Post-authorization observational study on the use of QUVIVIQ in standard clinical setting for the treatment of Chronic Insomnia in France

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Study Planned

Administrative details

EU PAS number

EUPAS1000000363

Study ID

1000000363

DARWIN EU® study

No

Study countries

☐ France

Study description

Insomnia is defined in the DSM-5® as a predominant complaint of dissatisfaction with sleep quantity or quality with one (or more) of the following symptoms: (i) difficulty initiating sleep, (ii) difficulty maintaining sleep characterized by frequent awakenings or problems returning to sleep after awakenings, and (iii) early-morning awakening with inability to return to sleep. Sleep disturbance causes clinically significant distress or impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning. In April 2022, the European Commission approved QUVIVIQ (daridorexant).

This dual orexin receptor antagonist (DORA) is a new option for the treatment of adult patients with insomnia characterized by symptoms present for at least 3 nights per week and for at least 3 months and considerable impact on daytime functioning. In May 2023, in recognition of the new treatment option provided by QUVIVIQ, the French National Authority for Health (Haute Autorité de Santé HAS) issued a favorable decision on its reimbursement in France, including a request for additional real-world data, to be provided.

In this context, the marketing-authorization holder, Idorsia France implements a study to describe the QUVIVIQ conditions of use and prescription modalities, and to assess the effectiveness over time of QUVIVIQ, on the insomnia severity and patient quality of life, in the standard clinical setting. This is a post-authorization, observational, prospective, longitudinal, multicenter single cohort study conducted in standard clinical setting, among general practitioners, psychiatrists and sleep centers in France.

Patients will be followed for a maximum of 12 months or until QUVIVIQ discontinuation (whichever comes first) with 4 evaluation points (1 month, 3, 6, and 12 months). The overall study period is approximately 3 years. Data will be collected from investigators and patients with online questionnaires.

Study status

Planned

Research institutions and networks

Institutions

IDORSIA PHARMACEUTICALS FRANCE

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Damien LEGER

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/03/2024

Actual: 26/03/2024

Study start date

Planned: 01/04/2025

Data analysis start date

Planned: 01/09/2025

Date of interim report, if expected
Planned: 01/05/2026

Date of final study report
Planned: 01/05/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IDORSIA PHARMACEUTICALS FRANCE SAS

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

ID RCB number: 2024-A01610-47

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Real-life post-authorization, observational, prospective, longitudinal, multicenter single cohort, among general practitioners, psychiatrists and sleep centers in France with a patients follow-up of a maximum of 12 months or until QUVIVIQ discontinuation and 4 evaluation points

Main study objective:

The main study objectives will be:
Objective 1: Characteristics of the effective population treated with QUVIVIQ. The study aims to comprehensively characterize the population receiving QUVIVIQ. Variables related to the selection criteria, sociodemographic characteristics, and clinical features will be collected. This includes data on age, sex, professional activity, weight, height, and comorbidities. Additionally, information on insomnia-related characteristics, risk factors, treatment history, reason for starting QUVIVIQ, and management of insomnia with QUVIVIQ will be documented.

Objective 2: Description of prescribing modalities by Healthcare Professionals (HCPs) involved in QUVIVIQ use.
An essential aspect of the study involves understanding the prescribing practices of Healthcare Professionals (HCPs) associated with QUVIVIQ. Variables related to prescription characteristics will be examined. This objective seeks to provide insights into how HCPs prescribe QUVIVIQ and the context in which these prescriptions occur.
Objective 3: Description of QUVIVIQ use by patients.
This objective focuses on elucidating how patients use QUVIVIQ. The compliance evaluation, measured through the Girerd questionnaire during follow-up, will provide valuable information on patient adherence to the prescribed treatment regimen. The collection of these variables aims to offer a comprehensive understanding of how patients engage with QUVIVIQ as part of their insomnia management.
Objective 4: Effectiveness over time of QUVIVIQ on Insomnia Severity and Patients’ Quality of Life
The study aims to assess the effectiveness of QUVIVIQ over time, specifically focusing on its impact on insomnia severity and patients' quality of life. Variables related to treatment satisfaction, Insomnia Severity Index (ISI), generic quality of life (EQ-5D-5L), and patient global impression of change (PGI-C) will be evaluated at inclusion and follow-up visits. These measures will provide valuable insights into the longitudinal effectiveness of QUVIVIQ in addressing insomnia and its associated impact on patients' well-being.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medicinal product name

QUVIVIQ

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

DARIDOREXANT HYDROCHLORIDE

Anatomical Therapeutic Chemical (ATC) code

(N05CJ03) daridorexant

daridorexant

Medical condition to be studied

Insomnia

Population studied

Short description of the study population

Study population will include adult patients (18 years old or more) eligible for QUVIVIQ and initiating the treatment at the time of inclusion, and having received the information letter and having agreed to participate in the study and having accepted to his/her personal data being processed.

The decision to initiate QUVIVIQ treatment remains that of the clinician and predates the patient's invitation to participate in the study. The therapeutic decision is therefore not linked to the patient's inclusion in the study, and the inclusion of a patient in the study in no way alters the clinician's usual practice or his or her choices for patient management.

Will be excluded patients unable to comply with the follow-up visits schedule for whatever reason, already participating in a clinical trial at the time of the inclusion, under legal guardianship or curatorship, unable to read, speak and understand French, and unable to complete an online questionnaire, including

absence of access to a connected device.

Age groups

- **Adult and elderly population (≥18 years)**

Estimated number of subjects

500

Study design details

Setting

The inclusion period will be one year, and patients will be followed during QUVIVIQ treatment for a maximum of 12 months (follow-up ends at treatment discontinuation or end of study (12 months) whichever comes first) with 4 evaluation points approximately at 1 months, 3, 6, and 12 months. No visits will be mandated. The logistics center will be in contact with healthcare professionals and patients, and visits will be monitored in real time.

Comparators

The description of the non-inclusion registry will be compared to the inclusion population to discuss its representativeness of our study population of patients.

Outcomes

Outcomes related to the objectives are:
- Effective population of patients treated with QUVIVIQ: patients demographic and socio-economic characteristics, general health characteristics, insomnia-related characteristics and therapies, co-morbidities.
- Prescribing patterns applied by the HCPs: dosage, frequency, duration of treatment, continuation/discontinuation of treatment at follow-up visits and the

reason if applicable.
- Description of use conditions by patients: adherence to treatment, discontinuation of treatment and the reason if applicable.
- Assessment of the effectiveness over time of QUVIVIQ including quality of life: change over time in the ISI and EQ-5D-5L scores.
- Outcomes related to safety: pregnancy occurring during the study, assessment of the safety over time of QUVIVIQ (AEs experienced by patients, regardless of relationship to QUVIVIQ).

Data analysis plan

A comparison between the active physician population and the total contacted physician population will be conducted to discuss the representativeness of the investigators (prescriber type, age, sex…), commercial data will be studied in parallel.

The description of the non-inclusion registry will be compared to the inclusion population to discuss its representativeness of our study population of patients.

For each dichotomous or categorical variable analyzed at inclusion and at different follow-up stages, the analysis will provide the number of non-missing observations, the frequency with percentage per category and the 95% confidence interval.

For each continuous variable analyzed at inclusion and at different follow-up stages, the analysis will provide the number of non-missing observation, the mean value, the standard deviation, the first quartile, the median, the third quartile and maxima.

The analyses will be performed with SAS® software (version 9.4, SAS Institute, North Carolina USA).

For safety analysis, the frequency with a 95% confidence interval will be reported for each adverse events coded with Medical Dictionary for Regulatory Activities (MedDRA version 24).

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

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No