EMA/585768/2016

European Medicines Agency decision

P/0255/2016

of 5 October 2016

on the acceptance of a modification of an agreed paediatric investigation plan for alogliptin (Vipidia), (EMEA-000496-PIP01-08-M05) 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 European Medicines Agency's decision P/93/2009 issued on 16 June 2009, the decision P/20/2011 issued on 25 January 2011, the decision P/299/2011 issued on 20 December 2011, the decision P/0242/2014 issued on 29 September 2014 and the decision P/0114/2015 issued on 5 June 2015,

Having regard to the application submitted by Takeda Development Centre Europe Ltd on 25 May 2016 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 19 August 2016, 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 (Vipidia), 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 Development Centre Europe Ltd, 61 Aldwych, WC2B 4AE – London, United Kingdom.

EMA/PDCO/370106/2016
London, 19 August 2016

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

EMEA-000496-PIP01-08-M05

Scope of the application

Active substance(s):

Alogliptin

Invented name:

Vipidia

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Takeda Development Centre Europe Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Development Centre Europe Ltd submitted to the European Medicines Agency on 25 May 2016 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, the decision P/20/2011 issued on 25 January 2011, the decision P/299/2011 issued on 20 December 2011, the decision P/0242/2014 issued on 29 September 2014 and the decision P/0114/2015 issued on 5 June 2015.

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

The procedure started on 21 June 2016.

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 Norwegian Paediatric Committee member agrees 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 annexes and appendix.

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 (PIP)

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(s)

Film-coated tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1:** Development of 12.5 mg strength
Non-clinical studies	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 studies	2	**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 in children from 10 to less than 18 years
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By January 2021
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

6. Reminder

Interventional clinical trials have to be registered with the EudraCT database.

All investigational medicinal products used in the studies or trials must be registered in the EudraVigilance Medicinal Product Dictionary by the sponsor.

Studies or trials which are inconclusive or not interpretable will be considered non-compliant.

The Clinical trials should be performed in accordance with Good Clinical Practice. Those conducted outside the community should be carried out in accordance with the ethical standards of Directive 2001/20/EC and those conducted within the community should be carried out in accordance with Directive 2001/20/EC.

Applicants are reminded that it is their responsibility to submit a request for modification of an agreed paediatric investigation plan, if they encounter difficulties with its implementation which render the plan unworkable or no longer appropriate.

Applicants are also reminded that in order to verify compliance with the agreed PIP, the study report must be submitted for any study that had to be completed (see Commission Guideline 2014/C338/01 of 27 September 2014 and EMA procedural advice). This is part of the validation of the application for marketing authorisation, variation or line extension. Applicants are therefore advised to consider the time necessary to produce the appropriate report for their planned date of submission. For authorised medicinal products, reports need to be submitted to the competent authority within 6 months of completion of the studies, according to article 46 of Regulation (EC) No 1901/2006.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of type 2 diabetes mellitus.

Authorised indication(s):

- Treatment of type 2 diabetes mellitus in adults aged 18 years and older to improve glycaemic control in combination with other glucose lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use