European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 27 March 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for sitagliptin phosphate monohydrate (Tesavel)[A1] (EMEA-000472-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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EUROPEAN MEDICINES AGENCY DECISION

of 27 March 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a deferral and on the granting of a waiver for sitagliptin phosphate monohydrate (Tesavel)[A2] (EMEA-000472-PIP01-08) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 Merck Sharp and Dohme (Europe), Inc. on 5 December 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 March 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation**,**

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

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 granting 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 sitagliptin phosphate monohydrate (Tesavel[A3]), film-coated tablet, oral 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 sitagliptin phosphate monohydrate (Tesavel[A4]), film-coated tablet, oral 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 sitagliptin phosphate monohydrate (Tesavel[A5]), film-coated tablet, oral 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 Merck Sharp and Dohme (Europe), Inc., 5 Clos du Lynx, B-1200, Brussels, Belgium.

Done at London, 27 March 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMEA/PDCO/122566/2009
EMEA- 000472-PIP01-08

OPINION OF THE PAEDIATRIC COMMITTEE ON THE AGREEMENT OF A PAEDIATRIC INVESTIGATION PLAN AND A DEFERRAL AND A WAIVER

Scope of the application

Active substance(s):
Sitagliptin phosphate monohydrate

Invented name:
Tesavel

Condition(s):
Type 2 Diabetes Mellitus

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 16(1) of Regulation (EC) No 1901/2006 as amended, Merck Sharp and Dohme (Europe), Inc. submitted for agreement to the EMEA on 5 December 2008 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 8 January 2009.

A meeting with the Paediatric Committee took place on 5 March 2009.

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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 Icelandic and the Norwegian Paediatric Committee members agree 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 Agency, together with its annex(es) and appendix.

London, 6 March 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

Type 2 diabetes mellitus

B. WAIVER

- **Condition**

  Type 2 diabetes mellitus

  The waiver applies to:

  - Children of less than 10 years, for sitagliptin film-coated tablets, 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.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Type 2 diabetes mellitus

- **Proposed PIP indication**

  Treatment of type 2 diabetes mellitus

- **Subset(s) of the paediatric population concerned by the paediatric development**

  From 10 to less than 18 years.

- **Formulation(s)**

  Film-coated tablets, oral use, 25 mg, 50 mg and 100 mg

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	2	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. 2. Multicenter, double-blind, randomized, placebo- and metformin-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.

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 October 2017**

Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EMEA Procedure number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
EMEA/H/C/910/01	Tesavel	25 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	14
EMEA/H/C/910/02	Tesavel	25 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	28
EMEA/H/C/910/03	Tesavel	25 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	56
EMEA/H/C/910/04	Tesavel	25 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	84
EMEA/H/C/910/05	Tesavel	25 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	98
EMEA/H/C/910/06	Tesavel	25 mg	Film-coated tablet	Oral use	Perforated unit dose blister (PVC/PE/PVDC/alu)	50x1
EMEA/H/C/910/07	Tesavel	50 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	14
EMEA/H/C/910/08	Tesavel	50 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	28
EMEA/H/C/910/09	Tesavel	50 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	56
EMEA/H/C/910/10	Tesavel	50 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	84
EMEA/H/C/910/11	Tesavel	50 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	98
EMEA/H/C/910/12	Tesavel	50 mg	Film-coated tablet	Oral use	Perforated unit dose blister (PVC/PE/PVDC/alu)	50x1
EMEA/H/C/910/13	Tesavel	100 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	14
EMEA/H/C/910/14	Tesavel	100 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	28
EMEA/H/C/910/15	Tesavel	100 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	56
EMEA/H/C/910/16	Tesavel	100 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	84
EMEA/H/C/910/17	Tesavel	100 mg	Film-coated tablet	Oral use	Blister (PVC/PE/PVDC/alu)	98
EMEA/H/C/910/18	Tesavel	100 mg	Film-coated tablet	Oral use	Perforated unit dose blister (PVC/PE/PVDC/alu)	50x1