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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100022-PIP01-21

Scope of the Application

Active Substance(s)

Bimekizumab

Condition(s)

Hidradenitis suppurativa

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Subcutaneous use

Name / Corporate name of the PIP applicant

UCB PHARMA LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, UCB PHARMA LIMITED submitted to the licensing authority on 19/03/2021 12:13 GMT an application for a

The procedure started on 17/08/2021 09:29 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-100022-PIP01-21

Of 08/09/2021 13:56 BST

On the adopted decision for Bimekizumab (MHRA-100022-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 for Bimekizumab, Solution for injection , Subcutaneous use .

This decision is addressed to UCB PHARMA LIMITED, 208 Bath Road - Berkshire, Slough, United Kingdom, SL1 3WE

ANNEX I

1. Waiver

1.1 Condition:

Hidradenitis suppurativa The waiver applies / applied to: Paediatric Subset(s): The paediatric population prior to onset of puberty (Tanner stage less than 2) 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):

Hidradenitis suppurativa

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe hidradenitis suppurativa (acne inversa) in paediatric population with Tanner stage $\geq$2

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

The paediatric population from the onset of puberty (Tanner stage ≥2) 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 in paediatric patients up to 18 years of age at Tanner pubertal stage 2 or greater with moderate to severe HS to provide PK data to support the extrapolation of efficacy of bimekizumab from adults, with an extension period to evaluate safety.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and Simulation study for bimekizumab in paediatric patients up to 18 years of age at Tanner pubertal stage 2 or greater with moderate to severe 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:	30/11/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes