

To estimate the **Potential Peak Sales** for selpercatinib (Retevmo) in the indication of advanced or metastatic RET fusion-positive thyroid cancer 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 based on available data and reasonable assumptions. Since exact patient numbers, pricing, and market penetration data may not be publicly available in full detail, I will outline a methodology and provide illustrative calculations.

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## **Step 1: Key Assumptions and Methodology**

**1. Indication and Patient Population:** Selpercatinib is approved for advanced or metastatic RET fusion-positive thyroid cancer in patients who are radioactive iodine-refractory. RET fusions occur in a small subset of thyroid cancer patients (estimated at ~2-5% of medullary thyroid cancer [MTC] cases, and rare in other thyroid cancer types).

**2. Prevalence of Thyroid Cancer:**

- Thyroid cancer incidence varies by region, with higher rates in the US and EU5 compared to China and Japan.
- Advanced/metastatic cases represent ~5-10% of total thyroid cancer cases.
- RET fusion-positive cases are a small fraction of these (assume ~3% of advanced cases for calculation purposes).

**3. Treated Patient Share:** As per the query, assume selpercatinib captures 20-30% of treated patients in this indication.

**4. Pricing:** Selpercatinib is a targeted oncology drug, and pricing for such therapies is high. Based on available data, the annual cost in the US is approximately \$250,000 per patient. Costs in other regions may be lower due to healthcare system differences (assume ~50-70% of US pricing in EU5 and Japan, and ~30-40% in China due to price controls and negotiations).

**5. Peak Sales:** Peak sales are typically achieved 5-10 years after launch, assuming maximum market penetration and patient access.

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## **Step 2: Estimate Eligible Patient Population**

Using approximate incidence data for thyroid cancer and adjusting for advanced/metastatic RET fusion-positive cases:

**- US:**

- Thyroid cancer incidence: ~44,000 new cases/year (American Cancer Society).
- Advanced/metastatic cases: ~5-10% → ~2,200-4,400 patients/year.
- RET fusion-positive: ~3% → ~66-132 patients/year.

**- EU5 (combined):**

- Thyroid cancer incidence: ~50,000 new cases/year (based on European cancer statistics).

- Advanced/metastatic: ~5-10% → ~2,500-5,000 patients/year.
- RET fusion-positive: ~3% → ~75-150 patients/year.
- **China:**
  - Thyroid cancer incidence: ~200,000 new cases/year (high due to population size and rising rates).
  - Advanced/metastatic: ~5-10% → ~10,000-20,000 patients/year.
  - RET fusion-positive: ~3% → ~300-600 patients/year.
- **Japan:**
  - Thyroid cancer incidence: ~18,000 new cases/year.
  - Advanced/metastatic: ~5-10% → ~900-1,800 patients/year.
  - RET fusion-positive: ~3% → ~27-54 patients/year.

**Total Eligible Patients (Annual Incidence):**

- US: ~66-132
- EU5: ~75-150
- China: ~300-600
- Japan: ~27-54
- **Total:** ~468-936 patients/year.

(Note: These are rough estimates of new cases per year. Prevalent cases [existing patients eligible for treatment] could be 2-3x higher due to longer survival in thyroid cancer, but we'll use incidence for conservatism.)

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**Step 3: Estimate Treated Patients with Selpercatinib (20-30% Share)**

- **US:** 20-30% of 66-132 → ~13-40 patients/year.
- **EU5:** 20-30% of 75-150 → ~15-45 patients/year.
- **China:** 20-30% of 300-600 → ~60-180 patients/year.
- **Japan:** 20-30% of 27-54 → ~5-16 patients/year.
- **Total Treated Patients:** ~93-281 patients/year.

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**Step 4: Estimate Pricing per Patient per Year**

- **US:** ~\$250,000/patient/year.
- **EU5:** ~\$150,000/patient/year (60% of US price due to pricing negotiations).

- **China:** ~\$75,000/patient/year (30% of US price due to lower pricing and access programs).
- **Japan:** ~\$175,000/patient/year (70% of US price due to healthcare system).

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## **Step 5: Calculate Potential Peak Sales**

Peak sales are calculated as: **Number of treated patients × Annual cost per patient.**

- **US:** 13-40 patients × \$250,000 = **\$3.25M - \$10M.**
- **EU5:** 15-45 patients × \$150,000 = **\$2.25M - \$6.75M.**
- **China:** 60-180 patients × \$75,000 = **\$4.5M - \$13.5M.**
- **Japan:** 5-16 patients × \$175,000 = **\$0.875M - \$2.8M.**
- **Total Peak Sales:** **\$10.875M - \$33.05M** per year.

**Rounded Range for Potential Peak Sales:** ~\$11M - \$33M annually across all geographies for this indication.

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## **Step 6: Calculate \$ Value of 1% Share of Treated Patients**

First, calculate the total number of eligible patients and the revenue associated with 1% of them.

- **Total Eligible Patients:** 468-936 patients/year.
- **1% of Eligible Patients:** 4.68-9.36 patients/year.

Now, calculate revenue for 1% share using weighted pricing across regions (based on patient distribution):

- US (~14% of patients): 1% of 66-132 = 0.66-1.32 patients × \$250,000 = \$165K-\$330K.
- EU5 (~16% of patients): 1% of 75-150 = 0.75-1.5 patients × \$150,000 = \$112.5K-\$225K.
- China (~64% of patients): 1% of 300-600 = 3-6 patients × \$75,000 = \$225K-\$450K.
- Japan (~6% of patients): 1% of 27-54 = 0.27-0.54 patients × \$175,000 = \$47.25K-\$94.5K.

**Total Revenue for 1% Share:** ~\$550K - \$1.1M per year.

**Rounded \$ Value of 1% Share:** ~\$0.55M - \$1.1M annually.

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## **Final Answer**

- **Potential Peak Sales for Selpercatinib** in advanced or metastatic RET fusion-positive thyroid cancer (20-30% treated patient share):

- US, EU5, China, and Japan combined: **\$11M - \$33M annually**.

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

- **\$0.55M - \$1.1M annually**.

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## **Notes and Caveats**

1. These estimates are highly sensitive to assumptions about patient numbers, pricing, and market penetration. Actual numbers may vary based on real-world data, access programs, and competition.

2. The patient population for this rare indication is small, leading to relatively modest peak sales compared to broader oncology indications.

3. Prevalent cases (existing patients) could increase the total addressable market, but I've used incidence for a conservative estimate.

4. Additional indications for selpercatinib (e.g., RET-driven non-small cell lung cancer) would significantly increase overall peak sales, but this analysis is limited to thyroid cancer as specified.

If you have access to more specific data (e.g., exact patient numbers or pricing), I can refine the calculations further.