

EMA/241935/2019

## European Medicines Agency decision P/0181/2019

of 15 May 2019

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for efpeglenatide (EMA-001903-PIP01-15) 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 Hanmi Pharmaceutical Co., Ltd on 22 January 2016 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 29 March 2019, in accordance with Article 17 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 efpeglenatide, solution for injection, 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 deferral for efpeglenatide, solution for injection, 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**

A waiver for efpeglenatide, solution for injection, 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 4**

This decision is addressed to Sanofi-aventis recherche et développement, 1 avenue Pierre Brossolette, 91385 - Chilly-Mazarin Cedex, France.

EMA/PDCO/2162/2019 **Corr**

Amsterdam, 29 March 2019

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

EMA-001903-PIP01-15

### Scope of the application

**Active substance(s):**

Efpeglenatide

**Condition(s):**

Treatment of type 2 diabetes mellitus

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Subcutaneous use

**Name/corporate name of the PIP applicant:**

Sanofi-aventis recherche et développement

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Hanmi Pharmaceutical Co., Ltd submitted for agreement to the European Medicines Agency on 22 January 2016 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 1 March 2016.

Supplementary information was provided by the applicant on 19 December 2018. The applicant proposed modifications to the paediatric investigation plan.

On 19 December 2018 Hanmi Pharmaceutical Co., Ltd requested to transfer the paediatric investigation plan to Sanofi-aventis recherche et développement.

## 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 17(1) 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.

## **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 of age;
- solution for injection, 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

### 2.1.1. 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)

Solution for injection

### 2.1.4. Measures

| Area                    | Number of measures | Description                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Quality-related studies | 0                  | Not applicable.                                                                                                                                                                                                                                                                                                                                                                 |
| Non-clinical studies    | 1                  | <b>Study 1</b><br>Pre- and postnatal development study in rats.                                                                                                                                                                                                                                                                                                                 |
| Clinical studies        | 1                  | <b>Study 2</b><br>Double-blind, placebo-controlled, randomized, 2-arm, parallel group study comparing efpeglenatide once weekly to placebo in children and adolescents from 10 to less than 18 years of age with Type 2 diabetes mellitus, inadequately controlled with diet and exercise and who are either on metformin or on insulin alone ( <i>if patient intolerant to</i> |

|                                                 |   |                                                                                                                                                                                     |
|-------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                 |   | <i>metformin at all doses</i> ) or on a combination of metformin with insulin.<br>The objectives of this study are to evaluate PK, efficacy and safety of efpeglenatide (EFC16191). |
| 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 January 2025 |
| Deferral for one or more measures contained in the paediatric investigation plan:     | Yes             |