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-101354-PIP01-24

Scope of the Application

Active Substance(s)

UPADACITINIB

Condition(s)

Treatment of alopecia areata

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 14/02/2024 08:31 GMT an application for a Paediatric Investigation Plan

The procedure started on 03/12/2024 14:30 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 and to link this PIP with related PIP Decisions covering all authorised indications of Upadacitinib for treatment of Crohn's disease, for treatment of vasculitides, for treatment of vitiligo, for treatment of ulcerative colitis, for treatment of systemic lupus erythematosus, and for treatment of chronic idiopathic arthritis, including all subsequent modifications thereof.

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-101354-PIP01-24

Of 21/01/2025 09:31 GMT

On the adopted decision for UPADACITINIB (MHRA-101354-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 Road, Maidenhead, Berkshire, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of alopecia areata The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 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 clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of alopecia areata

2.2 Indication(s) targeted by the PIP:

Treatment of severe alopecia areata (AA) in patients 6 years of age and older

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

The paediatric population from 6 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 an age-appropriate oral liquid dosage form for paediatric patients who are unable to swallow tablets or weigh less than 30 kg.
Non-Clinical Studies	1	Study 2 Double-blind, randomised, placebo-controlled trial to evaluate safety and efficacy of upadacitinib in children from 6 years to less than 18 years of age with alopecia areata.
Clinical Studies	2	Study 3 Population PK Modelling of adult / adolescent subjects with alopecia areata to describe upadacitinib pharmacokinetics in adult / adolescent subjects with alopecia areata, to assess the impact of covariates on PK parameters and to inform the recommended dosing regimen in PIP Study 2. Study 4 Exposure-response model to characterise the relationship between upadacitinib plasma exposure and efficacy / safety parameters in children from 6 years to less than 18 years of age with alopecia areata.
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:	30/11/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes