

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

[gov.uk/mhra](https://www.gov.uk/mhra)

## **Decision Cover Letter**

### **Decision of the licensing authority to:**

grant a product specific waiver

MHRA-101122-PIP01-23

### **Scope of the Application**

#### **Active Substance(s)**

ENFORTUMAB VEDOTIN

#### **Condition(s)**

Treatment of head and neck epithelial malignant neoplasms

#### **Pharmaceutical Form(s)**

Powder for concentrate for solution for infusion

#### **Route(s) of Administration**

INTRAVENOUS USE

#### **Name / Corporate name of the PIP applicant**

Astellas Pharma Ltd

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, Astellas Pharma Ltd submitted to the licensing authority on 31/08/2023 12:33 BST an application for a Waiver

The procedure started on 04/12/2023 09:04 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 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-101122-PIP01-23

Of 13/02/2024 16:29 GMT

On the adopted decision for ENFORTUMAB VEDOTIN (MHRA-101122-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 ENFORTUMAB VEDOTIN, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Astellas Pharma Ltd, 300 Dashwood Lang Road, Addlestone, UNITED KINGDOM, KT15 2NX

## ANNEX I

### 1. Waiver

#### 1.1 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 concentrate 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 as clinical studies(s) are not feasible

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Not Applicable

**2.2 Indication(s) targeted by the PIP:**

Not Applicable
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**2.3 Subset(s) of the paediatric population concerned by the paediatric development:**

Not Applicable
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**2.4 Pharmaceutical Form(s):**

Not Applicable
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**2.5 Studies:**

<b>Study Type</b>	<b>Number of Studies</b>	<b>Study Description</b>
<b>Quality Measures</b>		
<b>Non-Clinical Studies</b>		
<b>Clinical Studies</b>		
<b>Extrapolation, Modeling &amp; Simulation Studies</b>		
<b>Other Studies</b>		
<b>Other Measures</b>		

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

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