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 of change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100216-PIP01-21-M02

Scope of the Application

Active Substance(s)

TRALOKINUMAB

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

LEO Pharma A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, LEO Pharma A/S submitted to the licensing authority on 25/03/2022 16:47 GMT an application for a Modification

The procedure started on 31/08/2022 09:55 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-100216-PIP01-21-M02

Of 19/09/2022 10:37 BST

On the adopted decision for TRALOKINUMAB (MHRA-100216-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 (including modification of a waiver or deferral included in that paediatric investigation plan)

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

This decision is addressed to LEO Pharma A/S, Industriparken 55, Ballerup, DENMARK, 2750

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 2 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS 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 atopic dermatitis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate-to-severe atopic dermatitis in adolescents (12-17 years) who are candidates for systemic treatment; Treatment of moderate-to-severe atopic dermatitis in children (2-11 years) who are candidates for systemic treatment.

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):

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	3	Study 1 (LP0162-1334) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of tralokinumab compared to placebo in adolescents with moderate-to-severe atopic dermatitis Study 2 (LP0162-1335) Assessor-blind, randomised trial to evaluate PK and safety of tralokinumab in children from 2 years to less than 12 years of age with moderate-to-severe atopic dermatitis Study 3 (LP0162-1336) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of tralokinumab as add-on to standard of care compared to placebo in children from 2 years to 12 years of age with moderate-to-severe atopic dermatitis.
Extrapolation, Modeling & Simulation Studies	2	Study 4 (Modelling and simulation 1) Modelling and simulation study to support the dose selection for PK and safety trial in children (Study 2). Study 5 (Modelling and simulation 2) Modelling and simulation study to support the dose selection for efficacy and safety trial in children (Study 3).
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:	31/03/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes