EMA/910511/2011

European Medicines Agency decision

P/286/2011

of 30 November 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for alemtuzumab (EMEA-001072-PIP01-10) 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 Genzyme Europe B.V. on 15 November 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 14 October 2011, 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 alemtuzumab, 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 alemtuzumab, 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 alemtuzumab, 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 Genzyme Europe B.V., Gooimeer 10, 1411DD - Naarden, The Netherlands.

Done at London, 30 November 2011

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

EMA/PDCO/650844/2011

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

EMEA-001072-PIP01-10

Scope of the application

Active substance(s):

Alemtuzumab

Condition(s):

Treatment of Multiple Sclerosis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Genzyme Europe B.V.

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Genzyme Europe B.V. submitted for agreement to the European Medicines Agency on 15 November 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 22 December 2010.

Supplementary information was provided by the applicant on 1 August 2011. The applicant proposed modifications to the paediatric investigation plan.

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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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, 14 October 2011

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 Multiple Sclerosis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 10 years of age;
- for concentrate for solution for infusion; intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of Multiple Sclerosis

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with relapsing-remitting forms of multiple sclerosis

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

From 10 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Concentrate for solution for infusion

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	5	Study 1 Toxicology study to evaluate toxic effects/disturbances resulting from alemtuzumab treatment of human CD52 transgenic (huCD52 Tg) male mice before cohabitation. Study 2 Toxicology study to evaluate toxic effects/disturbances resulting from alemtuzumab treatment of human CD52 transgenic (huCD52 Tg) female mice before cohabitation. Study 3 Intravenous Developmental Toxicity Study of alemtuzumab in huCD52 transgenic mice. Study 4 Intravenous developmental and perinatal/postnatal reproduction toxicity study of alemtuzumab in huCD52 transgenic mice, including a postnatal behavioral/functional evaluation and immunophenotyping and exposure in pups. Study 5 Developmental immunotoxicity study in huCD52 transgenic mice.
Clinical	1	Study 6 Randomised, parallel group, rater-blinded, efficacy, safety and tolerability study of alemtuzumab compared to an appropriate comparator in paediatric

Area	Number of studies	Description
		patients from 10 years to less than 18 years with relapsing remitting multiple sclerosis with disease activity on prior first-line disease modifying treatment (DMT).

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 September 2018
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):

Treatment of B-cell chronic lymphocytic leukaemia

Authorised indications:

Treatment of adult patients with B-cell chronic lymphocytic leukaemia (B-CLL) for whom fludarabine combination chemotherapy is not appropriate.

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/01/193/001	MabCampath	10 mg/ml	Concentrate for solution for infusion	Intravenous use	Ampoule (glass)	3 ml	3 ampoules
EU/1/01/193/002	MabCampath	30 mg/ml	Concentrate for solution for infusion	Intravenous use	Vial (glass)	1 ml	3 vials