



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/151862/2018

## European Medicines Agency decision

P/0128/2018

of 11 April 2018

on the acceptance of a modification of an agreed paediatric investigation plan for ponesimod (EMEA-000798-PIP01-09-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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on the acceptance of a modification of an agreed paediatric investigation plan for ponesimod (EMA-000798-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 European Medicines Agency's decision P/0286/2012 issued on 23 November 2012,

Having regard to the application submitted by Actellion Registration Limited on 8 December 2017 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 23 February 2018, 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.

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

Has adopted this decision:

**Article 1**

Changes to the agreed paediatric investigation plan for ponesimod, film-coated tablet, 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 Actelion Registration Ltd, Chiswick Tower 13th floor, 89 Chiswick High Road, W4 4AL – London, United Kingdom.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/828952/2017

London, 23 February 2018

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000798-PIP01-09-M01

### Scope of the application

**Active substance(s):**

Ponesimod

**Condition(s):**

Treatment of multiple sclerosis

**Pharmaceutical form(s):**

Film-coated tablet

**Route(s) of administration:**

Oral use

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

Actelion Registration Limited

### Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Actelion Registration Limited submitted to the European Medicines Agency on 8 December 2017 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/0286/2012 issued on 23 November 2012.

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

The procedure started on 3 January 2018.

### Scope of the modification

Some measures and 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 Norwegian Paediatric Committee member 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 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

Treatment of multiple sclerosis

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age;
- film-coated tablet, oral use ;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

# 2. Paediatric Investigation Plan

## 2.1. Condition

Treatment of multiple sclerosis

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

Treatment of paediatric patients with relapsing-remitting multiple sclerosis

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

From 10 to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Film-coated tablet

### 2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	1	<b>Study 1</b> 9 week repeated dose oral juvenile toxicity study of ponesimod in 4 week old rats, with a 4 week recovery period.
Clinical	1	<b>Study 2</b> Multi-centre, randomized, open-label, active controlled, parallel-group study to evaluate the pharmacokinetics, pharmacodynamics, efficacy, safety, and tolerability of ponesimod compared to interferon beta-1a during 24 months in paediatric patients from 10 to less than 18 years with relapsing-remitting multiple sclerosis (RRMS).

Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

### 3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2022
Deferral for one or more studies contained in the paediatric investigation plan:	Yes