EMA/716619/2010

European Medicines Agency decision

P/252/2010

of 26 November 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for anti-BAFF monoclonal antibody (LY2127399), (EMEA-000802-PIP01-09) 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 726/2004[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 Eli Lilly & Company Limited on 08 January 2010 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 8 October 2010, 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 anti-BAFF monoclonal antibody (LY2127399), solution for injection, 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 anti-BAFF monoclonal antibody (LY2127399), solution for injection, 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 anti-BAFF monoclonal antibody (LY2127399), solution for injection, 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 is addressed to Eli Lilly & Company Limited, Research Center Erl Wood Manor, Sunninghill Road Surrey, GU206PH Windlesham, Surrey, United Kingdom.

Done at London, 26 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/597122/2010

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

EMEA-000802-PIP01-09

Scope of the application

Active substance(s):

Anti-BAFF monoclonal antibody (LY2127399)

Condition(s):

Treatment of chronic autoimmune arthritis

Treatment of multiple sclerosis

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Eli Lilly & Company Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eli Lilly & Company Limited submitted for agreement to the European Medicines Agency on 08 January 2010 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 18 February 2010.

Supplementary information was provided by the applicant on 28 July 2010.

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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 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 Articles 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 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 European Medicines Agency, together with its annex(es) and appendix.

London, 08 October 2010

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 autoimmune arthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 6 years of age for solution for injection for 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).

1.2. Condition:

Treatment of multiple sclerosis.

The waiver applies to:

- All subsets of the paediatric population from birth to less than 10 years of age;
- for solution for injection for 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 autoimmune arthritis.

2.1.1. Indication(s) targeted by the PIP

Treatment of juvenile idiopathic arthritis with moderately to severely active polyarticular course

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

From 6 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of age appropriate vial containing the same pharmaceutical composition as in prefilled glass syringe for adults for subcutaneous use.
Non-clinical	2	Study 2 Pre- and post-natal developmental toxicity study in Cynomolgus monkeys including an immunotoxicology assessment of the F1 offspring. Study 3 Repeat-dose toxicity study in juvenile Cynomolgus monkeys including an immunotoxicology assessment.
Clinical	1	Study 4 Multicentre double-blind randomised placebo controlled withdrawal study to evaluate safety, tolerability, pharmacokinetics and efficacy of anti-BAFF monoclonal antibody in children with juvenile idiopathic arthritis with polyarticular course.

2.2. Condition:

Treatment of multiple sclerosis.

2.2.1. Indication(s) targeted by the PIP

Treatment of remitting relapsing multiple sclerosis.

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

From 10 to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Solution for injection.

2.2.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Same as for condition Treatment of chronic autoimmune arthritis.

Non-clinical	2	Study 2 Same as for condition Treatment of chronic autoimmune arthritis. Study 3 Same as for condition Treatment of chronic autoimmune arthritis.
Clinical	1	Study 5 Multicentre open-label treatment randomised active comparator (Interferon beta-1a) controlled study to evaluate safety, tolerability, pharmacokinetics and efficacy of anti-BAFF monoclonal antibody in children with remitting relapsing multiple sclerosis.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2023
Deferral for one or more studies contained in the paediatric investigation plan:	Yes