MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100698-PIP01-22) and to the deferral

MHRA-100698-PIP01-22-M01

Scope of the Application

Active Substance(s)

nemvaleukin alfa

Condition(s)

Treatment of all conditions included in the category of malignant neoplasms (except CNS, haematopoietic and lymphoid tissue) , Treatment of malignant neoplasms of the lymphoid tissue

Pharmaceutical Form(s)

Powder and solvent for solution for injection

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Mural Oncology, Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Mural Oncology, Inc. submitted to the licensing authority on 21/10/2024 13:17 BST an application for a Modification

The procedure started on 02/12/2024 08:44 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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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-100698-PIP01-22-M01

Of 28/02/2025 17:32 GMT

On the adopted decision for nemvaleukin alfa (MHRA-100698-PIP01-22-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for nemvaleukin alfa, Powder and solvent for solution for injection , INTRAVENOUS USE .

This decision is addressed to Mural Oncology, Inc., 852 Winter Street, Waltham, UNITED STATES OF AMERICA, MA 02451

ANNEX I

1. Waiver

1.1 Condition:

Condition 1: Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Powder and solvent for solution for injection Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s). Condition 2: Treatment of malignant neoplasms of the lymphoid tissue The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Powder and solvent for solution for injection Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Condition 1: Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue) Condition 2:Treatment of malignant neoplasms of the lymphoid tissue

2.2 Indication(s) targeted by the PIP:

Condition 1: Treatment in combination with pembrolizumab of patients 6 months to less than 18 years of age, with relapsed or refractory or newly diagnosed non-CNS solid malignant tumours Condition 2:Treatment in combination with pembrolizumab of patients, 6 months to less than 18 years of age, with relapsed or refractory or newly diagnosed non-Hodgkin's Lymphoma

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

For both Conditions: The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

For both Conditions: Powder and solvent for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Same studies for both Conditions: Study 1 Open label study to evaluate the pharmacokinetics, safety, immunogenicity and antitumour activity of nemvaleukin used in combination with pembrolizumab in paediatric patients from 6 months to less than 18 years of age (and young adults) with relapsed or refractory or newly diagnosed non-CNS solid tumour or a non-Hodgkin lymphoma, with a dose finding phase (Part A) and an expansion phase (Part B). Study 2 Randomised, active controlled study to evaluate the efficacy, safety and pharmacokinetics of nemvaleukin in combination

		with pembrolizumab compared to appropriate standard of care in paediatric patients from 6 months to less than 18 years of age (and young adults) with relapsed or refractory or newly diagnosed non-CNS solid tumour or a non-Hodgkin lymphoma selected based on the results of Study 1.
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:	Yes
Date of completion of the paediatric investigation plan:	31/05/2041
Deferral of one or more studies contained in the paediatric investigation plan:	Yes