EMA/666520/2016

European Medicines Agency decision

P/0296/2016

of 4 November 2016

on the acceptance of a modification of an agreed paediatric investigation plan for sodium zirconium cyclosilicate (EMEA-001539-PIP01-13-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.

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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/0210/2014 issued on 12 August 2014,

Having regard to the application submitted by ZS Pharma, Inc. on 24 June 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 September 2016, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

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 on the granting of a waiver.

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

(3) It is therefore appropriate to adopt a decision on the granting of a 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 sodium zirconium cyclosilicate, oral powder, age-appropriate paediatric formulation, oral use, gastric use, rectal 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

A waiver for sodium zirconium cyclosilicate, oral powder, age-appropriate paediatric formulation, oral use, gastric use, rectal use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to ZS Pharma, Inc, 508 Wrangler Dr., Suite 100, Coppell, TX 75019 – Coppell, United States.

EMA/PDCO/453756/2016
London, 16 September 2016 Corr

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

EMEA-001539-PIP01-13-M01

Scope of the application

Active substance(s):

Sodium zirconium cyclosilicate

Condition(s):

Treatment of hyperkalaemia

Pharmaceutical form(s):

Oral powder

Age-appropriate paediatric formulation

Route(s) of administration:

Oral use

Gastric use

Rectal use

Name/corporate name of the PIP applicant:

ZS Pharma, Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, ZS Pharma, Inc. submitted to the European Medicines Agency on 24 June 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0210/2014 issued on 12 August 2014.

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

The procedure started on 19 July 2016.

Scope of the modification

Some measures 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 in the scope set out in the Annex I of this opinion;
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 hyperkalaemia

The waiver applies to:

- newborn infants less than 30 weeks gestation or under 1500 g birth weight;
- oral powder, age-appropriate paediatric formulation, oral use, gastric use, rectal 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 hyperkalaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of hyperkalaemia

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

From birth (excluding newborn infants less than 30 weeks gestation or under 1500 g birth weight) to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral powder

Age appropriate paediatric formulation

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	2	**Study 1** Development of an age-appropriate oral formulation. **Study 2** Development of an age-appropriate rectal formulation.
Non-clinical studies	0	Not applicable.
Clinical studies	1	*Study 3 deleted during procedure EMEA-001539-PIP01-13-M01*

		Study 4 Ascending-dose, open-label followed by double-blind, placebo-controlled safety and efficacy study in children less than 18 years of age with hyperkalaemia.
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 January 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes