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

**First published:** 18/06/2021

**Last updated:** 13/02/2026

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

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

**Last updated:** 01/02/2024

**Institution**

# Contact details

**Study institution 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

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**Study start date**

Planned: 04/03/2020

Actual: 04/03/2020

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**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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)

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**Special population of interest**

Pregnant women

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**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.

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**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