MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100932-PIP01-23-M01) and to the deferral

MHRA-100932-PIP01-23-M02

Scope of the Application

Active Substance(s)

Defatted powder of peanuts

Condition(s)

Treatment of peanut allergy

Pharmaceutical Form(s)

Oral powder Capsule

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Aimmune Therapeutics Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Aimmune Therapeutics Inc submitted to the licensing authority on 19/10/2023 19:20 BST an application for a Modification

The procedure started on 25/10/2023 14:48 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100932-PIP01-23-M02

Of 31/10/2023 11:00 GMT

On the adopted decision for Defatted powder of peanuts (MHRA-100932-PIP01-23-M02) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan

This decision applies to a Modification for Defatted powder of peanuts, Oral powder Capsule , ORAL USE .

This decision is addressed to Aimmune Therapeutics Inc, 1007 US Hwy 202/206, Bldg JR2, Bridgewater, UNITED STATES OF AMERICA, NJ 08807

ANNEX I

1. Waiver

1.1 Condition:

Treatment of peanut allergy. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age. Pharmaceutical form(s): Oral powder Capsule Route(s) of administration: ORAL USE Reason for granting waiver: 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(s):

Treatment of peanut allergy.

2.2 Indication(s) targeted by the PIP:

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

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 1 year to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Oral powder Capsule

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not Applicable.
Non-Clinical Studies	0	Not Applicable.
Clinical Studies	6	Study 1 (ARC001) 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. Study 2 (ARC002) 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. Study 3 (ARC003) 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. Study 4 (ARC004) 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. Study 5 (ARC005) 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. Study 6 (ARC010) 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.
Extrapolation, Modeling & Simulation Studies	0	Not Applicable.
Other Studies	0	Not Applicable.
Other Measures	0	Not Applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	31/12/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes