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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100276-PIP01-21-M02) and to grant a full product specific waiver

MHRA-100276-PIP01-21-M03

Scope of the Application

Active Substance(s)

BRODALUMAB

Condition(s)

Treatment of psoriasis

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 09/06/2023 14:24 BST an application for a Modification

The procedure started on 13/10/2023 07:40 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 grant a product specific 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-100276-PIP01-21-M03

Of 02/11/2023 15:47 GMT

On the adopted decision for BRODALUMAB (MHRA-100276-PIP01-21-M03) 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 BRODALUMAB, Solution for injection , SUBCUTANEOUS USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Treatment of psoriasis The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years 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 as the needs are already covered

2. Paediatric Investigation Plan:

2.1 Condition(s):

Studies 1, 3, 4 and 5 were deleted during procedure MHRA-100276-PIP01-21-M03 and replaced with a product specific waiver. Study 2 was deleted in a previous procedure EMEA-001089-PIP01-13-M01.

2.2 Indication(s) targeted by the PIP:

Not applicable

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

Not applicable

2.4 Pharmaceutical Form(s):

Not applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	0	Not applicable
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	