EMA/930300/2022

European Medicines Agency decision

P/0533/2022

of 30 December 2022

on the agreement of a paediatric investigation plan for posoleucel (EMEA-002908-PIP01-20) 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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on the agreement of a paediatric investigation plan for posoleucel (EMEA-002908-PIP01-20) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by AlloVir International DAC on 23 October 2022 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 November 2022, in accordance with Article 17 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 agreement of a paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

Has adopted this decision:

Article 1

A paediatric investigation plan for posoleucel , dispersion for infusion, intravenous use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

This decision is addressed to AlloVir International DAC, 25-28 - North Wall Quay, D01H104 – Dublin Ireland.

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

EMA/PDCO/699876/2022
Amsterdam, 11 November 2022

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan

EMEA-002908-PIP01-20

Scope of the application

Active substance(s):

Posoleucel

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of viral diseases in haematopoietic stem cell transplantation

Pharmaceutical form(s):

Dispersion for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

AlloVir International DAC

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, AlloVir International DAC submitted for agreement to the European Medicines Agency on 23 October 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 1 December 2020.

Supplementary information was provided by the applicant on 5 August 2022. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

A meeting with the Paediatric Committee took place on 9 November 2022.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation.

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

2. The measures and timelines of the agreed paediatric investigation plan 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of viral diseases in haematopoietic stem cell transplantation

2.1.1. Indication(s) targeted by the PIP

Treatment of virus-associated haemorrhagic cystitis in patients following allogeneic haematopoietic stem cell transplantation

Treatment of adenovirus infection in patients following allogeneic haematopoietic stem cell transplantation

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Dispersion for infusion

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (EudraCT number: 2020-000722-26)** Double-blind, randomised, placebo controlled trial to evaluate safety and efficacy of posoleucel in children from birth to less than 18 years of age (and adults) with virus-associated haemorrhagic cystitis (HC) following allogeneic haematopoietic stem cell transplantation **Study 2 (EudraCT number: 2021-003450-22)** Double-blind, randomised, placebo controlled trial to evaluate safety and activity of posoleucel in children from birth to less than 18 years of age (and adults) with adenovirus infection following allogeneic haematopoietic stem cell transplantation.
Modelling and simulation studies	Not applicable
Other studies	Not applicable

Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By January 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.