EMA/626229/2021

# European Medicines Agency decision

P/0529/2021

of 3 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for ceftobiprole medocaril (sodium), (Zevtera and associated names), (EMEA-000205-PIP02-11-M05) 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.**

# European Medicines Agency decision

P/0529/2021

of 3 December 2021

on the acceptance of a modification of an agreed paediatric investigation plan for ceftobiprole medocaril (sodium), (Zevtera and associated names), (EMEA-000205-PIP02-11-M05) 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 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 and the decision P/0311/2020 issued on 14 August 2020,

Having regard to the application submitted by Basilea Pharmaceutica International Ltd. on 29 June 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 15 October 2021, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

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, 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 International Ltd., Grenzacherstrasse 487, 4005 – Basel, Switzerland.

EMA/PDCO/412853/2021 Corr
Amsterdam, 15 October 2021

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

EMEA-000205-PIP02-11-M05

## Scope of the application

**Active substance(s):**

Ceftobiprole medocaril (sodium)

**Invented name:**

Zevtera and associated names

**Condition(s):**

Treatment of pneumonia

**Authorised indication(s):**

See Annex II

**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 International Ltd.

**Information about the authorised medicinal product:**

See Annex II

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Basilea Pharmaceutica International Ltd. submitted to the European Medicines Agency on 29 June 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/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 and the decision P/0311/2020 issued on 14 August 2020.

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

The procedure started on 17 August 2021.

## Scope of the modification

Some measures 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 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 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 | Number of studies | Description |
|---|---|---|
| Quality-related studies | 1 | **Study 1**<br>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 | 2 | **Study 2**<br>Subcutaneous Pilot Toxicity Study with an Intravenous Comparative Phase (TOX8087)<br>**Study 3**<br>Subcutaneous Toxicity Study in Neonatal and Juvenile Albino Rats (TOX8611) |
| Clinical studies | 4 | **Study 4**<br>Multicentre, open-label, single-dose, pharmacokinetic and tolerability study in children 3 months to less than 18 years of age<br>**Study 5**<br>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)<br>**Study 6**<br>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)<br>**Study 7**<br>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 2023 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

## Condition(s) and authorised indication(s)

1. Treatment of pneumonia

Authorised indication(s):

Treatment of the following infections in adults:

- hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP);
- community-acquired pneumonia (CAP).

## Authorised pharmaceutical form(s)

Powder for concentrate for solution for infusion

## Authorised route(s) of administration

Intravenous use