EMA/29053/2024

European Medicines Agency decision

P/0027/2024

of 29 January 2024

on the acceptance of a modification of an agreed paediatric investigation plan for ceftobiprole medocaril (sodium) (Zevtera and associated names), (EMEA-000205-PIP02-11-M06) 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/0209/2012 issued on 27 September 2012, the decision P/0083/2014 issued on 4 April 2014, the decision P/0317/2016 issued on 5 December 2016, the decision P/0406/2018 issued on 20 December 2018, the decision P/0311/2020 issued on 17 March 2021 and the decision P/0529/2021 issued on 3 December 2021,

Having regard to the application submitted by Basilea Pharmaceutica Deutschland GmbH on 5 September 2023 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 15 December 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 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 ceftobiprole medocaril (sodium) (Zevtera and associated names), 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 Basilea Pharmaceutica Deutschland GmbH, Marie-Curie-Strasse 8, 79539 - Lörrach, Germany.

EMA/PDCO/417132/2023
Amsterdam, 15 December 2023

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

EMEA-000205-PIP02-11-M06

Scope of the application

Active substance(s):

Ceftobiprole medocaril (sodium)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of pneumonia

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Basilea Pharmaceutica Deutschland GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Basilea Pharmaceutica Deutschland GmbH submitted to the European Medicines Agency on 5 September 2023 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0209/2012 issued on 27 September 2012, the decision P/0083/2014 issued on 4 April 2014, the decision P/0317/2016 issued on 5 December 2016, the decision P/0406/2018 issued on 20 December 2018, the decision P/0311/2020 issued on 17 March 2021 and the decision P/0529/2021 issued on 3 December 2021.

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

The procedure started on 16 October 2023.

Scope of the modification

Some 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 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 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 pneumonia

2.1.1. Indication(s) targeted by the PIP

Treatment of nosocomial pneumonia

Treatment of community-acquired pneumonia

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	**Study 1** Development of age appropriate infusion solutions with concentrations higher than 2 mg ceftobiprole/mL for use in term and pre-term neonates
Non-clinical studies	**Study 2** Subcutaneous Pilot Toxicity Study with an Intravenous Comparative Phase (TOX8087) **Study 3** Subcutaneous Toxicity Study in Neonatal and Juvenile Albino Rats (TOX8611)
Clinical studies	**Study 4** Multicentre, open-label, single-dose, pharmacokinetic and tolerability study in children 3 months to less than 18 years of age **Study 5** Multicentre, randomised, investigator-blind, active controlled study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftobiprole versus intravenous standard of care cephalosporin treatment in paediatric patients aged from 3 months to less than 18 years with nosocomial pneumonia or community-acquired pneumonia (BPR-PIP-002)

	Study 6 Open-label study to evaluate the single-dose pharmacokinetics and safety of ceftobiprole in neonates and infants up to 3 months of age (BPR-PIP-001) **Study 7** Multicentre, open label study to evaluate the safety, tolerability, pharmacokinetics and efficacy multiple doses of ceftobiprole in term and pre-term neonates and infants up to 3 months of age with late-onset sepsis (BPR-PIP-003)
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 and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2024
Deferral for one or more studies 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 pneumonia

Authorised indication(s):

- Treatment of the following infections in term neonates, infants, children, adolescents and adults: hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP); community-acquired pneumonia (CAP).
  - Invented name(s): Zevtera and associated names
  - Authorised pharmaceutical form(s): Powder for concentrate for solution for infusion
  - Authorised route(s) of administration: Intravenous use
  - Authorised via decentralised procedure