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-100188-PIP01-21-M01); MHRA-100188-PIP01-21-M02

Scope of the Application

Active Substance(s)

lebrikizumab

Condition(s)

treatment of atopic dermatitis

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 08/06/2023 15:25 BST an application for a Modification

The procedure started on 15/09/2023 18:50 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;

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-100188-PIP01-21-M02

Of 31/10/2023 15:27 GMT

On the adopted decision for lebrikizumab (MHRA-100188-PIP01-21-M02) 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

This decision applies to a Modification for lebrikizumab, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, Netherlands, Utrecht, NETHERLANDS, 3528

ANNEX I

1. Waiver

1.1 Condition:

Treatment of atopic dermatitis. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months 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):

Treatment of atopic dermatitis.

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe atopic dermatitis (AD) inadequately controlled by prescription topical medications.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 months 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	0	Not applicable.
Clinical Studies	8	Study 1 (DRM06-AD04) Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of lebrikizumab in adolescent patients from 12 years to less than 18 years weighing at least 40 kg (and adults) with moderate-to-severe atopic dermatitis (AD). Study 2 (DRM06-AD05) Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of lebrikizumab in adolescent patients from 12 years to less than 18 years weighing at least 40 kg (and adults) with moderate-to-severe AD. Study 3 (DRM06-AD06) Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of lebrikizumab when used in combination with topical corticosteroid treatment in adolescent patients from 12 years to less than 18 years weighing at least 40 kg (and adults) with moderate-to-severe atopic dermatitis (AD). Study 4 (DRM06-AD13) Randomised, double-blind, placebo controlled study to evaluate PK, efficacy and safety of lebrikizumab in patients

		from 6 years to less than 12 years of age and patients from 12 years to less than 18 years of age who weigh less than 40 kg with moderate to severe atopic dermatitis. Study 5 Deleted during procedure MHRA-100188-PIP01-21-M01. Study 6 (DRM06-AD17) Open-label, single-arm study to assess the safety and efficacy of lebrikizumab in adolescent patients from 12 years to less than 18 years with moderate-to-severe atopic dermatitis.
Extrapolation, Modeling & Simulation Studies	2	Study 7 (DRM06-Model study 1) Dose finding population PK model to estimate doses in patients from 6 years to less than 18 years of age. Study 8 (DRM06-Model study 2) Dose finding population PK model to estimate doses in patients from 6 months to less than 6 years of age.
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:	30/04/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes