European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 15 July 2009

on the agreement of a Paediatric Investigation Plan and on the granting of a waiver for insulin glargine (Lantus) (EMEA-000387-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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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 Sanofi-Aventis Deutschland GmbH on 9 October 2008 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 May 2009, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 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 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 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 insulin glargine (Lantus), solution for injection, solution for injection in a vial, solution for injection in a cartridge, subcutaneous 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 waiver for insulin glargine (Lantus), solution for injection, solution for injection in a vial, solution for injection in a cartridge, subcutaneous 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

This decision is addressed to Sanofi-Aventis Deutschland GmbH, Brueningstrasse 50, 65926 Frankfurt am Main, Germany.

Done at London, 15 July 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/283911/2009
EMEA-000387-PIP01-08

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

Scope of the application

Active substance(s):
Insulin glargine

Invented name:
Lantus

Condition(s):
Diabetes mellitus

Pharmaceutical form(s):
Solution for injection
Solution for injection in a vial
Solution for injection in a cartridge

Route(s) of administration:
Subcutaneous use

Name/corporate name of the PIP applicant:
Sanofi-Aventis Deutschland GmbH

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, Sanofi-Aventis Deutschland GmbH submitted for agreement to the EMEA on 9 October 2008 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 13 November 2008.

Supplementary information was provided by the applicant on 19 March 2009.

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 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 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, 29 May 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 1 diabetes mellitus
Type 2 diabetes mellitus

B. WAIVER

- **Condition**

Type 1 diabetes mellitus

The waiver applies to:

- Children less than one year old, for insulin glargine, solution for injection, solution for injection in a vial, solution for injection in a cartridge, subcutaneous use, on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population;

- Children from 6 to less than 18 year old, for insulin glargine, solution for injection, solution for injection in a vial, solution for injection in a cartridge, subcutaneous use, on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

- **Condition**

Type 2 diabetes mellitus

The waiver applies to:

- Children less than 10 years old, for insulin glargine, solution for injection, solution for injection in a vial, solution for injection in a cartridge, 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;

- Children from 10 to less than 18 year old, for insulin glargine, solution for injection, solution for injection in a vial, solution for injection in a cartridge, subcutaneous use, on the grounds that that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Type 1 diabetes mellitus

- **Proposed PIP indication**

  Treatment of type 1 diabetes mellitus

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

  From 1 to less than 6 years.

- **Formulation(s)**

  solution for injection, solution for injection in a vial, solution in injection in cartridge, subcutaneous use

- **Studies**

Area	Number of studies	Description
Quality		Not applicable.
Non-clinical		Not applicable.
Clinical	1	24-week, multicentre, randomized, open-label 2-arm parallel group trial of efficacy and safety of insulin glargine compared to NPH human insulin, in type 1 diabetic children from 1 to less than 6 years.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	**By December 2011**
Deferral for some or all studies contained in the paediatric investigation plan:	**No**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/00/134/001	Lantus	100 Units/ml	Solution for injection in a vial	Subcutaneous use	vial (glass)	5 ml	1 vial
EU/1/00/134/002	Lantus	100 Units/ml	Solution for injection in a vial	Subcutaneous use	vial (glass)	5 ml	2 vials
EU/1/00/134/003	Lantus	100 Units/ml	Solution for injection in a vial	Subcutaneous use	vial (glass)	5 ml	5 vials
EU/1/00/134/004	Lantus	100 Units/ml	Solution for injection in a vial	Subcutaneous use	vial (glass)	5 ml	10 vials
EU/1/00/134/005	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	4 cartridges
EU/1/00/134/006	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	5 cartridges
EU/1/00/134/007	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	10 cartridges
EU/1/00/134/008	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	3 pre-filled pens
EU/1/00/134/009	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	4 pre-filled pens
EU/1/00/134/010	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	5 pre-filled pens
EU/1/00/134/011	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	10 pre-filled pens
EU/1/00/134/012	Lantus	100 Units/ml	Solution for injection in a vial	Subcutaneous use	vial (glass)	10 ml	1 vial
EU/1/00/134/013	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	1 cartridge
EU/1/00/134/014	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	3 cartridges
EU/1/00/134/015	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	6 cartridges
EU/1/00/134/016	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	8 cartridges
EU/1/00/134/017	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass)	3 ml	9 cartridges

EU/1/00/134 /018	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	1 pre-filled pen
EU/1/00/134 /019	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	6 pre-filled pens
EU/1/00/134 /020	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	8 pre-filled pens
EU/1/00/134 /021	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (OptiSet)	3 ml	9 pre-filled pens
EU/1/00/134 /022	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	1 cartridge
EU/1/00/134 /023	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	3 cartridges
EU/1/00/134 /024	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	4 cartridges
EU/1/00/134 /025	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	5 cartridges
EU/1/00/134 /026	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	6 cartridges
EU/1/00/134 /027	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	8 cartridges
EU/1/00/134 /028	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	9 cartridges
EU/1/00/134 /029	Lantus	100 Units/ml	Solution for injection in a cartridge	Subcutaneous use	cartridge (glass) for OptiClik	3 ml	10 cartridges
EU/1/00/134 /030	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	1 pre-filled pen
EU/1/00/134 /031	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	3 pre-filled pens
EU/1/00/134 /032	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	4 pre-filled pens

EU/1/00/134 /033	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	5 pre-filled pens
EU/1/00/134 /034	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	6 pre-filled pens
EU/1/00/134 /035	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	8 pre-filled pens
EU/1/00/134 /036	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	9 pre-filled pens
EU/1/00/134 /037	Lantus	100 Units/ml	Solution for injection	Subcutaneous use	cartridge (glass) in a pre-filled pen (SoloStar)	3 ml	10 pre-filled pens