MHRA
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Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100257-PIP01-21

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 Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 24/11/2021 14:51 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/08/2022 17:10 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a deferral and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100257-PIP01-21

Of 03/10/2022 15:10 BST

On the adopted decision 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 (MHRA-100257-PIP01-21) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to 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 .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, United Kingdom, CT13 9NJ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of type 2 diabetes mellitus The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Tablet; Age-appropriate oral formulation. Route(s) of administration: Oral use Reason for granting waiver: 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(s):

Treatment of type 2 diabetes mellitus (T2DM)

2.2 Indication(s) targeted by the PIP:

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

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

The paediatric population from 10 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Tablet; Age-appropriate oral formulation.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 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	Study 2 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 (TD2M) in children from 10 years to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	3	Study 3 Modelling and simulations study for paediatric dose selection for PF-06882961. Study 4 Interim analysis of PK data from paediatric subjects in clinical study (study 2). Study 5 Population PK and PK/PD analysis of paediatric data.
Other Studies	0	Not applicable
Other Measures	0	Not applicable

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	30/11/2030

Deferral of one or more studies contained in the paediatric investigation plan:	Yes