

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 change(s) to the agreed paediatric investigation plan

MHRA-100718-PIP01-22-M02

Scope of the Application

Active Substance(s)

DEUCRAVACITINIB

Condition(s)

Treatment of psoriasis

Pharmaceutical Form(s)

FILM-COATED TABLET; AGE-APPROPRIATE ORAL SOLID 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 24/10/2023 09:59 BST an application for a Modification

The procedure started on 19/01/2024 14:28 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.

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Final Decision Letter

MHRA-100718-PIP01-22-M02

Of 25/01/2024 10:48 GMT

On the adopted decision for DEUCRAVACITINIB (MHRA-100718-PIP01-22-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.

This decision applies to a Modification for DEUCRAVACITINIB, FILM-COATED TABLET; AGE-APPROPRIATE ORAL SOLID 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 ORAL SOLID 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 to less than 18 years of age.

2.4 Pharmaceutical Form(s):

FILM-COATED TABLET. AGE-APPROPRIATE ORAL SOLID 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

