EMA/384157/2023

European Medicines Agency decision

P/0370/2023

of 8 September 2023

on the agreement of a paediatric investigation plan and on the granting of a deferral for funobactam (EMEA-003326-PIP01-22) 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 application submitted by Evopoint Biosciences USA, Inc. on 12 September 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 July 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

A paediatric investigation plan for funobactam, powder for solution for injection/infusion, intravenous age-appropriate dosage form, 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 funobactam, powder for solution for injection/infusion, intravenous age-appropriate dosage form, 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 Evopoint Biosciences USA, Inc., 300 Baker Avenue, Suite 300, MA 01742 – Concord, United States.

EMA/PDCO/199123/2023
Amsterdam, 21 July 2023

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

EMEA-003326-PIP01-22

Scope of the application

Active substance(s):

Funobactam

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of infections caused by Gram-negative organisms (in combination with imipenem and cilastatin)

Pharmaceutical form(s):

Powder for solution for injection/infusion

Intravenous age-appropriate dosage form

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Evopoint Biosciences USA, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Evopoint Biosciences USA, Inc. submitted for agreement to the European Medicines Agency on 12 September 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 17 October 2022.

Supplementary information was provided by the applicant on 21 March 2023. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

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 Paediatric Committee member of Norway 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 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 infections caused by Gram-negative organisms (in combination with imipenem and cilastatin)

2.1.1. Indication(s) targeted by the PIP

- Treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis (AP)
- Treatment of hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP)

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 solution for injection/infusion

Intravenous age-appropriate dosage form

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1:** Development of an intravenous age-appropriate dosage form
Non-clinical studies	**Study 2:** 28-day repeated intravenous infusion toxicity and toxicokinetic study of funobactam in combination with imipenem and cilastatin in the rat with a 28-day recovery period
Clinical studies	**Study 3:** Open-label, single dose study to evaluate pharmacokinetics, safety and tolerability of funobactam in combination with imipenem and cilastatin in paediatric patients from birth to less than 18 years of age with suspected or confirmed infections due to Gram-negative organisms (XNW4107-P001) **Study 4:** Open-label, randomised, active controlled trial to evaluate safety, tolerability, pharmacokinetics and efficacy of funobactam in combination with imipenem and cilastatin in paediatric patients from

	birth to less than 18 years of age with suspected or confirmed infections due to Gram-negative organisms (XNW4107-P002)
Modelling and simulation studies	**Study 5:** Modelling and simulation analysis to evaluate the use of funobactam in combination with imipenem and cilastatin for the treatment of paediatric patients from birth to less than 18 years of age with HAP/VAP and cUTI, including AP due to Gram-negative organisms.
Other studies	Not applicable
Extrapolation plan	Studies 3, 4 and 5 are part of the extrapolation plan covering the paediatric population from birth to less than 18 years of age, as agreed by the PDCO.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2029
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:

The product is not authorised anywhere in the European Community.