

# Global Lomitapide (Juxtapid and Lojuxta) Pregnancy Exposure Registry (PER)

**First published:** 18/02/2014

**Last updated:** 23/04/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS5329

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### Study ID

20497

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### DARWIN EU® study


No


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### Study countries

 Argentina

 Austria

 Brazil

 Canada

 Denmark

 France

-  Germany
  -  Italy
  -  Netherlands
  -  Norway
  -  Poland
  -  Spain
  -  Sweden
  -  Taiwan
  -  United Kingdom
  -  United States
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## **Study description**

Aegerion Pharmaceuticals, the Market Authorization Holder (MAH) for lomitapide (Juxtapid and Lojuxta), is seeking to evaluate the outcomes of pregnancy in women treated with lomitapide at any time within 30 days prior to the first day of Last Menstrual Period (LMP) or during pregnancy. The outcomes of primary interest are major congenital anomalies. This is a global, longitudinal, observational study. Data will be collected at enrolment and periodically during pregnancy from prescribers, gynaecologists, paediatricians and other Health Care Providers (HCPs) who may be caring for the patient during the pregnancy or caring for the child. HCPs will be contacted during the pregnancy (each trimester), within 4 weeks after the estimated delivery date (EDD), and for paediatric follow-up at 12 weeks of age and at 12 months of age. In the US and in other countries where patient contact is possible, data will also be collected directly from patients during each trimester, at the EDD, and, for paediatric patients, at 12 weeks and 12 months. The PER will include pregnancies identified from any country where the Aegerion Lomitapide Observational Worldwide Evaluation Registry (LOWER) is conducted including North America and Europe. The registry is non-interventional, all treatment decisions are made at the discretion of the patient's HCP, and are not mandated by the study

design or protocol.

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## Study status

Planned

## Research institutions and networks

### Institutions

#### United BioSource Corporation (UBC)

 Switzerland

**First published:** 25/04/2013

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[janine.collins@unitedbiosource.com](mailto:janine.collins@unitedbiosource.com)

### Primary lead investigator

Janine Collins

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Planned: 15/10/2013

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## **Study start date**

Planned: 15/09/2014

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## **Date of final study report**

Planned: 13/07/2028

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Aegerion Pharmaceuticals

# Study protocol

[aegr-733-027-V3 FINAL protocol 21 Nov2013.pdf](#) (678.87 KB)

# 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 2 (specific obligation of marketing authorisation)

# Methodological aspects

# Study type

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To evaluate the outcomes of pregnancy in women treated with lomitapide at any time within 30 days prior to first day of Last Menstrual Period (LMP) or during pregnancy. The outcomes of primary interest are major congenital anomalies.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Safety Registry

## Study drug and medical condition

**Medical condition to be studied**

Type IIa hyperlipidaemia

## Population studied

**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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### **Estimated number of subjects**

30

## Study design details

### **Outcomes**

The outcomes of primary interest are major congenital anomalies.

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### **Data analysis plan**

A formal statistical analysis plan (SAP) will include details of all planned analyses and presentation of PER data. Since this is an observational study, descriptive analyses will be provided. Descriptive statistics will comprise the number of observations (n), mean, standard deviation (SD), median, minimum, and maximum for continuous variables, and n and percent for categorical variables. Data will be presented for all patients enrolled in the PER. An analysis of all PER participants combined will be provided. Separate analyses will also be conducted for prospective and retrospective reports. All data will be pooled for an additional analysis that includes spontaneous and literature reports from patients not participating in the PER. The proportion of pregnancies and births that have been lost to follow-up will also be calculated and reported. The primary outcome is major congenital abnormalities.

## 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

Prospective patient-based data collection

## 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