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-100931-PIP01-23-M01)and to the deferral.

MHRA-100931-PIP01-23-M02

Scope of the Application

Active Substance(s)

MIRIKIZUMAB

Condition(s)

Treatment of ulcerative colitis, Treatment of Crohn's Disease

Pharmaceutical Form(s)

Concentrate for solution for infusion, Solution for injection

Route(s) of Administration

INTRAVENOUS USE; 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 19/02/2024 16:25 GMT an application for a Modification

The procedure started on 12/06/2024 16:53 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-100931-PIP01-23-M02

Of 17/06/2024 18:17 BST

On the adopted decision for MIRIKIZUMAB (MHRA-100931-PIP01-23-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 (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for MIRIKIZUMAB, Concentrate for solution for infusion, Solution for injection , INTRAVENOUS USE; SUBCUTANEOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Condition 1: Treatment of ulcerative colitis. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Concentrate for solution for infusion. Solution for injection. Route(s) of administration: INTRAVENOUS USE. SUBCUTANEOUS USE. Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. Condition 2: Treatment of Crohn's Disease. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age. Pharmaceutical form(s): Concentrate for solution for infusion. Solution for injection. Route(s) of administration: INTRAVENOUS USE. 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):

Condition 1: Treatment of ulcerative colitis. Condition 2: Treatment of Crohn's Disease.

2.2 Indication(s) targeted by the PIP:

Condition 1: Treatment of moderate to severely active ulcerative colitis. Condition 2: Treatment of Crohn's Disease.

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

The paediatric population from 2 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion. Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of pre-filled syringe presentations for subcutaneous use.
Non-Clinical Studies	1	Study 2 (20102344) Pre- and postnatal development study in cynomolgus monkeys.
Clinical Studies	3	Study 4 (I6T-MC-AMBA) Multicentre study to evaluate safety, tolerability, and efficacy of mirikizumab in children and adolescents from 2 years to less than 18 years of age with ulcerative colitis. Study 7 (AMBU) Multicentre, open-label pharmacokinetic (PK) study of mirikizumab in children and adolescents from 2 years to less than 18 years of age with ulcerative colitis. Study 5 (I6T-MC-AMAY) Multicentre study to evaluate safety, tolerability, pharmacokinetics, and efficacy of mirikizumab in children and adolescents from 2 to less than 18 years of age with Crohn's disease. Study 6 deleted during procedure MHRA-100931-PIP01-23-M01.

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:	No
Date of completion of the paediatric investigation plan:	31/07/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes