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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-101169-PIP01-23

Scope of the Application

Active Substance(s)

vibostolimab; PEMBROLIZUMAB

Condition(s)

Treatment of melanoma

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Limited submitted to the licensing authority on 24/10/2023 17:09 BST an application for a Paediatric Investigation Plan

The procedure started on 25/01/2024 12:42 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 agree a paediatric investigation plan and grant a 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-101169-PIP01-23

Of 06/03/2024 08:20 GMT

On the adopted decision for vibostolimab; PEMBROLIZUMAB (MHRA-101169-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:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for vibostolimab; PEMBROLIZUMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of melanoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 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 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):

Treatment of melanoma

2.2 Indication(s) targeted by the PIP:

Adjuvant treatment of resected high-risk melanoma in adolescent patients aged 12 years and older

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

The paediatric population from 12 years 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	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	2	Study 1 Pharmacokinetic modelling and simulation study to select the vibostolimab/pembrolizumab (MK-7684) dose in adolescents from 12 years to less than 18 years of age for treatment of melanoma. Extrapolation Plan Studies KV-010 [study of adjuvant pembrolizumab/ vibostolimab (MK-7684A) versus pembrolizumab for resected high-risk melanoma in participants with high-risk stage II-IV melanoma adolescent and adult data] and MK-9999-01B (paediatric platform substudy in the adolescent melanoma population paediatric data) along with modelling and simulation Study 1 are part of an extrapolation plan covering the paediatric population from 12 years to less than 18 years of age for the treatment of melanoma, as agreed by the Regulatory Agency.
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:	31/05/2026
Deferral of one or more studies contained in the paediatric investigation plan:	No