MHRA
10 South Colonnade
Canary Wharf
London
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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-100931-PIP01-23-M01

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 16/03/2023 11:57 GMT an application for a Modification

The procedure started on 20/06/2023 11:34 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-M01

Of 18/07/2023 13:28 BST

On the adopted decision for mirikizumab (MHRA-100931-PIP01-23-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 mirikizumab, Concentrate for solution for infusion, Solution for injection , INTRAVENOUS, SUBCUTANEOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Condition 1: Treatment of ulcerative colitis. Condition 2: Treatment of Crohn's disease. For Conditions 1 and 2, 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 moderate to severely active Crohn's disease.

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

For Conditions 1 and 2: The paediatric population from 2 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

For Conditions 1 and 2: 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.
Extrapolation, Modeling & Simulation Studies	0	N/A
Other Studies	0	N/A
Other Measures	0	N/A

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