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 (MHRA-100289-PIP01-21-M02) and to the deferral

MHRA-100289-PIP01-21-M03

Scope of the Application

Active Substance(s)

GALCANEZUMAB

Condition(s)

Prevention of migraine headache

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Eli Lilly Nederland B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Eli Lilly Nederland B.V. submitted to the licensing authority on 26/01/2023 11:31 GMT an application for a Modification

The procedure started on 02/06/2023 13:31 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-100289-PIP01-21-M03

Of 15/06/2023 17:41 BST

On the adopted decision for GALCANEZUMAB (MHRA-100289-PIP01-21-M03) 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 GALCANEZUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Eli Lilly Nederland B.V., Papendorpseweg 83, 352, Utrecht, Netherlands, Utrecht, NETHERLANDS, 352

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:

Prophylactic treatment 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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	3	Study 1 Enhanced pre- and postnatal development reproductive toxicity study in rats. Study 2 Definitive juvenile toxicity study in rats. Study 3 Fertility and early embryonic development reproductive toxicity study.
Clinical Studies	2	Study 4 (I5Q-MC-CGAS) Randomised double-blind placebo-controlled study trial to evaluate pharmacokinetics, safety, efficacy, of galcanezumab in children from 6 to less than 18 years of age with episodic migraine. Study 5 (I5Q-MC-CGAT) Randomised double-blind placebo-controlled study trial to evaluate, safety, efficacy, of galcanezumab in paediatric patients from 12 to less than 18 years of age with chronic migraine.
Extrapolation, Modeling & Simulation Studies	1	Study 6. Modelling and simulation study, to support initial dose determination of galcanezumab in children from 6 to less than 18 years of age with migraine and further paediatric development.
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:	31/01/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes