

To estimate the **Potential Peak Sales** for selpercatinib (Retevmo) in the indication of advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation 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 exact data (e.g., patient population, pricing, or market penetration) is not provided, I will use reasonable assumptions based on publicly available information, epidemiology data, and market trends for rare cancers and targeted therapies. The calculations will be approximate and should be refined with more specific data if available.

## **Step 1: Define the Target Indication and Patient Population**

Selpercatinib is approved for advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation. MTC is a rare form of thyroid cancer, and RET mutations are present in approximately 60-90% of hereditary MTC cases and 40-50% of sporadic MTC cases. For simplicity, we assume ~50% of MTC patients have a RET mutation.

#### Epidemiology of MTC:

- **US:** Thyroid cancer incidence is ~50,000 new cases/year. MTC accounts for ~1-2% of thyroid cancers (~500-1,000 new MTC cases/year). Of these, ~50% are advanced/metastatic at diagnosis or progress to this stage, so ~250-500 eligible patients/year. Cumulative prevalent cases (patients living with advanced/metastatic MTC) may be higher, estimated at ~1,500-2,000 (assuming 3-5 years survival).
- **EU5:** Combined population is ~2x the US. MTC incidence scales accordingly, so ~500-1,000 new cases/year, with ~250-500 advanced/metastatic. Prevalent cases ~3,000-4,000.
- **China:** Population is ~4x the US, but lower diagnosis rates and access to genetic testing reduce the eligible pool. Assume ~500-1,000 new MTC cases/year, with ~250-500 advanced/metastatic. Prevalent cases ~2,000-3,000.
- **Japan:** Population is ~1/3 of the US. Assume ~150-300 new MTC cases/year, with ~75-150 advanced/metastatic. Prevalent cases ~500-1,000.

**Total Prevalent Eligible Patients (Advanced/Metastatic MTC with RET mutation, ~50% of MTC):**

- US: ~750-1,000
- EU5: ~1,500-2,000
- China: ~1,000-1,500
- Japan: ~250-500
- **Total:** ~3,500-5,000 patients

## **Step 2: Treatment Rate and Market Share**

- **Treatment Rate:** Not all eligible patients will receive systemic therapy due to access issues, comorbidities, or alternative treatments (e.g., surgery). Assume 70-80% of eligible patients are treated with systemic therapy.
- **Market Share:** The query assumes a 20-30% share of treated patients for selpercatinib. This is reasonable for a targeted therapy in a rare indication with limited competition (e.g., vs. vandetanib or cabozantinib).

**Treated Patients with Selpercatinib (20-30% share of treated patients):**

- US:  $(750-1,000) * 0.75 * 0.25 = \sim 140-190$  patients
- EU5:  $(1,500-2,000) * 0.75 * 0.25 = \sim 280-375$  patients
- China:  $(1,000-1,500) * 0.75 * 0.25 = \sim 190-280$  patients
- Japan:  $(250-500) * 0.75 * 0.25 = \sim 50-95$  patients
- **Total:**  $\sim 660-940$  patients

### **Step 3: Pricing and Annual Cost of Therapy**

Selpercatinib is a targeted therapy for a rare disease, so pricing is high:

- **US:** Annual cost  $\sim \$250,000-\$300,000$  per patient (based on pricing for similar drugs like Retevmo, which is  $\sim \$20,000/\text{month}$ ).
- **EU5:** Pricing is typically 60-70% of US levels due to negotiations, so  $\sim \$150,000-\$200,000$  per patient.
- **Japan:** Similar to EU5,  $\sim \$150,000-\$200,000$  per patient.
- **China:** Pricing is lower due to market access challenges and generics pressure,  $\sim \$50,000-\$100,000$  per patient.

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

Peak sales are estimated based on the number of treated patients multiplied by the annual cost per patient.

#### **Peak Sales Calculation (Midpoint of Ranges):**

- **US:**  $165 \text{ patients} * \$275,000 = \sim \$45 \text{ million}$
- **EU5:**  $330 \text{ patients} * \$175,000 = \sim \$58 \text{ million}$
- **China:**  $235 \text{ patients} * \$75,000 = \sim \$18 \text{ million}$
- **Japan:**  $70 \text{ patients} * \$175,000 = \sim \$12 \text{ million}$
- **Total Peak Sales:**  $\sim \$133 \text{ million/year}$  (using midpoint of 25% market share)

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

- Low end (20% share):  $\sim \$106 \text{ million}$
- High end (30% share):  $\sim \$160 \text{ million}$

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

First, calculate the total treated patient population (assuming 75% treatment rate of eligible patients):

- US:  $(750-1,000) * 0.75 = \sim 560-750$  patients
- EU5:  $(1,500-2,000) * 0.75 = \sim 1,125-1,500$  patients
- China:  $(1,000-1,500) * 0.75 = \sim 750-1,125$  patients

- Japan:  $(250-500) * 0.75 = \sim 190-375$  patients

- **Total Treated Patients:**  $\sim 2,625-3,750$

**1% of Treated Patients:**

- US:  $5.6-7.5$  patients \*  $\$275,000 = \sim \$1.5-\$2.1$  million

- EU5:  $11.3-15$  patients \*  $\$175,000 = \sim \$2.0-\$2.6$  million

- China:  $7.5-11.3$  patients \*  $\$75,000 = \sim \$0.6-\$0.8$  million

- Japan:  $1.9-3.8$  patients \*  $\$175,000 = \sim \$0.3-\$0.7$  million

- **Total \$ Value of 1% Share:**  $\sim \$4.4-\$6.2$  million

**Final Answer:**

**Potential Peak Sales for Selpercatinib in MTC (20-30% market share):**

- US:  $\sim \$36-\$54$  million

- EU5:  $\sim \$46-\$69$  million

- China:  $\sim \$14-\$21$  million

- Japan:  $\sim \$10-\$15$  million

- **Total:**  $\sim \$106-\$160$  million/year

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

- US:  $\sim \$1.5-\$2.1$  million

- EU5:  $\sim \$2.0-\$2.6$  million

- China:  $\sim \$0.6-\$0.8$  million

- Japan:  $\sim \$0.3-\$0.7$  million

- **Total:**  $\sim \$4.4-\$6.2$  million

**Note:** These estimates are based on assumptions and should be validated with actual patient numbers, pricing data, and market access information. Selpercatinib is also approved for other indications (e.g., RET fusion-positive non-small cell lung cancer and thyroid cancer), which could significantly increase total sales but are outside the scope of this calculation.