EMA/709640/2017 Corr

European Medicines Agency decision

P/0346/2017

of 1 December 2017

on the acceptance of a modification of an agreed paediatric investigation plan for thrombomodulin alfa (EMEA-001363-PIP01-12-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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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/0211/2013 issued on 3 September 2013,

Having regard to the application submitted by Asahi Kasei Pharma America Corporation on 19 July 2017 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 13 October 2017, 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 thrombomodulin alfa, solution for 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 Asahi Kasei Pharma America Corporation, 200 Fifth Avenue, 02451 - Waltham, Massachusetts, United States.

EMA/PDCO/470157/2017 Corr
London, 13 October 2017

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

EMEA-001363-PIP01-12-M01

Scope of the application

Active substance(s):

Thrombomodulin alfa

Condition(s):

Treatment of sepsis

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Asahi Kasei Pharma America Corporation

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Asahi Kasei Pharma America Corporation submitted to the European Medicines Agency on 19 July 2017 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0211/2013 issued on 3 September 2013.

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

The procedure started on 15 August 2017.

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 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 sepsis

2.1.1. Indication targeted by the PIP

Treatment of patients with severe sepsis (respiratory failure and/or septic shock) with coagulopathy.

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

Solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable
Non-clinical	0	Not applicable
Clinical	3	**Measure 1** Exploratory in-vitro study to investigate pharmacodynamics of thrombomodulin alfa in plasma of children from birth to less than 8 years of age **Measure 2** Open-label, multi-centre, non-comparative study to evaluate pharmacokinetics, pharmacodynamics, safety and tolerability of thrombomodulin alfa as add-on to best standard of care in children from birth to less than 18 years of age with severe sepsis and coagulopathy **Measure 3** Randomised, placebo-controlled, multi-centre, double-blind study to evaluate the safety and efficacy of thrombomodulin alfa as add-on to best standard of care in children from birth to less than 18 years old with severe sepsis and coagulopathy

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 June 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes