MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101005-PIP02-26

Scope of the Application

Active Substance(s)

Bocunebart

Condition(s)

Preventive treatment of migraine

Pharmaceutical Form(s)

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 16/02/2026 17:10 GMT an application for a Paediatric Investigation Plan

The procedure started on 03/03/2026 17:25 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:

The agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver

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.

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Final Decision Letter

MHRA-101005-PIP02-26

Of 01/10/2026 10:51 BST

On the adopted decision for Bocunebart (MHRA-101005-PIP02-26) 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 Bocunebart, Solution for infusion , Intravenous use .

This decision is addressed to H. Lundbeck A/S, Ottiliavej 6-9, Valby, DENMARK, 2500

ANNEX I

1. Waiver

1.1 Condition:

Preventive treatment of migraine 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 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

2.2 Indication(s) targeted by the PIP:

Prevention 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 infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	2	Study 1 Dose range-finding toxicity study in juvenile rats. Study 2 Definitive toxicity study in juvenile rats
Clinical Studies	2	Study 3 Open-label, single-dose trial to evaluate the pharmacokinetics, safety, and tolerability of bocunebart (Lu AG09222) in children from 6 years to less than 18 years of age with migraine. Study 4 Double-blind, randomised, multiple-dose, placebo-controlled trial to evaluate the efficacy, safety and pharmacokinetics of bocunebart children from 6 years to less than 18 years of age with migraine.
Extrapolation, Modeling & Simulation Studies	3	Study 5 Population PK (PopPK) modelling and simulation analysis to determine the initial paediatric dose for PIP study 3. Study 6 Population PK (PopPK) modelling and simulation analysis to determine the paediatric dose for PIP study 4. Study 7 Population PK (PopPK) modelling and simulation analyses to modify or confirm the dosing recommendations for the paediatric population for the prevention of migraine.
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:	30/04/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes