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 (MHRA-100642-PIP01-22-M01) and to the deferral.

MHRA-100642-PIP01-22-M02

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 solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

AstraZeneca AB

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca AB submitted to the licensing authority on 21/07/2023 11:49 BST an application for a Modification

The procedure started on 12/10/2023 11:02 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 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-M02

Of 20/10/2023 09:33 BST

On the adopted decision for TREMELIMUMAB (MHRA-100642-PIP01-22-M02) 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 (including modification of a waiver or deferral included in that paediatric investigation plan);

This decision applies to a Modification for TREMELIMUMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to AstraZeneca AB, Forskargatan 18, Södertälje, SWEDEN, SE 151 85

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 solution 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:	31/08/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes