EMA/317985/2021

European Medicines Agency decision

P/0270/2021

of 9 July 2021

on the acceptance of a modification of an agreed paediatric investigation plan for cotadutide (EMEA-002287-PIP01-17-M02) 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

European Medicines Agency decision

P/0270/2021

of 9 July 2021

on the acceptance of a modification of an agreed paediatric investigation plan for cotadutide (EMEA-002287-PIP01-17-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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[1],

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[2],

Having regard to the European Medicines Agency's decision P/0235/2018 issued on 15 August 2018 and the decision P/0502/2020 issued on 22 December 2020,

Having regard to the application submitted by AstraZeneca AB on 12 February 2021 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 21 May 2021, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 cotadutide, solution for injection, subcutaneous use, 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 AstraZeneca AB, SE-151 85 - Södertälje, Sweden.

EMA/PDCO/131984/2021
Amsterdam, 21 May 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002287-PIP01-17-M02

Scope of the application

Active substance(s):

Cotadutide

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:

AstraZeneca AB

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, AstraZeneca AB submitted to the European Medicines Agency on 12 February 2021 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/0235/2018 issued on 15 August 2018 and the decision P/0502/2020 issued on 22 December 2020.

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

The procedure started on 23 March 2021.

Scope of the modification

Some 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 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, 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