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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101986-PIP01-25

Scope of the Application

Active Substance(s)

CEMIPLIMAB; FIANLIMAB

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

Regeneron UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Regeneron UK Ltd submitted to the licensing authority on 18/09/2025 19:37 BST an application for a Paediatric Investigation Plan

The procedure started on 04/11/2025 10:46 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 deferral 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.

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Final Decision Letter

MHRA-101986-PIP01-25

Of 10/03/2026 08:24 GMT

On the adopted decision for CEMIPLIMAB; FIANLIMAB (MHRA-101986-PIP01-25) 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 CEMIPLIMAB; FIANLIMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Regeneron UK Ltd, The Charter Building, Uxbridge, UNITED KINGDOM, UB8 1JG

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:

Treatment of unresectable locally advanced or metastatic melanoma in patients from 12 years to less than 18 years of age. Adjuvant treatment of completely resected melanoma in patients from 12 years to less than 18 years of age.

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	2	Study 1 (R3767-ONC-2011) Double-blind, randomised, controlled, multiple arm trial to evaluate pharmacokinetics, safety, efficacy, immunogenicity of fianlimab administered at two different doses in combination with cemiplimab (Arms A and A1) against pembrolizumab/ placebo combination (Arm B) and cemiplimab/ placebo combination (Arm C) in adolescents from 12 years to less than 18 years of age (and adults) with unresectable locally advanced or metastatic melanoma who have not received a previous systemic treatment for advanced disease, in terms of superiority of fianlimab in combination with cemiplimab over pembrolizumab/ placebo combination. Study 2 (R3767-ONC-2055) Double-blind, randomised, controlled, multiple arm trial to evaluate, in the adjuvant setting, fianlimab administered at two different doses in combination with cemiplimab (Arms A and B) against the combination pembrolizumab/placebo (Arm C) in adolescents from 12 years to less

		than 18 years of age (and adults) with completely resected high-risk melanoma.
Extrapolation, Modeling & Simulation Studies	2	Study 3 Modelling and simulation study to predict fianlimab and cemiplimab exposure in adolescents from 12 years to less than 18 years of age. Extrapolation Plan Studies 1, 2 and 3 are part of an extrapolation plan covering the paediatric population from 12 years to less than 18 years of age with condition unresectable or metastatic melanoma.
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:	31/03/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes