Postmarketing safety study based on Pregnancy Registry on women exposed to Palforzia during pregnancy and on infants exposed to Palforzia in utero

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Study Finalised

Administrative details

EU PAS number

EUPAS41546

Study ID

41547

DARWIN EU® study

No

Study countries

Austria

France

Germany

Switzerland

United Kingdom

United States

Study description

The purpose of the pregnancy registry is to collect postmarketing safety information on women exposed to Palforzia during pregnancy and on infants exposed to Palforzia in utero.

Study status

Finalised

Research institutions and networks

Institutions

Aimmune Therapeutics

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Katia Daghildjian

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/03/2020

Actual: 04/03/2020

Study start date

Planned: 04/03/2020

Actual: 04/03/2020

Date of final study report

Planned: 30/06/2025

Actual: 30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Marketing Authorization was transferred for Aimmune Therapeutics to Stallergenes during the course of the study.

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The purpose of the pregnancy registry is to collect, analyze, and report data on pregnancy outcomes and infant outcomes after exposure to Palforzia during

pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PALFORZIA

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

DEFATTED POWDER OF ARACHIS HYPOGAEA L., SEMEN (PEANUTS)

Anatomical Therapeutic Chemical (ATC) code

(V01AA08) food

food

Medical condition to be studied

Food allergy

Anaphylactic reaction

Term birth

Premature delivery

Abortion

Stillbirth

Population studied

Age groups

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

Special population of interest

Pregnant women

Estimated number of subjects

72

Study design details

Outcomes

The following outcomes will be examined: Episodes of anaphylaxis during pregnancy, whether the patient is taking Palforzia or discontinued treatment Outcome of the pregnancy (ie, term delivery, premature delivery, type of delivery, spontaneous abortion, fetal deaths) Infant outcome at birth

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Data analysis plan

Data will be analyzed on an annual basis and a cumulative annual report prepared. The annual data cutoff date will be the international birthdate for Palforzia (31 Jan 2020). The report will be due within 60 days after the international birthdate. The final cumulative registry report will be due no later than 1 year after the latest estimated due date for enrolled patients in the registry. The report will contain a descriptive analysis of the safety data collected. Because retrospective reporting is subject to bias, retrospective reports will be summarized separately. Prospective reports will comprise the primary analysis cohort and are used for rate calculations. Outcomes will be

reported by timing and duration of exposure to Palforzia by trimester. Attempts will be made to collect as much data as possible about reported episodes of maternal anaphylaxis.

Summary results

No pregnancy exposures were reported.

Therefore, there is no data on pregnancy exposures available

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)

Pregnancy registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

No

Check completeness

No

Check stability

No

Check logical consistency

No

Data characterisation

Data characterisation conducted

Not applicable