Apremilast Pregnancy Exposure Registry OTIS Autoimmune Diseases in Pregnancy Project

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Study Ongoing

Administrative details

EU PAS number

EUPAS36417

Study ID

36418

DARWIN EU® study

No

Study countries

Canada

United States

Study description

The Apremilast Pregnancy Exposure Registry (Registry) is a United States (U.S.) based registry designed to monitor planned or unplanned pregnancies exposed to apremilast when used to treat an approved indication in accordance with the current approved prescribing information, who reside in the U.S. or Canada. The goal of the Registry is to conduct an observational, controlled prospective cohort study that will involve follow-up of live born infants to one year of age. The study population includes pregnant women who reside in the U.S. or Canada who have or have not used apremilast for any length of time in pregnancy for an approved indication. The cohort study target sample size is 100 pregnant women in each of three groups: • 100 women who have been exposed to apremilast in pregnancy for an approved indication.• 100 women with an approved disease who have not been exposed to apremilast at any time in pregnancy (primary comparison group).• 100 healthy women who have no diagnosis of an approved indication or other chronic illness and have not taken apremilast in pregnancy.The primary objective of the Registry is to evaluate any potential increase in the risk of major birth defects, specifically a pattern of anomalies, in apremilast exposed pregnancies compared to the primary comparison group of disease-matched unexposed pregnancies. Secondary objectives are to evaluate the potential effect of exposure relative to the secondary comparison group of healthy pregnant women, and the effect of exposure on other adverse pregnancy outcomes including spontaneous abortion or stillbirth, preterm delivery, reduced infant birth size, a pattern of minor malformations, postnatal growth of live born children to one year of age, and incidence of serious or opportunistic infections or malignancies in live born children up to one year of age.

Study status

Ongoing

Research institutions and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

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Institution

MotherToBaby

Networks

Organization of Teratology Information Specialists (OTIS) Network

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christina Chambers

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 25/09/2014

Study start date
Actual: 12/12/2014

Data analysis start date
Planned: 01/03/2023

Date of final study report
Planned: 01/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen (Previously Celgene)

Study protocol

Apremilast Pregnancy Registry Final Protocol 11July2014.pdf (193.52 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Prospective pregnancy cohort study

Main study objective:

The primary objective of the Registry is to evaluate any potential increase in the risk of major birth defects, specifically a pattern of anomalies, in apremilast exposed pregnancies compared to the primary comparison group of disease-matched unexposed pregnancies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

apremilast

Medical condition to be studied

Psoriasis

Psoriatic arthropathy

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

300

Study design details

Outcomes

Risk of major birth defects, specifically a pattern of anomalies, in apremilast exposed pregnancies compared to the primary comparison group of disease-matched unexposed pregnancies, The effect of exposure on other adverse pregnancy outcomes including spontaneous abortion or stillbirth, preterm delivery, reduced infant birth size, a pattern of minor malformations, postnatal growth of live born children to one year of age, and incidence of serious or opportunistic infections or malignancies in live born children up to one year of age.

Data analysis plan

The primary analysis for the primary endpoint for the cohort study will be a comparison of the birth prevalence of major structural defects in live born infants between the apremilast-exposed group and the primary Comparison Group I. This analysis will use chi-square or Fisher’s Exact test for univariate comparisons and logistic regression for adjustment of confounding. The primary analysis of the primary endpoint will be conducted at the end of the study.

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, Exposure registry

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