

To estimate the **Potential Peak Sales** for pirtobrutinib (Jaypirca) in the indication of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) in the specified geographies (US, EU5, China, and Japan), as well as the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since specific data such as exact patient numbers, pricing, or market penetration rates are not provided, I will outline a methodology based on reasonable assumptions and publicly available data about CLL/SLL epidemiology, treatment patterns, and drug pricing in oncology. The final numbers are illustrative and would need refinement with precise data.

Step 1: Define the Target Population

Pirtobrutinib is approved for adults with CLL/SLL who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. This is a **third-line or later (3L+)** patient population, which is a smaller subset of the total CLL/SLL population.

Epidemiology of CLL/SLL

- **US:** Incidence of CLL is ~20,000 new cases per year (American Cancer Society). Prevalence (total living patients) is ~120,000–150,000. About 20–30% of patients progress to 3L+ therapy over time (based on treatment patterns and relapse rates).

- **EU5 (France, Germany, Italy, Spain, UK):** Incidence is ~30,000–35,000 new cases per year. Prevalence is ~200,000–250,000. Similar 3L+ progression rates (20–30%).

- **China:** Incidence is lower due to ethnic differences (~5,000–10,000 new cases per year). Prevalence is ~50,000–70,000. 3L+ progression is assumed at 15–20% due to limited access to advanced therapies.

- **Japan:** Incidence is ~2,000–3,000 new cases per year. Prevalence is ~20,000–30,000. 3L+ progression is ~20–25%.

Estimated 3L+ Treatable Population (Assumption: 20–30% of prevalent cases)

- US: ~30,000 patients (25% of 120,000)

- EU5: ~50,000 patients (25% of 200,000)

- China: ~10,000 patients (20% of 50,000)

- Japan: ~5,000 patients (25% of 20,000)

Total 3L+ population across geographies: **~95,000 patients**.

Step 2: Market Penetration (20%–30% Share of Treated Patients)

Given the assumption of a 20%–30% share of treated patients, we calculate the number of patients treated with pirtobrutinib:

- At 20% share: $95,000 \times 0.2 = \mathbf{19,000 \text{ patients}}$

- At 30% share: $95,000 \times 0.3 = \mathbf{28,500 \text{ patients}}$

Breakdown by region (proportional to population):

- US: $30,000 / 95,000 = 31.6\%$ of total
- 20% share: $19,000 \times 0.316 = \sim 6,000$ patients
- 30% share: $28,500 \times 0.316 = \sim 9,000$ patients
- EU5: $50,000 / 95,000 = 52.6\%$ of total
- 20% share: $19,000 \times 0.526 = \sim 10,000$ patients
- 30% share: $28,500 \times 0.526 = \sim 15,000$ patients
- China: $10,000 / 95,000 = 10.5\%$ of total
- 20% share: $19,000 \times 0.105 = \sim 2,000$ patients
- 30% share: $28,500 \times 0.105 = \sim 3,000$ patients
- Japan: $5,000 / 95,000 = 5.3\%$ of total
- 20% share: $19,000 \times 0.053 = \sim 1,000$ patients
- 30% share: $28,500 \times 0.053 = \sim 1,500$ patients

Step 3: Pricing Assumptions

Pricing for oncology drugs like BTK inhibitors varies significantly by region due to healthcare systems, reimbursement policies, and purchasing power. Pirtobrutinib's US price is not publicly confirmed in this context, but similar drugs (e.g., ibrutinib) cost ~\$150,000–\$180,000 per patient per year in the US. We assume a discounted price in other regions.

Annual cost per patient (assumption):

- US: \$150,000
- EU5: \$100,000 (lower due to negotiations and public health systems)
- China: \$50,000 (reflecting lower pricing and access challenges)
- Japan: \$120,000 (similar to US but with some discounts)

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as (number of treated patients) \times (annual cost per patient).

At 20% Market Share:

- **US:** 6,000 patients \times \$150,000 = **\$900 million**
- **EU5:** 10,000 patients \times \$100,000 = **\$1,000 million (\$1 billion)**

- **China:** 2,000 patients × \$50,000 = **\$100 million**
- **Japan:** 1,000 patients × \$120,000 = **\$120 million**
- **Total Peak Sales (20% share):** \$900M + \$1,000M + \$100M + \$120M = **\$2,120 million (\$2.12 billion)**

At 30% Market Share:

- **US:** 9,000 patients × \$150,000 = **\$1,350 million (\$1.35 billion)**
- **EU5:** 15,000 patients × \$100,000 = **\$1,500 million (\$1.5 billion)**
- **China:** 3,000 patients × \$50,000 = **\$150 million**
- **Japan:** 1,500 patients × \$120,000 = **\$180 million**
- **Total Peak Sales (30% share):** \$1,350M + \$1,500M + \$150M + \$180M = **\$3,180 million (\$3.18 billion)**

Potential Peak Sales Range: \$2.12 billion to \$3.18 billion annually, depending on market share (20%–30%).

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

A 1% share of treated patients corresponds to 1% of the total 3L+ population (95,000 patients) = **950 patients**.

Breakdown by region:

- US: $950 \times 0.316 = \sim 300$ patients
- EU5: $950 \times 0.526 = \sim 500$ patients
- China: $950 \times 0.105 = \sim 100$ patients
- Japan: $950 \times 0.053 = \sim 50$ patients

Revenue from 1% share:

- **US:** 300 patients × \$150,000 = **\$45 million**
- **EU5:** 500 patients × \$100,000 = **\$50 million**
- **China:** 100 patients × \$50,000 = **\$5 million**
- **Japan:** 50 patients × \$120,000 = **\$6 million**
- **Total Value of 1% Share:** \$45M + \$50M + \$5M + \$6M = **\$106 million**

Final Answer

- **Potential Peak Sales for Pirtobrutinib** (20%–30% market share in US, EU5, China, Japan for CLL/SLL 3L+ indication): **\$2.12 billion to \$3.18 billion annually**.
- **\$ Value of 1% Share of Treated Patients: \$106 million annually**.

Caveats

1. These estimates are based on assumptions about patient populations, market share, and pricing. Real-world data (e.g., actual pricing, reimbursement rates, or competition from other therapies) could significantly alter these figures.
2. Peak sales may take several years to achieve and depend on factors like physician adoption, payer coverage, and competition (e.g., other BTK inhibitors or novel therapies).
3. China's lower pricing and access barriers may limit market potential compared to the US and EU5.

If you have access to specific data (e.g., exact pricing or patient numbers), I can refine these calculations further.