



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/28876/2020

## European Medicines Agency decision P/0046/2020

of 29 January 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for atogepant (EMEA-002530-PIP01-18) 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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# 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the application submitted by Allergan Pharmaceuticals International Limited on 19 December 2018 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2019, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A paediatric investigation plan for atogepant, tablet, age appropriate oral solid formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

**Article 2**

A deferral for atogepant, tablet, age appropriate oral solid formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

**Article 3**

A waiver for atogepant, tablet, age appropriate oral solid formulation, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

**Article 4**

This decision is addressed to Allergan Pharmaceuticals International Limited, Clonshaugh Business & Technology Park, D17 E400 - Dublin 17, Ireland.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/545698/2019  
Amsterdam, 11 December 2019

## Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-002530-PIP01-18

### Scope of the application

**Active substance(s):**

Atogepant

**Condition(s):**

Prevention of migraine headaches

**Pharmaceutical form(s):**

Tablet

Age appropriate oral solid formulation

**Route(s) of administration:**

Oral use

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

Allergan Pharmaceuticals International Limited

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Allergan Pharmaceuticals International Limited submitted for agreement to the European Medicines Agency on 19 December 2018 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 29 January 2019.

Supplementary information was provided by the applicant on 9 September 2019. The applicant proposed modifications to the paediatric investigation plan.



## Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 annex 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:

Prevention of migraine headaches.

The waiver applies to:

- the paediatric population from birth to less than 6 years of age;
- tablet, age appropriate oral solid formulation, 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:

Prevention of migraine headaches

### 2.1.1. Indication(s) targeted by the PIP

Prevention of migraine headaches

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

From 6 to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Tablet

Age appropriate oral solid formulation

### 2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	<b>Study 1</b> Development of lower strength tablet/capsule appropriate to the paediatric population from 6 to less than 12 year of age and for those unable to swallow existing dose form to administer dose higher than 20mg.
Non-clinical studies	1	<b>Study 2</b> Definitive juvenile toxicity study to determine the safety of atogepant in juvenile rats (3101-XXX-052).

Clinical studies	3	<p><b>Study 3</b></p> <p>Randomized, double-blind, placebo-controlled, parallel group study to assess PK, efficacy, safety and tolerability of atogepant as compared to placebo for the preventive treatment of episodic migraine in paediatric patients from 6 to less than 18 years of age (Study 3101-307-002).</p> <p><b>Study 4</b></p> <p>Randomized, double-blind, placebo-controlled, parallel group study to assess PK, efficacy, safety and tolerability of atogepant as compared to placebo for the preventive treatment of chronic migraine in paediatric patients from 6 to less than 18 years of age (Study 3101-308-002).</p> <p><b>Study 5</b></p> <p>Open-label study to evaluate the long-term safety of daily administration of atogepant for preventive treatment of episodic migraine in paediatric patients from 6 to less than 18 years of age (3101-310-002).</p>
Extrapolation, modelling and simulation studies	1	<p><b>Study 6</b></p> <p>Development of Population PK model to support selection of initial paediatric dose(s) (3101-S03-000).</p>
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 April 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes