**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-101085-PIP01-23

# Scope of the Application

## Active Substance(s)

Humanised IgG1 monoclonal antibody against integrin beta-6 conjugated to monomethyl auristatin E via a valine-citrulline linker

## Condition(s)

Treatment of non-small cell lung cancer

## Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

## Route(s) of Administration

INTRAVENOUS USE

## Name / Corporate name of the PIP applicant

Seagen UK Ltd

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Seagen UK Ltd submitted to the licensing authority on 10/07/2023 12:18 BST an application for a Waiver

The procedure started on 23/11/2023 16:59 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-101085-PIP01-23

Of 13/02/2024 08:57 GMT

On the adopted decision for Humanised IgG1 monoclonal antibody against integrin beta-6 conjugated to monomethyl auristatin E via a valine-citrulline linker (MHRA-101085-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 Humanised IgG1 monoclonal antibody against integrin beta-6 conjugated to monomethyl auristatin E via a valine-citrulline linker, Powder for concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Seagen UK Ltd, The Charter Building, Charter Place, Uxbridge, UNITED KINGDOM, UB8 1JG

# ANNEX I

## 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of non-small cell lung 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 concentrate 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). |

## 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:** | |