

Actual: 26/05/2022

---

**Study start date**

Planned: 01/02/2024

---

**Data analysis start date**

Planned: 22/02/2024

---

**Date of interim report, if expected**

Planned: 20/11/2024

---

**Date of final study report**

Planned: 31/12/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pharmanovia (Atnahs Pharma UK 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:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

The study objectives differ slightly between the descriptive and prevalent new user designs. Prevalent new user: To estimate and compare the incidence rate of MACE in adults newly exposed to solriamfetol plus PAP vs patients exposed only to PAP (France). Descriptive: To estimate the incidence rate of MACE in adults newly exposed to solriamfetol irrespective of PAP use (France and Germany).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

SUNOSI

---

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

SOLRIAMFETOL HYDROCHLORIDE

---

**Anatomical Therapeutic Chemical (ATC) code**

(N06BA14) solriamfetol

solriamfetol

---

### **Medical condition to be studied**

Obstructive sleep apnoea syndrome

## Population studied

### **Short description of the study population**

Feasibility carried out in France and Germany suggests the study will have 13,800 and 3,328 patients, respectively, eligible within the solriamfetol group.

---

### **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)
- 

### **Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

---

### **Estimated number of subjects**

17128

## Study design details

## **Outcomes**

Prevalent new user: The primary outcome is a composite measure of MACE, i.e., the first event of the following: non-fatal acute myocardial infarction (MI), non-fatal stroke, and all-cause mortality.

Descriptive: The primary outcome is a composite measure of MACE, defined as the first event of the following: (fatal or non-fatal) acute MI, (fatal or non-fatal) stroke, and all-cause mortality.

Individual MACE components & other CV events of interest (arrhythmic events, unstable angina, heart failure, hospitalisation for revascularisation procedures) analysed separately. Serious psychiatric events assessed from hospitalisation records analysed. Outcomes include psychotic/manic symptoms, aggressive and hostile behaviour, anxiety, agitation/ tension, major depressive disorder, irritability

---

## **Data analysis plan**

For both approaches an exploratory descriptive analysis will be conducted. Continuous variables described using mean, standard deviation, median, first and third quartiles, minimum, maximum. Categorical variables described by the number and % of patients/category. The number of patients with missing data/variable reported. Estimates of incidence rates (with 95% CI) calculated. In the prevalent new user design, effect measure will be multivariable adjusted Hazard Ratio of MACE outcome comparing those exposed to solriamfetol plus PAP vs PAP only. This comparative analysis will be performed by identifying the comparator PAP patients for each patient newly exposed to solriamfetol plus PAP based on the duration of PAP use. Constructing time-conditional propensity scores to identify the comparator PAP only users most similar to the users of solriamfetol plus PAP. Cox proportional hazards model used to study the association between exposure and outcome by adjusting to time-fixed

covariates.

## 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)

German Pharmacoepidemiological Research Database

---

### Data source(s), other

French National Health Data System, France

---

### 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