MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-101352-PIP01-24-M01) and to grant a product specific waiver

MHRA-101352-PIP01-24-M02

Scope of the Application

Active Substance(s)

Autologous tumour-infiltrating lymphocytes (LN-144/LN-145)

Condition(s)

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

Pharmaceutical Form(s)

Dispersion of infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Iovance Biotherapeutics, Inc.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Iovance Biotherapeutics, Inc. submitted to the licensing authority on 30/06/2026 09:14 BST an application for a Modification

The procedure started on 20/07/2026 15:00 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:

accept change(s) to the agreed paediatric investigation plan and 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-101352-PIP01-24-M02

Of 30/09/2026 08:12 BST

On the adopted decision for Autologous tumour-infiltrating lymphocytes (LN-144/LN-145) (MHRA-101352-PIP01-24-M02) 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 and to grant a product specific waiver.

This decision applies to a Modification for Autologous tumour-infiltrating lymphocytes (LN-144/ LN-145), Dispersion of infusion , INTRAVENOUS USE .

This decision is addressed to Iovance Biotherapeutics, Inc., 825 Industrial Road, Suite 400, San Carlos, UNITED STATES OF AMERICA, 94070

ANNEX I

1. Waiver

1.1 Condition:

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Dispersion of infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: On the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible

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.