

# An Observational Post-Authorization Safety Surveillance (PASS) Study of SYCREST® (asenapine) among Patients aged 18 and older Diagnosed with Bipolar Disorder (P08307)

**First published:** 24/05/2017

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17631

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### Study ID

24619

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### DARWIN EU® study

No

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### Study countries

United Kingdom

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## Study description

This is a retrospective cohort study of new-users of asenapine in adult general practice patients in the United Kingdom (UK) from both the Clinical Practice Research Datalink (CPRD) and The Health Improvement Network (THIN) databases to assess incidence rates of identified and potential risks. Comparative analyses will be performed when adequate power is achieved.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Merck Sharp & Dohme LLC

United States

**First published:** 01/02/2024

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**Institution**

**Pharmaceutical company**

## Contact details

### Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.  
datasharing@organon.com

**Study contact**

**Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 02/12/2010

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**Study start date**

Actual: 01/07/2013

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**Data analysis start date**

Planned: 18/12/2017

Actual: 18/12/2017

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**Date of interim report, if expected**

Actual: 16/09/2014

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**Date of final study report**

Planned: 31/01/2018

Actual: 24/01/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme Corp.

## Study protocol

[8274-110+Protocol\\_final-redaction.pdf](#) (4.96 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

Merck protocol numbers: P08307, MK-8274-110ClinicalTrials.gov: NCT01495741

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To describe baseline demographic & clinical characteristics, to assess the incidence rates of identified & potential risks in bipolar disorder patients (aged 18+) newly prescribed asenapine, and to compare the incidence rates if adequate study power is achieved for asenapine users relative to two comparison cohorts (risperidone and olanzapine).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

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

Bipolar disorder

Schizophrenia

## **Population studied**

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

Patients treated with asenapine were identified within the Bipolar Disorder cohort identified from CPRD.

- 1) First written prescription for asenapine after entry into the Bipolar Disorder cohort or first written prescription for asenapine within 2 years before entry into the Bipolar Disorder cohort (treatment before diagnosis). In CPRD, among patients receiving a prescription of olanzapine and / or risperidone prior to their diagnosis (i.e., patients receiving treatment before diagnosis), the cumulative distribution shows approximately 70% have a duration of time between initiation of treatment and first diagnosis of Bipolar Disorder within 2 years.
  - 2) No use of asenapine within 365 days prior to the first written prescription for asenapine defined above
  - 3)  $\geq$  365 days of time accumulated between asenapine prescription date and the latter of either (a) the registration date with the general practitioner or (b) the database specific quality indicator date
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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**

Patients with schizophrenia, bipolar disorder or any other psychotic disorder

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### **Estimated number of subjects**

3000

## Study design details

### **Outcomes**

The identified and potential risks among bipolar disorder patients age 18+ prescribed asenapine. The identified risks include extrapyramidal symptoms, somnolence and sedation, neuroleptic malignant syndrome, seizure, hyperprolactinaemia, orthostatic hypotension, allergic reactions, dyslipidaemia and diabetes mellitus. The potential risks include rhabdomyolysis and neutropenia. The same list of identified and potential risks as those in the primary outcomes among patients age 18+ prescribed asenapine for schizophrenia and other diagnoses excluding bipolar disorder.

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### **Data analysis plan**

Baseline characteristics will be described for new users of the study drugs of interest. Incidence rates for each risk will be calculated among bipolar disorder patients aged 18+ prescribed asenapine. If pre-specified study power levels are achieved comparison of the identified and potential risks between asenapine and other two comparison cohorts (risperidone and olanzapine) will be performed. An epidemiology Safety Review Committee comprised of

independent clinicians and experts will perform integrated review of the findings of the study, and evaluate the safety data that emerge from the study using both clinical judgment and pre-specified statistical criteria as guidelines.

## Documents

### Study results

[MK-8274-110\\_final-report\\_NoAppendices\\_final-redaction.pdf](#) (2.85 MB)

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## 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)

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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**

Unknown