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-100586-PIP01-22-M01) and to the deferral

MHRA-100586-PIP01-22-M02

Scope of the Application

Active Substance(s)

DUPILUMAB

Condition(s)

Treatment of asthma

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

SANOFI WINTHROP INDUSTRIE

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SANOFI WINTHROP INDUSTRIE submitted to the licensing authority on 04/07/2023 16:11 BST an application for a Modification

The procedure started on 21/11/2023 15:15 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-100586-PIP01-22-M02

Of 19/12/2023 08:03 GMT

On the adopted decision for DUPILUMAB (MHRA-100586-PIP01-22-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 (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 SANOFI WINTHROP INDUSTRIE, 82 Avenue Raspail, Gentilly, FRANCE, 94250

ANNEX I

1. Waiver

1.1 Condition:

Treatment of asthma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of asthma

2.2 Indication(s) targeted by the PIP:

Treatment of persistent asthma in paediatric patients 6 years to less than 18 years of age that is inadequately controlled with medium to high doses of inhaled corticosteroids and a second controller medication Treatment of children 2 years to less than 6 years of age with recurrent severe asthmatic wheezing uncontrolled by inhaled corticosteroids

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

The paediatric population from 2 years 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 during procedure MHRA-100586-PIP01-22-M01.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	7	Study 2 Open-label study to characterize the safety and pharmacokinetics (PK) of a single administration of dupilumab in paediatric patients 6 years to less than 18 years of age. Study 3 Randomised, double-blind, placebo controlled, parallel group study to assess the efficacy and long term safety of dupilumab in adolescent (and in adult) patients with inadequately controlled asthma. Study 4 deleted during procedure EMEA-001501-PIP02-M01. Study 5 Study to evaluate the Safety, Pharmacokinetics (PK) and Efficacy of dupilumab in patients, 6 months to less than 6 years of age, with severe Atopic Dermatitis (AD). Study 6 Randomised, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in children 6 to less than 12 years old with persistent uncontrolled asthma.

		Study 7 Randomised, double-blind, placebo controlled study to assess the efficacy and long term safety of dupilumab in children 2 years to less than 6 years old with uncontrolled asthma and/or recurrent severe asthmatic wheeze. Study 8 Open-label follow-up study to evaluate the long-term safety and tolerability of dupilumab in adolescent (and in adult) patients who participated in previous dupilumab asthma clinical studies. Study 9 Open-label follow-up study to evaluate the long-term safety and tolerability of dupilumab in children 6 years to less than 12 years patients who participated in previous dupilumab asthma clinical studies.
Extrapolation, Modeling & Simulation Studies	0	Study 10 deleted during procedure MHRA-100586-PIP01-22-M02
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:	30/06/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes