To estimate the **Potential Peak Sales** for infigratinib (Truseltiq) in the indication of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or rearrangement 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 (e.g., exact patient numbers, pricing, or market penetration) may not be publicly available, I will outline the methodology and provide reasonable assumptions based on available information about the drug, disease prevalence, and market dynamics. The final numbers are illustrative and should be validated with real-world data.

Step 1: Define the Target Patient Population

Cholangiocarcinoma (CCA) is a rare cancer of the bile ducts, and the specific indication for infigratinib is for patients with FGFR2 fusion or rearrangement, which accounts for approximately **10-15% of CCA cases**. Additionally, the drug is approved for **previously treated** patients with **unresectable locally advanced or metastatic disease**, which further narrows the eligible population.

- **Total CCA Incidence (Annual New Cases)**:

- US: ~8,000-10,000 cases per year (based on American Cancer Society estimates).

- EU5: ~10,000-12,000 cases per year (based on population and incidence rates of ~1-2 per 100,000).

- China: ~40,000-50,000 cases per year (higher incidence in Asia, ~3-5 per 100,000).

- Japan: ~20,000-25,000 cases per year (higher incidence in Asia, ~5-6 per 100,000).

- **Proportion with FGFR2 Fusion/Rearrangement (10-15%)**:

- US: ~800-1,500 patients.

- EU5: ~1,000-1,800 patients.

- China: ~4,000-7,500 patients.

- Japan: ~2,000-3,750 patients.

- **Proportion of Previously Treated, Unresectable Locally Advanced or Metastatic CCA**:

- Approximately 70-80% of CCA cases are unresectable at diagnosis, and many progress to second-line treatment. Let's assume ~50% of FGFR2-positive patients are eligible for infigratinib (previously treated, advanced/metastatic).

- US: ~400-750 patients.

- EU5: ~500-900 patients.

- China: ~2,000-3,750 patients.

- Japan: ~1,000-1,875 patients.

- **Total Eligible Patients (Annual)**:

- US: ~500-750.

- EU5: ~600-900.

- China: ~2,500-3,750.

- Japan: ~1,200-1,800.

- **Total across geographies**: ~4,800-7,200 patients annually.

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

Given the assumption of a 20-30% share of treated patients:

- US: 100-225 patients treated with infigratinib annually.

- EU5: 120-270 patients.

- China: 500-1,125 patients.

- Japan: 240-540 patients.

- **Total treated patients**: ~960-2,160 patients annually.

Step 3: Estimate Drug Pricing

Infigratinib is a targeted therapy for a rare cancer, so pricing is expected to be high, similar to other kinase inhibitors or orphan drugs.

- **US Price**: ~$300,000-$400,000 per patient per year (based on pricing of similar drugs like pemigatinib for CCA).

- **EU5 Price**: ~$200,000-$300,000 per patient per year (lower due to pricing negotiations and healthcare systems).

- **China Price**: ~$100,000-$150,000 per patient per year (lower due to market access challenges and pricing controls).

- **Japan Price**: ~$200,000-$300,000 per patient per year (similar to EU5 due to regulated pricing).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as (Number of treated patients) x (Annual cost per patient). Using the midpoint of the ranges for simplicity:

- **US**: 160 patients x $350,000 = **$56 million**.

- **EU5**: 195 patients x $250,000 = **$48.75 million**.

- **China**: 810 patients x $125,000 = **$101.25 million**.

- **Japan**: 390 patients x $250,000 = **$97.5 million**.

- **Total Peak Sales**: **~$303.5 million annually** (at midpoint of 20-30% share).

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

A 1% share corresponds to 1% of the total eligible patients treated annually.

- **Total Eligible Patients**: ~6,000 (midpoint of 4,800-7,200).

- **1% of Eligible Patients**: ~60 patients.

- **Revenue per 1% Share** (using weighted average pricing across geographies):

- US: 5 patients x $350,000 = $1.75 million.

- EU5: 6 patients x $250,000 = $1.5 million.

- China: 30 patients x $125,000 = $3.75 million.

- Japan: 12 patients x $250,000 = $3 million.

- **Total $ Value of 1% Share**: **~$10 million annually**.

Final Answer

- **Potential Peak Sales for Infigratinib** (20-30% share of treated patients): **~$240-370 million annually** across the US, EU5, China, and Japan, with a midpoint estimate of **~$303.5 million**.

- **$ Value of 1% Share of Treated Patients**: **~$10 million annually** across these geographies.

Caveats and Notes

1. These estimates are based on assumptions about patient numbers, market penetration, and pricing. Real-world data (e.g., from clinical trial enrollment, market research, or sales reports) would provide more accurate figures.

2. Peak sales may take several years to achieve due to factors like market access, reimbursement, competition (e.g., pemigatinib, another FGFR inhibitor for CCA), and physician adoption.

3. Pricing in China and other markets may be significantly lower due to local policies, which could reduce overall sales.

4. The indication is for a rare disease, so sales potential is inherently limited by the small patient population.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market share projections), I can refine these calculations further.