MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100731-PIP01-22

Scope of the Application

Active Substance(s)

Deucravacitinib

Condition(s)

Treatment of systemic lupus erythematosus

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 16/01/2023 22:39 GMT an application for a Paediatric Investigation Plan

The procedure started on 05/06/2023 15:14 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-100731-PIP01-22

Of 20/06/2023 16:18 BST

On the adopted decision for Deucravacitinib (MHRA-100731-PIP01-22) 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 Paediatric Investigation Plan 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 systemic lupus erythematosus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 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 systemic lupus erythematosus

2.2 Indication(s) targeted by the PIP:

Treatment of systemic lupus erythematosus despite receiving standard of care. Treatment of lupus nephritis despite receiving standard of care.

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

The paediatric population from 5 years 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 (This is the same study as Study 1 in MHRA-100718-PIP01-22-M01 and subsequent modifications thereof) Development of age appropriate formulation for paediatric use.
Non-Clinical Studies	1	Study 2 (DN18003) (This is the same study as Study 2 in MHRA-100718-PIP01-22-M01 and subsequent modifications thereof.) Definitive juvenile toxicity study in rats.
Clinical Studies	2	Study 3 Double-blind, placebo-controlled, randomised withdrawal trial to evaluate safety and efficacy of deucravacitinib as add-on to standard of care in children from 5 years to less than 18 years of age with systemic lupus erythematosus. Study 4 Open-label trial to evaluate pharmacokinetics, safety and efficacy of deucravacitinib as add-on to standard of care in children from 5 years to less than 18 years of age with lupus nephritis.
Extrapolation, Modeling & Simulation Studies	2	Study 5 Modelling and simulation study incorporating paediatric systemic lupus erythematosus data to evaluate the use of deucravacitinib in children from 5 years to less than 18 years of age with systemic lupus

		erythematosus. Study 6 Modelling and simulation study incorporating paediatric lupus nephritis data to evaluate the use of deucravacitinib in children from 5 years to less than 18 years of age with systemic lupus erythematosus.
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:	31/01/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes