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 waiver

MHRA-101378-PIP01-24

Scope of the Application

Active Substance(s)

UPADACITINIB

Condition(s)

Treatment of hidradenitis suppurativa

Pharmaceutical Form(s)

Prolonged-release tablet, Age-appropriate oral liquid dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

AbbVie Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd. submitted to the licensing authority on 09/04/2024 14:07 BST an application for a Paediatric Investigation Plan

The procedure started on 04/06/2024 13:28 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 agree a paediatric investigation plan 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-101378-PIP01-24

Of 23/08/2024 08:24 BST

On the adopted decision for UPADACITINIB (MHRA-101378-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 UPADACITINIB, Prolonged-release tablet, Age-appropriate oral liquid dosage form , ORAL USE .

This decision is addressed to AbbVie Ltd., AbbVie House, Vanwall Business Park, Vanwall Rd, SL64UB, Maidenhead, Berkshire, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hidradenitis suppurativa The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Prolonged-release tablet Age-appropriate oral liquid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: 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).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hidradenitis suppurativa

2.2 Indication(s) targeted by the PIP:

Treatment of hidradenitis suppurativa (HS) in patients from 12 years of age

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

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Prolonged-release tablet Age-appropriate oral liquid dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate oral liquid dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	3	Study 2 Population pharmacokinetic dose finding model to support use of upadacitinib in adolescents from 12 years to less than 18 years of age with hidradenitis suppurativa (HS). Study 3 Exposure-response model to support use of upadacitinib in adolescents from 12 years to less than 18 years of age with HS. Extrapolation plan Studies 2 and 3 are part of an extrapolation plan covering the paediatric population from 12 years to less than 18 years of age with the condition hidradenitis suppurativa.
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:	No
Date of completion of the paediatric investigation plan:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	No