

EMA/414689/2020

European Medicines Agency decision

P/0300/2020

of 12 August 2020

on the acceptance of a modification of an agreed paediatric investigation plan for efpeglenatide (EMA-001903-PIP01-15-M01) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0181/2019 issued on 15 May 2019,

Having regard to the application submitted by Sanofi-aventis recherche et développement on 27 February 2020 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 26 June 2020, 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 efpeglenatide, 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 recherche et développement, 1 avenue Pierre Brossolette, 91385 - Chilly-Mazarin Cedex, France.

EMA/PDCO/204822/2020
Amsterdam, 26 June 2020

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001903-PIP01-15-M01

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 22 of Regulation (EC) No 1901/2006 as amended, Sanofi-aventis recherche et développement submitted to the European Medicines Agency on 27 February 2020 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/0181/2019 issued on 15 May 2019.

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

The procedure started on 30 April 2020.

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 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 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	Study 1 Pre- and postnatal development study in rats.
Clinical studies	1	Study 2 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</i>

		<i>to metformin at all doses</i>) or on a combination of metformin with insulin. 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 November 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes