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 and to the deferral

MHRA-100090-PIP01-21-M01

Scope of the Application

Active Substance(s)

DUPILUMAB

Condition(s)

Treatment of atopic dermatitis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

Regeneron Pharmaceuticals, Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Regeneron Pharmaceuticals, Inc submitted to the licensing authority on 16/04/2021 21:20 BST an application for a Modification

The procedure started on 02/12/2021 16:56 GMT

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-100090-PIP01-21-M01

Of 07/12/2021 15:04 GMT

On the adopted decision for DUPILUMAB (MHRA-100090-PIP01-21-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 waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for DUPILUMAB, Solution for injection , Subcutaneous use .

This decision is addressed to Regeneron Pharmaceuticals, Inc, 777 Old Saw Mill River Road, Tarrytown, United States, 10591

ANNEX I

1. Waiver

1.1 Condition:

Treatment of atopic dermatitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Subcutaneous use Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of atopic dermatitis

2.2 Indication(s) targeted by the PIP:

Treatment of severe atopic dermatitis

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 Deleted in modification procedure MHRA-100090-PIP01-21-M01.
Non-Clinical Studies	0	Not applicable
Clinical Studies	5	Study 2: Open-label study to characterize the safety and PK of a single administration of dupilumab in paediatric patients from 6 years to less than 18 years of age Study 3 Randomised, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in paediatric patients from 12 years to less than 18 years of age with moderate to severe atopic dermatitis Study 4 Study to evaluate the safety, pharmacokinetics (PK) and efficacy of dupilumab in patients from 6 months to less than 6 years of age with severe atopic dermatitis (AD) Study 5 Randomised, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in paediatric patients (from 6 years to less than 12 years of age) with severe atopic dermatitis Study 6 Randomised, double-blind, placebo controlled study to assess the efficacy of dupilumab in paediatric patients (from 6 months to less than 6 years of age) with severe atopic dermatitis
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:	31/03/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes