European Medicines Agency

Doc. Ref. EMEA/290591/2009
P/100/2009

EUROPEAN MEDICINES AGENCY DECISION

of 19 May 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for abatacept (ORENCIA) (EMEA-000118-PIP01-07-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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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 decision P/87/2008 of the European Medicines Agency on 14 October 2008,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 23 April 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 30 April 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

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 an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an 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 abatacept (ORENCIA), 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/87/2008, is addressed to Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UB8 1DH, Uxbridge, England.

Done at London, 19 May 2009

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/261658/2009
EMEA-000118-PIP01-07-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Abatacept

(Invented) name:
ORENCIA

Condition(s):
Rheumatoid Arthritis
Juvenile Arthritis

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 Pharma EEIG

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb Pharma EEIG submitted to the EMEA on 23 April 2009 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the EMEA decision P/87/2008 of 14 October 2008 proposing changes.

The procedure started on 30 April 2009.

Scope of the modification

The applicant proposed modifications to the agreed PIP to clarify and revise some of the agreed measures and timelines.

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Opinion
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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan

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 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(es) and appendix.

London, 30 April 2009

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)

- Rheumatoid arthritis
- Juvenile idiopathic arthritis

B. WAIVER

- **Condition**

- Rheumatoid arthritis

The waiver applies to:

– All subsets of the paediatric population from birth to less than 18 years of age for abatacept, powder for concentrate for solution for infusion (intravenous use)

- Juvenile Idiopathic Arthritis

The waiver applies to:

– Preterm newborn infants, Term newborn infants (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 months), Children from 2 to less than 6 years), for abatacept, powder for concentrate for solution for infusion (intravenous use)

C. PAEDIATRIC INVESTIGATION PLAN

- **Conditions to be investigated**

Juvenile Idiopathic Arthritis

- **Proposed PIP indication**

Treatment of children and adolescents with active polyarticular juvenile rheumatoid arthritis / Juvenile idiopathic arthritis

- **Subset(s) covered**

Children from 6 years of age to less than 18 years of age

- **Formulation(s)**

No development needed in addition to the authorised formulation: powder for concentrate for solution for infusion (250 mg/vial including graduated, silicone-free, syringe) for intravenous use.

- **Studies / Measures**

Area	Subarea	Number	Description
Non-clinical	Toxicity	3	Thirteen Week Subcutaneous/ Intravenous Toxicity Study in Juvenile Rats Three-Month Intermittent-Dose Subcutaneous and Intravenous Immunotoxicity Study in Juvenile Rats Three-Month Intermittent-Dose Intravenous Immunotoxicity Study In adult Rats
Clinical	Pharmacokinetic, efficacy and safety	1	A Phase 3 multi-center, multi-national, randomised, withdrawal study to evaluate the safety and efficacy of abatacept in children and adolescents with active polyarticular juvenile rheumatoid arthritis

Need for long-term follow-up on any potential safety issues in relation to paediatric use: yes
Date of completion of the paediatric investigation plan: by June 2008
A deferral has been granted: No

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EMEA Procedure number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
EU/1/07/389/001	ORENCIA	250 mg	Powder for concentrate for solution for infusion	Intravenous use	Vial (glass)	1 vial + 1 syringe
EU/1/07/389/002	ORENCIA	250 mg	Powder for concentrate for solution for infusion	Intravenous use	Vial (glass)	2 vials + 2 syringes
EU/1/07/389/003	ORENCIA	250 mg	Powder for concentrate for solution for infusion	Intravenous use	Vial (glass)	3 vials + 3 syringes