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-100975-PIP01-23-M01

Scope of the Application

Active Substance(s)

ERENUMAB

Condition(s)

Prevention of migraine headaches

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Novartis Pharmaceuticals UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novartis Pharmaceuticals UK Limited submitted to the licensing authority on 18/05/2023 16:04 BST an application for a

The procedure started on 15/09/2023 13:25 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 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-100975-PIP01-23-M01

Of 21/09/2023 11:47 BST

On the adopted decision for ERENUMAB (MHRA-100975-PIP01-23-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 for ERENUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, UNITED KINGDOM, W12 7FQ

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): Solution for injection Route(s) of administration: SUBCUTANEOUS 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:

Prophylaxis of migraine.

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):

Solution for injection.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of prefilled syringe for SC administration of the 35 mg dose in paediatric patients. Study 2 Deleted during procedure EMEA-001664-PIP02-15-M03.
Non-Clinical Studies	2	Study 3 Enhanced pre-postnatal development study in the cynomolgus monkey. Study 4 Juvenile toxicology study in cynomolgus monkey.
Clinical Studies	3	Study 5 (20160172) Randomised, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of erenumab in paediatric subjects from 6 years to less than 18 years old with Episodic Migraine (EM). Study 6 (20150125) (Added in procedure EMEA-001664-PIP02-15-M01) An open-label, multiple-dose, pharmacokinetic, safety and tolerability study of erenumab in paediatric subjects from 6 years to less than 18 years of age with migraine. Study 7 (20160354) (Added in procedure EMEA-001664-PIP02-15-M01) Randomised, double-blind, placebo-controlled parallel group study to evaluate the efficacy and safety of erenumab in paediatric subjects from 6 years to less than 18 years old with Chronic Migraine (CM).

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:	31/07/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes