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-M01) and to the deferral

MHRA-100276-PIP01-21-M02

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 29/11/2022 16:55 GMT an application for a Modification

The procedure started on 14/04/2023 17:13 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100276-PIP01-21-M02

Of 17/05/2023 17:21 BST

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

This decision is addressed to LEO Pharma A/S, BUILDING 5, FOUNDATION PARK ROXBOROUGH WAY, MAIDENHEAD, Berkshire, UNITED KINGDOM, SL6 3UD

ANNEX I

1. Waiver

1.1 Condition:

Treatment of psoriasis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 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):

Treatment of psoriasis

2.2 Indication(s) targeted by the PIP:

Treatment of chronic moderate to severe plaque psoriasis

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):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of a solution for injection in a prefilled syringe.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 2 Deleted in EMEA-001089-PIP01-13-M01. Study 3 Randomised, double-blind until week 12, placebo and active comparator (ustekinumab - open label), controlled multicentre study to evaluate safety, efficacy, and pharmacokinetics of brodalumab in paediatric subjects from 12 years to less than 18 years of age with moderate to severe psoriasis. Study 4 Single arm, open label study with brodalumab to determine the safety, efficacy and pharmacokinetics in children (aged 6 years to less than 12 years) with moderate to severe plaque psoriasis.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Population modelling and simulation study of the pharmacokinetics of brodalumab to support the choice of dose and dosing regimen in study 4.
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:	28/02/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes