EMA/444608/2019

European Medicines Agency decision

P/0298/2019

of 14 August 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for bempegaldesleukin (EMEA-002492-PIP01-18) 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Medicines Agency decision

P/0298/2019

of 14 August 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral for bempegaldesleukin (EMEA-002492-PIP01-18) 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 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 Nektar Therapeutics on 29 October 2018 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 26 July 2019, 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 bempegaldesleukin, powder for concentrate for solution 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

A deferral for bempegaldesleukin, powder for concentrate for solution 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 granted.

Article 3

This decision is addressed to Nektar Therapeutics, 455 Mission Bay Blvd South, 94158 - San Francisco USA.

EMA/PDCO/265751/2019
Amsterdam, 26 July 2019

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

EMEA-002492-PIP01-18

Scope of the application

Active substance(s):

Bempegaldesleukin

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoetic, and lymphoid tissue neoplasms)

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Nektar Therapeutics

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Nektar Therapeutics submitted for agreement to the European Medicines Agency on 29 October 2018 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 4 December 2018.

Supplementary information was provided by the applicant on 23 April 2019. 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 all conditions included in the category of malignant neoplasms (except nervous system, haematopoetic, and lymphoid tissue neoplasms)

2.1.1. Indication(s) targeted by the PIP

Bempegaldesleukin in combination with nivolumab (or with nivolumab and ipilimumab) for treatment of a relapsed or refractory paediatric malignant solid tumour in paediatric patients less than 18 years of age.

Bempegaldesleukin in combination with nivolumab (or with nivolumab and ipilimumab) for treatment of patients with unresectable or metastatic melanoma in the age group from 12 years to less than 18 years of age.

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

From birth to less than 18 years years of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 1** Open label trial in three parts (A, B and C) to evaluate safety, pharmacokinetics and pharmacodynamics of bempegaldesleukin in combination with nivolumab (Part A) or with nivolumab and ipilimumab (Part B) and to assess safety, pharmacokinetics, pharmacodynamics and efficacy of bempegaldesleukin in combination with nivolumab or with nivolumab and ipilimumab in children from birth to less than 18 years of age with a refractory or relapsed solid tumour.

Area	Number of measures	Description
		Study 2 Randomised, active-controlled trial to evaluate efficacy and safety of bempegaldesleukin in combination with nivolumab (or with nivolumab and ipilimumab) compared to the appropriate standard of care in paediatric patients from birth to less than 18 years of age with a solid tumour selected based on results from Study 1.
Extrapolation, modelling and simulation studies	1	**Study 3** Modelling and simulation study to evaluate PK and to recommend a dose regimen of bempegaldesleukin in combination with nivolumab, or with nivolumab plus ipilimumabin in the treatment of children from 12 years to less than 18 years of age with unresectable or metastatic melanoma.
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 May 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes