

To calculate the **Potential Peak Sales** for ibrutinib (IMBRUVICA) in the indication of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) 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 follow a structured approach. Since exact data on patient populations, treatment rates, and pricing may vary and are not provided, I will outline the methodology and use reasonable assumptions based on publicly available information and market trends for oncology drugs. You can refine these numbers with specific data if available.

Step 1: Define Key Assumptions and Parameters

1. **Indication:** Initial treatment of adult patients with CLL/SLL in combination with rituximab.
2. **Geographies:** US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan.
3. **Market Share:** Assuming 20% to 30% of treated patients in this indication will use ibrutinib.
4. **Peak Sales:** Represents the maximum annual revenue potential for the drug in this indication, typically achieved a few years after launch or label expansion, before patent expiry or competition impacts sales.
5. **Pricing:** Ibrutinib's cost varies by region due to healthcare systems, reimbursement policies, and pricing negotiations. For simplicity, I will use approximate annual treatment costs based on historical data:
 - US: ~\$150,000 per patient per year (based on list price, though discounts/rebates may apply).
 - EU5: ~\$80,000–\$100,000 per patient per year (varies by country due to pricing controls).
 - Japan: ~\$100,000 per patient per year.
 - China: ~\$50,000 per patient per year (lower due to pricing pressures and generics/biosimilars).
6. **Patient Population:** Estimate the number of eligible patients based on incidence, prevalence, and treatment rates for CLL/SLL. CLL is more common in Western countries, with lower incidence in Asia.
7. **Treatment Duration:** Assume an average treatment duration of 1 year for peak sales calculation (though CLL treatment can be chronic, often spanning multiple years).

Estimated Treated Patient Population for CLL/SLL

- **US:** Incidence of CLL is ~20,000 new cases per year (American Cancer Society). Assuming 50% are eligible for initial treatment with ibrutinib + rituximab (due to age, comorbidities, or other factors), and including prevalent patients, let's estimate ~30,000 treated patients annually at peak.
- **EU5:** Incidence is similar to the US per capita. With a combined population of ~320 million (vs. US ~330 million), estimate ~25,000–30,000 treated patients annually at peak.
- **Japan:** Lower incidence of CLL (more common in Western populations). Population ~125 million; estimate ~5,000 treated patients annually at peak.
- **China:** Much lower incidence of CLL, but a large population (~1.4 billion). Estimate ~10,000 treated patients annually at peak due to underdiagnosis and access issues.

Total treated patients across geographies at peak: ~70,000–75,000.

Step 2: Calculate Potential Peak Sales

Using the market share assumption of 20% to 30%, calculate the number of patients treated with ibrutinib and multiply by the annual cost per patient.

Number of Patients on Ibrutinib (20%–30% Share)

- **US:** 30,000 patients × 20%–30% = 6,000–9,000 patients.
- **EU5:** 30,000 patients × 20%–30% = 6,000–9,000 patients.
- **Japan:** 5,000 patients × 20%–30% = 1,000–1,500 patients.
- **China:** 10,000 patients × 20%–30% = 2,000–3,000 patients.
- **Total:** 15,000–22,500 patients globally in these geographies.

Peak Sales Calculation

- **US:** 6,000–9,000 patients × \$150,000 = **\$900M–\$1,350M**.
- **EU5:** 6,000–9,000 patients × \$90,000 (average) = **\$540M–\$810M**.
- **Japan:** 1,000–1,500 patients × \$100,000 = **\$100M–\$150M**.
- **China:** 2,000–3,000 patients × \$50,000 = **\$100M–\$150M**.
- **Total Peak Sales:** **\$1,540M–\$2,460M (or \$1.54B–\$2.46B)**.

Thus, the **Potential Peak Sales** for ibrutinib in this indication across the specified geographies is approximately **\$1.5 billion to \$2.5 billion** annually, assuming a 20%–30% market share.

Step 3: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treated patient population (~70,000–75,000), which is **700–750 patients**.

Revenue per 1% Share

- **US:** 1% of 30,000 = 300 patients × \$150,000 = **\$45M**.
- **EU5:** 1% of 30,000 = 300 patients × \$90,000 = **\$27M**.
- **Japan:** 1% of 5,000 = 50 patients × \$100,000 = **\$5M**.
- **China:** 1% of 10,000 = 100 patients × \$50,000 = **\$5M**.
- **Total \$ Value of 1% Share:** **\$82M** (based on ~700 patients).

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$82 million** annually.

Step 4: Key Considerations and Caveats

1. **Competition:** Ibrutinib faces competition from other BTK inhibitors (e.g., acalabrutinib, zanubrutinib) and novel therapies, which may reduce market share below 20%–30% over time.
2. **Pricing Variability:** Prices are estimates and may be lower due to discounts, rebates, or generic entry (ibrutinib's patent protection in some regions may expire in the coming years, e.g., US patent expiration expected around 2026–2032 depending on extensions).
3. **Access and Reimbursement:** In markets like China, access to high-cost drugs may be limited, reducing the treated patient pool or effective pricing.
4. **Patient Pool:** The number of treated patients may differ based on diagnosis rates, treatment guidelines, and physician adoption of ibrutinib + rituximab combination therapy.

Final Answer

- **Potential Peak Sales for ibrutinib** in the CLL/SLL initial treatment indication (assuming 20%–30% market share) across the US, EU5, China, and Japan: **\$1.5 billion to \$2.5 billion** annually.
- **\$ Value of 1% Share of Treated Patients** across these geographies: **\$82 million** annually.

If you have specific data on patient numbers, pricing, or market share, I can refine these estimates further.