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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100642-PIP01-22-M01

# Scope of the Application

## Active Substance(s)

Tremelimumab

## Condition(s)

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

## Pharmaceutical Form(s)

Concentrate for emulsion for infusion

## Route(s) of Administration

INTRAVENOUS USE

## Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 30/09/2022 12:16 BST an application for a Modification

The procedure started on 24/02/2023 12:10 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100642-PIP01-22-M01

Of 07/03/2023 17:26 GMT

On the adopted decision for Tremelimumab (MHRA-100642-PIP01-22-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

This decision applies to a Modification for Tremelimumab, Concentrate for emulsion for infusion , INTRAVENOUS USE .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square, 8th Floor, London, UNITED KINGDOM, N1C 4AG

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Not applicable. |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue). |

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

| |
|---|
| Treatment of paediatric patients from birth to less than 18 years old with a paediatric solid tumour. |

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

All subsets of the paediatric population from birth to less than 18 years of age.

## 2.4 Pharmaceutical Form(s):

Concentrate for emulsion for infusion

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 0 | Not applicable |
| **Non-Clinical Studies** | 1 | Study 1 (Same as study 1 in MHRA-100641-PIP01-22-M01 and subsequent modifications thereof) Non-clinical biomarker study in paediatric tumour tissues |
| **Clinical Studies** | 2 | Study 2 (Same as study 2 in MHRA-100641-PIP01-22-M01 and modification thereof) Multi-centre, open-label study, with a dose finding phase (phase 1) and an expansion phase (phase 2), to evaluate the safety, tolerability, pharmacokinetics and antitumor activity of durvalumab monotherapy, and durvalumab used in combination with tremelimumab in paediatric patients from birth to less than 18 years of age with a relapsed/refractory solid tumour or a relapsed/refractory haematological malignancy including lymphomas or a paediatric solid tumour or haematological malignancy for whom no curative standard treatment is available. Study 3 was deleted in procedure MHRA-100642-PIP01-22-M01. |
| **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:** | Yes |
| **Date of completion of the paediatric investigation plan:** | 30/06/2023 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | Yes |