A multi-center, observational prospective post-authorization safety study to compare the cardiovascular risks and long-term safety of OZAWADE® in patients with obstructive sleep apnoea treated or not by primary therapy and exposed or not to OZAWADE® when used in routine medical practice

First published: 16/12/2024

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## Administrative details

#### **EU PAS number**

EUPAS1000000147

### **Study ID**

1000000147

**DARWIN EU® study** 

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France

Germany

☐ Italy

### **Study status**

Ongoing

## Contact details

### **Study institution contact**

Pascale Vernade regulatory@bioprojet.com

Study contact

regulatory@bioprojet.com

## **Primary lead investigator**

Jean-Louis Pépin

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 16/09/2024 Actual: 23/09/2024

## Study start date

Planned: 30/09/2024

Actual: 24/01/2025 **Date of final study report** Planned: 15/12/2031 Study protocol OZAWADE\_PASS\_protocol\_V3 0\_23NOV2023\_redacted.pdf (1.68 MB) 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 type list

**Study topic:** 

Human medicinal product

**Study type:** 

#### Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

#### **Data collection methods:**

Primary data collection

#### Main study objective:

The primary objective of this study is to demonstrate that OZAWADE® supplementation in obstructive sleep

apnoea (OSA) patients does not increase the incidence of cardiovascular events (CVE) compared with

 $\label{eq:ozawade} {\tt OZAWADE} \$ \ \ {\tt unexposed \ patients} \ \ ({\tt non-inferiority}) \ \ {\tt and \ to \ evaluate \ the \ long-term}$  safety of  ${\tt OZAWADE} \$ \ \ {\tt when}$ 

used as per SmPC in patients with OSA.

# Study Design

## Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine

**OZAWADE** 

#### **Anatomical Therapeutic Chemical (ATC) code**

(N07XX11) pitolisant

pitolisant

#### Medical condition to be studied

Obstructive sleep apnoea syndrome

## 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The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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**

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## **Check stability**

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No