

# 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

**Last updated:** 12/05/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS107685

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### Study ID

108094

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### DARWIN EU® study

No

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### Study countries

United States

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### Study status

Finalised

## Research institutions and networks

# Institutions

## Amgen

United States

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

**Last updated:** 21/02/2024

Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto: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

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**Study start date**

Planned: 15/12/2023

Actual: 15/12/2023

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**Data analysis start date**

Planned: 01/10/2024

Actual: 01/10/2024

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**Date of final study report**

Planned: 30/06/2025

Actual: 08/05/2025

## 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

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

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**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

**Medicinal product name**

OTEZLA

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

APREMILAST

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA32) apremilast

apremilast

## Population studied

**Age groups**

- Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
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**Special population of interest**

Pregnant women

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**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.

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### **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.

## Documents

### **Study results**

[20210218\\_ORSR Abstract\\_21APR2025\\_Redacted.pdf](#) (904.44 KB)

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## Data management

## ENCePP Seal

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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)

[Administrative healthcare records \(e.g., claims\)](#)

## 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