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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100265-PIP01-21

Scope of the Application

Active Substance(s)

BARICITINIB

Condition(s)

Treatment of alopecia areata

Pharmaceutical Form(s)

Tablet, Oral suspension

Route(s) of Administration

Oral 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 16/09/2021 08:37 BST an application for a Paediatric Investigation Plan

The procedure started on 13/04/2022 15:38 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 agree a paediatric investigation plan and grant a deferral and grant 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.

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Final Decision Letter

MHRA-100265-PIP01-21

Of 28/04/2022 07:59 BST

On the adopted decision for BARICITINIB (MHRA-100265-PIP01-21) 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 BARICITINIB, Tablet, Oral suspension , Oral use .

This decision is addressed to ELI LILLY NEDERLAND B.V., Papendorpseweg 83, Utrecht, Netherlands, 352

ANNEX I

1. Waiver

1.1 Condition:

Treatment of alopecia areata The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 years of age Pharmaceutical form(s): Tablet; Oral suspension Route(s) of administration: Oral use Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of alopecia areata

2.2 Indication(s) targeted by the PIP:

Treatment of patients with alopecia areata

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):

Tablet; Oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral suspension suitable for patients younger than 10 years of age.
Non-Clinical Studies	1	Study 2 (9000909) Definitive juvenile toxicity study in Sprague -Dawley rats to evaluate neurobehavioral, reproductive, and immunological effects upon administration of baricitinib during postnatal development.
Clinical Studies	1	Study 3 Randomised, double-blind parallel group, , placebo-controlled study to evaluate the efficacy, safety, and pharmacokinetic (PK) of baricitinib in children from 6 years to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	1	Study 4 Extrapolation study to evaluate the use of baricitinib for the treatment if alopecia areata in children from 6 years to less than 12 years of age with severe alopecia areata.
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:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes