

To calculate the **Potential Peak Sales** for alectinib (Alecensa) in the adjuvant treatment of ALK-positive non-small cell lung cancer (NSCLC) 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 make several assumptions and follow a structured approach. Since specific data on patient numbers, pricing, and market penetration may not be publicly available or fully up-to-date, I'll outline a methodology using reasonable estimates based on general market trends, epidemiology, and drug pricing in oncology. Let's break this down step by step.

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## **Step 1: Define the Indication and Target Population**

Alectinib is approved for adjuvant treatment following tumor resection in patients with ALK-positive NSCLC. ALK-positive NSCLC accounts for approximately **3-5% of all NSCLC cases**. NSCLC itself represents about **85-90% of all lung cancer cases**. Adjuvant therapy is typically given to early-stage patients (Stage I-III) post-surgery to prevent recurrence, so the target population is a subset of early-stage ALK-positive NSCLC patients.

- **Global NSCLC Incidence:** Approximately 2.2 million new lung cancer cases annually (2020 data from WHO/IARC), of which ~85% are NSCLC (~1.87 million).
- **ALK-positive NSCLC:** ~5% of NSCLC cases (~93,500 patients globally).
- **Early-stage (resectable) NSCLC:** About 30-40% of NSCLC patients are diagnosed at an early stage (Stage I-III) and are eligible for surgery (~28,000-37,000 ALK-positive patients globally).
- **Geographic Distribution:** The incidence varies by region. The US, EU5, China, and Japan account for a significant portion of global cases due to population size and healthcare access.

Using approximate incidence rates and population data, let's estimate the number of eligible patients for adjuvant alectinib in these regions:

- **US:** ~30% of global NSCLC cases (~28,000 ALK-positive, ~8,400-11,200 early-stage).
- **EU5:** ~25% of global NSCLC cases (~23,000 ALK-positive, ~6,900-9,200 early-stage).
- **China:** ~35% of global NSCLC cases (~33,000 ALK-positive, ~9,900-13,200 early-stage).
- **Japan:** ~10% of global NSCLC cases (~9,000 ALK-positive, ~2,700-3,600 early-stage).

### **Total Estimated Early-Stage ALK-positive NSCLC Patients (Eligible for Adjuvant Therapy):**

- US: ~10,000 patients
- EU5: ~8,000 patients
- China: ~11,500 patients
- Japan: ~3,000 patients
- **Total:** ~32,500 patients

These are rough estimates and may vary based on actual epidemiology data, diagnosis rates, and surgical eligibility.

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## **Step 2: Estimate Market Penetration (20%-30% Share of Treated Patients)**

The problem assumes a **20%-30% share of treated patients** for alectinib in this indication. This accounts for competition from other ALK inhibitors (e.g., crizotinib, lorlatinib), diagnostic testing rates, and treatment adoption.

- **Low-end (20%):** ~6,500 treated patients across all regions.

- **High-end (30%):** ~9,750 treated patients across all regions.

Broken down by region (proportional to patient population):

- **US:** 20%-30% of 10,000 = 2,000-3,000 patients

- **EU5:** 20%-30% of 8,000 = 1,600-2,400 patients

- **China:** 20%-30% of 11,500 = 2,300-3,450 patients

- **Japan:** 20%-30% of 3,000 = 600-900 patients

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## **Step 3: Estimate Annual Treatment Cost per Patient**

Alectinib's pricing varies by region due to differences in healthcare systems, reimbursement, and purchasing power. Based on publicly available data and oncology drug pricing trends:

- **US:** ~\$15,000-\$20,000 per month. Assuming a 12-month adjuvant treatment duration, annual cost = **\$180,000-\$240,000 per patient.**

- **EU5:** Pricing is typically lower due to negotiations and health technology assessments. Annual cost = **\$100,000-\$150,000 per patient.**

- **Japan:** Pricing is similar to EU5, annual cost = **\$100,000-\$150,000 per patient.**

- **China:** Pricing is significantly lower due to government negotiations and local manufacturing. Annual cost = **\$30,000-\$50,000 per patient.**

For simplicity, let's use midpoint values for calculations:

- US: \$210,000/year

- EU5: \$125,000/year

- Japan: \$125,000/year

- China: \$40,000/year

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## **Step 4: Calculate Potential Peak Sales**

Peak sales are calculated as:

**Peak Sales = Number of Treated Patients × Annual Treatment Cost per Patient**

#### Low-End (20% Share)

- **US:** 2,000 patients × \$210,000 = **\$420 million**
- **EU5:** 1,600 patients × \$125,000 = **\$200 million**
- **China:** 2,300 patients × \$40,000 = **\$92 million**
- **Japan:** 600 patients × \$125,000 = **\$75 million**
- **Total Peak Sales (20% Share):** \$420M + \$200M + \$92M + \$75M = **\$787 million**

#### High-End (30% Share)

- **US:** 3,000 patients × \$210,000 = **\$630 million**
- **EU5:** 2,400 patients × \$125,000 = **\$300 million**
- **China:** 3,450 patients × \$40,000 = **\$138 million**
- **Japan:** 900 patients × \$125,000 = **\$112.5 million**
- **Total Peak Sales (30% Share):** \$630M + \$300M + \$138M + \$112.5M = **\$1,180.5 million (or ~\$1.18 billion)**

**Potential Peak Sales Range: \$787 million to \$1.18 billion** annually across the US, EU5, China, and Japan for this indication.

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## **Step 5: Calculate \$ Value of 1% Share of Treated Patients**

A 1% share of treated patients corresponds to 1% of the total eligible patient population being treated with alectinib.

- **Total Eligible Patients:** ~32,500
- **1% of Total Patients:** 325 patients

Breakdown by region:

- **US:** 1% of 10,000 = 100 patients
- **EU5:** 1% of 8,000 = 80 patients
- **China:** 1% of 11,500 = 115 patients
- **Japan:** 1% of 3,000 = 30 patients

Now calculate the revenue for 1% share:

- **US:** 100 patients × \$210,000 = **\$21 million**
- **EU5:** 80 patients × \$125,000 = **\$10 million**

- **China:** 115 patients × \$40,000 = **\$4.6 million**
- **Japan:** 30 patients × \$125,000 = **\$3.75 million**
- **Total \$ Value of 1% Share:** \$21M + \$10M + \$4.6M + \$3.75M = **\$39.35 million**

**\$ Value of 1% Share of Treated Patients: \$39.35 million** annually across the US, EU5, China, and Japan.

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## **Final Answer**

1. **Potential Peak Sales for Alectinib in Adjuvant ALK-positive NSCLC** (assuming 20%-30% market share):

- **Range: \$787 million to \$1.18 billion** annually across the US, EU5, China, and Japan.

2. **\$ Value of 1% Share of Treated Patients:**

- **Total: \$39.35 million** annually across the US, EU5, China, and Japan.

## **Notes and Caveats**

- These calculations are based on rough estimates of patient populations, pricing, and market share. Real-world data may differ due to variations in diagnosis rates, access to testing for ALK mutations, competition, and reimbursement policies.

- Adjuvant therapy duration may vary (e.g., 1-2 years), which could impact annual costs and peak sales.

- Peak sales may take several years to achieve post-approval as market penetration grows.

- Additional data on exact patient numbers, real-world pricing, and competitor dynamics would refine these estimates.

If you have access to more specific data (e.g., exact patient numbers or pricing), I can adjust the calculations accordingly.