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

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-100516-PIP01-22

Scope of the Application

Active Substance(s)

Toripalimab

Condition(s)

Malignant neoplasms (except CNS, haematopoietic and lymphoid tissue and melanoma).

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

TopAlliance Biosciences, Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, TopAlliance Biosciences, Inc. submitted to the licensing authority on 25/04/2022 16:21 BST an application for a Paediatric Investigation Plan

The procedure started on 04/07/2022 13:46 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 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-100516-PIP01-22

Of 25/08/2022 11:36 BST

On the adopted decision for Toripalimab (MHRA-100516-PIP01-22) 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 Paediatric Investigation Plan for Toripalimab, Concentrate for solution for infusion , Intravenous use .

This decision is addressed to TopAlliance Biosciences, Inc., 9430 Key West Ave, Suite 125, Rockville, UNITED STATES OF AMERICA, MD 20850

ANNEX I

1. Waiver

1.1 Condition:

Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue and melanoma). 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): 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 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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	