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Novartis Pharma AG
[redacted]

Dr. Bruno Sepodes
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

9th May 2025

Subject: Withdrawal of Type II variation application for Lutathera® (lutetium (^{177}Lu) oxodotreotide), 370 MBq/mL solution for infusion - EMEA/H/C/004123/II/0052

Dear Dr. Sepodes,

I would like to inform you that, at this point in time, Advanced Accelerator Applications, a Novartis Company, has taken the decision to withdraw the Type II variation application to extend the indication of Lutathera, for the treatment of newly diagnosed, unresectable or metastatic, well-differentiated (Grade (G2) and G3), somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adults.

This withdrawal is based on a company decision that is not related to the product's quality, efficacy or safety.

This withdrawal does not have any impact on clinical trials with Lutathera or on the use of Lutathera in its approved indication.

Advanced Accelerator Applications remains fully committed to further advancing the treatment of patients with GEP-NETs and reserves the right to make further applications to vary the terms of this Marketing Authorization at a future date.

We would like to sincerely thank the Rapporteurs, the EMA and the CHMP and PRAC members for the time dedicated to reviewing this application and the support provided during the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,

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