- Intelligence Simplified

Lutathera approved by USFDA Potential Blockbuster Drug Lutathera approved by USFDA

Lutathera (lutetium Lu 177 dotatate) is a radiolabeled somatostatin analog approved on Jan 26, 2018 as injection for intravenous use, 370 MBq/mL (10 mCi/mL) in single-dose vial for the treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) including foregut, midgut, and hindgut neuroendocrine tumors in adults.

Uniqueness: Being radiolabeled somatostatin analog it not only diagnoses the disease and but also binds to somatostatin receptor expressing cells, subtype 2 receptors (SSRT2), including malignant somatostatin receptor-positive tumors, the compound is internalized. The beta emission from Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and in neighbouring cells.

Safety: As per the clinical trials Lutatera demonstrated a 79% drop in disease progression compared to Novartis approved blockbuster drug Sandostatin. It is likely that Novartis will replace the patent expired products for this indication with Lutathera.

Peak Sales: Jefferies analysts have predicted $500 million to $1 billion in peak sales for the drug, while Baader Helvea analyst Bruno Bulic estimated peak sales potential at $2 billion.

First FDA approval for Peptide Receptor Radionuclide Therapy (PRRT)

Note: This product was developed by Advanced Accelerator Applications - a newly established subsidiary of Novartis.