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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100518-PIP01-22-M01

Scope of the Application

Active Substance(s)

APREMILAST

Condition(s)

Treatment of Behçet's Disease

Pharmaceutical Form(s)

Tablet; Oral suspension

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 13:49 BST an application for a Modification

The procedure started on 06/12/2022 07:52 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-100518-PIP01-22-M01

Of 15/12/2022 17:10 GMT

On the adopted decision for APREMILAST (MHRA-100518-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 suspension , 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 Behçet's Disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Tablet. Oral suspension Route(s) of administration: ORAL 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 Behçet's Disease

2.2 Indication(s) targeted by the PIP:

Treatment of active oral ulcers (with or without concurrent genital ulcers) associated with Behçet's disease 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 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet. Oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an oral formulation.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 (CC-10004-PBCT-001) Multi-centre, double-blind, placebo-controlled study to evaluate the efficacy, safety, tolerability and pharmacokinetics of apremilast in patients with Behçet's disease from 2 years to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	31/12/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes