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 waiver

MHRA-101538-PIP01-24

Scope of the Application

Active Substance(s)

NIVOLUMAB; RELATLIMAB

Condition(s)

Treatment of melanoma

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb Pharma EEIG

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb Pharma EEIG submitted to the licensing authority on 03/07/2024 16:15 BST an application for a Paediatric Investigation Plan

The procedure started on 15/07/2024 14:29 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 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-101538-PIP01-24

Of 05/11/2024 07:13 GMT

On the adopted decision for NIVOLUMAB; RELATLIMAB (MHRA-101538-PIP01-24) 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 NIVOLUMAB; RELATLIMAB, Solution for injection , SUBCUTANEOUS USE .

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, IRELAND, D15 T867

ANNEX I

1. Waiver

1.1 Condition:

Treatment of melanoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS 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).

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):

Solution for injection

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 solution for injection and subcutaneous use, to be used in paediatric patients from 12 years of age to less than 18 years of age with unresectable or metastatic melanoma. Extrapolation Plan Study 1 and Study CA224-127 (in participants from 12 years of age and older with previously untreated metastatic or unresectable melanoma) and other relevant paediatric and adult studies are part of the extrapolation plan of efficacy and safety data by exposure matching from adults to adolescents from 12 years to less than 18 years of age with 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:	30/06/2026

Deferral of one or more studies contained in the paediatric investigation plan:	No