

To estimate the **Potential Peak Sales** for selpercatinib (Retevmo) in the indication of locally advanced or metastatic solid tumors with RET gene fusion in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since specific data on patient populations, pricing, and market penetration may not be fully available, I will outline the methodology, use reasonable assumptions based on publicly available information, and provide a framework for calculation. If you have access to specific data (e.g., exact patient numbers or pricing), it can be plugged into this framework for more precise results.

Step 1: Define the Target Indication and Patient Population

Selpercatinib is approved for adult patients with locally advanced or metastatic solid tumors with a **RET gene fusion** that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. RET fusions are rare genetic alterations found in certain cancers, most notably non-small cell lung cancer (NSCLC) and thyroid cancer, but also in other solid tumors.

- **Prevalence of RET Fusions:** RET fusions occur in approximately:
 - 1-2% of NSCLC cases.
 - 10-20% of papillary thyroid cancer (PTC) cases.
 - Rare occurrences in other solid tumors (e.g., colorectal, breast, pancreatic cancers).
- **Eligible Population:** Focus on advanced/metastatic patients who have progressed on prior therapies or lack alternatives. This is a subset of the total RET fusion population, typically in later lines of therapy.

Given the rarity of RET fusions, the target population is small but high-value due to the lack of alternative treatments and the precision medicine approach.

Step 2: Estimate the Treated Patient Population in Each Geography

We will estimate the number of patients with RET fusion-driven solid tumors who are eligible for treatment in each geography (US, EU5, China, Japan). Since exact numbers are not publicly available, we use cancer incidence data and apply percentages for RET fusions and advanced/metastatic stages.

Assumptions:

1. **Total Cancer Incidence:** Use approximate annual incidence of relevant cancers (NSCLC, thyroid cancer, etc.) in each geography.
2. **RET Fusion Prevalence:** Assume 1-2% of NSCLC and 10-20% of thyroid cancer cases have RET fusions; for other solid tumors, assume <1%.
3. **Advanced/Metastatic Proportion:** Assume 50% of RET fusion patients are in advanced/metastatic stages and eligible for selpercatinib after progression on prior therapy.
4. **Market Penetration:** Assume 20-30% of eligible patients are treated with selpercatinib, as per the query.

Approximate Annual Incidence of Key Cancers (2023 estimates):

- **NSCLC** (major contributor to RET fusions):

- US: ~200,000 cases/year; RET fusion (1.5%) = ~3,000 patients.
- EU5: ~250,000 cases/year; RET fusion (1.5%) = ~3,750 patients.
- China: ~700,000 cases/year; RET fusion (1.5%) = ~10,500 patients.
- Japan: ~120,000 cases/year; RET fusion (1.5%) = ~1,800 patients.
- **Thyroid Cancer** (another key contributor):
- US: ~44,000 cases/year; RET fusion (15%) = ~6,600 patients.
- EU5: ~50,000 cases/year; RET fusion (15%) = ~7,500 patients.
- China: ~90,000 cases/year; RET fusion (15%) = ~13,500 patients.
- Japan: ~18,000 cases/year; RET fusion (15%) = ~2,700 patients.
- **Other Solid Tumors:** Assume negligible contribution for simplicity (or add ~10% to total RET fusion patients).

Total RET Fusion Patients (Rough Estimate):

- US: ~9,600 patients (NSCLC + Thyroid + Others).
- EU5: ~11,250 patients.
- China: ~24,000 patients.
- Japan: ~4,500 patients.

Advanced/Metastatic Eligible Patients (50% of RET fusion patients):

- US: ~4,800 patients.
- EU5: ~5,625 patients.
- China: ~12,000 patients.
- Japan: ~2,250 patients.

Treated Patients (20-30% Market Share):

- US: 960–1,440 patients.
- EU5: 1,125–1,688 patients.
- China: 2,400–3,600 patients.
- Japan: 450–675 patients.

Step 3: Estimate Drug Pricing and Annual Cost per Patient

Selpercatinib is a targeted therapy, and pricing reflects its status as a precision medicine for rare indications. Pricing varies by geography due to healthcare system differences and purchasing power.

Assumptions for Annual Cost per Patient (2023 estimates):

- US: ~\$250,000 per patient/year (based on typical pricing for targeted oncology drugs like selipergatinib; e.g., Retevmo list price is ~\$20,600 for a 30-day supply, or ~\$247,200/year).
- EU5: ~\$150,000 per patient/year (lower due to price negotiations and healthcare systems).
- China: ~\$80,000 per patient/year (lower pricing due to market access programs and local policies).
- Japan: ~\$180,000 per patient/year (similar to EU but adjusted for Japan's pricing model).

Step 4: Calculate Potential Peak Sales (20-30% Market Share)

Peak sales are calculated by multiplying the number of treated patients (at 20% and 30% market share) by the annual cost per patient in each geography.

Peak Sales at 20% Market Share:

- **US:** 960 patients × \$250,000 = **\$240 million.**
- **EU5:** 1,125 patients × \$150,000 = **\$168.75 million.**
- **China:** 2,400 patients × \$80,000 = **\$192 million.**
- **Japan:** 450 patients × \$180,000 = **\$81 million.**
- **Total (20% share):** \$240M + \$168.75M + \$192M + \$81M = **\$681.75 million.**

Peak Sales at 30% Market Share:

- **US:** 1,440 patients × \$250,000 = **\$360 million.**
- **EU5:** 1,688 patients × \$150,000 = **\$253.2 million.**
- **China:** 3,600 patients × \$80,000 = **\$288 million.**
- **Japan:** 675 patients × \$180,000 = **\$121.5 million.**
- **Total (30% share):** \$360M + \$253.2M + \$288M + \$121.5M = **\$1,022.7 million** or **~\$1.02 billion.**

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

To calculate the value of a 1% share, divide the total eligible patients by 100 and multiply by the annual cost per patient in each geography.

Eligible Patients (from Step 2):

- US: 4,800 patients; 1% = 48 patients.
- EU5: 5,625 patients; 1% = 56.25 patients.
- China: 12,000 patients; 1% = 120 patients.
- Japan: 2,250 patients; 1% = 22.5 patients.

\$ Value of 1% Share:

- **US:** 48 patients × \$250,000 = **\$12 million.**
- **EU5:** 56.25 patients × \$150,000 = **\$8.44 million.**

- **China:** 120 patients × \$80,000 = **\$9.6 million.**
- **Japan:** 22.5 patients × \$180,000 = **\$4.05 million.**
- **Total Value of 1% Share:** \$12M + \$8.44M + \$9.6M + \$4.05M = **\$34.09 million.**

Final Answer:

1. **Potential Peak Sales for Selpercatinib (20-30% Market Share)** in the US, EU5, China, and Japan for the indication of locally advanced or metastatic solid tumors with RET gene fusion:

- At 20% market share: **\$681.75 million.**
- At 30% market share: **\$1.02 billion.**

2. **\$ Value of 1% Share of Treated Patients** in these geographies:

- **\$34.09 million.**

Caveats and Notes:

- These estimates are based on rough assumptions for patient numbers, RET fusion prevalence, pricing, and market penetration. Real-world data (e.g., from Lilly's financial reports, epidemiology studies, or payer data) would refine these numbers.

- Peak sales could be influenced by factors like competition (e.g., other RET inhibitors such as pralsetinib), label expansions, or changes in pricing/reimbursement policies.

- The analysis assumes stable pricing and does not account for discounts, rebates, or patient assistance programs.

- If selpercatinib gains approval in additional indications or earlier lines of therapy, the patient pool and peak sales could increase significantly.

If you have specific data or would like to adjust assumptions (e.g., different pricing or patient numbers), I can recalculate accordingly.