EMA/337482/2016

European Medicines Agency decision

P/0163/2016

of 15 June 2016

on the agreement of a paediatric investigation plan and on the granting of a deferral for imipenem (monohydrate) / cilastatin (sodium) / relebactam (MK-7655A), (EMEA-001809-PIP01-15) 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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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 Merck Sharp & Dohme (Europe), Inc. on 5 June 2015 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 29 April 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 imipenem (monohydrate) / cilastatin (sodium) / relebactam (MK-7655A), powder for solution for infusion, parenteral 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 imipenem (monohydrate) / cilastatin (sodium) / relebactam (MK-7655A), powder for solution for infusion, parenteral 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 Merck Sharp & Dohme (Europe), Inc., Clos du Lynx, 5, 1200 – Brussels, Belgium

Done at London, 15 June 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/90220/2016
London, 29 April 2016

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

EMEA-001809-PIP01-15

Scope of the application

Active substance(s):

Imipenem (monohydrate) / cilastatin (sodium) / relebactam (MK-7655A)

Condition(s):

Treatment of Gram-negative bacterial infections

Pharmaceutical form(s):

Powder for solution for infusion

Route(s) of administration:

Parenteral use

Name/corporate name of the PIP applicant:

Merck Sharp & Dohme (Europe), Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp & Dohme (Europe), Inc. submitted for agreement to the European Medicines Agency on 5 June 2015 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 14 July 2015.

Supplementary information was provided by the applicant on 1 February 2016. 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 Gram-negative bacterial infections

2.1.1. Indication(s) targeted by the PIP

Treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP)

Treatment of serious bacterial infections including HABP, VABP, complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI) caused by known or clinically suspected carbapenem-resistant pathogens in patients with limited treatment options

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)

Powder for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	2	**Study 1** Dose range-finding juvenile toxicity study **Study 2** Definitive juvenile toxicity study

Area	Number of measures	Description
Clinical studies	3	**Study 3** Open-label study to evaluate the pharmacokinetics, safety and tolerability of a single dose of imipenem (monohydrate) / cilastatin (sodium) / relebactam (MK-7655A) and to identify the appropriate dose of MK-7655A in children from birth to less than 18 years of age with Gram-negative bacterial infections **Study 4** Open-label, randomised, active-controlled trial to evaluate safety, tolerability and efficacy of MK-7655A in children from birth to less than 18 years of age with Gram-negative bacterial infections **Study 5** Open-label, multiple-dose trial to evaluate pharmacokinetics, safety and tolerability of MK-7655A in children from birth to less than 3 months of age with late-onset sepsis
Extrapolation, modelling and simulation studies	2	**Study 6** Modelling and simulation study to select doses in children from birth to less than 18 years of age with Gram-negative bacterial infections **Study 7** Extrapolation study to evaluate the use of MK-7655A in the proposed paediatric indications in children from birth to less than 18 years of age with serious Gram-negative bacterial infections
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:	Yes
Date of completion of the paediatric investigation plan:	By March 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes