



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/281873/2015

European Medicines Agency decision

P/0096/2015

of 8 May 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for simtuzumab (EMEA-001511-PIPO2-13) 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.



European Medicines Agency decision

P/0096/2015

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on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for simtuzumab (EMA-001511-PIP02-13) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the CouncilThe 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 Gilead Sciences International Ltd on 14 February 2014 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 20 March 2015, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.
- (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.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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 simtuzumab, solution for injection, subcutaneous use, 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 simtuzumab, solution for injection, subcutaneous use, 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

A waiver for simtuzumab, solution for injection, subcutaneous use, 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 4

This decision is addressed to Gilead Sciences International Ltd, Flowers building, Granta Park, Abingdon, CB21 6GT – Cambridge, United Kingdom.

Done at London, 8 May 2015

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/35844/2015 corr
London, 20 March 2015

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

EMA-001511-PIP02-13

Scope of the application

Active substance(s):

Simtuzumab

Condition(s):

Treatment of hepatic fibrosis

Treatment of hepatic cirrhosis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Gilead Sciences International Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Gilead Sciences International Ltd submitted for agreement to the European Medicines Agency on 14 February 2014 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 21 May 2014.

Supplementary information was provided by the applicant on 19 December 2014. The applicant proposed modifications to the paediatric investigation plan.



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;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 agreed 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 hepatic fibrosis

The waiver applies to:

- the paediatric population from birth to less than 28 day of age;
- solution for injection, subcutaneous use, intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

1.2. Condition:

Treatment of hepatic cirrhosis

The waiver applies to:

- the paediatric population from birth to less than 28 day of age;
- solution for injection, subcutaneous use, intravenous use;
- 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 hepatic fibrosis

2.1.1. Indication(s) targeted by the PIP

Treatment of advanced hepatic fibrosis

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

From 28 days to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1 Development of an age-appropriate strength of the solution for subcutaneous injection enabling suitable injection volumes for children as young as 1 month of age.
Non-clinical studies	2	Study 2 Pre- and postnatal development (PPND) study in rats. Study 3 Toxicity study in juvenile rats to evaluate the effect of simtuzumab on elastin and collagen related parameters as well as on sexual maturation.
Clinical studies	1	Study 4 Open-label trial to evaluate safety, efficacy and pharmacokinetics of simtuzumab (SIM) in children from 28 days to less than 18 years of age with advanced hepatic fibrosis or cirrhosis.
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

2.2. Condition:

Treatment of hepatic cirrhosis

2.2.1. Indication(s) targeted by the PIP

Treatment of hepatic cirrhosis

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

From 28 days to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Solution for injection

2.2.4. Measures

Area	Number of measures	Description
Quality-related studies	1	<p>Study 1</p> <p>(Same measure as for condition "treatment of hepatic fibrosis")</p> <p>Development of an age-appropriate strength of the solution for subcutaneous injection enabling suitable injection volumes for children as young as 1 month of age.</p>
Non-clinical studies	2	<p>Study 2</p> <p>(Same measure as for condition "treatment of hepatic fibrosis")</p> <p>Pre- and postnatal development (PPND) study in rats.</p> <p>Study 3</p> <p>(Same measure as for condition "treatment of hepatic fibrosis")</p> <p>Toxicity study in juvenile rats to evaluate the effect of simtuzumab on elastin and collagen related parameters as well as on sexual maturation.</p>
Clinical studies	1	<p>Study 4</p> <p>(Same measure as for condition "treatment of hepatic fibrosis")</p> <p>Open-label trial to evaluate safety, efficacy and pharmacokinetics of simtuzumab (SIM) in children from 28 days to less than 18 years of age with advanced hepatic fibrosis or cirrhosis.</p>
Extrapolation, modelling and simulation studies	0	Not applicable.
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:	No
Date of completion of the paediatric investigation plan:	By September 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes