

To estimate the **Potential Peak Sales** for blinatumomab (Blincyto) in the specified indication (CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia [Ph-negative BCP ALL] in the consolidation phase) in the US, EU5 (France, Germany, Italy, Spain, UK), 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, and penetration rates are not provided, I will outline the methodology and use reasonable assumptions based on publicly available information and industry standards. The final numbers are illustrative and should be validated with real-world data.

****Step 1: Define the Target Patient Population****

- **Indication:** CD19-positive Ph-negative BCP ALL in the consolidation phase of multiphase chemotherapy for adult and pediatric patients (1 month and older).

- **Geography:** US, EU5, China, Japan.

- **Epidemiology:** ALL is a rare hematologic malignancy. Ph-negative BCP ALL accounts for a subset of ALL cases. We focus on patients in the consolidation phase, which is a specific stage of treatment after induction therapy.

Estimated incidence of ALL (new cases per year) and prevalence (total patients eligible for treatment) are as follows (based on general oncology data and literature):

- **US:** ~6,500 new ALL cases/year; ~70-75% are BCP ALL, and ~80-85% of these are Ph-negative. Assuming ~50% of patients reach the consolidation phase, the eligible population is ~2,000-2,500 patients/year.

- **EU5:** ~5,000 new ALL cases/year; similar proportions, leading to ~1,500-2,000 eligible patients/year.

- **China:** ~10,000 new ALL cases/year (higher population base); ~3,000-4,000 eligible patients/year.

- **Japan:** ~1,000 new ALL cases/year; ~300-400 eligible patients/year.

Total estimated eligible patients in consolidation phase across geographies: ~6,800-9,400 patients/year.

****Step 2: Estimate Treated Patient Share****

- The problem assumes a **20-30% share of treated patients** for blinatumomab. This reflects market penetration, accounting for competition (e.g., other therapies like chemotherapy, CAR-T therapies), physician adoption, and payer reimbursement.

- Midpoint estimate: 25% penetration.

- Treated patients: ~1,700-2,350 patients/year across all geographies (25% of 6,800-9,400).

Breakdown by geography (approximate, based on population distribution):

- **US:** ~500-625 patients.

- EU5: ~375-500 patients.
- China: ~750-1,000 patients.
- Japan: ~75-100 patients.

****Step 3: Estimate Pricing and Treatment Cost per Patient****

- Blinatumomab is a high-cost biologic therapy (BiTE antibody). Pricing varies by geography due to healthcare systems and purchasing power.
- **US:** Annual cost per patient is ~\$100,000-150,000 (based on reported costs for Blincyto in ALL indications, often administered in cycles).
- **EU5:** ~\$80,000-120,000 (lower due to negotiated pricing and discounts).
- **China:** ~\$40,000-60,000 (significantly lower due to pricing controls and generics/biosimilars competition).
- **Japan:** ~\$80,000-120,000 (similar to EU5, with high reimbursement rates).
- Midpoint pricing used for calculations: US (\$125,000), EU5 (\$100,000), China (\$50,000), Japan (\$100,000).

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

Peak sales are calculated as: (Number of treated patients) × (Annual cost per patient) for each geography, summed across all regions.

- **US:** 562 patients (midpoint) × \$125,000 = ~\$70.3 million.
- **EU5:** 437 patients × \$100,000 = ~\$43.7 million.
- **China:** 875 patients × \$50,000 = ~\$43.8 million.
- **Japan:** 87 patients × \$100,000 = ~\$8.7 million.
- **Total Peak Sales:** \$70.3M + \$43.7M + \$43.8M + \$8.7M = ~\$166.5 million/year.

Range (based on 20-30% penetration and patient range): ~\$133-200 million/year.

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

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

- Total eligible patients: ~6,800-9,400 (midpoint: 8,100).
- 1% share: ~81 patients/year.

Value of 1% share by geography (using midpoint patient distribution and pricing):

- **US:** ~25 patients × \$125,000 = ~\$3.1 million.
- **EU5:** ~19 patients × \$100,000 = ~\$1.9 million.
- **China:** ~35 patients × \$50,000 = ~\$1.8 million.
- **Japan:** ~2 patients × \$100,000 = ~\$0.2 million.
- **Total Value of 1% Share:** \$3.1M + \$1.9M + \$1.8M + \$0.2M = ~\$7.0 million.

Range (based on patient and pricing variability): ~\$6-8 million.

****Final Answer****

1. **Potential Peak Sales for blinatumomab** in the specified indication (Ph-negative BCP ALL, consolidation phase) with 20-30% treated patient share:

- ~ **\$133-200 million/year** (midpoint: ~\$166.5 million/year) across the US, EU5, China, and Japan.

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

- ~ **\$6-8 million** (midpoint: ~\$7.0 million) across the US, EU5, China, and Japan.

Note: These estimates are based on assumptions regarding epidemiology, pricing, and market penetration. Real-world data (e.g., from Amgen's financial reports, payer data, or oncology registries like SEER or GLOBOCAN) should be used to refine these figures. Factors such as competition, reimbursement policies, and off-label use could also impact the results.