EMA/380513/2016

European Medicines Agency decision

P/0160/2016

of 15 June 2016

on the acceptance of a modification of an agreed paediatric investigation plan for ferric citrate (coordination complex) (EMEA-001213-PIP02-12-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 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/0183/2013 issued on 31 July 2013 and the decision P/0218/2014 issued on 3 September 2014,

Having regard to the application submitted by Keryx Biopharmaceuticals, Inc. on 8 February 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 April 2016, 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 waiver.

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

[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 ferric citrate (coordination complex), film-coated tablet, powder for oral suspension, oral use, including changes to the waiver, 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 Keryx Biopharma UK Ltd., c/o Fieldfisher, Riverbank House, 2 Swan Lane EC4R 3TT – London, United Kingdom.

Done at London, 15 June 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/136532/2016
London, 29 April 2016

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

EMEA-001213-PIP02-12-M02

Scope of the application

Active substance(s):

Ferric citrate (coordination complex)

Invented name:

Fexeric

Condition(s):

Treatment of hyperphosphataemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Keryx Biopharmaceuticals, Inc.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Keryx Biopharmaceuticals, Inc. submitted to the European Medicines Agency on 8 February 2016 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0183/2013 issued on 31 July 2013 and the decision P/0218/2014 issued on 3 September 2014.

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

The procedure started on 1 March 2016.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 waiver 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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

1.1. Condition:

Treatment of hyperphosphataemia

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- for film-coated tablet, powder for oral suspension, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric investigation plan

2.1. Condition:

Treatment of hyperphosphataemia

2.1.1. Indication(s) targeted by the PIP

Treatment of hyperphosphataemia in patients with chronic kidney disease

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

Powder for oral suspension

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of a powder for oral suspension.
Non-clinical studies	0	**Study 2** *This study was deleted during procedure EMEA-001213-PIP02-12-M02.*
Clinical studies	1	**Study 3** Open-label, randomised, multi-centre, active controlled trial to evaluate safety and tolerability of ferric citrate in children from 1 to less than 18 years of age with hyperphosphataemia related to chronic kidney disease (CKD).

Extrapolation, modelling and simulation studies	0	Not applicable.
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:	Yes
Date of completion of the paediatric investigation plan:	By September 2020
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 hyperphosphataemia

Authorised indication(s):

- Control of hyperphosphataemia in adult patients with chronic kidney disease (CKD)

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use