EMA/364926/2015

European Medicines Agency decision

P/0159/2015

of 13 July 2015

on the acceptance of a modification of an agreed paediatric investigation plan for meropenem (EMEA-000898-PIP01-10-M01) 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 meropenem (EMEA-000898-PIP01-10-M01) 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/26/2011 issued on 27 January 2011,

Having regard to the application submitted by NeoMero Consortium on 2 March 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 May 2015, 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 meropenem, powder for solution for injection/infusion, intravenous 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 NeoMero Consortium, Fondazione PENTA Onlus, Corso Stati Uniti 4 c/o Torre di Ricerca Pediatrica, 35127 - Padova, Italy.

Done at London, 13 July 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/146260/2015 corr
London, 22 May 2015

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

EMEA-000898-PIP01-10-M01

Scope of the application

Active substance(s):

Meropenem

Condition(s):

Treatment of bacterial sepsis

Treatment of bacterial meningitis

Pharmaceutical form(s):

Powder for solution for injection/infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

NeoMero Consortium

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, NeoMero Consortium submitted to the European Medicines Agency on 2 March 2015 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/26/2011 issued on 27 January 2011.

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

The procedure started on 24 March 2015.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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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 and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

1.1. Condition

Treatment of bacterial sepsis

The waiver applies to:

- all subsets of the paediatric population from 3 months to less than 18 years of age;
- for powder for solution for injection or infusion, intravenous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

1.2. Condition

Treatment of bacterial meningitis

The waiver applies to:

- all subsets of the paediatric population from 3 months to less than 18 years of age;
- for powder for solution for injection or infusion, intravenous use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of bacterial sepsis

2.1.1. Indication(s) targeted by the PIP

Treatment of bacterial sepsis in neonates and infants below 3 months of age

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

From birth to less than 3 months of age

2.1.3. Pharmaceutical form(s)

Powder for solution for injection or infusion

2.1.4. Studies

Area	Number of studies	Description
Quality-related studies	0	Not applicable.

Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 1** Open label, randomised, multicentre, active comparator-controlled, efficacy and safety study in neonates and infants with bacterial sepsis.

2.2. Condition

Treatment of bacterial meningitis

2.2.1. Indication(s) targeted by the PIP

Treatment of bacterial meningitis in neonates and infants below 3 months of age

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

From birth to less than 3 months of age

2.2.3. Pharmaceutical form(s)

Powder for solution for injection or infusion

2.2.4. Studies

Area	Number of studies	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 2** Multicentre, single arm, open label PK and safety study in neonates and infants with bacterial meningitis.

3. Follow-up, completion and deferral of PIP

Measures to address long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes