EMA/351212/2023

European Medicines Agency decision

P/0377/2023

of 8 September 2023

on the acceptance of a modification of an agreed paediatric investigation plan for brexucabtagene autoleucel (Tecartus), (EMEA-001862-PIP01-15-M03) 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/0238/2017 issued on 9 August 2017, the decision P/0002/2019 issued on 3 January 2019, and the decision P/0142/2020 issued on 18 April 2020,

Having regard to the application submitted by Kite Pharma EU B.V. on 24 April 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 21 July 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.

[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 brexucabtagene autoleucel (Tecartus), dispersion for injection, 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 Kite Pharma EU B.V., Tufsteen 1, 2132 – Hoofddorp, The Netherlands.

EMA/PDCO/202550/2023
Amsterdam, 21 July 2023

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

EMEA-001862-PIP01-15-M03

Scope of the application

Active substance(s):

Brexucabtagene autoleucel

Invented name:

See Annex II

Condition(s):

Treatment of acute lymphoblastic leukaemia

Pharmaceutical form(s):

Dispersion for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Kite Pharma EU B.V.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Kite Pharma EU B.V. submitted to the European Medicines Agency on 24 April 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/0238/2017 issued on 9 August 2017, the decision P/0002/2019 issued on 3 January 2019, and the decision P/0142/2020 issued on 18 April 2020.

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

The procedure started on 22 May 2023.

Scope of the modification

Some measures 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 acute lymphoblastic leukaemia

The waiver applies to:

- the paediatric population weighing less than 6 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 acute lymphoblastic leukaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of relapsed or refractory B-precursor acute lymphoblastic leukaemia (r/r ALL)

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

Less than 18 years of age and weighing at least 6 kg

2.1.3. Pharmaceutical form(s)

Dispersion for infusion

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of a formulation of brexucabtagene autoleucel (KTE-X19) suitable for administration to paediatric patients with a minimum weight of 6 kg.
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** Open-label, single arm, 2-phase trial to evaluate safety and activity, of brexucabtagene autoleucel (KTE-X19) in children weighing at least 6 kg with B-cell acute lymphoblastic leukaemia (cohort 1) or with B-cell non-Hodgkin lymphoma (cohort 2) whose disease is refractory to a standard chemotherapy regimen, relapsed after stem cell transplantation (SCT).

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 2023
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 mantle cell lymphoma

Authorised indication(s):

- Tecartus is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor
  - Invented name(s): Tecartus
  - Authorised pharmaceutical form(s): Dispersion for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure

2. Treatment of acute lymphoblastic leukaemia

Authorised indication(s):

- Tecartus is indicated for the treatment of adult patients 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL)
  - Invented name(s): Tecartus
  - Authorised pharmaceutical form(s): Dispersion for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised procedure