EMA/126246/2011

European Medicines Agency decision

P/59/2011

of 21 February 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for chimeric monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E (SGN-35) (EMEA-000980-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 Takeda Global Research and Development Centre (Europe) Ltd on 3 May 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 January 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 chimeric monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E (SGN-35), powder for 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 chimeric monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E (SGN-35), powder for 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 chimeric monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E (SGN-35), powder for 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 Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, London WC2B 4AE, United Kingdom.

Done at London, 21 February 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/783903/2010

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

EMEA-000980-PIP01-10

Scope of the application

Active substance(s):

Chimeric monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E (SGN-35)

Condition(s):

Treatment of Hodgkin lymphoma

Treatment of anaplastic large cell lymphoma

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Takeda Global Research and Development Centre (Europe), Ltd

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Takeda Global Research and Development Centre (Europe), Ltd submitted for agreement to the European Medicines Agency on 3 May 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 10 June 2010.

Supplementary information was provided by the applicant on 8 November 2010. The applicant proposed modifications to the paediatric investigation plan.

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A meeting with the Paediatric Committee took place on 12 January 2011.

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 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 annex and appendix.

London, 14 January 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 Hodgkin lymphoma

The waiver applies to:

- The paediatric population from birth to less than 5 years of age
- for powder for concentrate for solution for infusion for intravenous 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 anaplastic large cell lymphoma

The waiver applies to:

- The paediatric population from birth to less than 2 years of age
- for powder for concentrate for solution for infusion for intravenous 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 Hodgkin lymphoma

2.1.1. Indication(s) targeted by the PIP

Treatment of newly diagnosed, relapsed or refractory Hodgkin lymphoma

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

From 5 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder for concentrate for solution for infusion, intravenous use

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	1	Study 1: Immunotoxicity study in cynomolgus monkeys
Clinical	2	Study 2: Open-label, single-arm, dose-escalating, multi-centre trial with extension cohort to evaluate pharmacokinetics, safety, tolerability and activity in children from 2 years to less than 18 years of age with relapsed or

Area	Number of studies	Description
		recurrent anaplastic large cell lymphoma or relapsed or recurrent Hodgkin lymphoma Study 3: Open-label, single-arm, dose-escalating, multi-centre trial to evaluate pharmacokinetics, safety, tolerability and activity of SGN-35 in combination with standard therapy in children with high-risk newly-diagnosed Hodgkin lymphoma from 5 years to less than 18 years

2.2. Condition: Treatment of anaplastic large cell lymphoma

2.2.1. Indication(s) targeted by the PIP

Treatment of first and subsequent relapse or refractory systemic anaplastic large cell lymphoma

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

From 2 years to less than 18 years of age

2.2.3. Pharmaceutical form(s)

Same as for condition treatment of Hodgkin lymphoma

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable
Non-clinical	1	Study 1: Same as for condition treatment of Hodgkin lymphoma
Clinical	1	Study 2: Same as for condition treatment of Hodgkin lymphoma

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By December 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes