20 July 2017
EMA/CHMP/437314/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lutathera

lutetium (^{177}Lu) oxodotreotide

On 20 July 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lutathera, a radiopharmaceutical medicinal product indicated for the treatment of well differentiated gastroenteropancreatic neuroendocrine tumours (GEP-NETs). Lutathera was designated as an orphan medicinal product on 31 January 2008. The applicant for this medicinal product is Advanced Accelerator Applications.

Lutathera will be available as a 370 MBq/ml solution for infusion. The active substance of Lutathera is lutetium (^{177}Lu) oxodotreotide, a radiolabelled peptide that has high affinity for subtype 2 somatostatin receptors (sst2) (ATC code: V10XX04). It targets malignant cells which overexpress sst2 receptors and has a limited effect on neighbouring noncancerous cells.

The benefits with Lutathera are its ability to improve progression-free survival compared with octreotide LAR, a somatostatin receptor agonist, in patients with well differentiated GEP-NET tumours.

The most common side effects are nausea, vomiting, haematological toxicity (thrombocytopenia, lymphopenia, anaemia, pancytopenia), fatigue and decreased appetite.

The full indication is: "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." Lutathera should be administered only by persons authorised to handle radiopharmaceuticals in designated clinical settings and after evaluation of the patient by a qualified physician.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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