

To estimate the **Potential Peak Sales** for lutetium Lu 177 vipivotide tetraxetan (Pluvicto) in the indication of PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data such as exact patient numbers, pricing, and penetration rates are not provided, I will use reasonable assumptions based on publicly available information, market research trends, and oncology drug pricing patterns. The final numbers should be validated with actual data for precision.

Step 1: Define the Target Patient Population

The indication is for adults with PSMA-positive mCRPC who have been treated with androgen receptor pathway inhibitors (ARPI) and are appropriate to delay taxane-based chemotherapy. This is a subset of mCRPC patients.

- **US:** Approximately 30,000–35,000 new mCRPC cases annually. Assuming ~70% are PSMA-positive (based on diagnostic imaging studies), and ~50% of these have progressed on ARPI and are pre-taxane, the eligible population is ~10,000–12,000 patients.
- **EU5:** Combined incidence of mCRPC is roughly similar to the US, adjusted for population (~30,000–35,000). Applying similar filters, the eligible population is ~10,000–12,000 patients.
- **China:** Prostate cancer incidence is lower than in Western countries but growing. mCRPC cases are estimated at ~15,000–20,000 annually. With PSMA-positivity and pre-taxane criteria, the eligible population is ~5,000–7,000 patients.
- **Japan:** Prostate cancer incidence is lower, with ~5,000–7,000 mCRPC cases annually. Eligible population after filters is ~2,000–3,000 patients.

Total Eligible Population (approximate):

- US: 11,000
- EU5: 11,000
- China: 6,000
- Japan: 2,500
- **Total:** ~30,500 patients

Step 2: Estimate Treated Patients (Market Penetration)

The problem assumes a 20% to 30% share of treated patients. This reflects the drug's penetration among eligible patients, considering factors like access, reimbursement, and competition (e.g., other therapies for mCRPC such as chemotherapy or other radiopharmaceuticals).

- At 20% penetration: ~6,100 patients treated annually.
- At 30% penetration: ~9,150 patients treated annually.

Step 3: Estimate Pricing per Patient

Lutetium Lu 177 vipivotide tetraxetan (Pluvicto) is a radiopharmaceutical with a high cost due to its novel mechanism and production complexity. Based on reported pricing:

- **US:** ~\$42,500 per dose, with a typical regimen of 6 doses = ~\$255,000 per patient per treatment course.
- **EU5:** Pricing is typically 60–70% of US prices due to healthcare system negotiations = ~\$150,000–\$180,000 per patient (assume \$165,000 average).
- **China:** Pricing is lower due to market dynamics and reimbursement challenges = ~\$100,000 per patient.
- **Japan:** Pricing aligns closer to EU levels = ~\$165,000 per patient.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated based on the number of treated patients and the price per patient in each geography.

At 20% Penetration (6,100 patients treated):

- **US:** 11,000 eligible * 20% = 2,200 patients * \$255,000 = **\$561M**
- **EU5:** 11,000 eligible * 20% = 2,200 patients * \$165,000 = **\$363M**
- **China:** 6,000 eligible * 20% = 1,200 patients * \$100,000 = **\$120M**
- **Japan:** 2,500 eligible * 20% = 500 patients * \$165,000 = **\$82.5M**
- **Total Peak Sales (20%):** \$561M + \$363M + \$120M + \$82.5M = **~\$1,127M (or \$1.13B)**

At 30% Penetration (9,150 patients treated):

- **US:** 11,000 eligible * 30% = 3,300 patients * \$255,000 = **\$841.5M**
- **EU5:** 11,000 eligible * 30% = 3,300 patients * \$165,000 = **\$544.5M**
- **China:** 6,000 eligible * 30% = 1,800 patients * \$100,000 = **\$180M**
- **Japan:** 2,500 eligible * 30% = 750 patients * \$165,000 = **\$123.75M**
- **Total Peak Sales (30%):** \$841.5M + \$544.5M + \$180M + \$123.75M = **~\$1,690M (or \$1.69B)**

Potential Peak Sales Range: \$1.13B to \$1.69B annually across the specified geographies, assuming 20% to 30% market penetration.

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

A 1% share corresponds to 1% of the eligible patient population being treated with Pluvicto.

- **Total Eligible Patients:** 30,500
- **1% of Eligible Patients:** 305 patients

Now calculate revenue for 305 patients across geographies, weighted by population and pricing:

- **US:** (11,000/30,500) * 305 ≈ 110 patients * \$255,000 = **\$28.05M**
- **EU5:** (11,000/30,500) * 305 ≈ 110 patients * \$165,000 = **\$18.15M**

- **China:** $(6,000/30,500) * 305 \approx 60$ patients * \$100,000 = **\$6M**
- **Japan:** $(2,500/30,500) * 305 \approx 25$ patients * \$165,000 = **\$4.125M**
- **Total \$ Value of 1% Share:** \$28.05M + \$18.15M + \$6M + \$4.125M = **~\$56.325M (or \$56.3M)**

\$ Value of 1% Share of Treated Patients: ~\$56.3M annually across the US, EU5, China, and Japan.

Final Answer

- **Potential Peak Sales for Lutetium Lu 177 Vipivotide Tetraxetan: \$1.13B to \$1.69B annually** at 20% to 30% market penetration in the US, EU5, China, and Japan for PSMA-positive mCRPC.
- **\$ Value of 1% Share of Treated Patients: ~\$56.3M annually** across the same geographies.

Notes and Assumptions

1. Patient population estimates are based on general prostate cancer epidemiology and mCRPC progression rates. Actual numbers may vary based on diagnostic access (e.g., PSMA PET scans) and regional differences.
2. Pricing is approximated based on Pluvicto's reported costs in the US and adjusted for other markets. Real-world pricing may differ due to negotiations, discounts, or access programs.
3. Penetration rates of 20–30% assume competition from existing therapies (e.g., taxanes, other ARPIs) and potential future entrants.
4. Peak sales assume steady-state adoption and do not account for initial ramp-up or potential market expansion (e.g., earlier lines of therapy).
5. These figures are directional and should be validated with primary market research or proprietary data sources for accuracy.

If you have specific data (e.g., exact patient numbers, pricing, or penetration forecasts), I can refine the calculations accordingly.