



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/666263/2012

European Medicines Agency decision P/0251/2012

of 24 October 2012

on the acceptance of a modification of an agreed paediatric investigation plan for peginesatide, (EMA-000646-PIP01-09-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 peginesatide, (EMA-000646-PIP01-09-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 726/2004¹,

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 European Medicines Agency's decision P/130/2012 issued on 28 July 2010,

Having regard to the application submitted by Takeda Global Research & Development Centre (Europe) Ltd on 18 June 2012 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 7 September 2012, 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 peginesatide, solution for injection, intravenous use, subcutaneous 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 Takeda Global Research & Development Centre (Europe) Ltd, 61 Aldwych, WC2B 4AE – London, United Kingdom.

Done at London, 24 October 2012

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



EUROPEAN MEDICINES AGENCY
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EMA/PDCO/475978/2012 Corr

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

EMA-000646-PIP01-09-M01

Scope of the application

Active substance(s):

Peginesatide

Condition(s):

Treatment of symptomatic anaemia associated with chronic kidney disease

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Subcutaneous use

Name/corporate name of the PIP applicant:

Takeda Global Research & Development Centre (Europe) Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Global Research & Development Centre (Europe) Ltd submitted to the European Medicines Agency on 18 June 2012 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/130/2010 issued on 28 July 2010.

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

The procedure started on 11 July 2012.

Scope of the modification

Some measures and/or 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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 7 September 2012

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

1.1. Condition: treatment of symptomatic anaemia associated with chronic kidney disease

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- for solution for injection, intravenous route, subcutaneous route;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: treatment of symptomatic anaemia associated with chronic kidney disease

2.1.1. Indication(s) targeted by the PIP

Treatment of symptomatic anaemia associated with chronic kidney disease in paediatric patients undergoing dialysis.

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

From 1 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	6	Study 1 Open-label, single-arm, multicentre, multiple-dose uncontrolled study to evaluate safety and pharmacokinetics (PK) of AF37702 injection for maintenance treatment of anaemia in children from 1 to less than 18 years with chronic kidney disease on haemodialysis and already receiving Erythropoietin Stimulating Agent (ESA) therapy. Study 2 Open-label, single arm follow-up study to evaluate the safety and tolerability of AF37702 injection for the maintenance treatment of

		<p>anaemia in children with chronic kidney disease undergoing dialysis. Subjects will be those who complete the titration/evaluation periods of study 1.</p> <p>Study 3</p> <p>Open-label, single-arm, dose titration study to evaluate safety and pharmacokinetics of AF37702 injection for correction of anemia in children from 1 to less than 18 years with chronic kidney disease who are undergoing dialysis and have not received previous treatment with Erythropoietin Stimulating Agent (ESA-naïve cases).</p> <p>Study 4</p> <p>Open-label, single arm follow-up study to evaluate the safety and tolerability of AF37702 injection for the treatment of anaemia in children with chronic kidney disease. Subjects will be those who complete the correction/titration and evaluation periods of study 3.</p> <p>Study 5</p> <p>Open-label, randomised, multicentre, active controlled, parallel group study to evaluate the efficacy and safety of AF37702 injection for the treatment of anaemia in children from 1 to less than 18 years with chronic kidney disease undergoing dialysis, all currently receiving Erythropoietin Stimulating Agent (ESA) treatment.</p> <p>Study 6</p> <p>Open-label, single arm follow-up study to evaluate the safety and tolerability of AF37702 injection for the treatment of anaemia in children with chronic kidney disease undergoing dialysis. Subjects will be those who complete the titration/evaluation periods of study 5.</p>
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3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By June 2027
Deferral for one or more studies contained in the paediatric investigation plan:	Yes