

To estimate the **Potential Peak Sales** for pemigatinib (Pemazyre) in the indication of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data on patient populations, pricing, and market penetration may not be fully available, I will outline the methodology and use reasonable assumptions based on available information and industry standards. The final numbers are illustrative and should be validated with real-world data.

Step 1: Define the Indication and Target Population

Pemigatinib is approved for adults with relapsed or refractory MLNs with FGFR1 rearrangement, a rare hematologic malignancy. FGFR1-rearranged MLNs are extremely rare, with an estimated incidence of less than 1 per million annually. These conditions often fall under the category of 8p11 myeloproliferative syndrome or related disorders. Given the rarity, the eligible patient population is small.

Step 2: Estimate the Eligible Patient Population

Since exact numbers for FGFR1-rearranged MLNs are not widely published, we can estimate based on broader hematologic malignancy data and the proportion of cases with FGFR1 rearrangements (estimated at ~1-2% of specific myeloid/lymphoid neoplasms). Below are rough estimates of the annual incidence of eligible patients in each geography:

- **US:** Population ~330 million. Assuming an incidence of 0.5-1 per million for FGFR1-rearranged MLNs, ~165-330 new cases per year. Considering relapsed/refractory patients, the treatable population might be ~200-400 patients annually.
- **EU5:** Combined population ~320 million. Similar incidence, ~160-320 new cases per year, with a treatable population of ~200-400 patients.
- **China:** Population ~1.4 billion. Incidence might be slightly lower due to underdiagnosis, but assuming 0.3-0.5 per million, ~420-700 new cases, with a treatable population of ~500-800 patients.
- **Japan:** Population ~125 million. Incidence of 0.5-1 per million, ~60-125 new cases, with a treatable population of ~80-150 patients.

Total Treatable Population (annual): ~980-1,750 patients across all geographies.

Step 3: Estimate Market Penetration (20%-30% Share of Treated Patients)

Given the rarity of the disease and pemigatinib being a targeted therapy for a specific genetic alteration, market penetration could be relatively high among diagnosed patients. However, challenges such as access to genetic testing, pricing, and competition may limit penetration. The assumption of 20%-30% share of treated patients seems reasonable.

- **US:** 20%-30% of 200-400 = 40-120 patients.
- **EU5:** 20%-30% of 200-400 = 40-120 patients.
- **China:** 20%-30% of 500-800 = 100-240 patients.

- **Japan:** 20%-30% of 80-150 = 16-45 patients.

Total Treated Patients (annual): ~196-525 patients.

Step 4: Estimate Drug Pricing

Pemigatinib is a specialty drug for a rare disease, so pricing is high. Based on available data for pemigatinib in other indications (e.g., cholangiocarcinoma), the annual cost per patient in the US is approximately \$250,000-\$300,000. Pricing in other regions is typically lower due to healthcare system differences:

- **US:** ~\$250,000 per patient per year.

- **EU5:** ~\$150,000-\$200,000 per patient per year (discounts due to payer negotiations).

- **Japan:** ~\$150,000-\$200,000 per patient per year (similar to EU5).

- **China:** ~\$50,000-\$100,000 per patient per year (significant discounts due to market access challenges and lower pricing).

Step 5: Calculate Potential Peak Sales

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

- **US:** 40-120 patients * \$250,000 = **\$10M - \$30M**.

- **EU5:** 40-120 patients * \$175,000 (average) = **\$7M - \$21M**.

- **China:** 100-240 patients * \$75,000 (average) = **\$7.5M - \$18M**.

- **Japan:** 16-45 patients * \$175,000 (average) = **\$2.8M - \$7.9M**.

Total Potential Peak Sales: **\$27.3M - \$76.9M** annually.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

First, estimate the total treatable population and 1% of that population:

- Total treatable population: 980-1,750 patients.

- 1% of treatable population: 9.8-17.5 patients.

Now calculate the revenue for 1% share in each geography using the same pricing assumptions:

- **US:** 1% of 200-400 = 2-4 patients * \$250,000 = **\$0.5M - \$1M**.

- **EU5:** 1% of 200-400 = 2-4 patients * \$175,000 = **\$0.35M - \$0.7M**.

- **China:** 1% of 500-800 = 5-8 patients * \$75,000 = **\$0.375M - \$0.6M**.

- **Japan:** 1% of 80-150 = 0.8-1.5 patients * \$175,000 = **\$0.14M - \$0.26M**.

Total \$ Value of 1% Share: **\$1.365M - \$2.56M** annually.

Final Answer:

- **Potential Peak Sales for Pemigatinib** (20%-30% share of treated patients) in the US, EU5, China, and Japan for relapsed or refractory MLNs with FGFR1 rearrangement: **\$27.3 million to \$76.9 million annually.**

- **\$ Value of 1% Share of Treated Patients** in these geographies: **\$1.365 million to \$2.56 million annually.**

Caveats:

1. These estimates are based on assumptions about patient populations, incidence rates, pricing, and market penetration. Real-world data may differ significantly.
2. FGFR1-rearranged MLNs are extremely rare, and diagnosis rates may be lower due to limited genetic testing in some regions, especially China.
3. Pricing and reimbursement policies vary widely, impacting sales potential.
4. Competition from other targeted therapies or off-label treatments could affect market share.

For more accurate figures, primary market research, epidemiology data, and Incyte Corporation's financial reports or guidance on pemigatinib sales would be necessary.