EMA/526330/2023

European Medicines Agency decision

P/0461/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for lutetium (177Lu) oxodotreotide (Lutathera), (EMEA-002950-PIP01-20-M01) 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

P/0461/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for lutetium (177Lu) oxodotreotide (Lutathera), (EMEA-002950-PIP01-20-M01) 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0503/2021 issued on 3 December 2021,

Having regard to the application submitted by Advanced Accelerator Applications on 3 July 2023 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 October 2023, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for lutetium (177Lu) oxodotreotide (Lutathera), solution for infusion, intravenous 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 Advanced Accelerator Applications, 8-10 Rue Henri Sainte-Claire Deville 92500 - Rueil-Malmaison, France.

EMA/PDCO/317022/2023
Amsterdam, 13 October 2023

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

EMEA-002950-PIP01-20-M01

Scope of the application

Active substance(s):

Lutetium (177Lu) oxodotreotide

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of gastroenteropancreatic neuroendocrine tumours

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Advanced Accelerator Applications

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Advanced Accelerator Applications submitted to the European Medicines Agency on 3 July 2023 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0503/2021 issued on 3 December 2021.

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

The procedure started on 14 August 2023.

Scope of the modification

Some measures and 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 Paediatric Committee member of Norway 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 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	Description
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	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 pheochromocytoma and paragangliomas (PPGLs) as a pooled cohort. (CAAA601A32201).
Extrapolation, modelling and simulation studies	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/PPGL.

Other studies	Not applicable.
Other measures	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 October 2024
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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
  - Invented name(s): Lutathera
  - Authorised pharmaceutical form(s): solution for infusion
  - Authorised route(s) of administration: intravenous use
  - Authorised via centralised procedure