Pregnancy Registry Protocol for Palforzia

First published: 18/06/2021

Last updated: 06/05/2025

Study Ongoing

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

Ongoing

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

Delphine Vandenberghe

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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aimmune Therapeutics Inc. US and its subsidiaries

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

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

Anatomical Therapeutic Chemical (ATC) code

(V01AA08) food

food

Medical condition to be studied

Food allergy

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.

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

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