

To estimate the **Potential Peak Sales** for glofitamab-gxbm (Columvi) in the indication of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) or large B-cell lymphoma (LBCL) arising from follicular lymphoma after two or more lines of systemic therapy, and to calculate the **\$ value of a 1% share of treated patients** in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, we need to follow a structured approach based on available data and reasonable assumptions. Since specific data (e.g., exact patient numbers, pricing, or market penetration) may not be publicly available, I will outline the methodology and use realistic estimates based on industry trends, epidemiology, and market dynamics for such therapies.

## **Step 1: Define Key Parameters**

1. **Target Patient Population:** Identify the number of eligible patients for glofitamab-gxbm in the specified indication (relapsed/refractory DLBCL or LBCL after  $\geq 2$  lines of therapy).
2. **Treatment Rate:** Estimate the percentage of eligible patients who receive treatment.
3. **Market Share:** Use the given assumption of 20% to 30% market share of treated patients for glofitamab-gxbm.
4. **Pricing:** Estimate the annual cost of therapy per patient for glofitamab-gxbm, a bispecific antibody therapy.
5. **Peak Sales:** Calculate peak sales based on the above parameters.
6. **1% Share Value:** Calculate the revenue associated with 1% of treated patients.

## **Step 2: Epidemiology of DLBCL/LBCL (Relapsed/Refractory)**

DLBCL is the most common type of non-Hodgkin lymphoma (NHL), and a subset of patients relapse or become refractory after initial therapies. The target population here is patients who have failed  $\geq 2$  lines of therapy.

- **US:** Approximately 80,000 new cases of NHL annually, with DLBCL accounting for ~30-40% (24,000-32,000 cases). Of these, ~30-40% relapse or are refractory after first-line therapy, and a smaller subset (~10-15% of total DLBCL cases) fail  $\geq 2$  lines of therapy. Estimated eligible patients: ~3,000-5,000.

- **EU5:** Incidence rates are similar to the US, with a combined population of ~450 million (vs. 330 million in the US). Scaling by population, eligible patients: ~4,000-7,000.

- **China:** With a population of ~1.4 billion, NHL incidence is lower per capita than in the US/EU, but total cases are significant. Estimated DLBCL cases: ~50,000-60,000 annually, with ~5,000-8,000 eligible for  $\geq 3$ rd-line therapy.

- **Japan:** Population ~125 million, with a high standard of healthcare. Estimated DLBCL cases: ~10,000-12,000 annually, with ~1,000-1,500 eligible for  $\geq 3$ rd-line therapy.

### **Total Eligible Patients (Approximate):**

- US: 4,000
- EU5: 5,500
- China: 6,500
- Japan: 1,250

- **Total across geographies:** ~17,250 patients

### **Step 3: Treatment Rate**

Not all eligible patients receive treatment due to factors like comorbidities, access to healthcare, or palliative care preferences. A reasonable treatment rate for advanced therapies like glofitamab-gxbm in relapsed/refractory settings is ~60-80%.

- **Assumed Treatment Rate:** 70%
- **Treated Patients:**
  - US:  $4,000 \times 0.7 = 2,800$
  - EU5:  $5,500 \times 0.7 = 3,850$
  - China:  $6,500 \times 0.7 = 4,550$
  - Japan:  $1,250 \times 0.7 = 875$
- **Total Treated Patients:** ~12,075

### **Step 4: Market Share for Glofitamab-gxbm**

Assuming a market share of 20% to 30% among treated patients:

- **20% Share:**  $12,075 \times 0.2 = \sim 2,415$  patients
- **30% Share:**  $12,075 \times 0.3 = \sim 3,623$  patients

### **Step 5: Pricing of Glofitamab-gxbm**

Glofitamab-gxbm is a bispecific antibody therapy, and similar therapies (e.g., CAR-T therapies or other targeted immunotherapies for DLBCL) have high annual costs. For instance:

- CAR-T therapies like axicabtagene ciloleucel (Yescarta) cost ~\$373,000 per treatment in the US.
- Bispecific antibodies may have recurring dosing, so annual costs could range from \$100,000 to \$200,000 per patient in the US.

**Assumed Annual Cost per Patient** (accounting for differences in pricing across geographies):

- US: \$150,000
- EU5: \$120,000 (lower due to pricing negotiations and healthcare systems)
- China: \$80,000 (lower due to market access and pricing constraints)
- Japan: \$130,000 (similar to EU, slightly higher due to advanced healthcare system)

### **Step 6: Calculate Potential Peak Sales**

Peak sales are calculated as: (Number of treated patients with glofitamab-gxbm)  $\times$  (Annual cost per patient).

#### At 20% Market Share:

- **US:**  $2,800 \times 0.2 \times \$150,000 = \$84$  million
- **EU5:**  $3,850 \times 0.2 \times \$120,000 = \$92.4$  million
- **China:**  $4,550 \times 0.2 \times \$80,000 = \$72.8$  million
- **Japan:**  $875 \times 0.2 \times \$130,000 = \$22.75$  million
- **Total Peak Sales (20% Share):**  $\$84M + \$92.4M + \$72.8M + \$22.75M = \$271.95$  million

#### At 30% Market Share:

- **US:**  $2,800 \times 0.3 \times \$150,000 = \$126$  million
- **EU5:**  $3,850 \times 0.3 \times \$120,000 = \$138.6$  million
- **China:**  $4,550 \times 0.3 \times \$80,000 = \$109.2$  million
- **Japan:**  $875 \times 0.3 \times \$130,000 = \$34.125$  million
- **Total Peak Sales (30% Share):**  $\$126M + \$138.6M + \$109.2M + \$34.125M = \$407.925$  million

**Potential Peak Sales Range: \$272 million to \$408 million** annually across the US, EU5, China, and Japan.

## **Step 7: Calculate \$ Value of 1% Share of Treated Patients**

A 1% share of treated patients corresponds to 1% of the total treated patient population (12,075 patients) = ~121 patients.

- **US:**  $2,800 \times 0.01 \times \$150,000 = \$4.2$  million
- **EU5:**  $3,850 \times 0.01 \times \$120,000 = \$4.62$  million
- **China:**  $4,550 \times 0.01 \times \$80,000 = \$3.64$  million
- **Japan:**  $875 \times 0.01 \times \$130,000 = \$1.1375$  million
- **Total \$ Value of 1% Share:**  $\$4.2M + \$4.62M + \$3.64M + \$1.1375M = \$13.5975$  million

## **Final Answer:**

1. **Potential Peak Sales for Glofitamab-gxbm** (20%-30% market share) in the US, EU5, China, and Japan for relapsed/refractory DLBCL/LBCL after  $\geq 2$  lines of therapy:

- **Range: \$272 million to \$408 million annually**

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

- **Total: \$13.6 million annually**

## **Notes:**

- These estimates are based on assumptions about patient numbers, treatment rates, market share, and pricing. Real-world data may vary due to competition (e.g., CAR-T therapies, other bispecific antibodies), market access challenges, reimbursement policies, and regional differences.
- Pricing in China may be significantly lower due to government negotiations and local production, which could impact total sales.
- Peak sales may take several years to achieve post-launch, depending on adoption rates and regulatory approvals in each region.