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-100297-PIP01-21-M03) and to the deferral

MHRA-100297-PIP01-21-M04

Scope of the Application

Active Substance(s)

Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (rocatinlimab)

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

Amgen Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Amgen Limited submitted to the licensing authority on 01/11/2024 13:17 GMT an application for a Modification

The procedure started on 02/12/2024 08:49 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-100297-PIP01-21-M04

Of 20/03/2025 16:12 GMT

On the adopted decision for Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (rocatinlimab) (MHRA-100297-PIP01-21-M04) 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 Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (rocatinlimab), Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Amgen Limited, 216 Cambridge Science Park Milton Road, Cambridge, UNITED KINGDOM, CB4 0WA

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 moderate to severe atopic dermatitis (AD) with or without topical corticosteroids

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 Compatibility study of the solution for injection to ensure that the dosage preparation procedure and presentation is age appropriate.
Non-Clinical Studies	1	Study 2 (SBL303-238) Enhanced pre- and postnatal development reproductive toxicity study.
Clinical Studies	3	Study 3 (20210145) A randomised, double-blind, placebo-controlled, parallel group two part study to investigate the efficacy and safety of human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (rocatinlimab) in adolescents 12 years to less than 18 years of age with moderate to severe atopic dermatitis. Study 4 (20210261) A randomised, double-blind, placebo-controlled study to investigate the safety and efficacy of rocatinlimab in combination with topical corticosteroids (TCS) in subjects aged 6 years to less than 12 years with moderate to severe atopic dermatitis. Study 5 (20210262) A two part open label dose finding (Part A) and randomised, double blind, placebo controlled study (Part B) to investigate pharmacokinetics (PK), pharmacodynamics (PD),

		safety and efficacy, of rocatinlimab in combination with topical corticosteroids (TCS) in children aged 6 months to less than 6 years, with moderate to severe atopic dermatitis.
Extrapolation, Modeling & Simulation Studies	1	Study 6 Modelling and simulation study to evaluate the use of the product in the treatment of moderate to severe atopic dermatitis in children from 6 months to less than 18 years of age with moderate to severe atopic dermatitis.
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:	31/08/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes