

To estimate the **Potential Peak Sales** for crizotinib (Xalkori) in the indication of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive in pediatric patients and young adults 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 on patient numbers, pricing, and market penetration may not be fully available, I will outline a methodology using reasonable assumptions based on epidemiology, pricing, and market dynamics. Note that actual figures may vary based on proprietary data, real-world evidence, and market access conditions.

Step 1: Indication and Target Population

- **Indication:** Relapsed or refractory systemic ALK-positive ALCL in pediatric patients (1 year and older) and young adults.

- **Target Population:** Pediatric and young adult patients with ALK-positive ALCL who have relapsed or are refractory to prior treatments. ALCL is a rare subtype of non-Hodgkin lymphoma (NHL), and ALK-positive ALCL accounts for a subset of cases, primarily in younger patients.

Step 2: Epidemiology and Patient Pool Estimation

ALCL is rare, with an incidence of approximately 1-2 per million in children and young adults. ALK-positive ALCL represents about 50-60% of ALCL cases in this age group. We will estimate the number of eligible patients (relapsed/refractory) in each geography. Since relapsed/refractory patients are a subset of incident cases (typically 20-30% of diagnosed cases), we will use conservative estimates.

- US:

- Incidence of ALCL in pediatrics/young adults: ~100-150 new cases per year (based on population and rarity).

- ALK-positive: ~50-60% → ~50-90 cases.

- Relapsed/Refractory: ~20-30% → ~10-25 patients annually.

- EU5 (combined):

- Similar incidence rates, adjusted for population (~60% of US population): ~60-90 new cases.

- ALK-positive: ~30-50 cases.

- Relapsed/Refractory: ~6-15 patients annually.

- China:

- Larger population (~4x US), but lower diagnosis rates due to healthcare access: ~200-300 new cases.

- ALK-positive: ~100-180 cases.

- Relapsed/Refractory: ~20-50 patients annually.

- Japan:

- Smaller population (~40% of US), high diagnosis rates: ~40-60 new cases.

- ALK-positive: ~20-35 cases.

- Relapsed/Refractory: ~4-10 patients annually.

Total Eligible Patients (Relapsed/Refractory ALK-positive ALCL):

- US: ~10-25
- EU5: ~6-15
- China: ~20-50
- Japan: ~4-10
- **Total:** ~40-100 patients annually across all geographies.

Since this is a chronic condition with potential multi-year treatment, we can assume a **prevalent pool** of patients (cumulative over 2-3 years) to be approximately **2-3x the annual incident cases**:

- Total prevalent eligible patients: ~80-300 patients across geographies at peak.

Step 3: Market Share Assumption

The problem states a **20-30% share of treated patients** for crizotinib. Given that crizotinib is specifically approved for ALK-positive ALCL in this population and has limited competition (other therapies like brentuximab vedotin exist but may not be directly competing in all cases), this market share seems reasonable.

- **Treated Patients with Crizotinib:** 20-30% of ~80-300 = ~16-90 patients annually at peak.

Step 4: Pricing of Crizotinib

Crizotinib (Xalkori) is a targeted therapy with a high annual cost. Pricing varies by geography due to healthcare systems and negotiations:

- **US:** Annual cost ~\$200,000-\$250,000 per patient (based on oncology drug pricing for rare indications).
- **EU5:** ~\$150,000-\$200,000 per patient (discounted due to payer negotiations).
- **China:** ~\$80,000-\$120,000 per patient (lower due to market access and pricing controls).
- **Japan:** ~\$150,000-\$200,000 per patient (similar to EU5).

Average Annual Cost per Patient (weighted by region): ~\$150,000 for simplicity.

Step 5: Potential Peak Sales Calculation

Peak sales are calculated as:

Peak Sales = Number of Treated Patients x Annual Cost per Patient

- **Treated Patients at Peak (20-30% share):** 16-90 patients.
- **Annual Cost:** \$150,000 per patient.
- **Peak Sales:** (16 x \$150,000) to (90 x \$150,000) = **\$2.4 million to \$13.5 million annually.**

Breakdown by Geography (approximate distribution of patients):

- US (~30% of patients): \$0.7M - \$4.0M
- EU5 (~20% of patients): \$0.5M - \$2.7M
- China (~40% of patients): \$0.9M - \$5.4M
- Japan (~10% of patients): \$0.2M - \$1.4M

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

- **Total Eligible Patients:** ~80-300.
- **1% Share:** 0.8-3 patients.
- **Annual Cost:** \$150,000 per patient.
- **\$ Value of 1% Share:** $(0.8 \times \$150,000)$ to $(3 \times \$150,000) = \text{\$120,000 to \$450,000 annually.}$

Breakdown by Geography (approximate):

- US: \$36,000 - \$135,000
- EU5: \$24,000 - \$90,000
- China: \$48,000 - \$180,000
- Japan: \$12,000 - \$45,000

Final Answer

- **Potential Peak Sales for Crizotinib in ALK-positive ALCL (Relapsed/Refractory, Pediatric/Young Adults)** in US, EU5, China, and Japan (assuming 20-30% market share): **\$2.4 million to \$13.5 million annually.**
- **\$ Value of 1% Share of Treated Patients** in these geographies: **\$120,000 to \$450,000 annually.**

Caveats

- These estimates are based on assumptions about epidemiology, pricing, and market share. Real-world data on patient numbers and uptake may differ.
- Pricing may vary significantly due to payer negotiations, access programs, or generic/biosimilar entry.
- The small patient pool reflects the ultra-rare nature of this indication, leading to modest sales potential despite high per-patient costs.