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 (France, Germany, 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 on patient numbers, pricing, and market penetration may not be fully available, I will outline the methodology and provide reasonable assumptions based on publicly available information and typical market dynamics for rare oncology drugs. Please note that these are illustrative figures and should be validated with up-to-date market research or proprietary data.

Step 1: Define the Target Population

RET fusion-positive NSCLC is a rare subset of NSCLC, accounting for approximately **1-2% of all NSCLC cases**. We will estimate the total NSCLC patient population and then derive the RET fusion-positive subset.

Incidence and Prevalence Estimates:

- **NSCLC Incidence**: Annual new cases of NSCLC are approximately 85% of all lung cancer cases. We will use incidence rates to estimate the target population, as metastatic NSCLC patients are often diagnosed at an advanced stage.

- **RET Fusion-Positive NSCLC**: ~1-2% of NSCLC cases. For simplicity, we assume 1.5% of NSCLC patients are RET fusion-positive.

- **Metastatic NSCLC**: Approximately 40-50% of NSCLC patients are diagnosed at a metastatic stage (Stage IV). We assume 45% for this calculation.

Using approximate annual NSCLC incidence rates (per 100,000 population) and population sizes:

- **US**: Incidence ~55/100,000; Population ~330M $\rightarrow$ ~180,000 new NSCLC cases/year.

- **EU5**: Incidence ~50/100,000; Population ~260M $\rightarrow$ ~130,000 new NSCLC cases/year.

- **China**: Incidence ~35/100,000; Population ~1,400M $\rightarrow$ ~490,000 new NSCLC cases/year.

- **Japan**: Incidence ~40/100,000; Population ~125M $\rightarrow$ ~50,000 new NSCLC cases/year.

Now calculate **RET fusion-positive metastatic NSCLC new cases**:

- **US**: 180,000 * 1.5% * 45% = ~1,215 new cases/year.

- **EU5**: 130,000 * 1.5% * 45% = ~878 new cases/year.

- **China**: 490,000 * 1.5% * 45% = ~3,307 new cases/year.

- **Japan**: 50,000 * 1.5% * 45% = ~338 new cases/year.

- **Total**: ~5,738 new cases/year across these geographies.

Since pralsetinib is for metastatic patients and treatment duration may span multiple years (e.g., 1-2 years), we also consider **prevalence** (existing patients eligible for treatment). Assuming an average treatment duration of 1.5 years, the prevalent patient pool is roughly 1.5x the annual incidence:

- **US**: 1,215 * 1.5 = ~1,823 prevalent patients.

- **EU5**: 878 * 1.5 = ~1,317 prevalent patients.

- **China**: 3,307 * 1.5 = ~4,961 prevalent patients.

- **Japan**: 338 * 1.5 = ~507 prevalent patients.

- **Total**: ~8,608 prevalent patients.

Step 2: Market Penetration (20%-30% Share of Treated Patients)

Given the rarity of RET fusion-positive NSCLC and the targeted nature of pralsetinib, along with competition from other therapies (e.g., selpercatinib by Eli Lilly), we assume a market share of **20%-30%** of treated patients at peak sales. For calculation, we use the midpoint of **25%**.

- **US**: 1,823 * 25% = ~456 treated patients.

- **EU5**: 1,317 * 25% = ~329 treated patients.

- **China**: 4,961 * 25% = ~1,240 treated patients.

- **Japan**: 507 * 25% = ~127 treated patients.

- **Total**: ~2,152 treated patients at peak.

Step 3: Pricing Assumptions

Pralsetinib is a high-cost targeted therapy. Based on pricing for similar drugs in oncology (e.g., selpercatinib), we assume the following annual treatment costs (adjusted for purchasing power and healthcare system differences):

- **US**: ~$200,000 per patient/year (list price; net price may be lower due to discounts).

- **EU5**: ~$150,000 per patient/year (lower due to price negotiations).

- **Japan**: ~$150,000 per patient/year (similar to EU5).

- **China**: ~$50,000 per patient/year (lower due to market access challenges and pricing controls).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients multiplied by the annual cost per patient:

- **US**: 456 patients * $200,000 = ~$91.2M.

- **EU5**: 329 patients * $150,000 = ~$49.4M.

- **China**: 1,240 patients * $50,000 = ~$62.0M.

- **Japan**: 127 patients * $150,000 = ~$19.1M.

- **Total Peak Sales**: ~$221.7M annually.

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

A 1% share corresponds to 1% of the total prevalent patients in each geography:

- **US**: 1,823 * 1% = 18.23 patients * $200,000 = ~$3.65M.

- **EU5**: 1,317 * 1% = 13.17 patients * $150,000 = ~$1.98M.

- **China**: 4,961 * 1% = 49.61 patients * $50,000 = ~$2.48M.

- **Japan**: 507 * 1% = 5.07 patients * $150,000 = ~$0.76M.

- **Total for 1% Share**: ~$8.87M.

Summary

- **Potential Peak Sales for Pralsetinib (25% market share)**:

- US: $91.2M

- EU5: $49.4M

- China: $62.0M

- Japan: $19.1M

- **Total**: $221.7M annually

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

- US: $3.65M

- EU5: $1.98M

- China: $2.48M

- Japan: $0.76M

- **Total**: $8.87M

Caveats and Assumptions

1. **Epidemiology Data**: Incidence and prevalence estimates are based on general NSCLC data and may vary by country.

2. **Pricing**: Prices are illustrative and may differ based on negotiations, reimbursement policies, and competition.

3. **Market Share**: The 20%-30% range (25% used) assumes moderate competition and successful market access. Actual share may vary based on clinical differentiation and payer dynamics.

4. **Treatment Duration**: Assumed at 1.5 years; real-world data on progression-free survival may adjust this.

5. **Diagnosis Rates**: Not all RET fusion-positive patients may be tested or identified due to diagnostic access limitations, especially in China.

For more accurate figures, primary market research, real-world evidence on testing rates, and updated pricing data are recommended. If you have access to specific data (e.g., exact patient numbers or pricing), I can refine the calculations accordingly.