EMA/764433/2016

European Medicines Agency decision

P/0340/2016

of 25 November 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral for peramivir (EMEA-001856-PIP02-16) 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 peramivir (EMEA-001856-PIP02-16) 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 BioCryst UK Ltd. on 8 August 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 11 November 2016, 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 peramivir, concentrate for solution for infusion, intravenous 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 peramivir, concentrate for solution for infusion, intravenous 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 BioCryst UK Ltd. (c/o Morgan Lewis & Bockius), Condor House, 5 - 10 St. Paul's Churchyard, EC4M 8AL – London, United Kingdom.

EMA/PDCO/692901/2016
London, 11 November 2016

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

EMEA-001856-PIP02-16

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 UK Ltd.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, BioCryst UK Ltd. submitted for agreement to the European Medicines Agency on 8 August 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 13 September 2016.

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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 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** Open-label, randomised, active-controlled superiority trial to evaluate pharmacokinetics, safety and efficacy of peramivir compared to oseltamivir in patients hospitalized with serious influenza infection from birth to less than 18 years of age (BCX1812-307)

Extrapolation, modelling and simulation studies	2	**Study 4** Extrapolation study to evaluate the use of peramivir in paediatric patients from birth to less than 18 years of age with uncomplicated influenza (BCX1812-PPK-2 (Part1)) **Study 5** Extrapolation study to evaluate the use of peramivir in paediatric patients from birth to less than 18 years of age at high risk of influenza complications (BCX1812-PPK-2 (Part 2))
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 May 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes