EMA/130959/2023

European Medicines Agency decision

P/0103/2023

of 24 March 2023

on the acceptance of a modification of an agreed paediatric investigation plan for defatted powder of peanuts (PALFORZIA), (EMEA-001734-PIP01-14-M06) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0222/2015 issued on 2 October 2015, the decision P/0275/2016 issued on 7 October 2016, the decision P/0170/2018 issued on 15 June 2018, the decision P/0377/2018 issued on 7 December 2018, the decision P/0114/2019 issued on 29 March 2019 and the decision P/0132/2021 issued on 14 April 2021,

Having regard to the application submitted by Aimmune Therapeutics Inc on 18 November 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 February 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for defatted powder of peanuts (PALFORZIA), oral powder, capsule, oral use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Aimmune Therapeutics Inc, 8000 Marina Boulevard, Suite 300, 94005 - Brisbane, United States.

EMA/PDCO/916130/2022
Amsterdam, 24 February 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001734-PIP01-14-M06

Scope of the application

Active substance(s):

Defatted powder of peanuts

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of peanut allergy

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oral powder

Capsule

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Aimmune Therapeutics Inc

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Aimmune Therapeutics Inc submitted to the European Medicines Agency on 18 November 2022 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0222/2015 issued on 2 October 2015, the decision P/0275/2016 issued on 7 October 2016, the decision P/0170/2018 issued on 15 June 2018, the decision P/0377/2018

issued on 7 December 2018, the decision P/0114/2019 issued on 29 March 2019 and the decision P/0132/2021 issued on 14 April 2021.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 3 January 2023.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition

Treatment of peanut allergy

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- oral powder, capsule, for oral use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition

Treatment of peanut allergy

2.1.1. Indication(s) targeted by the PIP

Peanut oral immunotherapy for reduction in clinical reactivity to accidental exposure in peanut allergic children and adults

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral powder

Capsule

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	6	**Study 1** Double-blind, randomised, placebo-controlled Phase 2 trial to evaluate safety and efficacy of peanut powder in terms of superiority over placebo in children from 4 years to less than 18 years of age (and adults) with peanut allergy (ARC001)

		Study 2 Open-label, follow-on Phase 2 study to assess long-term safety and efficacy of peanut powder in children from 4 years to less than 18 years of age (and adults) with peanut allergy (ARC002) **Study 3** Double-blind, randomised, placebo-controlled Phase 3 trial to evaluate efficacy and safety of peanut powder in terms of superiority over placebo in children from 4 years to less than 18 years of age (and adults) with peanut allergy (ARC003) **Study 4** Open-label, follow-on Phase 3 study to assess long-term safety and efficacy of peanut powder in children from 4 years to less than 18 years of age (and adults) with peanut allergy (ARC004) **Study 5** Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of peanut powder in terms of superiority over placebo in children from 1 year to less than 4 years of age with peanut allergy (ARC005) **Study 6** Double-blind, randomised, placebo-controlled EU only trial to evaluate safety and efficacy of peanut powder in terms of superiority over placebo in children from 4 years to less than 18 years of age with peanut allergy (ARC010)
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s)

1. Treatment of peanut allergy

Authorised indication(s):

- PALFORZIA is indicated for the treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy. PALFORZIA may be continued in patients 18 years of age and older.
- Invented name(s): PALFORZIA
- Authorised pharmaceutical form(s): Oral powder in capsules for opening or sachet
- Authorised route(s) of administration: Oral administration
- Authorised via centralised procedure