EMA/127825/2023

European Medicines Agency decision

P/0142/2023

of 14 April 2023

on the acceptance of a modification of an agreed paediatric investigation plan for rimegepant (Vydura), (EMEA-002812-PIP02-20-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 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/0063/2021 issued on 18 February 2021 and the decision P/0299/2022 issued on 10 August 2022,

Having regard to the application submitted by Biohaven Pharmaceutical Ireland DAC on 16 November 2022 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 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 rimegepant (Vydura), oral lyophilisate, 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 Biohaven Pharmaceutical Ireland DAC, 6th Floor, South Bank House, Barrow Street, D04 TR29 - Dublin 4, Ireland.

EMA/PDCO/906619/2022
Amsterdam, 24 February 2023

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

EMEA-002812-PIP02-20-M02

Scope of the application

Active substance(s):

Rimegepant

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of migraine headaches

Pharmaceutical form(s):

Oral lyophilisate

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Biohaven Pharmaceutical Ireland DAC

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Biohaven Pharmaceutical Ireland DAC submitted to the European Medicines Agency on 16 November 2022 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/0063/2021 issued on 18 February 2021 and the decision P/0299/2022 issued on 10 August 2022.

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

The procedure started on 3 January 2023.

Scope of the modification

Some timelines 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 planand 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 migraine headaches

- the paediatric population from birth to less than 6 years of age;
- oral lyophilisate, 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 migraine headaches

2.1.1. Indication(s) targeted by the PIP

Treatment of migraine attacks in children and adolescents

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

From 6 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oral lyophilizate

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Development of an age appropriate oral lyophilisate.
Non-clinical studies	Not applicable.
Clinical studies	**Study 2** Open-label, single dose pharmacokinetic and tolerability study of rimegepant in paediatric subjects from 6 years to less than 12 years of age with a history of migraine headache including assessment of palatability of the formulation. **Study 3** Double-blind, placebo-controlled, group sequential placebo-controlled study to assess the efficacy and safety of rimegepant for the acute treatment of migraine (with or

	without aura) in children and adolescents from 6 to less than 18 years of age. **Study 4** Open-label study to assess the safety and tolerability of long term use of rimegepant taken up to once per day by children and adolescents (from 6 to less than 18 years of age) with migraine.
Extrapolation, modelling and simulation studies	**Study 5** Population PK model based on adult data to establish paediatric doses to be used in paediatric studies 1, 2 and 3 and confirmation of appropriateness of these doses.
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 October 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 migraine

Authorised indication(s):

- Acute treatment of migraine with or without aura in adults;
  - Invented name(s): Vydura
  - Authorised pharmaceutical form(s): Oral lyophilisate
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure
- Preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month
  - Invented name(s): Vydura
  - Authorised pharmaceutical form(s): Oral lyophilisate
  - Authorised route(s) of administration: Oral use
  - Authorised via centralised procedure