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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100023-PIP01-21-M02

Scope of the Application

Active Substance(s)

BIMEKIZUMAB

Condition(s)

Treatment of psoriasis

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 01/07/2022 17:36 BST an application for a Modification

The procedure started on 10/11/2022 16:35 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 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-100023-PIP01-21-M02

Of 17/11/2022 18:24 GMT

On the adopted decision for BIMEKIZUMAB (MHRA-100023-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 BIMEKIZUMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to UCB Pharma Limited, 208 Bath Road, Slough, UNITED KINGDOM, SL1 3WE

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 over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of psoriasis

2.2 Indication(s) targeted by the PIP:

Treatment of moderate to severe chronic 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	0	Not applicable
Non-Clinical Studies	1	Study 1 (NCD2676) Embryofetal and peri- and postnatal (ePPND) toxicity study in Cynomolgus monkeys
Clinical Studies	2	Study 2 (PS0020) Open label study to assess the pharmacokinetics (PK), efficacy and safety of bimekizumab in adolescents from 12 years to less than 18 years of age with moderate to severe plaque psoriasis (PSO). Study 3 (PS0021) Randomised parallel-group, double blind active controlled study to compare the efficacy and safety of bimekizumab to ustekinumab in children and adolescents from 6 years to less than 18 years of age, with moderate to severe plaque psoriasis. (PSO).
Extrapolation, Modeling & Simulation Studies	1	Study 4 Population pharmacokinetic and pharmacodynamic modelling and simulation study.
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