



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/464759/2014

## European Medicines Agency decision

P/0214/2014

of 1 September 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for ertugliflozin (EMEA-001533-PIP01-13) 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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by Merck Sharp and Dohme (Europe), Inc. on 10 October 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 July 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 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 agreeing 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.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A paediatric investigation plan for ertugliflozin, 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 ertugliflozin, 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 ertugliflozin, 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., Clos du Lynx 5, Binnenhof, 1200 - Brussels, Belgium.

Done at London, 1 September 2014

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

EMA/PDCO/265373/2014 corr

## Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-001533-PIP01-13

### Scope of the application

**Active substance(s):**

Ertugliflozin

**Condition(s):**

Treatment of type II 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.

### 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 European Medicines Agency on 10 October 2013 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 18 December 2013.

Supplementary information was provided by the applicant on 25 April 2014.

## 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 Article 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 Norwegian Paediatric Committee member agrees 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 European Medicines Agency, together with its annex and appendix.

London, 18 July 2014

On behalf of the Paediatric Committee  
Dr Dirk Mentzer, 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 (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;
- for 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 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 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 | 0                  | Not applicable.                                                                                                                                                                                                                                                   |
| Non-clinical studies    | 1                  | Study 1<br><br>Juvenile toxicity study in the rat to further evaluate the safety profile of ertugliflozin on the developing organism.                                                                                                                             |
| Clinical studies        | 1                  | Study 2<br><br>Randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of two doses of ertugliflozin in paediatric patients from 10 to less than 18 years of age with type 2 diabetes mellitus and inadequate glycaemic control on |

| Area                                            | Number of measures | Description                                                                                                                                                                               |
|-------------------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                 |                    | metformin monotherapy.                                                                                                                                                                    |
| Extrapolation, modelling and simulation studies | 1                  | Study 3<br>Population PK modelling study to evaluate the appropriate dose of ertugliflozin in the treatment of type 2 diabetes mellitus in children from 10 to less than 18 years of age. |
| 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 March 2026. |
| Deferral for one or more measures contained in the paediatric investigation plan:     | Yes            |