

To estimate the **Potential Peak Sales** for pralsetinib (Gavreto) in the indication of metastatic RET fusion-positive non-small cell lung cancer (NSCLC) 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 specific data such as exact patient numbers, pricing, or market penetration rates may not be publicly available, I will outline the methodology using reasonable assumptions based on available epidemiology data, market trends, and typical pricing for targeted oncology drugs. You can adjust these assumptions based on more precise data if available.

Step 1: Define Key Parameters and Assumptions

1. **Indication:** Metastatic RET fusion-positive NSCLC.
2. **Target Population:** RET fusion-positive NSCLC patients account for approximately 1-2% of all NSCLC cases. NSCLC itself represents about 85% of all lung cancer cases.
3. **Market Share:** Assuming pralsetinib captures 20-30% of treated patients in this indication.
4. **Geographies:** US, EU5, China, Japan.
5. **Pricing:** Targeted oncology drugs like pralsetinib often have high annual costs, ranging from \$100,000 to \$200,000 per patient per year in the US, with lower prices in other regions due to healthcare system differences and negotiations (e.g., 50-70% of US price in EU5 and Japan, and significantly lower in China).
6. **Treatment Duration:** Assuming an average treatment duration of 1 year for metastatic NSCLC patients (based on progression-free survival and overall survival data for targeted therapies).

Epidemiology Assumptions

- **Lung Cancer Incidence:** Using approximate annual incidence rates for lung cancer (NSCLC is ~85% of total lung cancer cases, and RET fusion-positive is ~1.5% of NSCLC).
- US: ~225,000 new lung cancer cases → ~191,250 NSCLC → ~2,869 RET fusion-positive.
- EU5: ~315,000 new lung cancer cases → ~267,750 NSCLC → ~4,016 RET fusion-positive.
- China: ~735,000 new lung cancer cases → ~624,750 NSCLC → ~9,371 RET fusion-positive.
- Japan: ~125,000 new lung cancer cases → ~106,250 NSCLC → ~1,594 RET fusion-positive.
- **Prevalence Adjustment:** Since metastatic NSCLC patients are a subset of incident cases (assume ~50% are metastatic at diagnosis or progress to metastatic stage), we adjust the target population:
- US: ~1,435 metastatic RET fusion-positive NSCLC patients.
- EU5: ~2,008 metastatic RET fusion-positive NSCLC patients.
- China: ~4,686 metastatic RET fusion-positive NSCLC patients.
- Japan: ~797 metastatic RET fusion-positive NSCLC patients.
- **Total Target Population Across Geographies:** ~8,926 patients annually.

Pricing Assumptions (Annual Cost per Patient)

- US: \$150,000 per year.
- EU5: \$90,000 per year (60% of US price due to pricing controls).
- China: \$30,000 per year (20% of US price due to lower pricing and generics competition).
- Japan: \$105,000 per year (70% of US price due to negotiated pricing).

Step 2: Calculate Total Addressable Market (TAM)

The TAM is calculated as the number of metastatic RET fusion-positive NSCLC patients multiplied by the annual treatment cost per patient in each geography.

- **US:** 1,435 patients × \$150,000 = **\$215.3 million.**
- **EU5:** 2,008 patients × \$90,000 = **\$180.7 million.**
- **China:** 4,686 patients × \$30,000 = **\$140.6 million.**
- **Japan:** 797 patients × \$105,000 = **\$83.7 million.**
- **Total TAM Across Geographies:** \$215.3M + \$180.7M + \$140.6M + \$83.7M = **\$620.3 million.**

Step 3: Estimate Potential Peak Sales (20-30% Market Share)

Assuming pralsetinib captures 20-30% of the treated patient population in this indication, we calculate the peak sales range.

- **20% Market Share:**
 - US: 1,435 × 0.2 × \$150,000 = **\$43.1 million.**
 - EU5: 2,008 × 0.2 × \$90,000 = **\$36.1 million.**
 - China: 4,686 × 0.2 × \$30,000 = **\$28.1 million.**
 - Japan: 797 × 0.2 × \$105,000 = **\$16.7 million.**
 - **Total Peak Sales (20%):** \$43.1M + \$36.1M + \$28.1M + \$16.7M = **\$124.1 million.**
- **30% Market Share:**
 - US: 1,435 × 0.3 × \$150,000 = **\$64.6 million.**
 - EU5: 2,008 × 0.3 × \$90,000 = **\$54.2 million.**
 - China: 4,686 × 0.3 × \$30,000 = **\$42.2 million.**
 - Japan: 797 × 0.3 × \$105,000 = **\$25.1 million.**
 - **Total Peak Sales (30%):** \$64.6M + \$54.2M + \$42.2M + \$25.1M = **\$186.1 million.**

Potential Peak Sales Range: \$124.1 million to \$186.1 million annually across the US, EU5, China, and Japan.

Step 4: Calculate \$ Value of 1% Share of Treated Patients

The value of a 1% share of treated patients is calculated as 1% of the TAM in each geography.

- **US:** $1,435 \times 0.01 \times \$150,000 = \$2.15 \text{ million}$.

- **EU5:** $2,008 \times 0.01 \times \$90,000 = \$1.81 \text{ million}$.

- **China:** $4,686 \times 0.01 \times \$30,000 = \$0.28 \text{ million}$.

- **Japan:** $797 \times 0.01 \times \$105,000 = \0.84 million .

- **Total Value of 1% Share Across Geographies:** $\$2.15\text{M} + \$1.81\text{M} + \$0.28\text{M} + \$0.84\text{M} = \$5.08 \text{ million}$.

\$ Value of 1% Share of Treated Patients: \$5.08 million annually across the US, EU5, China, and Japan.

Final Answer

1. **Potential Peak Sales for Pralsetinib** (assuming 20-30% market share):

- **Range:** \$124.1 million to \$186.1 million annually across the US, EU5, China, and Japan.

- Breakdown by Geography (at 20-30% share):

- US: \$43.1M - \$64.6M

- EU5: \$36.1M - \$54.2M

- China: \$28.1M - \$42.2M

- Japan: \$16.7M - \$25.1M

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

- **Total:** \$5.08 million annually across the US, EU5, China, and Japan.

- Breakdown by Geography:

- US: \$2.15M

- EU5: \$1.81M

- China: \$0.28M

- Japan: \$0.84M

Notes and Caveats

- **Epidemiology Data:** The incidence and prevalence numbers are estimates based on general lung cancer statistics and the known rarity of RET fusion-positive NSCLC. More precise data from clinical studies or market research (e.g., ARROW trial data for pralsetinib) could refine these numbers.

- **Pricing Variability:** Drug pricing varies widely by country due to reimbursement policies, negotiations, and competition. The assumed prices are indicative and can be adjusted based on real-world data.

- **Market Dynamics:** Peak sales depend on factors like competition (e.g., selipercatinib, another RET inhibitor), market access, and physician adoption.

- **Patient Access:** Not all eligible patients may receive treatment due to cost, diagnosis rates, or access to testing for RET fusions.

If you have access to more specific data on patient numbers, pricing, or market share projections, I can refine the calculations accordingly.