

EMA/447233/2020

European Medicines Agency decision P/0382/2020

of 18 September 2020

on the acceptance of a modification of an agreed paediatric investigation plan for cefiderocol (Fetcroja), (EMA-002133-PIP01-17-M01) 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/0382/2020

of 18 September 2020

on the acceptance of a modification of an agreed paediatric investigation plan for cefiderocol (Fetcroja), (EMA-002133-PIP01-17-M01) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0266/2018 issued on 14 August 2018,

Having regard to the application submitted by Shionogi Limited on 26 March 2020 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 24 July 2020, 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 cefiderocol (Fetcroja), powder 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 Shionogi B.V., 33 Kingsway, Holborn, WC2B 6UF – London, United Kingdom.

EMA/PDCO/227308/2020
Amsterdam, 24 July 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002133-PIP01-17-M01

Scope of the application

Active substance(s):

Cefiderocol

Invented name:

Fetroja

Condition(s):

Treatment of infections due to aerobic Gram-negative bacteria

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Shionogi Limited

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Shionogi Limited submitted to the European Medicines Agency on 26 March 2020 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0266/2018 issued on 14 August 2018.

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

The procedure started on 26 May 2020.

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 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 infections due to aerobic Gram-negative bacteria

2.1.1. Indication(s) targeted by the PIP

Treatment of infections due to aerobic Gram-negative bacteria in children with limited therapeutic options

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 infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Generation of in-use stability data using water for injection, 5% dextrose and 0.45% sodium chloride injection as diluents for the powder for solution for infusion.
Non-clinical studies	1	Study 2: 3-week subcutaneous and intravenous toxicity study of cefiderocol in juvenile rats. (S-649266-TF-274-L)
Clinical studies	2	Study 3: Open-label, single-arm, uncontrolled trial to evaluate safety, tolerability and pharmacokinetics of single and multiple doses of cefiderocol in hospitalised paediatric patients from 3 months to less than 18 years of age with suspected or confirmed infections due to aerobic Gram-negative bacteria. Study 4: Open-label, single-arm, uncontrolled trial to evaluate safety, tolerability and pharmacokinetics of single and multiple doses of cefiderocol in hospitalised paediatric patients from birth to less than 3 months of age with suspected or confirmed infections due to aerobic Gram-negative bacteria.
Extrapolation, modelling and simulation studies	2	Study 5: Modelling and simulation study to evaluate the use of cefiderocol for the treatment of children from birth to less than 18 years of age with suspected or confirmed infections due to aerobic Gram-negative bacteria.

		Study 6: Extrapolation study to evaluate the use of cefiderocol for the treatment of children from birth to less than 18 years of age with suspected or confirmed infections due to aerobic Gram-negative bacteria.
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:	No
Date of completion of the paediatric investigation plan:	By March 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of infections due to aerobic Gram-negative bacteria

Authorised indication(s):

- Fetcroja is indicated for the treatment of infections due to aerobic Gram-negative organisms in adults

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use