MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan

MHRA-100718-PIP01-22-M01

Scope of the Application

Active Substance(s)

deucravacitinib

Condition(s)

Treatment of psoriasis

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate solid oral dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb Pharmaceuticals Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb Pharmaceuticals Limited submitted to the licensing authority on 07/10/2022 18:46 BST an application for a Modification

The procedure started on 21/02/2023 09:04 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

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-100718-PIP01-22-M01

Of 01/03/2023 07:44 GMT

On the adopted decision for deucravacitinib (MHRA-100718-PIP01-22-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 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 deucravacitinib, Film-coated tablet; Age-appropriate solid oral dosage form , ORAL USE .

This decision is addressed to Bristol-Myers Squibb Pharmaceuticals Limited, ARC Uxbridge, Sanderson Road, New Denham, Denham, Buckinghamshire, United Kingdom, Buckinghamshire, UNITED KINGDOM, UB8 1DH

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): Film-coated tablet Age-appropriate solid oral dosage form Route(s) of administration: ORAL 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 plaque psoriasis in paediatric patients 6 years of age and older

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):

Film-coated tablet Age-appropriate solid oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of age appropriate formulation for paediatric use.
Non-Clinical Studies	1	Study 2 (DN18003) Definitive juvenile toxicity study in rats.
Clinical Studies	1	Study 3 (IM011-126) Pharmacokinetic, safety and efficacy study in children and adolescents from 6 years to less than 18 years of age with moderate to severe psoriasis. Study 4 Deleted during procedure MHRA-100718-PIP01-22-M01.
Extrapolation, Modeling & Simulation Studies	1	Study 5 Modelling and simulation dose finding 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:	31/03/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes