European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 3 November 2008

on the application for agreement of a Paediatric Investigation Plan for belatacept (EMEA-000157-PIP01-07) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Bristol-Myers Squibb International Corporation on 6 February 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and 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 September 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

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

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given a positive opinion.

(2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.

(3) It is therefore appropriate to adopt a Decision granting a waiver.

(4) 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 belatacept, powder for concentrate for 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 waiver for belatacept, powder for concentrate for solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for belatacept, powder for concentrate for solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Bristol-Myers Squibb International Corporation, Parc de l'Alliance, Avenue de Finlande 8, Braine l'Alleud, 1420, Belgium.

Done at London, 3 November 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/474089/2008
EMEA-000157-PIP01-07

POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON A REQUEST FOR AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN FOR

Scope of the application

Active substance:
Belatacept

Condition(s):
Renal Transplantation

Pharmaceutical form(s):
Powder for concentrate for solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Bristol-Myers Squibb International Corporation

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb International Corporation submitted for agreement to the EMEA on 06 February 2008 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 13 March 2008.

Supplementary information was provided by the applicant on 16 July 2008.

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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 agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, 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 Agency, together with its annex and appendix.

London, 19 September 2008

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

Renal Transplantation

B. WAIVER

- **Condition**

Renal Transplantation

The waiver applies to :

newborn infants (from birth to less than 28 days), and infants and toddlers (from 28 days to less than 24 months) for powder for concentrate for solution for infusion, intravenous use, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit in the above mentioned condition.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Renal transplantation

- **Proposed PIP indication**

Prevention of acute rejection following renal transplantation

- **Subset(s) of the paediatric population concerned by the paediatric development**

From two years to less than 18 years

- **Formulation(s)**

Powder for concentrate for solution for infusion, 100mg and 250 mg/vial
Intravenous use

- **Studies**

Area	Subarea	Number	Description
Pre-clinical	Juvenile animal study	**1**	Thirteen-week subcutaneous/intravenous toxicity study in juvenile rats
	Juvenile animal study	**1**	Three-month intermittent-dose subcutaneous and intravenous immunotoxicity study in juvenile rats
	Animal study	**1**	Three-month intermittent-dose intravenous immunotoxicity study in rats
	In-vitro study	**1**	In vitro evaluation of CD86 receptor occupancy in pediatric blood
Clinical	PK, safety and tolerability	**1**	multicenter, multiple-dose, PK/conversion study in stable renal transplant adolescents (2 to less than 18 years of age)
	Descriptive safety and Efficacy	**1**	Efficacy and safety study in de novo renal transplant recipients 2 to less than 18 years old

Measures to address long term follow-up on potential safety issues in relation to paediatric use: Yes

Deferral for initiation of some or all studies contained in the paediatric investigation plan: Yes

Deferral for completion of some or all studies contained in the paediatric investigation plan: Yes

Date of completion of the paediatric investigation plan: by December 2021