To estimate the **Potential Peak Sales** for pemigatinib (Pemazyre) in the indication of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or rearrangement 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 such as exact patient numbers, pricing, and market penetration may not be publicly available, I will outline the methodology and use reasonable assumptions based on available information about the disease prevalence, treatment landscape, and drug pricing.

Please note that this is a high-level estimation and should be validated with real-world data from market research reports, clinical trial data, or company disclosures (e.g., Incyte Corporation's financial reports).

Step 1: Define the Target Population

Cholangiocarcinoma (CCA) is a rare cancer of the bile ducts. The target population for pemigatinib is a subset of patients with:

- Previously treated, unresectable locally advanced or metastatic CCA.

- FGFR2 fusion or rearrangement (approximately 10-15% of CCA patients have this genetic alteration).

Incidence and Prevalence of CCA:

- **US**: ~8,000 new cases of CCA per year. Assuming 50% are advanced/metastatic and previously treated, and 10-15% have FGFR2 alterations, the target population is ~400-600 patients annually.

- **EU5**: ~10,000-12,000 new cases per year across EU5. Applying similar filters, the target population is ~500-900 patients annually.

- **China**: Higher incidence due to larger population and risk factors (e.g., liver fluke infections). ~30,000-40,000 new cases per year. Target population is ~1,500-3,000 patients annually.

- **Japan**: ~5,000 new cases per year. Target population is ~250-400 patients annually.

Total Target Population (Annual Incident Cases):

- US: ~500 patients

- EU5: ~700 patients

- China: ~2,250 patients

- Japan: ~325 patients

- **Total**: ~3,775 patients annually across these geographies.

Treated Patient Share:

The question assumes a 20-30% share of treated patients for pemigatinib. This accounts for competition (e.g., other targeted therapies, chemotherapy) and access barriers (e.g., cost, diagnostic testing for FGFR2 alterations). Therefore:

- At 20% share: ~755 patients treated annually.

- At 30% share: ~1,133 patients treated annually.

Step 2: Estimate Drug Pricing

Pemigatinib is a targeted oncology drug, and pricing for such therapies is typically high due to the rarity of the indication and R&D; costs. Based on available data:

- **US**: Annual cost of pemigatinib is approximately $250,000-$300,000 per patient (based on pricing for similar rare cancer drugs and initial reports for Pemazyre).

- **EU5**: Pricing is often 20-30% lower than the US due to healthcare system negotiations. Assume ~$175,000-$210,000 per patient annually.

- **China**: Pricing is significantly lower due to market access challenges and government negotiations. Assume ~$50,000-$75,000 per patient annually.

- **Japan**: Pricing is often aligned with the US or slightly lower. Assume ~$200,000-$250,000 per patient annually.

Average Annual Cost per Patient (Midpoint):

- US: $275,000

- EU5: $192,500

- China: $62,500

- Japan: $225,000

Step 3: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients multiplied by the annual cost per patient in each geography. We assume peak sales occur when the drug achieves maximum market penetration (20-30% share) and stable pricing.

At 20% Share of Treated Patients:

- **US**: 500 patients * 20% = 100 patients * $275,000 = **$27.5 million**

- **EU5**: 700 patients * 20% = 140 patients * $192,500 = **$26.95 million**

- **China**: 2,250 patients * 20% = 450 patients * $62,500 = **$28.13 million**

- **Japan**: 325 patients * 20% = 65 patients * $225,000 = **$14.63 million**

- **Total Peak Sales at 20% Share**: **$97.21 million**

At 30% Share of Treated Patients:

- **US**: 500 patients * 30% = 150 patients * $275,000 = **$41.25 million**

- **EU5**: 700 patients * 30% = 210 patients * $192,500 = **$40.43 million**

- **China**: 2,250 patients * 30% = 675 patients * $62,500 = **$42.19 million**

- **Japan**: 325 patients * 30% = 98 patients * $225,000 = **$22.05 million**

- **Total Peak Sales at 30% Share**: **$145.92 million**

Potential Peak Sales Range: **$97.21 million to $145.92 million** annually across the US, EU5, China, and Japan for this indication.

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

A 1% share of treated patients corresponds to 1% of the total target population being treated with pemigatinib.

Total Target Population: 3,775 patients

- 1% share = 37.75 patients (rounded to 38 patients for simplicity).

Breakdown by Geography:

- **US**: 500 patients * 1% = 5 patients * $275,000 = **$1.38 million**

- **EU5**: 700 patients * 1% = 7 patients * $192,500 = **$1.35 million**

- **China**: 2,250 patients * 1% = 22.5 patients (rounded to 23) * $62,500 = **$1.44 million**

- **Japan**: 325 patients * 1% = 3.25 patients (rounded to 3) * $225,000 = **$0.68 million**

- **Total $ Value of 1% Share**: **$4.85 million**

$ Value of 1% Share of Treated Patients: Approximately **$4.85 million** annually across the US, EU5, China, and Japan.

Summary of Results:

1. **Potential Peak Sales for Pemigatinib** in the specified indication (previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or rearrangement) at 20-30% share of treated patients:

- **Range**: **$97.21 million to $145.92 million** annually across the US, EU5, China, and Japan.

2. **$ Value of 1% Share of Treated Patients**: Approximately **$4.85 million** annually across the same geographies.

Caveats and Assumptions:

- **Patient Population**: The incidence numbers and FGFR2 alteration rates are approximations based on general epidemiology data for cholangiocarcinoma. Real-world numbers may vary.

- **Pricing**: Drug pricing is assumed based on typical costs for rare oncology drugs and may differ due to negotiations, reimbursement policies, or generics/biosimilars in the future.

- **Market Share**: The 20-30% share assumes moderate competition and access. Actual market penetration may be influenced by factors like diagnostic testing availability, physician adoption, and payer coverage.

- **Peak Sales Timing**: Peak sales are assumed to be achieved within a few years post-launch, but this depends on market dynamics and regulatory approvals in each region (pemigatinib is already approved in the US, EU, and Japan as of recent data, but China approval status may vary).

For more accurate estimates, primary data from Incyte Corporation, market research (e.g., EvaluatePharma, GlobalData), or real-world evidence on patient numbers and pricing should be consulted.