EMA/149056/2022

European Medicines Agency decision

P/0099/2022

of 18 March 2022

on the acceptance of a modification of an agreed paediatric investigation plan for bempegaldesleukin (EMEA-002492-PIP01-18-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/0298/2019 issued on 14 August 2019 and the decision P/0273/2020 issued on 15 July 2020,

Having regard to the application submitted by Nektar Therapeutics on 19 November 2021 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 25 February 2022, 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 bempegaldesleukin, powder for concentrate for solution 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 is addressed to Nektar Therapeutics, 455 Mission Bay Blvd South, 94158 - San Francisco, United States.

EMA/PDCO/710099/2021 Corr
Amsterdam, 25 February 2022

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

EMEA-002492-PIP01-18-M02

Scope of the application

Active substance(s):

Bempegaldesleukin

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic, 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 22 of Regulation (EC) No 1901/2006 as amended, Nektar Therapeutics submitted to the European Medicines Agency on 19 November 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0298/2019 issued on 14 August 2019 and the decision P/0273/2020 issued on 15 July 2020.

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

The procedure started on 4 January 2022.

Scope of the modification

Some measures and 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 Norwegian Paediatric Committee member 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 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, haematopoietic, and lymphoid tissue neoplasms).

2.1.1. Indication(s) targeted by the PIP

Bempegaldesleukin in combination with nivolumab 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 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 of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Open label trial in two parts (A and B) to evaluate safety, pharmacokinetics and pharmacodynamics of bempegaldesleukin in combination with nivolumab (Part A) and to assess safety, pharmacokinetics, pharmacodynamics and efficacy of bempegaldesleukin in combination with nivolumab (Part B) in children and adolescent from birth to less than 18 years of age with a refractory or relapsed solid tumour. **Study 2** Randomised, active-controlled trial to evaluate efficacy and safety of bempegaldesleukin in combination with nivolumab 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	**Study 3** Modelling and simulation study to evaluate PK and to recommend a dose regimen of bempegaldesleukin in combination with nivolumab in the treatment of children from 12 years to less than 18 years of age with unresectable or metastatic melanoma.
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 May 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes