

To estimate the **Potential Peak Sales** for lutetium Lu 177 dotatate (Lutathera) in the indication of somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data such as exact patient numbers, pricing, or market penetration rates may not be publicly available in full detail, I will outline the methodology and provide a reasonable estimate based on available information and assumptions.

Step 1: Define the Target Population

- **Indication:** SSTR-positive GEP-NETs (including foregut, midgut, and hindgut neuroendocrine tumors) in adults and pediatric patients (12 years and older).

- **Geographies:** US, EU5, China, Japan.

- **Prevalence/Incidence:** GEP-NETs are rare tumors. According to literature, the incidence of NETs is approximately 6-7 per 100,000 people annually in the US and EU, with GEP-NETs constituting a significant portion. China and Japan may have slightly different epidemiology due to genetic and environmental factors, but data is less robust.

- **US:** ~170,000-200,000 prevalent cases (based on historical data and SEER database estimates for NETs).

- **EU5:** ~150,000-180,000 prevalent cases (based on population size and similar incidence rates).

- **China:** ~300,000-400,000 prevalent cases (larger population, but lower diagnosis rates due to healthcare access).

- **Japan:** ~40,000-50,000 prevalent cases (smaller population, high diagnosis rates).

- **Eligible Patients:** Not all prevalent cases are SSTR-positive or eligible for treatment with Lutathera (e.g., due to disease stage or other factors). It is estimated that ~50-60% of GEP-NET patients are SSTR-positive and may be eligible for peptide receptor radionuclide therapy (PRRT) like Lutathera.

- **Pediatric Patients:** Pediatric cases (12 years and older) are a small fraction of the total, likely <5% of the patient population, as GEP-NETs are extremely rare in children.

Step 2: Estimate Treated Patients

- **Assumption:** Only a fraction of eligible patients receive treatment due to factors like access to therapy, reimbursement, and physician/patient preference. Based on the query, we assume a **20-30% share of treated patients** for Lutathera among eligible patients.

- **Estimated Eligible Patients** (SSTR-positive and suitable for PRRT):

- US: ~85,000-120,000

- EU5: ~75,000-108,000

- China: ~150,000-240,000

- Japan: ~20,000-30,000

- **Treated Patients (20-30% share):**

- US: ~17,000-36,000
- EU5: ~15,000-32,400
- China: ~30,000-72,000
- Japan: ~4,000-9,000

Step 3: Pricing and Treatment Cost

- **Cost of Lutathera:** The drug is administered in 4 cycles (one every 8 weeks). In the US, the cost per cycle is approximately \$47,500 (based on historical data and reports), leading to a total cost of ~\$190,000 per patient for a full course. Pricing in other regions is typically lower due to healthcare system differences:

- EU5: ~\$120,000-\$150,000 per patient (varies by country due to reimbursement and pricing negotiations).
- China: ~\$80,000-\$100,000 per patient (lower pricing, limited access).
- Japan: ~\$130,000-\$160,000 per patient (similar to EU, high reimbursement but smaller market).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients multiplied by the cost per patient. We will use the midpoint of the 20-30% share range (25%) for simplicity and provide a range based on pricing variations.

- US:

- Treated patients (25%): ~26,250
- Cost per patient: \$190,000
- Peak Sales: ~\$4.99 billion (range: \$3.23B-\$6.84B for 20-30% share)

- EU5:

- Treated patients (25%): ~23,625
- Cost per patient: \$135,000 (midpoint)
- Peak Sales: ~\$3.19 billion (range: \$1.8B-\$4.86B for 20-30% share)

- China:

- Treated patients (25%): ~52,500
- Cost per patient: \$90,000 (midpoint)
- Peak Sales: ~\$4.73 billion (range: \$2.4B-\$7.2B for 20-30% share)

- Japan:

- Treated patients (25%): ~6,250
- Cost per patient: \$145,000 (midpoint)

- Peak Sales: ~\$0.91 billion (range: \$0.52B-\$1.44B for 20-30% share)

- **Total Peak Sales (across geographies):**

- Midpoint estimate (25% share): ~\$13.82 billion

- Range (20-30% share): ~\$8.0B-\$20.34B

Step 5: Calculate \$ Value of 1% Share of Treated Patients

The 1% share of treated patients corresponds to 1% of the eligible patients being treated with Lutathera. Using the midpoint of eligible patients and pricing:

- **US:**

- 1% of eligible patients: ~1,025 (midpoint of 85,000-120,000)

- Cost per patient: \$190,000

- \$ Value of 1% share: ~\$194.75 million

- **EU5:**

- 1% of eligible patients: ~915 (midpoint of 75,000-108,000)

- Cost per patient: \$135,000

- \$ Value of 1% share: ~\$123.53 million

- **China:**

- 1% of eligible patients: ~1,950 (midpoint of 150,000-240,000)

- Cost per patient: \$90,000

- \$ Value of 1% share: ~\$175.5 million

- **Japan:**

- 1% of eligible patients: ~250 (midpoint of 20,000-30,000)

- Cost per patient: \$145,000

- \$ Value of 1% share: ~\$36.25 million

- **Total \$ Value of 1% Share (across geographies): ~\$530.03 million**

Summary

1. Potential Peak Sales for Lutathera in GEP-NETs (20-30% share of treated patients):

- US: \$3.23B-\$6.84B (midpoint ~\$4.99B)

- EU5: \$1.8B-\$4.86B (midpoint ~\$3.19B)

- China: \$2.4B-\$7.2B (midpoint ~\$4.73B)

- Japan: \$0.52B-\$1.44B (midpoint ~\$0.91B)
- **Total:** \$8.0B-\$20.34B (midpoint ~\$13.82B)

2. \$ Value of 1% Share of Treated Patients:

- US: ~\$194.75M
- EU5: ~\$123.53M
- China: ~\$175.5M
- Japan: ~\$36.25M
- **Total:** ~\$530.03M

Caveats and Assumptions

- **Epidemiology Data:** Patient numbers are estimates based on literature and may vary with updated studies or diagnostic improvements.
- **Pricing:** Pricing is based on US figures and adjusted for other regions; actual costs may differ due to negotiations, reimbursement, or generics/competition.
- **Market Share:** The 20-30% share is an assumption as per the query; actual penetration may depend on competition (e.g., other PRRTs or therapies) and access.
- **Pediatric Impact:** Pediatric patients are a small fraction and unlikely to significantly impact total sales.

These estimates provide a high-level view and should be refined with more specific data on patient populations, real-world pricing, and market dynamics if available. If you have additional data or specific assumptions, I can adjust the calculations accordingly.