



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/426751/2012

European Medicines Agency decision P/0133/2012

of 2 July 2012

on the acceptance of a modification of an agreed paediatric investigation plan for abatacept (Orencia), (EMA-000118-PIP02-10-M01) 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 726/2004¹,

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 European Medicines Agency's decision P/64/2011 issued on 10 March 2011,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 22 March 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 June 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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), solution for injection (in a pre-filled syringe), subcutaneous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UB8 1DH - Uxbridge, United Kingdom.

Done at London, 2 July 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/221474/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000118-PIP02-10-M01

Scope of the application

Active substance(s):

Abatacept

Invented name:

Orencia

Condition(s):

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection (in a pre-filled syringe)

Route(s) of administration:

Subcutaneous 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 European Medicines Agency on 22 March 2012 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/64/2011 issued on 10 March 2011.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 16 April 2012.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. 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 changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

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 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(es) and appendix.

London, 8 June 2012

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

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

1. Waiver

1.1. Condition: Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

The waiver applies to:

- children from birth to less than 2 years;
- for powder for concentrate for solution for infusion, intravenous use and-for solution for injection in the pre-filled syringe, subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition: Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

2.1.1. Indication(s) targeted by the PIP

Treatment of moderate to severe polyarticular JIA.

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

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

Solution for injection (in a pre-filled syringe).

2.1.4. Studies

For measures in this condition that are not specified in the table below, reference is made to PIP no. EMEA-000118-PIP01-07 that has been agreed pursuant to EMA decision no. P/87/2008 dated 14 October 2008 including any subsequent modifications. Compliance check for these measures has been performed as per PDCO opinion no. EMEA/PDCO/329594/2009 (EMA-C-000118-PIP01-07-M01).

Area	Number of studies	Description
Quality	1	Study 1 Development of solution for injection in pre-filled syringes (0.4 and 0.7 ml) for paediatric use
Non-	0	Not applicable.

Area	Number of studies	Description
clinical		
Clinical	2	Study 2 Pharmacokinetic modelling and simulation study Study 3 Open-label study to evaluate pharmacokinetics, treatment response and safety of abatacept administered subcutaneously in patients with juvenile idiopathic arthritis

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of rheumatoid arthritis

Authorised indications:

ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor.

2. Treatment of juvenile idiopathic arthritis

Authorised indication:

ORENCIA in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor.

EU Number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/07/389/001	Orencia	250 mg	Powder for concentrate for solution for infusion	Intravenous use	vial (glass)	vial: 250 mg	1 vial + 1 syringe
EU/1/07/389/002	Orencia	250 mg	Powder for concentrate for solution for infusion	Intravenous use	vial (glass)	vial: 250 mg	2 vials + 2 syringes
EU/1/07/389/003	Orencia	250 mg	Powder for concentrate for solution for infusion	Intravenous use	vial (glass)	vial: 250 mg	3 vials + 3 syringes