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:

grant a product specific waiver

MHRA-101315-PIP01-23

Scope of the Application

Active Substance(s)

NIVOLUMAB; relatlimab

Condition(s)

Treatment of all conditions in the category of malignant neoplasms (except nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms and melanoma)

Pharmaceutical Form(s)

Solution for injection Concentrate for solution for infusion

Route(s) of Administration

SUBCUTANEOUS USE; INTRAVENOUS 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 19/12/2023 08:59 GMT an application for a Waiver

The procedure started on 02/07/2024 13:44 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 grant a product specific 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-101315-PIP01-23

Of 18/07/2024 11:28 BST

On the adopted decision for NIVOLUMAB; relatlimab (MHRA-101315-PIP01-23) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for NIVOLUMAB; relatlimab, Solution for injection Concentrate for solution for infusion , SUBCUTANEOUS USE; INTRAVENOUS 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 all conditions included in the category of malignant neoplasms (except nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms and melanoma) The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Solution for injection Concentrate for solution for infusion. Route(s) of administration: SUBCUTANEOUS USE INTRAVENOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not Applicable

2.2 Indication(s) targeted by the PIP:

Not Applicable

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

Not Applicable

2.4 Pharmaceutical Form(s):

Not Applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	