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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101408-PIP01-24

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 asthma

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 25/03/2024 17:30 GMT an application for a Paediatric Investigation Plan

The procedure started on 13/02/2025 16:12 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-101408-PIP01-24

Of 29/04/2025 09:49 BST

On the adopted decision for Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (rocatinlimab) (MHRA-101408-PIP01-24) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan 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 asthma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: On the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments Reason for Refusing Waiver: Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of asthma

2.2 Indication(s) targeted by the PIP:

Treatment of moderate-to-severe asthma

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

The paediatric population from birth to less than 5 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	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1 Double blind, randomized, placebo-controlled trial evaluating safety and efficacy following subcutaneous (SC) administration of rocatinlimab in adolescents from 12 to under 18 years of age with moderate to severe asthma. Study 2 Double-blind, placebo-controlled trial evaluating safety and efficacy of rocatinlimab in paediatric subjects from 5 years to less than 12 years of age with moderate to severe asthma
Extrapolation, Modeling & Simulation Studies	1	Study 3 Pharmacokinetic (PK)/ Pharmacodynamic (PD) modelling and simulation study using data from Study 1 to identify the optimal dose for use in children from 5 years to less than 12 years of age.
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:	28/02/2037
Deferral of one or more studies contained in the paediatric investigation plan:	Yes