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-100468-PIP01-22-M01

Scope of the Application

Active Substance(s)

EPTINEZUMAB

Condition(s)

Prevention of migraine headaches

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

H. Lundbeck A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, H. Lundbeck A/S submitted to the licensing authority on 21/03/2022 13:41 GMT an application for a Modification

The procedure started on 15/09/2022 16:17 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-100468-PIP01-22-M01

Of 25/11/2022 15:16 GMT

On the adopted decision for EPTINEZUMAB (MHRA-100468-PIP01-22-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 EPTINEZUMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to H. Lundbeck A/S, Ottiliavej 9, Valby, DENMARK, 2500

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): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS 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):

Concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	1	Study 1 (ALD403-086-TOX) Study in juvenile rats to determine the potential toxicity of eptinezumab when administered once weekly (IV).
Clinical Studies	3	Study 2 Single arm, single-dose, pharmacokinetic study of eptinezumab in migraine patients from 6 years to less than 18 years of age for determination of effective dose. Study 3 Randomised, double blind, placebo-controlled study to evaluate the efficacy and safety of eptinezumab for the prevention of chronic migraine (CM) in paediatric patients from 12 years to less than 18 years of age. Study 4 Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of eptinezumab for the prevention of episodic migraine (EM) in paediatric patients from 6 to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	1	Study 5 (ALD403-088-PK) Population PK model to establish the initial paediatric dose to be used in the clinical efficacy and safety studies 3 and 4.
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:	31/10/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes