

EMA/13161/2017

European Medicines Agency decision

P/0005/2017

of 16 January 2017

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for abatacept (Orencia), (EMA-000118-PIP03-15) 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 application submitted by Bristol-Myers Squibb Pharma EEIG on 22 January 2016 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 December 2016, in accordance with Article 18 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) 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 abatacept (Orencia), powder for concentrate for solution for infusion, solution for injection, intravenous use, 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 agreed.

Article 2

A deferral for abatacept (Orencia), powder for concentrate for solution for infusion, solution for injection, intravenous use, 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

A waiver for abatacept (Orencia), powder for concentrate for solution for infusion, solution for injection, intravenous use, 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 4

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decisions P/87/2008 issued on 14 October 2008 and P/64/2011 of 10 March 2011 including subsequent modifications thereof.

Article 5

This decision is addressed to Bristol-Myers Squibb International Corporation, Parc de l'Alliance, Avenue de Finlande 4, 1420 - Braine-l'Alleud, Belgium.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/662093/2016 Corr
London, 16 December 2016

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-000118-PIP03-15

Scope of the application

Active substance(s):

Abatacept

Invented name:

Orencia

Condition(s):

Treatment of systemic lupus erythematosus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Solution for injection

Route(s) of administration:

Intravenous use

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 16(1) of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb Pharma EEIG submitted for agreement to the European Medicines Agency on 22 January 2016 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 1 March 2016.

Supplementary information was provided by the applicant on 26 September 2016. The applicant proposed modifications to the paediatric investigation plan and waiver.

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 said Regulation;
- to grant a deferral in accordance with Article 21 of said Regulation;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

The Norwegian Paediatric Committee member agrees 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 European Medicines Agency, together with its annexes and appendix.

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 (PIP)

1. Waiver

1.1. Condition:

Treatment of systemic lupus erythematosus

The waiver applies to:

- the paediatric population from birth less than 5 years of age;
- powder for concentrate for solution for infusion, intravenous use;
- solution for injection, 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 systemic lupus erythematosus.

2.1.1. Indication(s) targeted by the PIP

Treatment of childhood-onset lupus nephritis caused by systemic lupus erythematosus (SLE) with abatacept in combination with mycophenolate mofetil (MMF) or cyclophosphamide (CF), and corticosteroids (CS) in paediatric patients 5 years of age and older who are newly diagnosed or who had an insufficient response to MMF or CF, and CS.

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

From 5 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion.

Solution for injection.

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.

Clinical studies	2	Study 1 Randomized, double-blinded study to evaluate the efficacy, safety, and pharmacokinetic (PK) of abatacept together with background medications vs placebo across 2 intravenous (IV) dosing regimens to identify an appropriate IV dosing regimen (induction and maintenance), in paediatric patients from 5 to less than 18 years of age with lupus nephritis (LN). Study 2 Open-label study to evaluate the efficacy, safety, and PK of abatacept as subcutaneous (SC) dosing regimen as an add-on to background therapy in paediatric patients from 5 to less than 18 years of age with LN.
Extrapolation, modelling and simulation studies	3	Study 3 Modelling and simulation stage 1: population PK study. Study 4 Modelling and simulation stage 2: exposure response model study. Study 5 Modelling and simulation stage 3: extrapolation/interpolation study.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2028
Deferral for one or more measures 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 indication(s):

Orencia in combination with methotrexate is indicated for:

- the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying antirheumatic drugs (DMARDs) including methotrexate or a tumour-necrosis-factor (TNF)-alfa inhibitor;
- the treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate;
- A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate.

2. Treatment of Polyarticular juvenile idiopathic arthritis

Authorised indication(s):

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

Authorised pharmaceutical form(s):

Solution for injection.

Powder for concentrate for solution for infusion.

Authorised route(s) of administration:

Intravenous use.

Subcutaneous use.