To estimate the **Potential Peak Sales** for ensartinib in the indication of ALK-positive locally advanced or metastatic 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 on ensartinib's pricing, patient population, and market penetration are not publicly available in real-time, I will base this analysis on reasonable assumptions derived from market research, epidemiology data for NSCLC, and benchmarks for similar ALK inhibitors (e.g., crizotinib, alectinib).

Step 1: Define the Target Patient Population

Ensartinib is indicated for adult patients with ALK-positive locally advanced or metastatic NSCLC who have not previously received an ALK inhibitor (first-line treatment). ALK-positive NSCLC accounts for approximately **3-5%** of all NSCLC cases. We will use the following steps to estimate the target population:

1. **Total NSCLC Incidence**: Use epidemiology data to estimate the number of new NSCLC cases annually in each geography.

2. **ALK-Positive Proportion**: Assume 4% of NSCLC cases are ALK-positive (midpoint of 3-5%).

3. **Locally Advanced or Metastatic**: Assume ~60% of NSCLC cases are diagnosed at stage IIIB/IV (locally advanced or metastatic).

4. **First-Line Eligible**: Assume all ALK-positive metastatic patients are eligible for first-line ALK inhibitors (as per the indication).

Estimated NSCLC Incidence (Annual New Cases, 2023 Estimates)

- **US**: ~238,000 new lung cancer cases; ~85% are NSCLC = ~202,300 cases.

- **EU5**: ~317,000 new lung cancer cases; ~85% are NSCLC = ~269,450 cases.

- **China**: ~1,000,000 new lung cancer cases; ~85% are NSCLC = ~850,000 cases.

- **Japan**: ~125,000 new lung cancer cases; ~85% are NSCLC = ~106,250 cases.

ALK-Positive Metastatic NSCLC (First-Line Eligible)

- **ALK-Positive (4%) and Metastatic (60%)**:

- US: 202,300 * 0.04 * 0.6 = ~4,856 patients.

- EU5: 269,450 * 0.04 * 0.6 = ~6,467 patients.

- China: 850,000 * 0.04 * 0.6 = ~20,400 patients.

- Japan: 106,250 * 0.04 * 0.6 = ~2,550 patients.

- **Total Eligible Patients Across Geographies**: ~34,273 patients.

Step 2: Estimate Treated Patient Share

The query assumes a **20-30% share of treated patients** for ensartinib. This accounts for competition from other ALK inhibitors like alectinib (Alecensa), crizotinib (Xalkori), brigatinib (Alunbrig), and lorlatinib (Lorbrena). We will use the midpoint of **25%** for peak sales estimation.

- **Treated Patients with Ensartinib (25% Share)**:

- US: 4,856 * 0.25 = ~1,214 patients.

- EU5: 6,467 * 0.25 = ~1,617 patients.

- China: 20,400 * 0.25 = ~5,100 patients.

- Japan: 2,550 * 0.25 = ~638 patients.

- **Total Treated Patients**: ~8,569 patients.

Step 3: Estimate Annual Cost of Treatment

Pricing for ALK inhibitors varies by region due to differences in healthcare systems, reimbursement policies, and purchasing power. Based on benchmarks for drugs like alectinib and crizotinib, we assume the following annual costs per patient (hypothetical, based on public data and market reports):

- **US**: $150,000 per year (high due to lack of price controls).

- **EU5**: $80,000 per year (lower due to negotiated pricing and reimbursement).

- **Japan**: $100,000 per year (mid-range, reflects pricing in a developed market with controls).

- **China**: $30,000 per year (lower due to pricing regulations and potential local manufacturing).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients multiplied by the annual cost per patient in each geography.

- **US**: 1,214 patients * $150,000 = **$182.1 million**.

- **EU5**: 1,617 patients * $80,000 = **$129.4 million**.

- **China**: 5,100 patients * $30,000 = **$153.0 million**.

- **Japan**: 638 patients * $100,000 = **$63.8 million**.

- **Total Peak Sales**: $182.1M + $129.4M + $153.0M + $63.8M = **$528.3 million**.

Thus, the **Potential Peak Sales for ensartinib** in this indication across the US, EU5, China, and Japan, assuming a 25% share of treated patients, is approximately **$528 million annually**.

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

A 1% share of treated patients corresponds to 1% of the eligible patient population in each geography. Using the eligible patient numbers calculated earlier:

- **US**: 4,856 * 0.01 = 48.56 patients * $150,000 = **$7.3 million**.

- **EU5**: 6,467 * 0.01 = 64.67 patients * $80,000 = **$5.2 million**.

- **China**: 20,400 * 0.01 = 204 patients * $30,000 = **$6.1 million**.

- **Japan**: 2,550 * 0.01 = 25.5 patients * $100,000 = **$2.6 million**.

- **Total Value of 1% Share**: $7.3M + $5.2M + $6.1M + $2.6M = **$21.2 million**.

Thus, the **$ value of a 1% share of treated patients** across these geographies is approximately **$21.2 million annually**.

Key Assumptions and Caveats

1. **Epidemiology Data**: Incidence rates are based on 2023 estimates from sources like the American Cancer Society, WHO, and GLOBOCAN. Actual numbers may vary.

2. **ALK-Positive Rate**: Assumed at 4%, though it can range from 3-5% depending on the population.

3. **Pricing**: Annual costs are hypothetical and based on benchmarks for similar drugs. Actual pricing for ensartinib may differ.

4. **Market Share**: A 25% share assumes moderate penetration amidst competition. Real-world uptake depends on clinical differentiation, payer dynamics, and physician preference.

5. **Treatment Duration**: Assumes patients are treated for a full year; actual duration may vary based on progression-free survival and tolerability.

Final Answer

- **Potential Peak Sales for Ensartinib (20-30% share, midpoint 25%)**: Approximately **$528 million annually** across the US, EU5, China, and Japan.

- **$ Value of 1% Share of Treated Patients**: Approximately **$21.2 million annually** across the same geographies.

If you have specific data on pricing, patient numbers, or market share projections for ensartinib, I can refine these estimates further.