EMA/943611/2011

European Medicines Agency decision

P/299/2011

of 20 December 2011

on the acceptance of a modification of an agreed paediatric investigation plan for alogliptin benzoate, (EMEA-000496-PIP01-08-M02) 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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on the acceptance of a modification of an agreed paediatric investigation plan for alogliptin benzoate, (EMEA-000496-PIP01-08-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 European Medicines Agency's decision P/93/2009 issued on 16 June 2009, the decision P/20/2011 issued on 25 January 2011,

Having regard to the application submitted by Takeda Global Research and Development Centre (Europe) Ltd on 26 August 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 November 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for alogliptin benzoate, film-coated tablet, oral use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Takeda Global Research and Development Centre (Europe) Ltd, 61 Aldwych, WC2B 4AE London, United Kingdom.

Done at London, 20 December 2011

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

EMA/943611/2011

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000496-PIP01-08-M02

Scope of the application

Active substance(s):

Alogliptin benzoate

Condition(s):

Treatment of type 2 diabetes mellitus

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Takeda Global Research and Development Centre (Europe) Ltd

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Global Research and Development Centre (Europe) Ltd submitted to the European Medicines Agency on 26 August 2011 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/93/2009 issued on 16 June 2009 and the decision P/20/2011 issued on 25 January 2011.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 14 September 2011.

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Scope of the modification

Some measures and timelines of the paediatric investigation plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   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 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, 11 November 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: Type 2 diabetes mellitus

The waiver applies to:

- All subsets of the paediatric population from birth to less than 10 years of age
- for film-coated tablet, oral 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.

2. Paediatric Investigation Plan

2.1. Condition: Type 2 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Treatment of Type 2 diabetes mellitus

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

From 10 to less than 18 years of age.

2.1.3. Pharmaceutical form

Film-coated tablet, 12.5 and 25 mg

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of 12.5 mg strength
Non-clinical	2	Study 2: 4-week oral toxicity study in male and female juvenile rats Study 3: 8-week oral toxicity study in male juvenile rats to evaluate potential alogliptin-related effects on the male reproductive organs
Clinical	3	Study 4: Open-label, single dose of 12.5 or 25 mg, PK/PD study, with a matched adult control group Study 5: Multicentre, randomised, double-blind, placebo-controlled study to evaluate safety and efficacy of alogliptin vs placebo (with a metformin reference arm) in children from 10 to less than 18 years. Study 6: Double-blind, active-controlled (metformin), extension of the safety and efficacy study

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By January 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes