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 and to the deferral

MHRA-101692-PIP01-24-M01

Scope of the Application

Active Substance(s)

ATOGEPANT MONOHYDRATE

Condition(s)

Prevention of migraine headaches

Pharmaceutical Form(s)

Tablet Age appropriate oral solid formulation

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 16/01/2025 10:56 GMT an application for a Modification

The procedure started on 03/02/2025 11:54 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-101692-PIP01-24-M01

Of 07/02/2025 10:19 GMT

On the adopted decision for ATOGEPANT MONOHYDRATE (MHRA-101692-PIP01-24-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 ATOGEPANT MONOHYDRATE, Tablet Age appropriate oral solid formulation , ORAL USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of migraine headaches. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age. Pharmaceutical form(s): Tablet Age appropriate oral solid formulation 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 over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of migraine headaches.

2.2 Indication(s) targeted by the PIP:

Prevention of migraine headaches.

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):

Tablet Age appropriate oral solid formulation

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of lower strength tablet/capsule appropriate to the paediatric population from 6 to less than 12 year of age and for those unable to swallow existing dose form to administer dose higher than 20mg.
Non-Clinical Studies	1	Study 2 (3101-XXX-052) Definitive juvenile toxicity study to determine the safety of atogepant in juvenile rats.
Clinical Studies	3	Study 3 (3101-307-002) Randomized, double-blind, placebo-controlled, parallel group study to assess PK, efficacy, safety and tolerability of atogepant as compared to placebo for the preventive treatment of episodic migraine in paediatric patients from 6 years to less than 18 years of age. Study 4 (3101-308-002) Randomized, double-blind, placebo-controlled, parallel group study to assess PK, efficacy, safety and tolerability of atogepant as compared to placebo for the preventive treatment of chronic migraine in paediatric patients from 12 years to less than 18 years of age. Study 5 (3101-310-002) Open-label study to evaluate the long-term safety of daily administration of atogepant for preventive treatment of episodic

		migraine in paediatric patients from 6 years to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	1	Study 6 (3101-S03-000) Development of Population PK model to support selection of initial paediatric dose(s).
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:	31/03/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes