EMADOC-1700519818-1809724

European Medicines Agency decision

EMA/PE/0000183827

of 3 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for tabelecleucel (Ebvallo) 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.

European Medicines Agency decision

EMA/PE/0000183827

of 3 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for tabelecleucel (Ebvallo) 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 European Medicines Agency's decision P/0490/2020 issued on 21 December 2020,

Having regard to the application submitted by Pierre Fabre Medicament on 12 August 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 November 2024, 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 and to the deferral.

(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 tabelecleucel (Ebvallo), including changes to the deferral, 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 Pierre Fabre Medicament, Les Cauquillous, 81500 - Lavaur, France.

EMADOC-1700519818-1665435
Amsterdam, 15 November 2024

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

EMA/PE/0000183827

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:

Pierre Fabre Medicament

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pierre Fabre Medicament submitted to the European Medicines Agency on 12 August 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0490/2020 issued on 21 December 2020.

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

The procedure started on 16 September 2024.

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 and to the deferral 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 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 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	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**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	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:	Yes
Date of completion of the paediatric investigation plan:	By December 2028
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:

Condition(s) and authorised indication(s)

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

Authorised indication(s):

- Indicated as monotherapy for treatment of adult and paediatric patients 2 years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate.
  - Invented name(s): Ebvallo
  - Authorised pharmaceutical form(s): Dispersion for injection
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure