European Medicines Agency

Doc. Ref. EMA/44293/2010
P/8/2010

EUROPEAN MEDICINES AGENCY DECISION

of 29 January 2010

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for Teplizumab (EMEA-000524-PIP01-08) 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 application submitted by Eli Lilly and Company Limited on 2 March 2009 under Article 16(1) 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 11 December 2009, 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 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 Teplizumab, 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 deferral for Teplizumab, 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 granted.

Article 3

A waiver for Teplizumab, 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 granted.

Article 4

This decision is addressed to Eli Lilly and Company Limited, Erl Wood Manor, Sunninghill Road, GU20 6 PH Windlesham, United Kingdom.

Done at London, 29 January 2010

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. EMA/PDCO/794811/2009
EMEA-000524-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Teplizumab

Condition(s):
Type I Diabetes mellitus

Pharmaceutical form(s):
Concentrate for solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Eli Lilly and Company Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Eli Lilly and Company Limited submitted for agreement to the EMEA on 2 March 2009 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 30 April 2009.

Supplementary information was provided by the applicant on 1 October 2009.

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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 Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

The Norwegian Paediatric Committee member does 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(es) and appendix.

London, 11 December 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)

Type I diabetes mellitus

B. WAIVER

- **Condition**

Type I diabetes mellitus

The waiver applies to:

- Children from birth to less than 2 years;
- for concentrate for solution for infusion for intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Type I diabetes mellitus

- **Proposed PIP indication**

Treatments of Type I diabetes mellitus

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

From 2 to less than 18 years.

- **Formulation(s)**

concentrate for solution for infusion, intravenous use

- **Studies**

Area	Number of studies	Description
Quality	none	Not applicable.
Non-clinical	3	1. Female fertility and early embryonic development, toxicokinetic and immunophenotyping study in mice. 2. Male fertility, toxicokinetic and immunophenotyping study in mice. 3. Toxicity study in mice.
Clinical	6	4. Randomised open label multiple-dose pharmacokinetic, safety and efficacy study. 5. Randomised double-blind placebo controlled efficacy and safety study in patients with recent onset Type I Diabetes mellitus. 6. Randomised, double-blind, multicentre, 4-arm, controlled, dose-ranging efficacy and safety study in children and adults with recent-onset Type 1 Diabetes mellitus. 7. Multicentre, long-term efficacy and safety study in children and

		adults with recent-onset Type 1 Diabetes mellitus. 8. Randomised, double-blind, placebo-controlled dose ranging 4-arm efficacy and safety study, in children and adults with recent-onset Type 1 Diabetes mellitus. 9. Randomised, double-blind, multicentre, 2-arm, controlled, dose-ranging efficacy and safety study in children with recent onset Type I Diabetes mellitus.

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 2018**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**