

# An observational, real world evidence study to describe clinical experience with lurasidone in the treatment of adult patients with schizophrenia in routine clinical practice in Europe (LATUDA)

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS28735

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### Study ID

46673

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### DARWIN EU® study

No

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### Study countries

Netherlands

Switzerland

United Kingdom

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### **Study description**

This is an international, multi-centre observational, real world evidence study. This study will be conducted in 4 to 8 mental health centres in the United Kingdom (UK), Netherlands and Switzerland. The study is based on both retrospective and prospective collection of data from patients' medical records. It is a single group study without a comparator, to reflect real world clinical practice. There will be no changes to patient management for the purposes of any part of the study and no additional tests, investigations or visits will be required. The population for this study is adult patients diagnosed with schizophrenia who received treatment with a medicine called lurasidone as part of their standard clinical care. It is expected to recruit 80 patients in total. The main purpose is to find out more about how lurasidone is used to treat patients with schizophrenia in the real world and how well it works.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Multiple centres: 7 centres are involved in the study

### Contact details

**Study institution contact**

Andrew Jones [medinfo@cnx-therapeutics.com](mailto:medinfo@cnx-therapeutics.com)

Study contact

[medinfo@cnx-therapeutics.com](mailto:medinfo@cnx-therapeutics.com)

**Primary lead investigator**

Matthew Sargeant

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 18/10/2017

Actual: 18/10/2017

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**Study start date**

Planned: 04/02/2019

Actual: 12/02/2019

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**Data analysis start date**

Planned: 29/05/2020

Actual: 01/04/2021

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**Date of final study report**

Planned: 31/08/2020

Actual: 06/12/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

CNX Therapeutics Ltd (formerly Sunovion Pharmaceuticals Ltd)

## Study protocol

[PT-SUNOVION LATUDA Study Protocol V3 0 20SEP18 FINAL.pdf](#) (885.02 KB)

[PT\\_Sunovion LATUDA\\_v4 0\\_25OCT19\\_clean.pdf](#) (504.4 KB)

## Regulatory

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

No

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

Not applicable

## Other study registration identification numbers and links

NP-LAT-721-18

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe the dose titration process, dosing regimens, treatment duration and reasons for discontinuation following initiation of lurasidone in adult patients with schizophrenia.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Multicentre observational study

## Study drug and medical condition

## **Medicinal product name**

LATUDA

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## **Medical condition to be studied**

Schizophrenia

## **Population studied**

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

Population with schizophrenia treated with lurasidone in routine clinical practice.

#### Inclusion criteria

1. Aged  $\geq 18$  years of age at time of initiation of lurasidone.
2. Provided consent for access to medical records for study data collection (applicable to living patients only).
3. Documented diagnosis of schizophrenia before the initiation of lurasidone.
4. Initiated on lurasidone after the 1st January 2016.
5. Judged to have capacity by their clinician to provide valid written informed consent to participate in this study.

#### Exclusion criteria

1. Patients whose medical records were unavailable for review.
  2. Patients who participated in a clinical trial of an investigational medicinal product during the post-index observation period.
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### **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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### **Special population of interest**

Other

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### **Special population of interest, other**

Schizophrenia patients

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### **Estimated number of subjects**

80

## Study design details

### **Outcomes**

Summary measures of lurasidone treatment duration i.e. Proportion of patients taking treatment for full 12 months, Summary measures of baseline demographics and clinical characteristics Summary measures of treatment history for schizophrenia Dose distribution of lurasidone prescribed and summary measures of dose regimen Time until first relapse following lurasidone initiation Adverse events following lurasidone initiation Summary measures of healthcare resource utilisation

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### **Data analysis plan**

All primary endpoint (and secondary endpoint) analyses will be descriptive in nature. For continuous variables (such as duration of time with disease) the mean, standard deviation, median, interquartile range and range will be calculated. For nominal variables, frequencies and proportions in the form of percentages will be calculated for each group. For investigating changes in

weight, blood glucose, lipid levels and liver function from baseline at 3,6,9 and 12 months following initiation of lurasidone, changes will be described using summary measures as described for continuous variables above for each time, they will then be compared using a paired t-test (or Wilcoxon signed rank test if distributions are non-normal), although based upon a previous study of changes in weight(10) as a result of treatment change, it is expected that any change will be too small to detect a significant change with feasible sample size for the study.

## Documents

### Study results

[CSR\\_Sunovion LATUDA\\_v1 0\\_FINAL.pdf](#) (701.75 KB)

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### Study, other information

[18 LO 1591 250852 Favourable\\_opinion\\_12.10.18.pdf](#) (256.47 KB)

## 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 sources (types)**

Other

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### **Data sources (types), other**

Retrospective and prospective collection of data from patients' medical records

## **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