EMA/711130/2017

European Medicines Agency decision

P/0337/2017

of 30 October 2017

on the acceptance of a modification of an agreed paediatric investigation plan for sotagliflozin (EMEA-001517-PIP02-14-M02) 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/0150/2015 issued on 10 July 2015 and the decision P/0227/2017 issued on 9 August 2017,

Having regard to the application submitted by sanofi-aventis R&D on 18 August 2017 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 13 October 2017, 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 sotagliflozin, granules, tablets, 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 sanofi-aventis R&D, 1, avenue Pierre Brossolette, 91385 - Chilly-Mazarin Cedex, France.

EMA/PDCO/564637/2017
London, 13 October 2017

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

EMEA-001517-PIP02-14-M02

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:

sanofi-aventis R&D

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, sanofi-aventis R&D submitted to the European Medicines Agency on 18 August 2017 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/0150/2015 issued on 10 July 2015 and the decision P/0227/2017 issued on 9 August 2017.

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

The procedure started on 12 September 2017.

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Scope of the modification

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 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 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	7	**Study 3** Placebo-controlled, double-blind, multiple ascending dose 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** Placebo-controlled, double-blind, multiple ascending dose 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** Placebo-controlled, double-blind, multiple ascending dose 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*** *Removed in procedure EMEA-001517-PIP02-14-M01.* **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 October 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes