Generic Name:
Lutetium Lu 177 dotatate
Trade Name:
Lutathera
Company:
Advanced Accelerator Applications
Notes:

FDA approved lutetium Lu 177 dotatate for treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs), a rare type of cancer that affects the pancreas or gastrointestinal tract. This is the first time a radioactive drug, or radiopharmaceutical, has been approved for treatment of GEP-NETs. The agent is indicated for adult patients with somatostatin receptor-positive GEP-NETs.

GEP-NETs can be present in the pancreas and in different parts of the gastrointestinal tract such as the stomach, intestines, colon, and rectum. Approximately 1 out of 27,000 people are diagnosed with GEP-NETs per year.

The radioactive drug works by binding to a somatostatin receptor, which may be present on certain tumors. After binding to the receptor, the drug enters the cell, allowing radiation to cause damage to the tumor cells.

Approval was supported by two studies. The first was a randomized clinical trial in 229 patients with a certain type of advanced somatostatin receptor-positive GEP-NET. Patients in the trial either received either lutetium Lu 177 dotatate in combination with the drug octreotide or octreotide alone.

The study measured the length of time the tumors did not grow after treatment (progression-free survival). Progression-free survival was longer for patients taking lutetium Lu 177 dotatate with octreotide compared with patients who received octreotide alone. This means the risk of tumor growth or patient death was lower for patients who received lutetium Lu 177 dotatate with octreotide compared with that of patients who received only octreotide.

The second study was based on data from 1,214 patients with somatostatin receptor-positive tumors, including GEP-NETS, who received lutetium Lu 177 dotatate at a single site in the Netherlands.

Complete or partial tumor shrinkage was reported in 16% of a subset of 360 patients with GEP-NETs who were evaluated for response by FDA. Patients initially enrolled in the study received lutetium Lu 177 dotatate as part of an expanded access program, a way for patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives to gain access to investigational drugs for treatment use.

Common adverse effects include lymphopenia, high levels of enzymes in certain organs (increased GGT, AST, and/or ALT), vomiting, nausea, hyperglycemia, and hypokalemia.

Serious adverse effects include myelosuppression, development of certain blood or bone

marrow cancers, kidney damage, liver damage, abnormal levels of hormones in the body, and infertility.

The agent can cause harm to a developing fetus; women should be advised of the potential risk to the fetus and to use effective contraception.

Patients taking lutetium Lu 177 dotatate are exposed to radiation. Exposure of other patients, medical personnel, and household members should be limited in accordance with radiation safety practices.

Medication Monitor Categories:

New Drug Approvals
