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

Last updated: 16/12/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000147

EU PAS number

EUPAS1000000147

Study ID

1000000147

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy

Study status

Planned

Contact details

Study institution contact

Pascale Vernade

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

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:

Non-interventional study

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
OZAWADE® unexposed patients (non-inferiority) and to evaluate the long-term safety of OZAWADE® 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

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