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 other 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 based on available epidemiology data, market assumptions, and pricing information. Since exact data might not be publicly available, I will outline the methodology and use reasonable assumptions to provide an illustrative calculation. Note that real-world data and specific market research would be required for precise figures.

Step 1: Indication Overview and Target Population

- **Indication**: Pemigatinib is approved for adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or rearrangement.

- **Disease Context**: Cholangiocarcinoma is a rare cancer of the bile ducts. The FGFR2 fusion/rearrangement occurs in approximately 10-15% of intrahepatic cholangiocarcinoma cases.

- **Treatment Line**: This is a second-line or later therapy, so only a subset of patients will qualify after failing first-line treatment (typically gemcitabine-based chemotherapy).

Step 2: Epidemiology and Eligible Patient Population

We will estimate the number of eligible patients in each geography based on incidence rates of cholangiocarcinoma, the proportion with FGFR2 alterations, and the share of patients who progress to second-line treatment.

Incidence of Cholangiocarcinoma (Annual New Cases)

- **US**: ~8,000-10,000 cases per year.

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

- **China**: ~50,000-60,000 cases per year (higher incidence in Asia, ~2-6 per 100,000).

- **Japan**: ~20,000-25,000 cases per year (incidence ~2-3 per 100,000).

Proportion with FGFR2 Fusion/Rearrangement

- FGFR2 alterations are found in ~10-15% of intrahepatic cholangiocarcinoma cases. Assuming 12% as an average:

- US: ~1,000-1,200 eligible patients.

- EU5: ~1,200-1,400 eligible patients.

- China: ~6,000-7,200 eligible patients.

- Japan: ~2,400-3,000 eligible patients.

Proportion Progressing to Second-Line Treatment

- Approximately 50-60% of patients may progress to second-line treatment after first-line failure (due to disease progression or toxicity). Assuming 55%:

- US: ~550-660 patients.

- EU5: ~660-770 patients.

- China: ~3,300-3,960 patients.

- Japan: ~1,320-1,650 patients.

Total Eligible Treated Patients (Assuming 20-30% Market Share)

- Assuming pemigatinib captures 20-30% of second-line eligible patients (due to competition, access, or physician preference):

- US: ~110-198 patients (25% average = ~138 patients).

- EU5: ~132-231 patients (25% average = ~165 patients).

- China: ~660-1,188 patients (25% average = ~825 patients).

- Japan: ~264-495 patients (25% average = ~330 patients).

Total treated patients across geographies at 25% market share: **~1,458 patients**.

Step 3: Pricing and Revenue per Patient

Pemigatinib is a targeted therapy for a rare cancer, so pricing is high. We will estimate annual treatment costs based on available data and typical pricing for orphan drugs in oncology.

- **US**: Annual cost of pemigatinib is ~$250,000-$300,000 per patient (based on reported costs and typical pricing for rare cancer drugs). Assume $275,000.

- **EU5**: Pricing is typically 60-70% of US prices due to negotiations and health systems. Assume $180,000 per patient.

- **China**: Pricing is lower due to market access challenges and local policies. Assume $80,000 per patient.

- **Japan**: Pricing is often closer to EU levels. Assume $180,000 per patient.

Revenue per Treated Patient (Annual)

- US: $275,000

- EU5: $180,000

- China: $80,000

- Japan: $180,000

Step 4: Potential Peak Sales Calculation

Using the estimated number of treated patients (at 25% market share) and revenue per patient:

- **US**: 138 patients × $275,000 = **$37.95 million**

- **EU5**: 165 patients × $180,000 = **$29.7 million**

- **China**: 825 patients × $80,000 = **$66.0 million**

- **Japan**: 330 patients × $180,000 = **$59.4 million**

Total Potential Peak Sales (at 25% market share):

$37.95M (US) + $29.7M (EU5) + $66.0M (China) + $59.4M (Japan) = **$193.05 million annually**

Range for 20-30% Market Share

- At 20% market share: ~$154.4 million

- At 30% market share: ~$231.7 million

Thus, **Potential Peak Sales** for pemigatinib in this indication across the specified geographies is estimated to be **$154M to $232M annually**, with a midpoint of ~$193M.

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

To calculate the value of 1% market share, we divide the total number of eligible second-line patients by 100 and multiply by the revenue per patient.

Eligible Second-Line Patients (from Step 2)

- US: 550-660 (average 605) $\rightarrow$ 1% = 6.05 patients

- EU5: 660-770 (average 715) $\rightarrow$ 1% = 7.15 patients

- China: 3,300-3,960 (average 3,630) $\rightarrow$ 1% = 36.3 patients

- Japan: 1,320-1,650 (average 1,485) $\rightarrow$ 1% = 14.85 patients

Revenue for 1% Market Share

- **US**: 6.05 patients × $275,000 = **$1.66 million**

- **EU5**: 7.15 patients × $180,000 = **$1.29 million**

- **China**: 36.3 patients × $80,000 = **$2.90 million**

- **Japan**: 14.85 patients × $180,000 = **$2.67 million**

Total $ Value of 1% Share Across Geographies:

$1.66M (US) + $1.29M (EU5) + $2.90M (China) + $2.67M (Japan) = **$8.52 million**

Final Answer

1. **Potential Peak Sales for Pemigatinib** in the specified indication across the US, EU5, China, and Japan (assuming 20-30% market share): **$154 million to $232 million annually** (midpoint ~$193 million).

2. **$ Value of 1% Share of Treated Patients** across these geographies: **$8.52 million annually**.

Caveats and Assumptions

- These estimates are based on publicly available epidemiology data and assumptions about market share, pricing, and patient eligibility. Real-world data may differ.

- Pricing may vary due to negotiations, reimbursement policies, and local market dynamics.

- Competition from other FGFR inhibitors (e.g., infigratinib, futibatinib) or other therapies may impact market share.

- Peak sales assume steady-state market penetration, which may take several years post-launch to achieve.