EMA/80301/2015

European Medicines Agency decision

P/0037/2015

of 6 March 2015

on the acceptance of a modification of an agreed paediatric investigation plan for lixisenatide (Lyxumia) (EMEA-000916-PIP01-10-M04) 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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on the acceptance of a modification of an agreed paediatric investigation plan for lixisenatide (Lyxumia) (EMEA-000916-PIP01-10-M04) in accordance with Regulation (EC) No 1901/2006 of the European Parliament 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/18/2011 issued on 24 January 2011, the decision P/225/2011 issued on 27 September 2011, P/0076/2012 issued on 25 April 2012 and P/0035/2013 issued on 27 February 2013,

Having regard to the application submitted by Sanofi-Aventis R&D on 23 October 2014 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 16 January 2015, 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 lixisenatide (Lyxumia), solution for injection, subcutaneous use, including changes to the deferral, 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, France.

Done at London, 6 March 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/676479/2014 corr

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

EMEA-000916-PIP01-10-M04

Scope of the application

Active substance(s):

Lixisenatide

Invented name:

Lyxumia

Condition(s):

Treatment of type 2 diabetes mellitus

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Sanofi-Aventis R&D

Information about the authorised medicinal product:

See Annex II

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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 23 October 2014 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/18/2011 issued on 24 January 2011, the decision P/225/2011 issued on 27 September 2011, P/0076/2012 issued on 25 April 2012 and P/0035/2013 issued on 27 February 2013.

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

The procedure started on 19 November 2014.

Scope of the modification

Some measures and 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 Icelandic and the Norwegian Paediatric Committee members agree 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.

London, 16 January 2015

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 solution for injection (in a pre-filled pen), subcutaneous 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).

2. Paediatric Investigation Plan

2.1. Condition

Treatment of type 2 diabetes mellitus

2.2. Indication(s) targeted by the PIP

Treatment of type 2 diabetes mellitus

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

From 10 to less than 18 years of age.

2.3.1. Pharmaceutical form(s)

Solution for injection (in a pre-filled pen)

2.4. Measures

Area	Number of studies	Description
Quality-related studies	1	**Study 1:** Development of a disposable fixed-dose pen administering 0.1 mL / 5 micrograms per dose, for subcutaneous use.
Non-clinical studies	3	**Study 2**: Exploratory 2-week twice a day (BID) subcutaneous pharmacokinetic study in male juvenile dogs **Study 3:** 8-month BID/QD subcutaneous toxicity study in male juvenile dogs with a 2 month recovery period **Study 4:** Toxicity Study in Juvenile Rat
Clinical studies	2	**Study 5:** Randomized, double-blind, placebo controlled trial to assess safety, tolerability, pharmacokinetics and pharmacodynamics of lixisenatide in paediatric and adult

Area	Number of studies	Description
		patients with type 2 diabetes mellitus (PKD11475). **Study 6:** Safety and efficacy study of lixisenatide as monotherapy and add on treatment to metformin and/or basal insulin in paediatric patients with type 2 diabetes mellitus (EFC11476).
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 issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2022
Deferral for one or more measures 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 indication(s):

1. Lyxumia is indicated for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Subcutaneous use