EMA/624371/2021

European Medicines Agency decision

P/0503/2021

of 3 December 2021

on the agreement of a paediatric investigation plan and on the granting of a waiver for lutetium (^{177}Lu) oxodotreotide (Lutathera), (EMEA-002950-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.

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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[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 application submitted by Advanced Accelerator Applications on 18 December 2020 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 October 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 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 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 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 lutetium (^{177}Lu) oxodotreotide (Lutathera), solution for infusion, intravenous 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 waiver for lutetium (^{177}Lu) oxodotreotide (Lutathera), solution for infusion, intravenous 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

This decision is addressed to Advanced Accelerator Applications, 20 rue Diesel, 01630 - Saint Genis Pouilly, France.

EMA/PDCO/435024/2021
Amsterdam, 15 October 2021

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

EMEA-002950-PIP01-20

Scope of the application

Active substance(s):

Lutetium (^{177}Lu) oxodotreotide

Invented name:

Lutathera

Condition(s):

Treatment of gastroenteropancreatic neuroendocrine tumours

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Advanced Accelerator Applications

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Advanced Accelerator Applications submitted for agreement to the European Medicines Agency on 18 December 2020 an application for a paediatric investigation plan for the above-mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 26 January 2021.

Supplementary information was provided by the applicant on 2 July 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 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 annexes 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 gastroenteropancreatic neuroendocrine tumours

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- solution for infusion, intravenous 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 gastroenteropancreatic neuroendocrine tumours

2.1.1. Indication(s) targeted by the PIP

Treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NET)

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

From 12 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	1	Open-label trial to evaluate safety and dosimetry of lutetium (^{177}Lu) oxodotreotide in adolescents from 12 years to less than 18 years of age with somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NET) and, as an exploratory cohort, with somatostatin receptor positive pheochromocytoma and paragangliomas (PPGLs). (CAAA601A32201).

Extrapolation, modelling and simulation studies	1	Modelling and simulation study to evaluate pharmacokinetic (PK) parameters and dosimetry of lutetium (^{177}Lu) oxodotreotide in adolescents from 12 years to less than 18 years of age with somatostatin receptor positive GEP-NET.
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:	No
Date of completion of the paediatric investigation plan:	By January 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of gastroenteropancreatic neuroendocrine tumours.

Authorised indication(s):

- Lutathera is indicated for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adults.

Authorised pharmaceutical form(s):

Solution for infusion

Authorised route(s) of administration:

Intravenous use