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-101049-PIP01-23

Scope of the Application

Active Substance(s)

retifanlimab

Condition(s)

Treatment of Merkel cell carcinoma

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

All routes of administration

Name / Corporate name of the PIP applicant

INCYTE BIOSCIENCES UK LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, INCYTE BIOSCIENCES UK LIMITED submitted to the licensing authority on 20/11/2023 11:19 GMT an application for a Paediatric Investigation Plan

The procedure started on 09/02/2024 10:11 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-101049-PIP01-23

Of 31/12/2024 10:20 GMT

On the adopted decision for retifanlimab (MHRA-101049-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 Paediatric Investigation Plan for retifanlimab, All pharmaceutical forms , All routes of adminstration .

This decision is addressed to INCYTE BIOSCIENCES UK LIMITED, First Floor 1, Q1 The Square, Randalls Way, Leatherhead, UNITED KINGDOM, KT22 7TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Merkel cell carcinoma

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	Not applicable	Not applicable
Non-Clinical Studies	Not applicable	Not applicable
Clinical Studies	Not applicable	Not applicable
Extrapolation, Modeling & Simulation Studies	Not applicable	Not applicable
Other Studies	Not applicable	Not applicable
Other Measures	Not applicable	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:	Not applicable
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	Not applicable