EMA/312727/2017

European Medicines Agency decision

P/0135/2017

of 7 June 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral for pimodivir (EMEA-001975-PIP01-16) 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 agreement of a paediatric investigation plan and on the granting of a deferral for pimodivir (EMEA-001975-PIP01-16) 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[1],

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[2],

Having regard to the application submitted by Janssen-Cilag International NV on 16 May 2016 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 21 April 2017, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 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.

(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.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for pimodivir, tablet, age-appropriate oral dosage form, oral use, gastric 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 pimodivir, tablet, age-appropriate oral dosage form, oral use, gastric 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

This decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, 2340 – Beerse, Belgium.

EMA/PDCO/120895/2017
London, 21 April 2017

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

EMEA-001975-PIP01-16

Scope of the application

Active substance(s):

Pimodivir

Condition(s):

Treatment of influenza

Pharmaceutical form(s):

Tablet

Age-appropriate oral dosage form

Route(s) of administration:

Oral use

Gastric use

Name/corporate name of the PIP applicant:

Janssen-Cilag International NV

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted for agreement to the European Medicines Agency on 16 May 2016 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 21 June 2016.

Supplementary information was provided by the applicant on 30 January 2017. 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 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   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 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

Not applicable.

2. Paediatric investigation plan

2.1. Condition

Treatment of influenza

2.1.1. Indication(s) targeted by the PIP

Treatment of influenza type A in children from birth to less than 18 years of age at risk of influenza-related complications including hospitalized patients

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Tablet, age-appropriate oral dosage form

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate oral formulation (dispersible tablets or oral solution) for children younger than 13 years of age.
Non-clinical studies	1	**Study 2** Definitive juvenile toxicity study
Clinical studies	3	**Study 3** Randomized, double-blind, placebo-controlled, multicentre study to evaluate the efficacy and safety of pimodivir in combination with oseltamivir compared to placebo in combination with oseltamivir in hospitalized patients with influenza A infection from 13 to less than 18 years of age (and adults) (Study 63623872FLZ3001). **Study 4** Randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of pimodivir compared to placebo in combination with oseltamivir in non-hospitalized patients with influenza A infection who are at risk of developing influenza related complications from 13 years to less than 18 years of age (and adults) (Study 63623872FLZ3002).

		Study 5 Open-label study to evaluate the safety, tolerability, activity (antiviral effect, clinical outcome) and pharmacokinetics of pimodivir in combination with oseltamivir in hospitalised paediatric patients with influenza A infection OR non-hospitalized paediatric patients with influenza A infection who are at risk of developing influenza related complications from birth to less than 13 years of age.
Extrapolation, modelling and simulation studies	1	**Study 6** Modelling and simulation study to evaluate the use and support dosing regimen of pimodivir in paediatric patients from birth to less than 18 years of age with influenza A infection hospitalized and at high risk of developing influenza related complications.
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 June 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes