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-100152-PIP01-21

Scope of the Application

Active Substance(s)

cosibelimab; cosibelimab

Condition(s)

Treatment of cutaneous squamous cell carcinoma

Pharmaceutical Form(s)

All forms , All forms

Route(s) of Administration

All routes of administration , All routes of administration

Name / Corporate name of the PIP applicant

Checkpoint Therapeutics, Inc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Checkpoint Therapeutics, Inc submitted to the licensing authority on 07/07/2021 13:23 BST an application for a Waiver

The procedure started on 29/09/2021 17:15 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-100152-PIP01-21

Of 22/10/2021 15:05 BST

On the adopted decision for cosibelimab (MHRA-100152-PIP01-21) 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 cosibelimab, All forms , Intravenous use .

This decision is addressed to Checkpoint Therapeutics, Inc, 2 Gansevoort Street, 9th Floor, New York, United States, NY 10014

ANNEX I

1. Waiver

1.1 Condition:

1.1 Condition: Treatment of cutaneous squamous cell carcinoma 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): All Pharmaceutical forms; Route(s) of administration: All Routes of Administration; 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:	