EMA/143484/2023

European Medicines Agency decision

P/0106/2023

of 14 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for patiromer calcium (Veltassa), (EMEA-001720-PIP01-14-M03) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0235/2015 issued on 27 October 2015, the decision P/0027/2017 issued on 31 January 2017 and the decision P/0367/2021 issued on 8 September 2021,

Having regard to the application submitted by Vifor Fresenius Medical Care Renal Pharma France on 31 October 2022 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 February 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for patiromer calcium (Veltassa), powder for oral suspension, oral 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 Vifor Fresenius Medical Care Renal Pharma France, 100-101 Terrasse Boieldieu - Tour Franklin La Defense 8, 92042 - Paris La Defense Cedex, France.

EMA/PDCO/915598/2022
Amsterdam, 24 February 2023

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

EMEA-001720-PIP01-14-M03

Scope of the application

Active substance(s):

Patiromer calcium

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hyperkalaemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for oral suspension

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Vifor Fresenius Medical Care Renal Pharma France

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Vifor Fresenius Medical Care Renal Pharma France submitted to the European Medicines Agency on 31 October 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0235/2015 issued on 27 October 2015, the decision P/0027/2017 issued on 31 January 2017 and the decision P/0367/2021 issued on 8 September 2021.

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

The procedure started on 3 January 2023.

Scope of the modification

Some measures 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 Paediatric Committee member of Norway 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 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 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for oral suspension

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Open-label study to evaluate dose, safety and tolerability of patiromer calcium in children from 6 years to less than 18 years of age with hyperkalaemia due to chronic kidney disease. (RLY5016-206P) **Study 2** Single-blind dose titration study to evaluate efficacy and safety of patiromer calcium in the treatment of hyperkalaemia in children from 2 years to less than 18 years of age with chronic kidney disease. (RLY5016-305P) **Study 3** Open label, multiple dose, safety and pharmacodynamic study in children from birth to less than 6 years of age with hyperkalaemia. (RLY5016-208P)
Extrapolation, modelling and simulation studies	**Study 4** (study deleted in procedure EMEA-001720-PIP01-14-M03)

Area	Description
	Study 5 (new study added in procedure EMEA-001720-PIP01-14-M03) Extrapolation/interpolation population pharmacodynamic (PD) model to perform simulations to compare serum potassium response among paediatric and adult subjects.
Other studies	Not applicable
Other measures	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 June 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of hyperkalaemia

Authorised indication(s):

Veltassa is indicated for the treatment of hyperkalaemia in adults.

- Invented name(s): Veltassa
- Authorised pharmaceutical form(s): Powder for oral suspension
- Authorised route(s) of administration: Oral use
- Authorised via centralised procedure