

EMA/480850/2018

European Medicines Agency decision

P/0235/2018

of 15 August 2018

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for his-Ser-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Lys(γ -Glu-palmitoyl)-Ser-Glu-Tyr-Leu-Asp-Ser-Glu-Arg-Ala-Arg-Asp-Phe-Val-Ala-Trp-Leu-Glu-Ala-Gly-Gly-OH (MEDI0382) (EMA-002287-PIP01-17) 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 application submitted by MedImmune Limited on 23 November 2017 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 June 2018, 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.

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 for his-Ser-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Lys(γ -Glu-palmitoyl)-Ser-Glu-Tyr-Leu-Asp-Ser-Glu-Arg-Ala-Arg-Asp-Phe-Val-Ala-Trp-Leu-Glu-Ala-Gly-Gly-OH (MEDI0382), 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 his-Ser-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Lys(γ -Glu-palmitoyl)-Ser-Glu-Tyr-Leu-Asp-Ser-Glu-Arg-Ala-Arg-Asp-Phe-Val-Ala-Trp-Leu-Glu-Ala-Gly-Gly-OH (MEDI0382), 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 his-Ser-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Lys(γ -Glu-palmitoyl)-Ser-Glu-Tyr-Leu-Asp-Ser-Glu-Arg-Ala-Arg-Asp-Phe-Val-Ala-Trp-Leu-Glu-Ala-Gly-Gly-OH (MEDI0382), 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 MedImmune Limited, Milstein Building, Granta Park, CB21 6GH - Cambridge, United Kingdom.

EMA/PDCO/255750/2018 **Corr**

London, 29 June 2018

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

EMA-002287-PIP01-17

Scope of the application

Active substance(s):

His-Ser-Gln-Gly-Thr-Phe-Thr-Ser-Asp-Lys(γ -Glu-palmitoyl)-Ser-Glu-Tyr-Leu-Asp-Ser-Glu-Arg-Ala-Arg-Asp-Phe-Val-Ala-Trp-Leu-Glu-Ala-Gly-Gly-OH (MEDI0382)

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:

MedImmune Limited

Information about the authorised medicinal product:

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, MedImmune Limited submitted for agreement to the European Medicines Agency on 23 November 2017 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 3 January 2018.

Supplementary information was provided by the applicant on 2 May 2018. 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(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, as adjunct therapy to diet and exercise and metformin, with or without additional insulin

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 Nonclinical pharmacokinetic/ tissue distribution study in rats to investigate potential brain penetration of MEDI0382
Clinical studies	2	Study 2 Open-label, uncontrolled, multiple-dose study in children from 10 to less than 18 years of age with type 2 diabetes mellitus to evaluate the pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability of

		MEDI0382 and confirm a suitable dose for the subsequent pivotal paediatric study (Part A) Study 3 Randomised, double-blind, placebo-controlled 26-week confirmatory study, with a 26-week open label extension period, in children from 10 to less than 18 years of age (and adults) with type 2 diabetes mellitus to evaluate the efficacy and safety of MEDI0382 (Part B)
Extrapolation, modelling and simulation studies	3	Study 4 Population PK/PD model, based on MEDI0382 PK and PD data from adults (below and above 25 years of age) to help characterize MEDI0382's dose-exposure-response after SC administration and support the dose selection in the paediatric clinical PK/PD study (PIP Study 2, Part A) Study 5 Population PK/PD model, based on MEDI0382 PK and PD data from children 10 to less than 18 years of age (PIP Study 1, Part A), to help characterize MEDI0382's dose-exposure-response after SC administration and to support dose selection in the confirmatory paediatric clinical trial (PIP Study 3, Part B) Study 6 Population PK/PD model, based on MEDI0382 PK and PD data from children 10 to less than 18 years of age (PIP Study 2, Part A and PIP Study 3, Part B), to: 1. help characterize the paediatric PK using population PK modelling and identify the relevant PK covariates 2. to explore the exposure-response in paediatrics and support paediatric dosing
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 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes