

To estimate the **Potential Peak Sales** for pomalidomide (POMALYST) in the indication of Kaposi sarcoma (KS) 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 the methodology and provide reasonable assumptions based on available information and typical market dynamics for rare diseases like Kaposi sarcoma. Let's break this down step by step.

Step 1: Understand the Indication and Target Population

Pomalidomide has been approved for:

1. **AIDS-related Kaposi sarcoma (KS)** after failure of highly active antiretroviral therapy (HAART).
2. **KS in HIV-negative adult patients.**

Kaposi sarcoma is a rare cancer, often associated with HIV/AIDS, though it can also occur in HIV-negative individuals (e.g., classic KS in older men of Mediterranean or African descent, or iatrogenic KS in transplant patients). The prevalence of KS is significantly higher in HIV-positive patients, particularly in regions with high HIV prevalence.

Epidemiology of Kaposi Sarcoma

- **US:** The incidence of KS in HIV-positive individuals has declined with HAART, but there are still ~1,000-2,000 new cases per year. Approximately 20-30% of these may fail HAART and become eligible for second-line therapies like pomalidomide.
- **EU5:** Similar trends to the US, with a slightly lower incidence due to better HIV control in some countries. Estimated new cases are ~1,500-2,500 annually across EU5.
- **China:** Lower HIV prevalence, but a growing number of cases. KS incidence is less documented, likely ~500-1,000 cases annually.
- **Japan:** Very low incidence of KS due to low HIV prevalence. Estimated cases are ~100-200 annually.
- **HIV-negative KS:** This population is smaller, often linked to specific demographics (e.g., elderly men in Mediterranean regions for classic KS) or post-transplant immunosuppression. This adds a small fraction to the total eligible population.

Eligible Patient Population (Assumption)

Assuming only 20-30% of KS patients fail HAART (for HIV-related KS) or are eligible due to HIV-negative status and disease progression, we can estimate the treatable population as follows (rough estimates for new cases eligible for pomalidomide annually):

- **US:** ~300-600 patients
- **EU5:** ~400-800 patients
- **China:** ~100-300 patients
- **Japan:** ~20-50 patients
- **Total:** ~820-1,750 patients annually across all regions.

These numbers are conservative and represent patients who fail first-line therapies and are eligible for pomalidomide.

Step 2: Market Share Assumption

The query assumes a **20-30% share of treated patients** for pomalidomide in this indication. This is reasonable for a second-line therapy in a rare disease setting, where competition may include chemotherapy (e.g., liposomal doxorubicin, paclitaxel) or other immunomodulatory drugs, but pomalidomide's oral administration and efficacy could drive uptake.

Let's calculate the treated patient share:

- At 20-30% market share:
- **US**: 60-180 patients
- **EU5**: 80-240 patients
- **China**: 20-90 patients
- **Japan**: 4-15 patients
- **Total**: 164-525 patients annually.

Step 3: Pricing and Treatment Duration

Pomalidomide is a high-cost drug, often priced based on indication and region. Pricing for pomalidomide in other indications (e.g., multiple myeloma) can serve as a benchmark:

- **US**: ~\$10,000-\$15,000 per month per patient.
- **EU5**: ~\$7,000-\$10,000 per month (varies by country due to healthcare negotiations).
- **China**: ~\$5,000-\$8,000 per month (lower due to pricing controls and generics).
- **Japan**: ~\$8,000-\$12,000 per month (similar to EU5).

Treatment Duration: KS treatment with pomalidomide is likely chronic or until disease progression, similar to its use in multiple myeloma. Assume an average treatment duration of **6-12 months** per patient.

Annual cost per patient (midpoint of pricing and 9 months average duration):

- **US**: \$112,500 (\$12,500/month x 9 months)
- **EU5**: \$81,000 (\$9,000/month x 9 months)
- **China**: \$58,500 (\$6,500/month x 9 months)
- **Japan**: \$90,000 (\$10,000/month x 9 months)

Step 4: Potential Peak Sales Calculation

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

At 20% Market Share:

- **US:** 60 patients x \$112,500 = **\$6.75M**
- **EU5:** 80 patients x \$81,000 = **\$6.48M**
- **China:** 20 patients x \$58,500 = **\$1.17M**
- **Japan:** 4 patients x \$90,000 = **\$0.36M**
- **Total at 20%: \$14.76M**

At 30% Market Share:

- **US:** 180 patients x \$112,500 = **\$20.25M**
- **EU5:** 240 patients x \$81,000 = **\$19.44M**
- **China:** 90 patients x \$58,500 = **\$5.27M**
- **Japan:** 15 patients x \$90,000 = **\$1.35M**
- **Total at 30%: \$46.31M**

Potential Peak Sales Range: \$14.8M to \$46.3M annually across the US, EU5, China, and Japan for this indication.

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

To calculate the value of a 1% share of treated patients, we divide the total eligible patient population by 100 and multiply by the annual cost per patient in each region.

Eligible Patients (Midpoint of Range):

- **US:** 450 patients → 1% = 4.5 patients
- **EU5:** 600 patients → 1% = 6 patients
- **China:** 200 patients → 1% = 2 patients
- **Japan:** 35 patients → 1% = 0.35 patients

Value of 1% Share:

- **US:** 4.5 patients x \$112,500 = **\$506,250**
- **EU5:** 6 patients x \$81,000 = **\$486,000**

- **China:** 2 patients x \$58,500 = **\$117,000**
- **Japan:** 0.35 patients x \$90,000 = **\$31,500**
- **Total Value of 1% Share:** **\$1,140,750**

\$ Value of 1% Share of Treated Patients: Approximately **\$1.14M annually** across these geographies.

Summary of Results

1. Potential Peak Sales for Pomalidomide in Kaposi Sarcoma (20-30% Market Share):

- Range: **\$14.8M to \$46.3M annually** across the US, EU5, China, and Japan.

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

- Approximately **\$1.14M annually** across the same geographies.

Caveats and Notes

- These estimates are based on rough epidemiological data and assumptions about pricing and treatment duration. Real-world data on KS incidence, patient eligibility, and regional pricing may vary.
- Kaposi sarcoma is a rare indication, and sales in this segment are likely a small fraction of pomalidomide's total revenue (which is dominated by multiple myeloma).
- Market access, reimbursement policies, and competition (e.g., generic chemotherapies or other therapies) could impact market share and pricing.
- Peak sales may take several years to achieve due to gradual uptake in a rare disease setting.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market research), these estimates can be refined further.