EMA/811258/2012

European Medicines Agency decision

P/0311/2012

of 21 December 2012

on the granting and on the refusal of a product specific waiver for expanded autologous bone marrow-derived osteoblastic cells (EMEA-001329-PIP01-12) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Bone Therapeutics S.A. on 31 July 2012 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 November 2012 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the granting and on the refusal of a product specific waiver.

(2) It is therefore appropriate to adopt a decision granting and refusing a waiver taking into account the conditions concerned.

[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 waiver for expanded autologous bone marrow-derived osteoblastic cells, suspension for injection, intraosseous use, in the condition treatment of non-union fracture, 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

A waiver for expanded autologous bone marrow-derived osteoblastic cells, suspension for injection, intraosseous use, in the condition treatment of osteonecrosis, 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 3

This decision is addressed to Bone Therapeutics S.A., Rue Adrienne Bolland, 8, B-6041 Gosselies, Belgium.

Done at London, 21 December 2012

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

EMA/PDCO/582474/2012

Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMEA-001329-PIP01-12

Scope of the application

Active substance(s):

Expanded autologous bone marrow-derived osteoblastic cells

Condition(s):

Treatment of non-union fracture

Treatment of osteonecrosis

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intraosseous use

Name/corporate name of the PIP applicant:

Bone Therapeutics S.A.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Bone Therapeutics S.A. submitted to the European Medicines Agency on 31 July 2012 an application for a product-specific waiver for treatment of osteonecrosis and treatment of non-union fracture on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 12 September 2012.

A meeting with the Paediatric Committee took place on 7 November 2012.

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Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to grant a product-specific waiver for all subsets of the paediatric population and the condition treatment of non-union fracture 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 and
   - to refuse the granting of a product-specific waiver for the condition treatment of osteonecrosis as it does not meet the grounds detailed in Article 11(1) of said Regulation.

   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 for the condition treatment of non-union fracture and the grounds for refusal of the waiver for the condition treatment of osteonecrosis 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, 9 November 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

Grounds for the granting of the waiver for the condition treatment of non-union fracture and grounds for refusal of the waiver for the condition treatment of osteonecrosis

1. Waiver granted

1.1. Condition: Treatment of non-union fracture

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for suspension for injection, intraosseous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Waiver refused

2.1. Condition: Treatment of osteonecrosis

The request for the waiver applied to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for suspension for injection, intraosseous use.

The waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

(a) the specific medicinal product is likely to be ineffective or unsafe in the paediatric population;

(b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;

(c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients;

because:

- the PDCO disagreed with the applicant's argumentation that the specific medicinal product is likely to be ineffective or unsafe;
- the disease or condition for which the specific medicinal product is intended, does occur in the paediatric population;
- the specific medicinal product may represent a significant therapeutic benefit as the needs are not met.

The waiver request is therefore refused by the PDCO.