EMA/81537/2024

European Medicines Agency decision

P/0058/2024

of 7 March 2024

on the acceptance of a modification of an agreed paediatric investigation plan for difelikefalin (Kapruvia), (EMEA-002565-PIP02-19-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 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/0172/2020 issued on 13 May 2020,

Having regard to the application submitted by Vifor Fresenius Medical Care Renal Pharma France on 11 October 2023 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 January 2024, 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 difelikefalin (Kapruvia), solution for injection/infusion, intravenous 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 Defense 8, 92042 – Glattbrugg, France.

EMA/PDCO/480670/2023
Amsterdam, 19 January 2024

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

EMEA-002565-PIP02-19-M01

Scope of the application

Active substance(s):

Difelikefalin

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of chronic kidney disease associated pruritus

Pharmaceutical form(s):

Solution for injection/infusion

Route(s) of administration:

Intravenous 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 11 October 2023 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/0172/2020 issued on 13 May 2020.

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

The procedure started on 20 November 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 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 chronic kidney disease associated pruritus

The waiver applies to:

- the paediatric population from birth to less than 12 years;
- solution for injection/infusion, intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of chronic kidney disease associated pruritus

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic kidney disease associated pruritus in haemodialysis patients

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

From 12 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection/infusion

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	Open-label, non-comparative trial to evaluate pharmacokinetics, safety and activity of difelikefalin in paediatric subjects on haemodialysis from 12 to less than 18 years of age with chronic kidney disease associated pruritus.
Extrapolation, modelling and simulation studies	Not applicable.
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 March 2026
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 chronic kidney disease associated pruritus

Authorised indication(s):

- Treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis
  - Invented name(s): Kapruvia
  - Authorised pharmaceutical form(s): solution for injection
  - Authorised route(s) of administration: Intravenous use
  - Authorised via centralised