EMA/83093/2020

European Medicines Agency decision

P/0069/2020

of 18 March 2020

on the acceptance of a modification of an agreed paediatric investigation plan for Sodium zirconium cyclosilicate (Lokelma) (EMEA-001539-PIP01-13-M04) 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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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, the decision P/0296/2016 issued on 4 November 2016, the decision P/0226/2017 issued on 11 August 2017, and the decision P/0053/2018 issued on 1 March 2018,

Having regard to the application submitted by AstraZeneca AB on 25 October 2019 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 31 January 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 and to the deferral 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 deferral and 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 Sodium zirconium cyclosilicate (Lokelma), oral powder, oral use, nasogastric use, including changes to the deferral and 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 AstraZeneca AB, SE-15185- Södertälje, Sweden.

EMA/PDCO/609927/2019
Amsterdam, 31 January 2020

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

EMEA-001539-PIP01-13-M04

Scope of the application

Active substance(s):

Sodium zirconium cyclosilicate

Invented name:

Lokelma

Condition(s):

Treatment of hyperkalaemia

Pharmaceutical form(s):

Oral powder

Route(s) of administration:

Oral use

Nasogastric use

Name/corporate name of the PIP applicant:

AstraZeneca AB

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 25 October 2019 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/0210/2014 issued on 12 August 2014, the decision P/0296/2016 issued on

4 November 2016, the decision P/0226/2017 issued on 11 August 2017, and the decision P/0053/2018 issued on 1 March 2018.

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

The procedure started on 3 December 2019.

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 deferral 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 hyperkalaemia

The waiver applies to:

- newborn infants less than 37 weeks gestation or under 2500 g birth weight;
- oral powder, oral use, nasogastric 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 37 weeks gestation or under 2500 g birth weight) to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral powder

2.1.4. Measures

Area	**Number of measures**	**Description**
Quality-related studies	1	**Study 1** Development of an age-appropriate oral formulation *Study 2 deleted during procedure EMEA-001539-PIP01-13-M02*
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 2022
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 hyperkalaemia

Authorised indication(s):

- Lokelma is indicated for the treatment of hyperkalaemia in adult patients

Authorised pharmaceutical form(s):

Powder for oral suspension

Authorised route(s) of administration:

Oral use