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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100932-PIP01-23-M01

Scope of the Application

Active Substance(s)

Peanut Flour

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 28/06/2023 23:28 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100932-PIP01-23-M01

Of 31/10/2023 10:02 GMT

On the adopted decision for Peanut Flour (MHRA-100932-PIP01-23-M01) 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 (including modification of a deferral included in that paediatric investigation plan);

This decision applies to a Modification for Peanut Flour , ORAL POWDER; CAPSULE , ORAL USE .

This decision is addressed to Aimmune Therapeutics Inc. , 8000 Marina Boulevard, Suite 300, Brisbane, UNITED STATES OF AMERICA, 94005-1884

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