MHRA
10 South Colonnade
Canary Wharf
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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-101248-PIP01-23

Scope of the Application

Active Substance(s)

UPADACITINIB

Condition(s)

Treatment of systemic lupus erythematosus

Pharmaceutical Form(s)

Prolonged-release tablet; Age-appropriate oral 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 12/12/2023 13:47 GMT an application for a Paediatric Investigation Plan

The procedure started on 03/12/2024 14:39 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 atopic dermatitis, for treatment of ulcerative colitis, for treatment of vitiligo 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-101248-PIP01-23

Of 16/12/2024 15:22 GMT

On the adopted decision for UPADACITINIB (MHRA-101248-PIP01-23) 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 dosage form , ORAL USE .

This decision is addressed to AbbVie Ltd, AbbVie House, Vanwall road, Maidenhead, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of systemic lupus erythematosus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age Pharmaceutical form(s): Prolonged-release tablet Age-appropriate oral dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of systemic lupus erythematosus

2.2 Indication(s) targeted by the PIP:

Treatment of systemic lupus erythematosus

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):

Prolonged-release tablet Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age-appropriate oral dosage form.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 2 Double-blind, randomised, placebo-controlled trial to evaluate the efficacy and safety of upadacitinib in children from 5 years to less than 18 years of age with systemic lupus erythematosus.
Extrapolation, Modeling & Simulation Studies	3	Study 3 Modelling and simulation study to characterise the pharmacokinetics and support dose-finding for the use of upadacitinib in children from 5 years to less than 18 years of age with systemic lupus erythematosus. Study 4 Modelling and simulation study to characterise the exposure-response relationship and support dose-finding for the use of upadacitinib in children from 5 years to less than 18 years of age with systemic lupus erythematosus. Extrapolation plan Studies 2, 3 and 4 are part of an extrapolation plan covering the paediatric population from 5 years to less than 18 years of age with systemic lupus erythematosus.
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:	30/06/2033
Deferral of one or more studies contained in the paediatric investigation plan:	Yes