EMA/796526/2018

European Medicines Agency decision

P/0355/2018

of 7 December 2018

on the acceptance of a modification of an agreed paediatric investigation plan for potassium citrate monohydrated / potassium hydrogen carbonate (EMEA-001357-PIP01-12-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/0257/2014 issued on 1 October 2014 and the decision P/0106/2016 issued on 15 April 2016,

Having regard to the application submitted by Advicenne Pharma on 16 July 2018 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 19 October 2018, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for potassium citrate monohydrated / potassium hydrogen carbonate, prolonged-release granules, oral 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 Advicenne Pharma, 2 rue Briçonnet, 30000 – Nîmes, France.

EMA/PDCO/493584/2018
London, 19 October 2018

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

EMEA-001357-PIP01-12-M02

Scope of the application

Active substance(s):

Potassium citrate monohydrated / potassium hydrogen carbonate

Condition(s):

Treatment of renal tubular acidosis

Pharmaceutical form(s):

Prolonged-release granules

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Advicenne Pharma

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Advicenne Pharma submitted to the European Medicines Agency on 16 July 2018 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/0257/2014 issued on 1 October 2014 and the decision P/0106/2016 issued on 15 April 2016.

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

The procedure started on 21 August 2018.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 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 annex 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 renal tubular acidosis

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- prolonged-release granules, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of renal tubular acidosis

2.1.1. Indication(s) targeted by the PIP

Treatment of distal renal tubular acidosis

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

From 6 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Prolonged-release granules

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Compatibility study of Potassium citrate monohydrated / Potassium hydrogen carbonate prolonged-release granules with food.
Non-clinical studies	0	Not applicable.
Clinical studies	2	**Study 2** Multicentre, open-label, non-inferiority, sequential study to evaluate the relative efficacy of Potassium citrate monohydrated / Potassium hydrogen carbonate prolonged-release granules and standard of care (SoC) on correcting metabolic acidosis (B21CS).

Area	Number of measures	Description
		Study 3 Multicentre, open-label extension study to evaluate the safety and tolerability of Potassium citrate monohydrated / Potassium hydrogen carbonate prolonged-release granules in subjects presenting a distal renal tubular acidosis (B22CS).
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:	No
Date of completion of the paediatric investigation plan:	By May 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes