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:

accept change(s) to the agreed paediatric investigation plan and to grant a product specific waiver

MHRA-101630-PIP01-24-M01

Scope of the Application

Active Substance(s)

LISOCABTAGENE MARALEUCEL

Condition(s)

Treatment of B-lymphoblastic leukaemia/lymphoma, Treatment of mature B-cell neoplasm

Pharmaceutical Form(s)

Dispersion for infusion

Route(s) of Administration

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 18/09/2024 22:11 BST an application for a Modification

The procedure started on 19/09/2024 08:17 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 accept change(s) to the agreed paediatric investigation plan and 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-101630-PIP01-24-M01

Of 19/09/2024 11:04 BST

On the adopted decision for LISOCABTAGENE MARALEUCEL (MHRA-101630-PIP01-24-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 and the granting a waiver in all age groups for the listed condition(s);

This decision applies to a Modification for LISOCABTAGENE MARALEUCEL, Dispersion for infusion , 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:

Condition 1: Treatment of B-lymphoblastic leukaemia/lymphoma 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): Dispersion for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments Condition 2: Treatment of mature B-cell neoplasm 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): Dispersion for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments Reason for Refusing Waiver:

2. Paediatric Investigation Plan:

2.1 Condition(s):

Studies 1, 2 and 3 for both conditions were deleted during procedure MHRA-101630-PIP01-24.

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	0	Not Applicable
Non-Clinical Studies	0	Not Applicable
Clinical Studies	0	Not Applicable
Extrapolation, Modeling & Simulation Studies	0	Not Applicable
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	