EMA/114881/2015

European Medicines Agency decision

P/0054/2015

of 9 March 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral for ceftriaxone / sulbactam (EMEA-001568-PIP03-14) 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 Venus Pharma GmbH on 9 June 2014 under Article 16(1) of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 February 2015, 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 ceftriaxone / sulbactam, powder for solution for injection or 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 ceftriaxone / sulbactam, powder for solution for injection or 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 Venus Pharma GmbH, Am Bahnhof 1-3, D 59368 – Werne, Germany.

Done at London, 9 March 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/721804/2014

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

EMEA-001568-PIP03-14

Scope of the application

Active substance(s):

Ceftriaxone / Sulbactam

Condition(s):

Treatment of bacterial infections

Pharmaceutical form(s):

Powder for solution for injection or infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Venus Pharma GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Venus Pharma GmbH submitted for agreement to the European Medicines Agency on 9 June 2014 an application for a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 16 July 2014.

Supplementary information was provided by the applicant on 19 November 2014. The applicant proposed modifications to the paediatric investigation plan and requested a deferral.

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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.

London, 13 February 2015

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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 bacterial infections

2.1.1. Indication(s) targeted by the PIP

Treatment of lower respiratory tract infections

Treatment of urinary tract infections

Treatment of bacterial sepsis

Treatment of chronic suppurative otitis media

Treatment of bone infections

Treatment of joint infections

Treatment of skin infections

Treatment of soft tissue infections

Prophylaxis of perioperative infections

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 injection or infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	1	**Study 1:** Juvenile toxicity study to evaluate the toxicity of Sodium Ethylene Diamine Tetra acetic Acid (Na-EDTA)
Clinical studies	1	**Study 2:** Open label pharmacokinetic study in neonates with bacterial infections.

Area	Number of measures	Description
Extrapolation, modelling and simulation studies	1	**Study 3:** Extrapolation, Modelling and simulation study, to evaluate the use of the product in the proposed paediatric indication in children from 6 months to less than 18 years of age.
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 June 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes