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-101181-PIP01-23) and to the deferral

MHRA-101181-PIP01-23-M01

Scope of the Application

Active Substance(s)

Amlitelimab

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

Sanofi Winthrop Industrie

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Winthrop Industrie submitted to the licensing authority on 12/03/2025 14:02 GMT an application for a Modification

The procedure started on 10/04/2025 16:30 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-101181-PIP01-23-M01

Of 16/06/2025 06:25 BST

On the adopted decision for Amlitelimab (MHRA-101181-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 waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Amlitelimab, 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 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 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 atopic dermatitis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate-to-severe atopic dermatitis (AD) in patients who are candidates for systemic therapy

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	1	Study 1 Development of a lower strength of solution for injection, appropriate for the paediatric population from 6 months to less than 12 years of age.
Non-Clinical Studies	1	Study 2 (TER0761) Reprotox: (enhanced) pre- and postnatal development study in cynomolgus monkeys.
Clinical Studies	5	Study 3 (EFC17559, COAST 1) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in adolescents from 12 years to less than 18 years of age (and adults) with moderate to severe atopic dermatitis (AD). Study 4 (EFC17560, COAST 2) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in adolescents from 12 years to less than 18 years of age (and adults) with moderate to severe AD. Study 5 (EFC17561, SHORE) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in adolescents from 12 years to less than 18 years of age (and adults) with moderate to severe AD on background topical corticosteroids. Study 6 (EFC17600, ESTUARY)

		Double-blind, randomised, placebo-controlled trial to evaluate treatment response and safety of amlitelimab monotherapy compared to treatment withdrawal in participants in Study 3 (EFC17559), Study 4 (EFC17560) and Study 5 (EFC17561). Study 7 (EFC18128) Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of amlitelimab in children from 6 months to less than 12 years of age with moderate to severe AD.
Extrapolation, Modeling & Simulation Studies	1	Study 8 Population pharmacokinetic (PK) analysis to determine the PK of amlitelimab in children from 6 months to less than 12 years of age with moderate to severe AD.
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:	31/12/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes