Lutathera® (lutetium Lu 177 dotatate) – Expanded indication

- On April 23, 2024, Novartis announced the FDA approval of Lutathera (lutetium Lu 177 dotatate), for the treatment of adult and pediatric patients 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.
    - Lutathera was previously approved in adults only.
- The approval of Lutathera for the expanded indication was supported by evidence from an adequate and well-controlled study of Lutathera in adults with additional safety, pharmacokinetic, and dosimetry data in pediatric patients aged 12 years and older with somatostatin receptor-positive tumors, including 4 pediatric patients with GEP-NETs.
    - The risks of radiation exposure associated with Lutathera are greater in pediatric patients than in adult patients due to longer life expectancy. Continued follow-up is recommended for evaluation of long-term effects.
- The recommended Lutathera dosage for adult and pediatric patients 12 years and older is 7.4 GBq (200 mCi) via intravenous infusion every 8 weeks (± 1 week) for a total of 4 doses.