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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100545-PIP01-22

Scope of the Application

Active Substance(s)

Lutetium (177Lu) edotreotide

Condition(s)

Treatment of gastro-entero-pancreatic neuroendocrine tumours (GEP-NETs)

Pharmaceutical Form(s)

Solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

ITM Solucin GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ITM Solucin GmbH submitted to the licensing authority on 16/05/2022 13:11 BST an application for a Paediatric Investigation Plan

The procedure started on 12/12/2022 12:41 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-100545-PIP01-22

Of 06/03/2023 10:09 GMT

On the adopted decision for Lutetium (177Lu) edotreotide (MHRA-100545-PIP01-22) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Lutetium (177Lu) edotreotide, Solution for infusion , INTRAVENOUS USE .

This decision is addressed to ITM Solucin GmbH, Lichtenbergstrasse 1, Garching/Munich, GERMANY, 85748

ANNEX I

1. Waiver

1.1 Condition:

Treatment of gastro-entero-pancreatic neuroendocrine tumours (GEP-NETs). The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of gastro-entero-pancreatic neuroendocrine tumours (GEP-NETs).

2.2 Indication(s) targeted by the PIP:

Treatment of gastro-entero-pancreatic neuroendocrine tumours (GEP-NETs).

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

The paediatric population from 2 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 Open-label trial to evaluate dosimetry of lutetium (177Lu) edotreotide as an add-on to best standard of care (SOC) in children from 2 years to less than 18 years of age with somatostatin receptor imaging positive (SRI+) solid tumours and lymphoma.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Modelling and simulation study to evaluate the PK parameters and dosimetry in children from 2 years to less than 18 years of age with GEP-NETS.
Other Studies	1	The COMPETE (NCT03049189) and COMPOSE (NCT04919266) studies in adults and PIP study 1 are part of an extrapolation plan covering the paediatric population from 2 years to less than 18 years of age, as agreed by the Regulatory Agency.
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:	30/06/2028
Deferral of one or more studies contained in the paediatric investigation plan:	Yes