EMA/115438/2020

European Medicines Agency decision

P/0078/2020

of 18 March 2020

on the acceptance of a modification of an agreed paediatric investigation plan for alogliptin (Vipidia), (EMEA-000496-PIP01-08-M07) 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, the decision P/0114/2015 issued on 5 June 2015, the decision P/0255/2016 issued on 5 October 2016 and the decision P/0097/2019 issued on 22 March 2019,

Having regard to the application submitted by Takeda Development Centre Europe Ltd on 28 October 2019 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 31 January 2020, 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.

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

[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, 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, 1 Kingdom Street, W2 6BD – London, United Kingdom.

EMA/PDCO/614560/2019
Amsterdam, 31 January 2020

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

EMEA-000496-PIP01-08-M07

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

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 28 October 2019 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, the decision P/0114/2015 issued on 5 June 2015, the decision P/0255/2016 issued on 5 October 2016 and the decision P/0097/2019 issued on 22 March 2019.

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

The procedure started on 3 December 2019.

Scope of the modification

Some measures 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 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

Treatment of type 2 diabetes mellitus

The waiver applies to:

- all subsets of the paediatric population from birth to less than 10 years of age;
- 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

Treatment of 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 film-coated tablet 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 (SYR-322_104)

		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 (SYR-322_309)
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 October 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes