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-101542-PIP01-24

Scope of the Application

Active Substance(s)

lutikizumab

Condition(s)

Treatment of hidradenitis suppurativa

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

AbbVie Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AbbVie Ltd submitted to the licensing authority on 22/10/2024 14:22 BST an application for a Paediatric Investigation Plan

The procedure started on 13/01/2025 12:11 GMT

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-101542-PIP01-24

Of 25/02/2025 09:49 GMT

On the adopted decision for lutikizumab (MHRA-101542-PIP01-24) 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 lutikizumab, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to AbbVie Ltd, Abbvie House Vanwall Road , Maidenhead, UNITED KINGDOM, SL6 4UB

ANNEX I

1. Waiver

1.1 Condition:

Treatment of hidradenitis suppurativa The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of hidradenitis suppurativa

2.2 Indication(s) targeted by the PIP:

Treatment of hidradenitis suppurativa

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

The paediatric population from 12 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	1	Study 1 Open-label study to evaluate the pharmacokinetics and safety of lutikizumab in adolescents from 12 years to less than 18 years of age with moderate to severe hidradenitis suppurativa (HS).
Extrapolation, Modeling & Simulation Studies	2	Study 2 Dose-finding modelling and simulation study to support initial dose selection for the pharmacokinetic study in adolescent subjects with HS (PIP study 1), as well as confirm the final lutikizumab dose recommendation in this patient population. Extrapolation plan PIP studies 1 and 2 are part of an extrapolation plan of efficacy data from adult patients to the paediatric population from 12 years to less than 18 years of age with hidradenitis suppurativa.
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:	No
Date of completion of the paediatric investigation plan:	30/09/2031

Deferral of one or more studies contained in the paediatric investigation plan:	Yes