



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/521826/2021

## European Medicines Agency decision P/0452/2021

of 29 October 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for 2-[(4-{6-[(4-cyano-2-fluorobenzyl)oxy]pyridin-2-yl}piperidin-1-yl)methyl]-1-[(2S)-oxetan-2-ylmethyl]-1H-benzimidazole-6-carboxylic acid tris(hydroxymethyl)aminomethane salt (1:1) (PF-06882961) (EMEA-002944-PIP01-20) 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.**



# European Medicines Agency decision

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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 Pfizer Europe MA EEIG on 16 December 2020 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 10 September 2021, 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 2-[(4-{6-[(4-cyano-2-fluorobenzyl)oxy]pyridin-2-yl}piperidin-1-yl)methyl]-1-[(2S)-oxetan-2-ylmethyl]-1H-benzimidazole-6-carboxylic acid tris(hydroxymethyl)aminomethane salt (1:1) (PF-06882961), tablet, age-appropriate oral formulation, oral 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 2-[(4-{6-[(4-cyano-2-fluorobenzyl)oxy]pyridin-2-yl}piperidin-1-yl)methyl]-1-[(2S)-oxetan-2-ylmethyl]-1H-benzimidazole-6-carboxylic acid tris(hydroxymethyl)aminomethane salt (1:1) (PF-06882961), tablet, age-appropriate oral formulation, oral 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 2-[(4-{6-[(4-cyano-2-fluorobenzyl)oxy]pyridin-2-yl}piperidin-1-yl)methyl]-1-[(2S)-oxetan-2-ylmethyl]-1H-benzimidazole-6-carboxylic acid tris(hydroxymethyl)aminomethane salt (1:1) (PF-06882961), tablet, age-appropriate oral formulation, oral 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 Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 – Brussels, Belgium.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/20904/2021  
Amsterdam, 10 September 2021

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

EMA-002944-PIP01-20

### Scope of the application

#### Active substance(s):

2-[(4-{6-[(4-cyano-2-fluorobenzyl)oxy]pyridin-2-yl}piperidin-1-yl)methyl]-1-[(2S)-oxetan-2-ylmethyl]-1H-benzimidazole-6-carboxylic acid tris(hydroxymethyl)aminomethane salt (1:1)  
(PF-06882961)

#### Condition(s):

Treatment of type 2 diabetes mellitus

#### Pharmaceutical form(s):

Tablet

Age-appropriate oral formulation

#### Route(s) of administration:

Oral use

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

Pfizer Europe MA EEIG

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted for agreement to the European Medicines Agency on 16 December 2020 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 26 January 2021.

Supplementary information was provided by the applicant on 4 June 2021. The applicant proposed modifications to the paediatric investigation plan.



## 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 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;
- tablet, age-appropriate oral formulation, 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.

# 2. Paediatric investigation plan

## 2.1. Condition: Treatment of type 2 diabetes mellitus (T2DM)

### 2.1.1. Indication(s) targeted by the PIP

Add-on therapy for children and adolescents aged 10 to <18 years with T2DM receiving standard-of-care treatment

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

From 10 years to less than 18 years of age.

### 2.1.3. Pharmaceutical form(s)

Tablet

Age-appropriate oral formulation

### 2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	<b>Study 1</b> Development of an age-appropriate formulation for PF-06882961 suitable for oral use in the paediatric target population.
Non-clinical studies	0	Not applicable.
Clinical studies	1	<b>Study 2</b> Randomised, double-blind, placebo-controlled, parallel-group study to assess the efficacy in terms of superiority over placebo, the safety, and pharmacokinetics (PK) of PF-06882961 in the treatment of type 2 diabetes mellitus (T2DM) in children from 10 years to less than 18 years of age.

<b>Area</b>	<b>Number of measures</b>	<b>Description</b>
Extrapolation, modelling and simulation studies	3	<p><b>Study 3</b></p> <p>Modelling and simulation study for paediatric dose selection for PF-06882961.</p> <p><b>Study 4</b></p> <p>Interim analysis of PK data from paediatric subjects in clinical study (Study 2)</p> <p><b>Study 5</b></p> <p>Population PK and PK/PD analysis of paediatric data</p>
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 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes