MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100719-PIP01-22)

MHRA-100719-PIP01-22-M01

Scope of the Application

Active Substance(s)

LUTETIUM (177LU) OXODOTREOTIDE

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 the Decision

Pursuant to the Human Medicines Regulations 2012, Advanced Accelerator Applications submitted to the licensing authority on 25/10/2023 16:58 BST an application for a Modification

The procedure started on 01/02/2024 14:27 GMT

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 accept change(s) to the agreed paediatric investigation plan

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-100719-PIP01-22-M01

Of 04/03/2024 16:56 GMT

On the adopted decision for LUTETIUM (177LU) OXODOTREOTIDE (MHRA-100719-PIP01-22-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for LUTETIUM (177LU) OXODOTREOTIDE, Solution for infusion , INTRAVENOUS USE .

This decision is addressed to Advanced Accelerator Applications, 8-10 Rue Henri Sainte-Claire Deville, Rueil-Malmaison, FRANCE, 92500

ANNEX I

1. Waiver

1.1 Condition:

Treatment of gastroenteropancreatic neuroendocrine tumours The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age Pharmaceutical form(s): Solution for infusion Route(s) of administration: INTRAVENOUS 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 gastroenteropancreatic neuroendocrine tumours

2.2 Indication(s) targeted by the PIP:

Treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP-NETs) in adolescent patients (from 12 years to less than 18 years of age)

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

The paediatric population from 12 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (CAAA601A32201) Open-label trial to evaluate safety and dosimetry of lutetium (177Lu) 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.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to evaluate pharmacokinetic (PK) parameters and dosimetry of lutetium (177Lu) oxodotreotide in adolescents from 12 years to less than 18 years of age with somatostatin receptor positive GEP-NET/PPGL.
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:	No
Date of completion of the paediatric investigation plan:	31/10/2024

Deferral of one or more studies contained in the paediatric investigation plan:	No