

EMA/638303/2022

## European Medicines Agency decision P/0299/2022

of 10 August 2022

on the acceptance of a modification of an agreed paediatric investigation plan for rimegepant (Vydura), (EMA-002812-PIP02-20-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.**

# European Medicines Agency decision

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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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the European Medicines Agency's decision P/0063/2021 issued on 18 February 2021,

Having regard to the application submitted by Biohaven Pharmaceutical Ireland DAC on 21 March 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 June 2022, 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> 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/181280/2022  
Amsterdam, 24 June 2022

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002812-PIP02-20-M01

### Scope of the application

**Active substance(s):**

Rimegepant

**Invented name:**

Vydura

**Condition(s):**

Treatment of migraine headaches

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Oral lyophilisate

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Biohaven Pharmaceutical Ireland DAC

**Information about the authorised medicinal product:**

See Annex II

## **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 21 March 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.

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

The procedure started on 25 April 2022.

## **Scope of the modification**

Some measures of the Paediatric Investigation Plan have been modified. The pharmaceutical form was amended.

## **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 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 lyophilisate

### 2.1.4. Measures

| Area                    | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Quality-related studies | <b>Study 1</b><br>Development of an age appropriate oral lyophilisate.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Non-clinical studies    | Not applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Clinical studies        | <b>Study 2</b><br>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.<br><b>Study 3</b><br>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. |

|                                                 |                                                                                                                                                                                                                       |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                 | <b>Study 4</b><br><br>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 | <b>Study 5</b><br><br>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**

**Condition(s) and authorised indication(s):**

1. Treatment of migraine

Authorised indication(s):

- Acute treatment of migraine with or without aura in adults;
- Preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month

**Authorised pharmaceutical form(s):**

Oral lyophilisate

**Authorised route(s) of administration:**

Oral use