EMA/873049/2018

European Medicines Agency decision

P/0003/2019

of 3 January 2019

on the acceptance of a modification of an agreed paediatric investigation plan for pimodivir (EMEA-001975-PIP01-16-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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on the acceptance of a modification of an agreed paediatric investigation plan for pimodivir (EMEA-001975-PIP01-16-M02) 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 European Medicines Agency's decision P/0135/2017 issued on 7 June 2017,

Having regard to the application submitted by Janssen-Cilag International NV on 10 August 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 November 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.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for pimodivir, tablet, age-appropriate oral dosage form, oral use, gastric 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 Janssen-Cilag International NV, Turnhoutseweg 30, 2340 – Beerse, Belgium.

EMA/PDCO/574132/2018
London, 16 November 2018

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

EMEA-001975-PIP01-16-M02

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 22 of Regulation (EC) No 1901/2006 as amended, Janssen-Cilag International NV submitted to the European Medicines Agency on 10 August 2018 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0135/2017 issued on 7 June 2017.

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

The procedure started on 18 September 2018.

Scope of the modification

Some measures 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 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

To be used in combination with oseltamivir for the treatment of influenza A in children from birth to less than 18 years of age with complicated influenza or at high risk for complications

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 standard of care compared to placebo in combination with standard of care 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 in combination with standard of care compared to placebo in combination with standard of care 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** Study to evaluate the safety, tolerability, activity (antiviral effect, clinical outcome) and pharmacokinetics of pimodivir in combination with standard of care 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 Children from 2 to less than 13 years of age: double-blind, placebo-controlled design Children from birth to less than 2 years of age: open-label design
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