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

MHRA-100761-PIP01-22-M01

Scope of the Application

Active Substance(s)

NIVOLUMAB; relatlimab

Condition(s)

Treatment of melanoma

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb International Corporation

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb International Corporation submitted to the licensing authority on 11/11/2022 15:02 GMT an application for a Modification

The procedure started on 27/01/2023 13:04 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 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-100761-PIP01-22-M01

Of 06/02/2023 11:23 GMT

On the adopted decision for NIVOLUMAB; relatlimab (MHRA-100761-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 NIVOLUMAB; relatlimab, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Bristol-Myers Squibb International Corporation, Parc de l'Alliance, Avenue de Finlande 4, Braine-l'Alleud, BELGIUM, 1420

ANNEX I

1. Waiver

1.1 Condition:

Treatment of melanomaThe waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age. Pharmaceutical form(s): Concentrate for solution for infusion. Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). Reason for Refusing Waiver: Not Applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of melanoma

2.2 Indication(s) targeted by the PIP:

Treatment of adolescents from 12 years to less than 18 years of age with unresectable or metastatic melanoma.

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

The paediatric population from 12 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	2	Study 1 Modelling and simulation study to determine the dose of relatlimab/nivolumab fixed-dose combination to be used in paediatric patients from 12 years of age to less than 18 years of age with unresectable or metastatic melanoma. Study 2 Extrapolation study to evaluate the use of relatlimab/ nivolumab fixed-dose combination in adolescents from 12 to less than 18 years of age with unresectable or metastatic melanoma.
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:	Yes
Date of completion of the paediatric investigation plan:	30/09/2021
Deferral of one or more studies contained in the paediatric investigation plan:	No