EMA/312393/2021

European Medicines Agency decision

P/0257/2021

of 7 July 2021

on the acceptance of a modification of an agreed paediatric investigation plan for peramivir (EMEA-001856-PIP02-16-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 peramivir (EMEA-001856-PIP02-16-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/0340/2016 issued on 25 November 2016.

Having regard to the application submitted by BioCryst Ireland Limited on 15 February 2021 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 21 May 2021, 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 and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the 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

Changes to the agreed paediatric investigation plan for peramivir, concentrate for solution for infusion, intravenous use, including changes to the deferral, 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 BioCryst Ireland Limited, Block 4, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

EMA/PDCO/117167/2021
Amsterdam, 21 May 2021

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

EMEA-001856-PIP02-16-M02

Scope of the application

Active substance(s):

Peramivir

Condition(s):

Treatment of influenza

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

BioCryst Ireland Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, BioCryst Ireland Limited submitted to the European Medicines Agency on 15 February 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0340/2016 issued on 25 November 2016.

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

The procedure started on 23 March 2021.

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 and to the deferral 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

Treatment of influenza virus infection in the paediatric population from birth to less than 18 years of age

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)

Concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	3	**Study 1** Open-label, multicentre, non-controlled study to assess pharmacokinetics, safety and efficacy of peramivir, administered intravenously, in paediatric patients from 28 days to less than 16 years of age with influenza virus infection (Shionogi 0918T0633) **Study 2** Open-label, randomised, active-controlled trial to evaluate pharmacokinetics, safety and effectiveness of peramivir compared to oseltamivir in children from birth to less than 18 years of age with uncomplicated influenza (BCX1812-305) **Study 3** deleted in procedure EMEA-001856-PIP02-16-M02
Extrapolation, modelling and simulation studies	2	**Study 4** deleted in procedure EMEA-001856-PIP02-16-M02 **Study 5** deleted in procedure EMEA-001856-PIP02-16-M02

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 October 2019
Deferral for one or more measures contained in the paediatric investigation plan:	Yes