EMA/178727/2024

European Medicines Agency decision

P/0176/2024

of 6 May 2024

on the acceptance of a modification of an agreed paediatric investigation plan for brexucabtagene autoleucel (Tecartus), (EMEA-001862-PIP03-20-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/0002/2021 issued on 5 January 2021,

Having regard to the application submitted by Kite Pharma EU B.V. on 18 December 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 22 March 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 ,following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, 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 brexucabtagene autoleucel (Tecartus), dispersion for infusion, intravenous use, 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 covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0238/2017 issued on 9 August 2017, including subsequent modifications thereof.

Article 3

This decision is addressed to Kite Pharma EU B.V., Tufsteen 1, 2132 - Hoofddorp, The Netherlands.

EMA/PDCO/159541/2024
Amsterdam, 26 April 2024

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

EMEA-001862-PIP03-20-M02

Scope of the application

Active substance(s):

Brexucabtagene autoleucel

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of mature B-cell neoplasms

Pharmaceutical form(s):

Dispersion for infusion

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 18 December 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/0002/2021 issued on 5 January 2021.

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

An Opinion was adopted by the Paediatric Committee on 22 March 2024 for the above mentioned product. Kite Pharma EU B.V received the Paediatric Committee Opinion on 27 March 2024.

On 12 April 2024 Kite Pharma EU B.V submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 15 April 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and

- to agree to the changes regarding the measures and the timelines 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.

The measures and timelines of the agreed 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.

Waiver

1.1. Condition:

Treatment of mature B-cell neoplasms

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 mature B-cell neoplasms

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric and adolescent subjects with relapsed or refractory B-cell non-Hodgkin lymphoma

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 KTE-X19 suitable for administration to paediatric patients with a minimum weight of 6 kg.
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** (NHL portion of KTE-C19-104 (ZUMA-4)) Open-label, single arm trial to evaluate safety and activity of KTE-X19 in paediatric patients weighing at least 6 kg with relapsed or refractory B-cell non-Hodgkin lymphoma (r/r B-cell NHL).
Extrapolation, modelling and	Not applicable

simulation studies	
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 October 2026
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

- 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