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

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Decision Cover Letter

Decision of the licensing authority to:

accept a modification of an agreed paediatric investigation plan

MHRA-100023-PIP01-21-M01

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 15/02/2021 18:41 GMT an application for a

The procedure started on 30/04/2021 12:47 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:

The acceptance of a modification of an agreed paediatric investigation plan.

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-100023-PIP01-21-M01

Of 21/05/2021 13:49 BST

On the adopted decision for bimekizumab (MHRA-100023-PIP01-21-M01) 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 modification of 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, Slough, United Kingdom, SL1 3WE

ANNEX I

1. Waiver

1.1 Condition:

Treatment of psoriasis The waiver applies to the paediatric population from birth to less than 6 years; for the solution for injection, subcutaneous use; 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 Embryofetal and per- and postnatal (ePPND) toxicity study in Cynomolgus monkeys (NCD2676)
Clinical Studies	2	Study 2 (Modified during procedureMHRA-100023-PIP01-21-M01)Open label study to assess the pharmacokinetics (PK), efficacy and safety of bimekizumab in adolescents from12 years to less than 18 years of age with moderate to severe plaque psoriasis (PSO) (PS0020): Study 3 Randomised parallel-group, double blind, and single (assessor) blind, active controlled study to compare the efficacy and safety of bimekizumab to placebo (PBO) in children and adolescents from 6 years to less than 18 years of age, with moderate to severe chronic plaque psoriasis. (PSO). (PS0021)
Extrapolation, Modeling & Simulation Studies	1	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