

To estimate the **Potential Peak Sales** for crizotinib (Xalkori) in the indication of unresectable, recurrent, or refractory inflammatory ALK-positive myofibroblastic tumors (IMT) 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 make several assumptions and follow a structured approach. Since specific data on patient numbers, pricing, and market penetration for this rare indication may not be publicly available in full detail, this analysis will rely on reasonable estimates and proxies based on available information about rare diseases, oncology drug pricing, and market dynamics.

Step 1: Define the Indication and Patient Population

- **Indication:** Unresectable, recurrent, or refractory inflammatory ALK-positive myofibroblastic tumors (IMT) in adult and pediatric patients (1 year and older).

- **Disease Rarity:** IMT is a very rare tumor, and ALK-positive IMT represents a subset of these cases. Exact incidence and prevalence data are scarce, but IMT is estimated to have an incidence of less than 1 per million per year in most populations. ALK positivity occurs in approximately 50% of IMT cases.

- **Target Population:** Given the rarity, we will estimate the number of eligible patients in each geography based on population size and assumed incidence/prevalence.

Estimated Patient Population

- **US:** Population ~330 million. Assuming an incidence of 0.5 per million for ALK-positive IMT, there are ~165 new cases per year. Prevalence (existing cases) may be higher due to chronicity; assume ~500-1,000 total treatable patients.

- **EU5:** Population ~260 million. Incidence of 0.5 per million yields ~130 new cases per year. Prevalence estimate: ~400-800 patients.

- **China:** Population ~1.4 billion. Incidence of 0.5 per million yields ~700 new cases per year. Prevalence estimate: ~2,000-4,000 patients.

- **Japan:** Population ~125 million. Incidence of 0.5 per million yields ~63 new cases per year. Prevalence estimate: ~200-400 patients.

Total Treatable Patients (Prevalence Estimate, Midpoint):

- US: 750 patients

- EU5: 600 patients

- China: 3,000 patients

- Japan: 300 patients

- **Total:** 4,650 patients across these geographies.

Share of Treated Patients (20%-30%)

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

- **Low End (20%):** 930 patients treated.

- **High End (30%):** 1,395 patients treated.

Step 2: Estimate Drug Pricing

Crizotinib is a targeted oncology drug, and pricing varies by region due to healthcare systems, reimbursement policies, and purchasing power. Based on current pricing for crizotinib in other indications (e.g., ALK-positive non-small cell lung cancer), we can estimate annual costs per patient:

- **US:** ~\$150,000 - \$200,000 per patient per year (based on list prices for oncology drugs).
- **EU5:** ~\$80,000 - \$120,000 per patient per year (lower due to negotiated prices and health system discounts).
- **China:** ~\$30,000 - \$50,000 per patient per year (lower pricing due to market access programs and generics/biosimilars competition).
- **Japan:** ~\$100,000 - \$150,000 per patient per year (similar to US but with some discounts).

Midpoint Annual Cost per Patient:

- US: \$175,000
- EU5: \$100,000
- China: \$40,000
- Japan: \$125,000

Step 3: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients (at 20% and 30% share) by the annual cost per patient in each geography.

Treated Patients by Geography (20%-30% Share)

- **US:** 150-225 patients (750 * 20%-30%)
- **EU5:** 120-180 patients (600 * 20%-30%)
- **China:** 600-900 patients (3,000 * 20%-30%)
- **Japan:** 60-90 patients (300 * 20%-30%)

Peak Sales Calculation (Low End - 20% Share)

- **US:** 150 patients * \$175,000 = \$26.25 million
- **EU5:** 120 patients * \$100,000 = \$12.00 million
- **China:** 600 patients * \$40,000 = \$24.00 million
- **Japan:** 60 patients * \$125,000 = \$7.50 million
- **Total Peak Sales (20% Share):** \$69.75 million

Peak Sales Calculation (High End - 30% Share)

- **US:** 225 patients * \$175,000 = \$39.38 million
- **EU5:** 180 patients * \$100,000 = \$18.00 million
- **China:** 900 patients * \$40,000 = \$36.00 million
- **Japan:** 90 patients * \$125,000 = \$11.25 million
- **Total Peak Sales (30% Share):** \$104.63 million

Potential Peak Sales Range: \$69.75 million to \$104.63 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 treatable patient population (4,650 patients) = **46.5 patients**.

\$ Value of 1% Share by Geography

- **US:** 7.5 patients (750 * 1%) * \$175,000 = \$1.31 million
- **EU5:** 6 patients (600 * 1%) * \$100,000 = \$0.60 million
- **China:** 30 patients (3,000 * 1%) * \$40,000 = \$1.20 million
- **Japan:** 3 patients (300 * 1%) * \$125,000 = \$0.38 million
- **Total \$ Value of 1% Share:** \$3.49 million annually

\$ Value of 1% Share of Treated Patients: \$3.49 million annually across the US, EU5, China, and Japan.

Key Assumptions and Caveats

1. **Patient Population:** Due to the rarity of ALK-positive IMT, patient numbers are rough estimates based on assumed incidence/prevalence. Real-world data may differ.
2. **Pricing:** Pricing varies by country and over time due to negotiations, generics, or biosimilars. The estimates are based on current oncology drug pricing trends.
3. **Market Share:** The 20%-30% share assumption accounts for competition, access issues, and treatment duration. Actual penetration could be higher or lower.
4. **Treatment Duration:** Assumes patients are treated for a full year, though actual duration may vary based on response, progression, or toxicity.
5. **Indication Scope:** This analysis is specific to ALK-positive IMT and does not account for other approved indications of crizotinib (e.g., NSCLC), which contribute significantly to overall sales.

Final Answer

- **Potential Peak Sales for Crizotinib in ALK-positive IMT** (20%-30% share of treated patients): **\$69.75 million to \$104.63 million annually** across the US, EU5, China, and Japan.
- **\$ Value of 1% Share of Treated Patients: \$3.49 million annually** across the same geographies.