EMA/523992/2019

European Medicines Agency decision

P/0358/2019

of 4 October 2019

on the acceptance of a modification of an agreed paediatric investigation plan for sitagliptin (Januvia (and associated names)), (EMEA-000470-PIP01-08-M11) 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/61/2009 issued on 27 March 2009, the decision P/211/2009 issued on 30 October 2009, the decision P/171/2010 issued on 6 September 2010, the decision P/19/2011 issued on 25 January 2011, the decision P/134/2011 issued on 8 June 2011, the decision P/298/2011 issued on 20 December 2011, the decision P/0312/2012 issued on 21 December 2012, the decision P/0123/2013 issued on 28 May 2013, the decision P/0170/2014 issued on 9 July 2014, the decision P/0062/2015 issued on 1 April 2015 and the decision P/0033/2018 issued on 30 January 2018,

Having regard to the application submitted by Merck Sharp and Dohme (Europe), Inc. on 15 July 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 20 September 2019, 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 sitagliptin Januvia (and associated names), 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 Merck Sharp and Dohme (Europe), Inc., 5 Clos du Lynx, 1200 – Brussels, Belgium.

EMA/PDCO/410736/2019
Amsterdam, 20 September 2019

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

EMEA-000470-PIP01-08-M11

Scope of the application

Active substance(s):

Sitagliptin

Invented name:

Januvia (and associated names)

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:

Merck Sharp and Dohme (Europe), Inc.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Merck Sharp and Dohme (Europe), Inc. submitted to the European Medicines Agency on 15 July 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/61/2009 issued on 27 March 2009, the decision P/211/2009 issued on 30 October 2009, the decision P/171/2010 issued on 6 September 2010, the decision P/19/2011 issued on 25 January 2011, the decision P/134/2011 issued on 8 June 2011, the decision P/298/2011 issued on 20 December 2011, the decision P/0312/2012 issued on 21 December 2012, the decision P/0123/2013 issued on 28 May 2013, the decision P/0170/2014 issued on 9 July 2014, the decision P/0062/2015 issued on 1 April 2015 and the decision P/0033/2018 issued on 30 January 2018.

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

The procedure started on 20 August 2019.

Scope of the modification

Some 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

Treatment of type 2 diabetes mellitus

The waiver applies to:

- 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 subsets.

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 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	**Study 1** Randomized, double-blind, placebo-controlled, single-dose trial to evaluate the pharmacokinetics of sitagliptin in children from 10 to less and 18 years of age, with type 2 diabetes mellitus. (081-01) **Study 2** Multicenter, double-blind, randomized, placebo-controlled trial to evaluate the safety and efficacy of sitagliptin in children from 10 to less than 18 years of age, with type 2 diabetes mellitus with inadequate glycaemic control. (083-00)

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 October 2019
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):

1. Treatment of type 2 diabetes mellitus

   Authorised indications:

   - In adults for the treatment of type 2 diabetes mellitus as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.
   - In adults for the treatment of type 2 diabetes mellitus as dual oral therapy in combination with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.
   - In adults for the treatment of type 2 diabetes mellitus as dual oral therapy in combination a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance.
   - In adults for the treatment of type 2 diabetes mellitus as dual therapy in combination a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e. a thiazolidinedione) when use of a PPARγ agonist is appropriate and when diet and exercise plus the PPARγ agonist alone do not provide adequate glycaemic control.
   - In adults for the treatment of type 2 diabetes mellitus as triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control.
   - In adults for the treatment of type 2 diabetes mellitus as triple oral therapy in combination with a PPARγ agonist and metformin when use of a PPARγ agonist is appropriate and when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control.
   - In adults for the treatment of type 2 diabetes mellitus as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.

Authorised pharmaceutical formulation(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use