An Observational Study to Describe Women Exposed to Apremilast During Pregnancy and Infant Outcomes During the First Year of Life (20210218)

First published: 06/12/2023
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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/108094

EU PAS number
EUPAS107685

Study ID
108094

DARWIN EU® study
No

Study countries
United States

Study status
Ongoing

Research institution 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

medinfo@amgen.com
Primary lead investigator
Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
16/11/2023
Actual:
30/08/2023

Study start date
Planned:
15/12/2023
Actual:
15/12/2023

Data analysis start date
Planned:
01/10/2024

Date of final study report
Planned:
30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol-Published Original apremilast 20210218 .pdf(875.11 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Main study objective:
Among women exposed to Otezla during pregnancy, the main objective of the study is to estimate the proportion of pregnancy and maternal complications, adverse events in the developing fetuses and neonates, and among their infants, adverse events during the first year of life.

Study Design

Non-interventional study design
Other

Study drug and medical condition

Name of medicine
Otezla

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

Anatomical Therapeutic Chemical (ATC) code
(L04AA32) apremilast

Population studied

Age groups
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)

Special population of interest
Pregnant women

Estimated number of subjects
350

Study design details

Outcomes
Number of cases reporting pregnancy and maternal complications, 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 and adverse events at 6 months and 12 months of age.

Data analysis plan
All analyses will be descriptive. Analysis will include the exposed cases overall, and, where possible, group cases by whether outcomes were known when the exposure was reported (retrospectively) or whether the exposure was reported prior to occurrence of outcomes (prospectively). Pregnancy and infant outcomes will be summarized overall and separately for cases identified retrospectively and prospectively. These data constitute a case series, thus line listings of pregnancy and maternal complications, pregnancy outcomes, infant outcomes and adverse events will be summarized along with tabulations of the numbers and proportions of outcomes based on timing of exposure (first, second, or third trimester), and indication for use of the medication.

Data management

Data sources

Data sources (types)
Administrative data (e.g. claims)

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