MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-102299-PIP01-26

Scope of the Application

Active Substance(s)

CRB-701

Condition(s)

Treatment of cervical cancer, Treatment of head and neck epithelial malignant neoplasms

Pharmaceutical Form(s)

Powder for solution for infusion

Route(s) of Administration

INTRAVENOUS

Name / Corporate name of the PIP applicant

Corbus Pharmaceuticals

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Corbus Pharmaceuticals submitted to the licensing authority on 23/01/2026 09:10 GMT an application for a

The procedure started on 29/01/2026 07:54 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 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-102299-PIP01-26

Of 19/05/2026 14:22 BST

On the adopted decision for CRB-701 (MHRA-102299-PIP01-26) 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 for CRB-701, Powder for solution for infusion , INTRAVENOUS .

This decision is addressed to Corbus Pharmaceuticals, 500 River Ridge Drive, Norwood, UNITED STATES OF AMERICA, MA 02062

ANNEX I

1. Waiver

1.1 Condition:

Treatment of cervical cancer 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): Powder 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). 1.2 Condition Treatment of head and neck epithelial malignant neoplasms 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) Powder for solution 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.

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	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:	Not applicable
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	Not applicable