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

Study ID

20497

DARWIN EU® study

No

Study countries

- Argentina
- Austria
- Brazil
- Canada
- Denmark
- France

- Germany
- Italy
- Netherlands
- Norway
- Poland
- Spain
- Sweden
- Taiwan
- United Kingdom
- United States

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.

Study status

Planned

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

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Last updated: 06/03/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Janine Collins

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/10/2013

Study start date
Planned: 15/09/2014

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

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

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

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)

Estimated number of subjects

30

Study design details

Outcomes

The outcomes of primary interest are major congenital anomalies.

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 enroled 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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No