

To estimate the **Potential Peak Sales** for selpercatinib (Retevmo) in the specified indication across 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 make several assumptions and follow a structured approach. Since the specific indication for selpercatinib in pediatric patients (as per the FDA approval for patients aged 2 years and older) is not fully detailed in the query, I will assume it relates to RET fusion-positive solid tumors, thyroid cancer, or non-small cell lung cancer (NSCLC), as these are the primary indications for selpercatinib. Additionally, since pediatric cases for these conditions are rare, the patient population will be smaller compared to adult indications.

The analysis will be based on the following steps:

1. Estimate the target patient population (pediatric patients with the relevant indication).
2. Estimate the percentage of treated patients (20%-30% as given).
3. Estimate the drug pricing and treatment duration to calculate revenue per patient.
4. Calculate potential peak sales based on market share.
5. Calculate the \$ value of a 1% share of treated patients.

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### **\*\*Key Assumptions\*\***

1. **Indication:** Selpercatinib is approved for pediatric patients (aged 2+) with RET fusion-positive solid tumors or thyroid cancer. Given the rarity of these conditions in pediatric populations, the target population is small.
2. **Patient Population:** Pediatric cases of RET fusion-positive cancers are rare. I will estimate the eligible population based on available epidemiology data for pediatric solid tumors and thyroid cancer, adjusted for RET mutations (typically 1-2% of cases for NSCLC and higher for thyroid cancer).
3. **Market Share:** As given, selpercatinib captures 20%-30% of treated patients.
4. **Pricing:** Selpercatinib's annual cost in the US is approximately \$250,000 per patient (based on adult pricing for Retevmo, adjusted for pediatric dosing if necessary). Pricing in other regions is lower due to healthcare system differences (e.g., 50-70% of US price in EU5, 30-50% in China and Japan).
5. **Treatment Duration:** Assume an average treatment duration of 1 year per patient (chronic treatment for advanced cancers).
6. **Penetration and Diagnosis Rates:** Not all eligible patients are diagnosed or treated due to rarity and access issues, especially in China and Japan.

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### **\*\*Step 1: Estimate Eligible Patient Population\*\***

Given the rarity of RET fusion-positive cancers in pediatric populations, we will estimate the number of eligible patients in each geography. Since precise data is not readily available, I will use approximate numbers based on general pediatric cancer incidence and RET mutation prevalence.

- **US:**

- Pediatric cancer incidence: ~15,000 new cases/year.
- RET fusion-positive cancers (e.g., thyroid cancer, solid tumors): ~1-2% of cases.
- Eligible patients: ~150-300 patients/year.
- **EU5:**
  - Pediatric cancer incidence: ~20,000 new cases/year (combined for EU5).
  - RET fusion-positive cancers: ~1-2%.
  - Eligible patients: ~200-400 patients/year.
- **China:**
  - Pediatric cancer incidence: ~40,000 new cases/year (due to larger population).
  - RET fusion-positive cancers: ~1-2%.
  - Eligible patients: ~400-800 patients/year.
- **Japan:**
  - Pediatric cancer incidence: ~2,500 new cases/year.
  - RET fusion-positive cancers: ~1-2%.
  - Eligible patients: ~25-50 patients/year.

**Total Eligible Patients (Midpoint Estimate):**

- US: 225
- EU5: 300
- China: 600
- Japan: 38
- **Total:** ~1,163 patients/year

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**\*\*Step 2: Estimate Treated Patients\*\***

Assume that only a fraction of eligible patients are diagnosed and treated due to rarity, access, and awareness. Let's assume a diagnosis and treatment rate of 50% across all regions (conservative estimate, likely lower in China).

- **Treated Patients** (50% of eligible):
  - US: 113
  - EU5: 150
  - China: 300
  - Japan: 19
  - **Total:** 582 patients/year

**Market Share for Selpercatinib (20%-30%):**

- At 25% (midpoint of 20%-30%) share of treated patients:
- US: 28 patients
- EU5: 38 patients
- China: 75 patients
- Japan: 5 patients
- **Total:** 146 patients/year

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**\*\*Step 3: Estimate Annual Revenue per Patient\*\***

Pricing varies by region due to differences in healthcare systems and purchasing power.

- **US:** \$250,000/year per patient.
- **EU5:** ~60% of US price = \$150,000/year per patient.
- **China:** ~40% of US price = \$100,000/year per patient.
- **Japan:** ~50% of US price = \$125,000/year per patient.

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**\*\*Step 4: Calculate Potential Peak Sales\*\***

Peak sales are calculated as: (Number of treated patients with selpercatinib) x (Annual revenue per patient).

- **US:** 28 patients x \$250,000 = **\$7.0 million**
- **EU5:** 38 patients x \$150,000 = **\$5.7 million**
- **China:** 75 patients x \$100,000 = **\$7.5 million**
- **Japan:** 5 patients x \$125,000 = **\$0.6 million**
- **Total Peak Sales: \$20.8 million/year** (at 25% market share)

**Range of Peak Sales (20%-30% market share):**

- At 20%: ~\$16.6 million/year
- At 30%: ~\$25.0 million/year

Thus, **Potential Peak Sales** for selpercatinib in this pediatric indication across the US, EU5, China, and Japan is approximately **\$17 million to \$25 million per year**.

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

A 1% share of treated patients corresponds to 1% of the total treated patient population (582 patients), which is ~5.82 patients.

Revenue from 1% share:

- **US:** (1% of 113 patients = 1.13) x \$250,000 = **\$0.28 million**
- **EU5:** (1% of 150 patients = 1.5) x \$150,000 = **\$0.23 million**
- **China:** (1% of 300 patients = 3) x \$100,000 = **\$0.30 million**
- **Japan:** (1% of 19 patients = 0.19) x \$125,000 = **\$0.02 million**
- **Total \$ Value of 1% Share: \$0.83 million/year**

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### **\*\*Final Answer\*\***

1. **Potential Peak Sales for Selpercatinib** (at 20%-30% market share of treated patients):

- **US, EU5, China, Japan combined: \$17 million to \$25 million per year.**

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

- **US, EU5, China, Japan combined: \$0.83 million per year.**

**Note:** These estimates are highly sensitive to assumptions about patient population, diagnosis rates, market share, and pricing. Real-world data on pediatric RET fusion-positive cancers, access to treatment, and regional pricing negotiations could significantly alter these figures. Additionally, since pediatric indications are rare, peak sales might be lower than typical adult indications for selpercatinib. If you have specific data on the indication or patient numbers, I can refine the analysis further.