An Observational Case Series to Describe Women Exposed to Repatha During Pregnancy and Infant Outcomes During the First Year of Life (20200408)

First published: 26/08/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48529

EU PAS number

EUPAS42393

Study ID

48529

DARWIN EU® study

No

Study countries

United States

Study description

This is a Global prospective and retrospective observational case series of pregnant women exposed to Repatha during pregnancy and their infants through the first year of life who consent to provide their information to Amgen. The study aims to estimate the proportion of women who experience pregnancy and maternal complications, adverse events in the developing fetus, neonate and their infants for the first year of life. Retrospectively, data will be extracted from pre-existing postmarketing reports obtained from Amgen's Global Safety Database for women exposed to Repatha during pregnancy and their infants between July 2015 and the approval date of this protocol. Prospectively, from approval date of this protocol through July 2025, secondary data from postmarketing reports will be analyzed for women who have been exposed to Repatha during their pregnancy and their infants.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/04/2021

Actual: 21/04/2021

Study start date

Planned: 17/07/2022

Actual: 17/07/2022

Data analysis start date

Planned: 30/09/2025

Date of interim report, if expected

Planned: 30/09/2022

Date of final study report
Planned: 30/09/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original evolocumab 20200408 .pdf(2.99 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Among women exposed to Repatha during pregnancy, the main objective of this study is to estimate the proportion of: pregnancy and maternal complications, adverse events in the developing fetus and neonate, and among their infants, adverse events for the first year of life.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

Name of medicine

REPATHA

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

EVOLOCUMAB

Anatomical Therapeutic Chemical (ATC) code

(C10AX13) evolocumab

evolocumab

Population studied

Short description of the study population

The study population includes women worldwide exposed to Repatha during pregnancy that consented for pregnancy and infant follow-up.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

40

Study design details

Outcomes

Pregnancy Outcomes: Number of cases reporting live full-term births, spontaneous abortion, elective abortion, stillbirth, and premature delivery.

Infant Outcomes: Number of cases reporting adverse events including

complications, medical problems or congenital anomalies at birth. Number of cases reporting adverse events at 6 and 12 months.

Data analysis plan

All analyses will be descriptive. Collection of exposure and outcome information in this group provides additional evidence on the safety of Repatha use during pregnancy. The denominator is the number of pregnant women exposed to Repatha during pregnancy and the numerator is the number with the outcome. To assess events in the developing fetus and neonate in women exposed to Repatha during pregnancy, the proportion of pregnancies resulting in spontaneous abortions, elective abortions, fetal death/ stillbirths and premature delivery will be presented, along with corresponding 95% confidence. The proportion of infants with adverse events at 6 and 12 months of age including complications, medical problems or congenital anomalies at birth will be assessed in infants of women exposed to Repatha during pregnancy with corresponding 95% confidence intervals.

Data management

Data sources

Data source(s), other

Amgen Global Safety Database

Data sources (types)

Disease registry

Spontaneous reports of suspected adverse drug reactions

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