

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, as well as 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. This involves estimating the addressable patient population, treatment rates, drug pricing, and market share assumptions. Since specific data on patient numbers, pricing, or uptake may not be fully available, I will use reasonable assumptions based on publicly available information, epidemiology data, and industry benchmarks for oncology drugs.

Step 1: Define the Indication and Target Population

Glofitamab-gxbm is approved for relapsed or refractory DLBCL (including LBCL arising from follicular lymphoma) after ≥ 2 lines of systemic therapy. This is a third-line or later (3L+) treatment setting for DLBCL, which is an aggressive form of non-Hodgkin lymphoma (NHL).

Epidemiology of DLBCL:

- **US:** DLBCL accounts for ~30-40% of NHL cases. The incidence of NHL in the US is ~74,000 cases/year (American Cancer Society, 2023). Thus, DLBCL incidence is ~22,000-30,000 cases/year. Approximately 30-40% of patients relapse or are refractory after first-line therapy, and a smaller subset reaches 3L+ treatment. Assuming ~20-25% of incident cases reach 3L+, the eligible population is ~4,500-7,500 patients/year.

- **EU5:** NHL incidence in Europe is ~93,000 cases/year (Globocan 2020). DLBCL is ~30-40% of cases, or ~28,000-37,000 cases/year in EU5 (scaled by population). Assuming a similar relapse/refractory rate, 3L+ patients are ~5,500-9,000 patients/year.

- **China:** NHL incidence is ~88,000 cases/year (Globocan 2020). DLBCL is ~26,000-35,000 cases/year. With lower access to advanced therapies historically, assume 10-15% reach 3L+, or ~2,600-5,000 patients/year.

- **Japan:** NHL incidence is ~30,000 cases/year. DLBCL is ~9,000-12,000 cases/year. Assuming 20-25% reach 3L+, the eligible population is ~1,800-3,000 patients/year.

Total Addressable 3L+ DLBCL Population (Annual Incident Cases):

- US: ~6,000 patients (midpoint)
- EU5: ~7,250 patients (midpoint)
- China: ~3,800 patients (midpoint)
- Japan: ~2,400 patients (midpoint)
- **Total:** ~19,450 patients/year

Treated Patient Share:

Not all eligible patients will receive treatment due to access, cost, or clinical ineligibility. Assuming a **treated patient share of 20-30%** as per the query, we calculate:

- **Total treated patients (20% share):** $19,450 * 0.2 = \sim 3,890$ patients/year
- **Total treated patients (30% share):** $19,450 * 0.3 = \sim 5,835$ patients/year

Breakdown by geography (midpoint estimates):

- **US:** $6,000 * 0.25$ (avg. of 20-30%) = ~1,500 treated patients/year
- **EU5:** $7,250 * 0.25$ = ~1,813 treated patients/year
- **China:** $3,800 * 0.25$ = ~950 treated patients/year
- **Japan:** $2,400 * 0.25$ = ~600 treated patients/year

Step 2: Pricing Assumptions

Glofitamab-gxbm is a bispecific antibody therapy, and pricing for such innovative oncology drugs in the 3L+ setting is high, especially in the US. Comparable therapies like CAR-T (e.g., Yescarta, Kymriah) are priced at ~\$373,000-\$475,000 per treatment in the US. However, glofitamab, as an off-the-shelf therapy, may be priced slightly lower.

Assumed Annual Cost per Patient (or per Treatment Course):

- **US:** \$300,000 (conservative estimate vs. CAR-T)
- **EU5:** \$200,000 (lower due to healthcare system negotiations)
- **Japan:** \$200,000 (similar to EU5)
- **China:** \$100,000 (significantly lower due to pricing controls and access challenges)

Step 3: Potential Peak Sales Calculation

Peak sales are calculated as: **Treated Patients * Annual Cost per Patient.**

At 20% Treated Patient Share:

- **US:** 1,200 patients ($6,000 * 0.2$) * \$300,000 = **\$360 million**
- **EU5:** 1,450 patients ($7,250 * 0.2$) * \$200,000 = **\$290 million**
- **China:** 760 patients ($3,800 * 0.2$) * \$100,000 = **\$76 million**
- **Japan:** 480 patients ($2,400 * 0.2$) * \$200,000 = **\$96 million**
- **Total Peak Sales (20% share):** \$360M + \$290M + \$76M + \$96M = **\$822 million**

At 30% Treated Patient Share:

- **US:** 1,800 patients ($6,000 * 0.3$) * \$300,000 = **\$540 million**
- **EU5:** 2,175 patients ($7,250 * 0.3$) * \$200,000 = **\$435 million**
- **China:** 1,140 patients ($3,800 * 0.3$) * \$100,000 = **\$114 million**
- **Japan:** 720 patients ($2,400 * 0.3$) * \$200,000 = **\$144 million**
- **Total Peak Sales (30% share):** \$540M + \$435M + \$114M + \$144M = **\$1,233 million**

Potential Peak Sales Range: \$822 million to \$1,233 million annually across the US, EU5, China, and Japan, assuming a 20-30% share of treated patients.

Step 4: \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total addressable treated population at the midpoint treatment rate (25% of eligible patients, or ~4,863 treated patients/year).

- **Total treated patients (25% share):** $19,450 * 0.25 = \sim 4,863$ patients
- **1% of treated patients:** $4,863 * 0.01 = \sim 49$ patients

Breakdown by geography:

- **US:** $1,500 * 0.01 = 15$ patients
- **EU5:** $1,813 * 0.01 = 18$ patients
- **China:** $950 * 0.01 = 9.5$ (~10 patients)
- **Japan:** $600 * 0.01 = 6$ patients

Value of 1% Share (49 patients total):

- **US:** 15 patients * \$300,000 = **\$4.5 million**
- **EU5:** 18 patients * \$200,000 = **\$3.6 million**
- **China:** 10 patients * \$100,000 = **\$1.0 million**
- **Japan:** 6 patients * \$200,000 = **\$1.2 million**
- **Total Value of 1% Share:** $\$4.5M + \$3.6M + \$1.0M + \$1.2M = \mathbf{\$10.3 \text{ million}}$

Final Answer:

1. Potential Peak Sales for Glofitamab-gxbm (20-30% share of treated patients):

- **Range: \$822 million to \$1,233 million annually** across the US, EU5, China, and Japan.
- Breakdown:
 - US: \$360M to \$540M
 - EU5: \$290M to \$435M
 - China: \$76M to \$114M
 - Japan: \$96M to \$144M

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

- **Total: \$10.3 million annually**
- Breakdown:
 - US: \$4.5M
 - EU5: \$3.6M
 - China: \$1.0M

- Japan: \$1.2M

Notes and Caveats:

- These estimates are based on assumptions for patient population, treatment rates, and pricing, which may vary based on real-world data, market access, competition (e.g., CAR-T therapies, other bispecifics), and payer dynamics.
- Peak sales assume steady-state market penetration, which may take several years post-launch to achieve.
- Pricing in China and other markets may be subject to significant discounts or government negotiations, potentially lowering estimates.
- If more precise data on epidemiology, pricing, or market share becomes available, these figures can be refined.