A Prospective Non-Interventional Study of Palforzia® in Children Aged 4-17 with Confirmed Peanut Allergy (AIMT-PAS-001)

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Study Planned

Administrative details

EU PAS number

EUPAS44821

Study ID

44822

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Peanut allergy is a common and serious condition that often affects children, and can be associated with severe reactions, including life-threatening anaphylaxis. AR101 (Palforzia®) was developed to address the need for a regulated therapy that can induce and maintain a state of desensitization to peanut protein. The results of previous clinical studies showed that desensitization to peanut protein with Palforzia® provides a clinically meaningful level of desensitization sufficient to reduce the incidence and severity of allergic reactions, including anaphylaxis, because of accidental exposure to peanut protein. This observational study is being conducted to collect data on safety, health related quality of life (HRQoL), and health resource utilization (HRU) in patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy treated with Palforzia® over a 24-month period in a real-world setting in Germany.

Study status

Planned

Research institutions and networks

Institutions

Universitäts AllergieCentrum (UAC)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christian Vogelberg

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/01/2022

Study start date

Planned: 19/01/2022

Data analysis start date

Planned: 12/10/2022

Date of interim report, if expected

Planned: 12/10/2022

Date of final study report

Planned: 30/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aimmune Therapeutics

Regulatory

Was the study required by a regulatory body?

No

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:

Drug utilisation

Main study objective:

This observational study is being conducted to collect data on safety, health related quality of life (HRQoL), and health resource utilization (HRU) in patients

aged 4 to 17 years with a confirmed diagnosis of peanut allergy treated with Palforzia® over a 24-month period in a real-world setting in Germany.

Study drug and medical condition

Medical condition to be studied

Food allergy

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

200

Study design details

Outcomes

• Incidence and description of all AEs and SAEs, related or not to Palforzia® • Incidence and description of all serious and non serious adverse drug reaction (ADRs) suspected to be related to Palforzia®, • Change in quality of life (EuroQol EQ-5D and Food Allergy Quality of Life Questionnaire FAQLQ) from baseline (i.e. enrollment visit) • Direct HRU (all-cause and related to Palforzia®): count and length (days) of hospitalizations and intensive care unit (ICU) stays, count of emergency room visits, outpatient visits, and epinephrine

injections, and a

Data analysis plan

Statistical analysis will be descriptive. No formal hypothesis testing will be performed. Continuous variables will be summarized with non-missing observations, mean and standard deviation, median and interquartile range, minimum and maximum, and number of missing data. Categorical variables will be summarized by the frequency and percent distribution in each category for non-missing data and missing data, as appropriate. 95% confidence intervals of means and percentages will be provided as appropriate. Time-to-event outcomes will be assessed using Kaplan-Meier analysis, as appropriate. Additional details, including subgroups of interest, will be described in the statistical analysis plan.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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