EMA/405627/2015

European Medicines Agency decision

P/0150/2015

of 10 July 2015

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for sotagliflozin (EMEA-001517-PIP02-14) 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 application submitted by Lexicon Celtic Limited on 7 August 2014 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 22 May 2015, 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.

[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 sotagliflozin, granules, tablets, 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 sotagliflozin, granules, tablets, 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 sotagliflozin, granules, tablets, 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 agreed PIP covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/0287/2014 issued on 28 October 2014, including subsequent modifications thereof.

Article 5

This decision is addressed to Lexicon Celtic Limited, 16 Charlotte Square, EH2 4DF - Edinburgh, Midlothian, United Kingdom.

Done at London, 10 July 2015

For the European Medicines Agency
Jordi Llinares Garcia
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/146501/2015
London, 22 May 2015

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

EMEA-001517-PIP02-14

Scope of the application

Active substance(s):

Sotagliflozin

Condition(s):

Treatment of type 1 diabetes mellitus

Pharmaceutical form(s):

Granules

Tablets

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Lexicon Celtic Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Lexicon Celtic Limited submitted for agreement to the European Medicines Agency on 7 August 2014 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 16 September 2014.

Supplementary information was provided by the applicant on 23 February 2015. The applicant proposed modifications to the paediatric investigation plan and to the deferral and to the waiver.

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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 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, and in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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.

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 1 diabetes mellitus

The waiver applies to:

- the paediatric population from birth to less than 6 months of age;
- granules, 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(s).

The waiver applies to:

- infants and toddlers from 6 months to less than 24 months of age;
- granules, tablets, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of type 1 diabetes mellitus

2.1.1. Indication(s) targeted by the PIP

Adjunct treatment to insulin to improve glycaemic control in children from 2 years of age and above with type 1 diabetes mellitus

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Granules

Tablets

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	**Study 1** Development of an age-appropriate oral formulation.

Non-clinical studies	1	**Study 2** Juvenile toxicity study
Clinical studies	8	**Study 3** Open-label, single-dose, dose-escalating study evaluating the safety/tolerability and pharmacokinetic/pharmacodynamic parameters of increasing doses of sotagliflozin as adjunct to insulin therapy in adolescents from 12 to less than 18 years of age with type 1 diabetes mellitus. **Study 4** Open-label, single-dose, dose-escalating study evaluating the safety/tolerability and pharmacokinetic/pharmacodynamic parameters of increasing doses of sotagliflozin as adjunct to insulin therapy in children from 6 to less than 12 years of age with type 1 diabetes mellitus. **Study 5** Open-label, single-dose, dose-escalating study evaluating the safety/tolerability and pharmacokinetic/pharmacodynamic parameters of increasing doses of sotagliflozin as adjunct to insulin therapy in children from 2 to less than 6 years of age with type 1 diabetes mellitus. **Study 6** Open-label, multiple-dose, study evaluating the safety/tolerability and pharmacokinetic/pharmacodynamic parameters of multiple doses of sotagliflozin as adjunct to insulin therapy in children from 2 to less than 12 years of age with type 1 diabetes mellitus. **Study 7** Randomised, 24-week double-blind, placebo-controlled study to evaluate the efficacy and safety of sotagliflozin compared to placebo as adjunct to insulin therapy followed by a 28 weeks open-label treatment period in adolescents from 12 to less than 18 years of age with type 1 diabetes mellitus. **Study 8** Randomised, 24-week double-blind, placebo-controlled study to evaluate the efficacy and safety of sotagliflozin compared to placebo as adjunct to insulin therapy followed by a 28 weeks open-label treatment period in children from 6 to less than 12 years of age with type 1 diabetes mellitus. **Study 9** Randomised, 24-week double-blind, placebo-controlled study to evaluate the efficacy and safety of sotagliflozin compared to placebo as adjunct to insulin therapy followed by a 28 weeks

		open-label treatment period in children from 2 to less than 6 years of age with type 1 diabetes mellitus. **Study 10** Single dose study comparing sotagliflozin tablets (reference) and sotagliflozin granules (test) to evaluate the bioavailability between the two formulations in healthy adult subjects.
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 June 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes