EMA/401495/2023

# European Medicines Agency decision

P/0440/2023

of 27 October 2023

on the acceptance of a modification of an agreed paediatric investigation plan for autologous tumour-infiltrating lymphocytes (LN-144/LN-145) (EMEA-002776-PIP01-20-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0022/2021 issued on 29 January 2021 and the decision P/0363/2021 issued on 8 September 2021,

Having regard to the application submitted by Iovance Biotherapeutics, Inc. on 30 June 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 September 2023, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for autologous tumour-infiltrating lymphocytes (LN-144/LN-145), dispersion for infusion, intravenous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to Iovance Biotherapeutics, Inc., 825 Industrial Road, Suite 400, 94070 - San Carlos, United States.

EMA/PDCO/317028/2023
Amsterdam, 08 September 2023

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002776-PIP01-20-M02

## Scope of the application

**Active substance(s):**

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

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

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

**Pharmaceutical form(s):**

Dispersion for infusion

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

Iovance Biotherapeutics, Inc.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Iovance Biotherapeutics, Inc. submitted to the European Medicines Agency on 30 June 2023 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0022/2021 issued on 29 January 2021 and the decision P/0363/2021 issued on 8 September 2021.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 14 August 2023.

## Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 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 to:

- the paediatric population weighing less than 8 kg;
- dispersion for infusion, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

# 2. Paediatric investigation plan

## *2.1. Condition:*

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

### 2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with a relapsed or refractory solid tumour for which no effective therapy is known

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

Less than 18 years of age and weighing at least 8 kg

### 2.1.3. Pharmaceutical form(s)

Dispersion for infusion

### 2.1.4. Measures

| **Area** | **Description** |
|---|---|
| Quality-related studies | Not applicable |
| Non-clinical studies | **Study 1**<br>In vitro study to assess the feasibility of producing tumour infiltrating lymphocytes (TIL) from paediatric tumour samples using the same process used to manufacture TIL products from tumour tissue from adults to characterise the phenotype of paediatric TILs (TP-19-028) |
| Clinical studies | **Study 2**<br>Multi-centre, open-label, single-arm study to evaluate the safety and tolerability and anti-tumour activity of autologous tumour-infiltrating lymphocytes (LN-144/LN-145) in paediatric patients from 8 kg of body |

| | |
|---|---|
| | weight and less than 18 years of age (and adults) with a relapsed or refractory solid malignant tumour for which no effective therapy is available (IOV-PED-101)<br><br>**Study 3**<br><br>Multi-centre, open-label, single-arm study to evaluate the safety and tolerability and anti-tumour activity of autologous tumour-infiltrating lymphocytes (LN-144/LN-145) in paediatric patients from 8 kg of body weight and less than 18 years of age (and adults) with a solid malignant tumour selected based on the results of study IOV-PED-101 (IOV-PED-201) |
| Extrapolation, modelling and simulation studies | Not applicable |
| Other studies | Not applicable |
| Other measures | Not applicable |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By January 2031 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

***Information provided by the applicant:***

**The product is not authorised anywhere in the European Community.**