

To estimate the **Potential Peak Sales** for bosutinib (Bosulif, Pfizer) in the specified indication (pediatric patients with chronic phase Ph+ chronic myelogenous leukemia [CML], newly diagnosed or resistant/intolerant to prior therapy) 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 calculations based on available data and reasonable estimates. Since exact figures (e.g., patient population, pricing, market penetration) are not provided, I will outline the methodology and use illustrative numbers. You can adjust these assumptions based on more specific data if available.

Step 1: Define the Indication and Patient Population

- **Indication:** Pediatric patients (1 year and older) with chronic phase (CP) Ph+ CML, either newly diagnosed (ND) or resistant/intolerant (R/I) to prior therapy.
- **Geographies:** US, EU5 (France, Germany, Italy, Spain, UK), China, Japan.
- **CML in Pediatrics:** CML is rare in children, accounting for ~2-3% of all pediatric leukemias. The annual incidence of CML in children is estimated at 0.6-1.2 per million children. Ph+ CML is the most common subtype.

Estimated Pediatric CML Patient Population (Annual Incidence)

Using population data and incidence rates:

- **US:** Population ~330M, pediatric population (~20%) ~66M. Incidence of 0.6-1.2 per million → ~40-80 new cases/year.
- **EU5:** Combined population ~330M, pediatric population (~20%) ~66M → ~40-80 new cases/year.
- **China:** Population ~1.4B, pediatric population (~17%) ~240M → ~140-280 new cases/year.
- **Japan:** Population ~125M, pediatric population (~15%) ~19M → ~10-20 new cases/year.

Total new cases per year across geographies: ~230-460.

Prevalent Population (Treated Patients)

CML is a chronic disease, and with treatment, patients can survive many years. Assuming a prevalence-to-incidence ratio of ~10-15 (based on survival data for CML), the prevalent population of pediatric CP Ph+ CML patients eligible for treatment is:

- **US:** ~400-1,200 patients.
- **EU5:** ~400-1,200 patients.
- **China:** ~1,400-4,200 patients.
- **Japan:** ~100-300 patients.

Total prevalent treated population: ~2,300-6,900 patients across geographies.

Step 2: Market Share Assumption

The problem states a **20%-30% share of treated patients** for bosutinib. This accounts for competition from other tyrosine kinase inhibitors (TKIs) like imatinib, dasatinib, and nilotinib, which are also

approved for CML, including in pediatric patients in some regions.

- **Low-end share (20%):** 460-1,380 patients treated with bosutinib.
- **High-end share (30%):** 690-2,070 patients treated with bosutinib.

Step 3: Pricing per Patient

Bosutinib pricing varies by region due to differences in healthcare systems and negotiations. Based on available data for Bosulif (adult dosing, as pediatric dosing may differ but is not widely reported):

- **US:** Annual cost of bosutinib is ~\$150,000-\$200,000 per patient (based on wholesale acquisition cost).
- **EU5:** Annual cost is lower due to pricing negotiations, ~\$50,000-\$80,000 per patient.
- **China:** Pricing is significantly lower due to generics and local policies, ~\$10,000-\$20,000 per patient.
- **Japan:** Pricing is moderate, ~\$60,000-\$90,000 per patient.

For simplicity, assume average annual pricing per patient:

- **US:** \$175,000
- **EU5:** \$65,000
- **China:** \$15,000
- **Japan:** \$75,000

Step 4: Potential Peak Sales Calculation

Peak sales are calculated as: (Number of treated patients) x (Annual cost per patient) for each region.

Low-End Estimate (20% Share)

- **US:** (80-240 patients) x \$175,000 = **\$14M - \$42M**
- **EU5:** (80-240 patients) x \$65,000 = **\$5.2M - \$15.6M**
- **China:** (280-840 patients) x \$15,000 = **\$4.2M - \$12.6M**
- **Japan:** (20-60 patients) x \$75,000 = **\$1.5M - \$4.5M**
- **Total Low-End Peak Sales: \$25M - \$75M**

High-End Estimate (30% Share)

- **US:** (120-360 patients) x \$175,000 = **\$21M - \$63M**
- **EU5:** (120-360 patients) x \$65,000 = **\$7.8M - \$23.4M**
- **China:** (420-1,260 patients) x \$15,000 = **\$6.3M - \$18.9M**
- **Japan:** (30-90 patients) x \$75,000 = **\$2.25M - \$6.75M**
- **Total High-End Peak Sales: \$37.35M - \$112.05M**

Potential Peak Sales Range: Approximately **\$25M - \$112M annually** across the US, EU5, China, and Japan, assuming 20%-30% market share.

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

A 1% share of the treated patient population corresponds to 1% of the total prevalent population (2,300-6,900 patients), i.e., 23-69 patients.

- **US:** (4-12 patients) x \$175,000 = **\$0.7M - \$2.1M**
- **EU5:** (4-12 patients) x \$65,000 = **\$0.26M - \$0.78M**
- **China:** (14-42 patients) x \$15,000 = **\$0.21M - \$0.63M**
- **Japan:** (1-3 patients) x \$75,000 = **\$0.075M - \$0.225M**
- **Total \$ Value of 1% Share:** **\$1.265M - \$3.735M**

\$ Value of 1% Share of Treated Patients: Approximately **\$1.3M - \$3.7M annually** across the specified geographies.

Summary

1. **Potential Peak Sales for Bosutinib** (20%-30% market share): **\$25M - \$112M annually** across the US, EU5, China, and Japan.
2. **\$ Value of 1% Share of Treated Patients:** **\$1.3M - \$3.7M annually** across the same geographies.

Caveats and Notes

- The patient population estimates are rough due to the rarity of pediatric CML and variability in prevalence data.
- Pricing assumptions are based on adult CML treatment costs and may differ for pediatric dosing or regional negotiations.
- Market share assumptions (20%-30%) account for competition from other TKIs, but actual penetration may vary based on clinical guidelines, physician preference, and payer policies.
- Peak sales may take several years to achieve due to gradual market uptake, especially in a rare disease setting.

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