EMA/635370/2020

European Medicines Agency decision

P/0490/2020

of 21 December 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral for tabelecleucel (EMEA-002025-PIP04-19) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Atara Biotherapeutics, Inc. on 24 February 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 November 2020, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 and on the granting of a deferral.

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

(3) It is therefore appropriate to adopt a decision granting a deferral.

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

Has adopted this decision:

Article 1

A paediatric investigation plan for tabelecleucel, dispersion for injection, 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

A deferral for tabelecleucel, dispersion for injection, 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 granted.

Article 3

This decision is addressed to Atara Biotherapeutics, Inc., 2380 Conejo Spectrum Street, Thousand Oaks, CA 91320 - California, USA.

EMA/PDCO/444983/2020
Amsterdam, 13 November 2020

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

EMEA-002025-PIP04-19

Scope of the application

Active substance(s):

Tabelecleucel

Condition(s):

Treatment of Epstein-Barr virus associated post-transplant lymphoproliferative disorder

Pharmaceutical form(s):

Dispersion for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Atara Biotherapeutics, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Atara Biotherapeutics, Inc. submitted for agreement to the European Medicines Agency on 24 February 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 31 March 2020.

Supplementary information was provided by the applicant on 10 August 2020. The applicant proposed modifications to the paediatric investigation plan.

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;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Norwegian Paediatric Committee member 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 annex 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 Epstein-Barr virus associated post-transplant lymphoproliferative disorder

2.1.1. Indication(s) targeted by the PIP

Treatment of patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) who have received one prior therapy for an EBV-associated lymphoproliferative disorder.

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 injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	5	**Study 1** Open-label, single-arm trial to evaluate safety and activity of Epstein-Barr virus cytotoxic T lymphocytes (EBV-CTLs) in patients from birth to less than 18 years of age (and adults) with Epstein-Barr virus (EBV)-associated malignancy or at high risk of developing an EBV-associated lymphoproliferative disorder (including lymphoma) due to EBV viraemia following an allogeneic haematopoietic cell transplant (HCT) or solid organ transplant (SOT). (95-024) **Study 2** Open-label, single-arm trial to evaluate safety and activity of tabelecleucel in patients from birth to less than 18 years of age (and adults) with EBV-associated malignancy or with an EBV viraemia

		following previous treatment for an EBV-associated lymphoproliferative disorder with chemotherapy and/or rituximab. (11-130) **Study 3** Open-label, single-arm trial to evaluate safety and activity of tabelecleucel in SOT or HCT transplant patients from birth to less than 18 years of age (and adults) with biopsy-proven EBV-associated post-transplant lymphoproliferative disease (PTLD) following (1) SOT after failure of rituximab (Subgroup A) and rituximab plus chemotherapy (Subgroup B) or (2) allogeneic HCT after failure of rituximab. (ATA129-EBV-302) **Study 4** Open-label, single-arm, adaptive two-stage trial of tabelecleucel to evaluate safety and activity in patients from birth to less than 18 years of age (and adults) with a) EBV^+ PTLD involving the central nervous system (CNS) and b) EBV+ PTLD where first-line rituximab or chemotherapy are not appropriate (including CD20-negative disease). (ATA129-EBV-205) **Study 5** Open label, non-interventional, retrospective chart review study of treatment outcomes in patients from birth to less than 18 years of age (and adults) with EBV-associated PTLD after HCT or SOT who are refractory to rituximab or rituximab plus chemotherapy or who have relapsed after treatment with those agents (ATA129-RS002)
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	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 February 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes