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-100517-PIP01-22-M01

Scope of the Application

Active Substance(s)

APREMILAST

Condition(s)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

Pharmaceutical Form(s)

Tablet, Oral liquid

Route(s) of Administration

ORAL 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 25/04/2022 09:55 BST an application for a Modification

The procedure started on 06/12/2022 07:48 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

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-100517-PIP01-22-M01

Of 23/12/2022 14:50 GMT

On the adopted decision for APREMILAST (MHRA-100517-PIP01-22-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 APREMILAST, Tablet, Oral liquid , ORAL 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 chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age. Pharmaceutical form(s): Tablet. Oral liquid Route(s) of administration: ORAL USE Reason for granting waiver: • For the paediatric population from birth to less than 1 year of age: 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). • For the paediatric population from 1 year to less than 2 years of age: on the grounds that the specific medicinal product is likely to be unsafe. • For the paediatric population from 2 years to less than 5 years of age: on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

2.2 Indication(s) targeted by the PIP:

Treatment of juvenile psoriatic arthritis (JPsA)

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

The paediatric population from 5 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet. Oral liquid

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of oral liquid for paediatric use.
Non-Clinical Studies	1	Study 2 (CC-10004-TOX-1125) Toxicity study in mice during the entire developmental phase from weaning to adulthood.
Clinical Studies	1	Study 3 This study was deleted as a result of procedure 000715-PIP02-11-M03. Study 4 This study was deleted as a result of procedure 000715-PIP02-11-M03. Study 5 This study was deleted as a result of procedure 000715-PIP02-11-M03. Study 6 (CC-10004-PSA-016; PEAPOD) This study was added as a result of procedure 000715-PIP02-11-M03. Double-blind, randomised, placebo-controlled trial to evaluate the efficacy, safety and pharmacokinetics of apremilast in children from 5 years to less than 18 years of age with active juvenile psoriatic arthritis (JPsA).
Extrapolation, Modeling & Simulation Studies	1	Study 7 This study was added as a result of procedure 000715-PIP02-11-M03. Extrapolation

		study to demonstrate/confirm the magnitude of effect of apremilast on efficacy outcomes in children from 5 years to less than18 years of age with juvenile psoriatic arthritis (JPsA).
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:	31/03/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes