



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/483101/2013

European Medicines Agency decision

P/0211/2013

of 3 September 2013

on the agreement of a paediatric investigation plan and on the granting of a deferral for thrombomodulin alfa (EMEA-001363-PIP01-12) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Asahi Kasei Pharma America Corporation on 2 October 2012 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 19 July 2013, 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 thrombomodulin alfa, 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 thrombomodulin alfa, 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 2

This decision is addressed to Asahi Kasei Pharma America Corporation, 200 Fifth Avenue, 02451 Waltham, Massachusetts, United States.

Done at London, 3 September 2013

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/261608/2013

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

EMA-001363-PIP01-12

Scope of the application

Active substance(s):

Thrombomodulin alfa

Condition:

Treatment of sepsis

Pharmaceutical form:

Solution for infusion

Route of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Asahi Kasei Pharma America Corporation

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Asahi Kasei Pharma America Corporation submitted for agreement to the European Medicines Agency on 2 October 2012 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 November 2012.

Supplementary information was provided by the applicant on 23 April 2013.

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, 19 July 2013

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

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 18 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 and 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