EMA/55121/2014

European Medicines Agency decision

P/0065/2014

of 10 March 2014

on the refusal of a paediatric investigation plan and on the granting of a waiver for recombinant human growth hormone modified by fusion with two hydrophilic polypeptide chains (VRS-317) (EMEA-001462-PIP01-13) 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.

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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 Versartis, Inc. on 30 April 2013 under Article 16(1) of Regulation (EC) No 1901/2006, also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 January 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and of its own motion in accordance with Article 12 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 refusal of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.

(3) 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 recombinant human growth hormone modified by fusion with two hydrophilic polypeptide chains (VRS-317), solution for injection, subcutaneous 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 refused.

Article 2

A product-specific waiver for recombinant human growth hormone modified by fusion with two hydrophilic polypeptide chains (VRS-317), solution for injection, subcutaneous 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 Versartis, Inc., 275 Shoreline Drive, Suite 450, 94065 - Redwood City, California, United States.

Done at London, 10 March 2014

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

EMA/PDCO/684675/2013

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-001462-PIP01-13

Scope of the application

Active substance(s):

Recombinant human growth hormone modified by fusion with two hydrophilic polypeptide chains (VRS-317)

Condition(s):

Treatment of growth hormone deficiency

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Versartis, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Versartis, Inc. submitted for agreement to the European Medicines Agency on 30 April 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 12 June 2013.

Supplementary information was provided by the applicant on 25 October 2013.

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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 refuse the paediatric investigation plan in accordance with Article 18 of said Regulation as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit;

   - to grant a product-specific waiver for all subsets of the paediatric population on its own motion in accordance with Article 12 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population and 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 grounds for the granting of the waiver are set out in 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, 17 January 2014

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

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: treatment of growth hormone deficiency

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product is likely to be unsafe; and
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.