Selpercatinib (Retevmo) is a targeted therapy approved by the FDA for specific indications, primarily for patients with RET-driven cancers. It has received accelerated approval for the following indications (as of the latest updates):

1. **Non-Small Cell Lung Cancer (NSCLC)**: Adult patients with metastatic RET fusion-positive non-small cell lung cancer.

2. **Thyroid Cancer**:

- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy.

- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).

3. **Other Solid Tumors**: Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion who have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options (as of more recent approvals).

Since your question focuses on calculating **Potential Peak Sales** and the **$ value of a 1% share of treated patients** for selpercatinib in a specific indication across the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, I will outline a general methodology and provide assumptions to arrive at an estimate. Given that the specific indication is not explicitly stated in your follow-up, I will assume the primary focus is on **RET fusion-positive NSCLC**, as it is one of the major indications with a larger patient population compared to thyroid cancer or other rare solid tumors. If you meant a different indication, please clarify.

## Step 1: Methodology for Estimating Potential Peak Sales

Potential Peak Sales are typically calculated based on:

1. **Total addressable patient population** (prevalence or incidence of the disease with the specific biomarker, e.g., RET fusion-positive NSCLC).

2. **Percentage of patients treated** (penetration rate or market share of the drug).

3. **Annual cost of therapy** per patient.

4. **Geographic market size** (US, EU5, China, Japan).

Given your assumption of a **20% to 30% share of treated patients**, we will use this range for market penetration.

## Step 2: Key Assumptions

Since exact data may vary based on epidemiology, pricing, and market access, I will use reasonable assumptions based on publicly available information and typical industry benchmarks as of 2023. These can be refined with more specific data if available.

#### 1. **Addressable Patient Population (RET Fusion-Positive NSCLC)**

- **RET fusions** occur in approximately **1-2% of NSCLC cases**.

- NSCLC accounts for ~85% of lung cancer cases.

- Annual incidence of lung cancer (used as a proxy for addressable metastatic patients):

- **US**: ~230,000 new lung cancer cases/year → NSCLC: ~195,500 → RET fusion-positive: ~1,955 to 3,910 patients.

- **EU5**: ~320,000 new lung cancer cases/year → NSCLC: ~272,000 → RET fusion-positive: ~2,720 to 5,440 patients.

- **China**: ~820,000 new lung cancer cases/year → NSCLC: ~697,000 → RET fusion-positive: ~6,970 to 13,940 patients.

- **Japan**: ~125,000 new lung cancer cases/year → NSCLC: ~106,250 → RET fusion-positive: ~1,063 to 2,125 patients.

- **Total Addressable Population (assuming metastatic/advanced stage, ~50-60% of cases)**: We'll use the midpoint of RET fusion prevalence (1.5%) and assume 55% are metastatic/advanced, eligible for systemic therapy.

**Estimated Annual Addressable Patients (Metastatic RET Fusion-Positive NSCLC):**

- US: ~1,600 patients

- EU5: ~2,200 patients

- China: ~5,700 patients

- Japan: ~900 patients

- **Total**: ~10,400 patients/year

#### 2. **Market Penetration (Share of Treated Patients)**

- As per your input, assume **20% to 30% of treated patients**.

- Midpoint for calculation: **25%**.

**Estimated Treated Patients (at 25% penetration):**

- US: 1,600 × 25% = 400 patients

- EU5: 2,200 × 25% = 550 patients

- China: 5,700 × 25% = 1,425 patients

- Japan: 900 × 25% = 225 patients

- **Total**: 2,600 patients/year

#### 3. **Annual Cost of Therapy**

- Selpercatinib's pricing varies by region due to differences in healthcare systems and negotiations.

- **US**: ~$20,000/month → ~$240,000/year per patient (based on list price; net price may be lower due to discounts).

- **EU5**: ~$120,000–$150,000/year (assuming ~50-60% of US price due to price controls).

- **China**: ~$60,000–$80,000/year (lower due to pricing regulations and potential inclusion in NRDL with discounts).

- **Japan**: ~$150,000–$180,000/year (similar to EU5, adjusted for market dynamics).

- For simplicity, use midpoint estimates:

- US: $240,000/year

- EU5: $135,000/year

- China: $70,000/year

- Japan: $165,000/year

#### 4. **Peak Sales Calculation (at 25% Penetration)**

Peak sales occur when the drug achieves maximum market penetration, typically 5-7 years post-launch, assuming no major competition or patent expiry.

**Peak Sales Estimate (25% Penetration):**

- US: 400 patients × $240,000 = **$96 million**

- EU5: 550 patients × $135,000 = **$74.25 million**

- China: 1,425 patients × $70,000 = **$99.75 million**

- Japan: 225 patients × $165,000 = **$37.13 million**

- **Total Peak Sales (25%)**: **~$307 million/year**

**Range for 20% to 30% Penetration:**

- 20% Penetration: Total ~$246 million/year

- 30% Penetration: Total ~$368 million/year

#### 5. **$ Value of 1% Share of Treated Patients**

- **1% of addressable patients treated** corresponds to:

- US: 1,600 × 1% = 16 patients → 16 × $240,000 = **$3.84 million**

- EU5: 2,200 × 1% = 22 patients → 22 × $135,000 = **$2.97 million**

- China: 5,700 × 1% = 57 patients → 57 × $70,000 = **$3.99 million**

- Japan: 900 × 1% = 9 patients → 9 × $165,000 = **$1.49 million**

- **Total $ Value of 1% Share**: **~$12.29 million**

## Final Answer

1. **Potential Peak Sales for Selpercatinib in RET Fusion-Positive NSCLC (20% to 30% Share of Treated Patients):**

- US: $76.8M (20%) to $115.2M (30%)

- EU5: $59.4M (20%) to $89.1M (30%)

- China: $79.8M (20%) to $119.7M (30%)

- Japan: $29.7M (20%) to $44.6M (30%)

- **Total**: **$245.7M (20%) to $368.6M (30%) per year**

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

- US: $3.84M

- EU5: $2.97M

- China: $3.99M

- Japan: $1.49M

- **Total**: **$12.29M**

## Caveats and Notes

- These estimates are based on RET fusion-positive NSCLC as the indication. If you meant a different indication (e.g., thyroid cancer), the patient population would be smaller, significantly reducing peak sales.

- Pricing and patient numbers are approximations and may vary based on real-world data, competition (e.g., other RET inhibitors like pralsetinib), and market access.

- Peak sales could be influenced by label expansions, combination therapies, or changes in standard of care.

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

Please let me know if you'd like to focus on a different indication or adjust any assumptions!