

To estimate the **Potential Peak Sales** for tafasitamab-cxix (Monjuvi) in the indication of relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. Since exact data on patient numbers, pricing, and market penetration may not be publicly available, I will outline the methodology and use reasonable assumptions based on publicly available data, epidemiology, and market trends for DLBCL and oncology drugs. The final numbers will be approximate and should be validated with primary data or market research reports (e.g., from GlobalData, Evaluate Pharma, or company filings).

Step 1: Indication and Patient Population

Tafasitamab-cxix is approved for adult patients with **relapsed or refractory DLBCL** who are not eligible for autologous stem cell transplant (ASCT). DLBCL is the most common type of non-Hodgkin lymphoma (NHL), accounting for about 25-30% of NHL cases. R/R DLBCL represents a subset of DLBCL patients who have failed first-line therapy (typically R-CHOP) or subsequent treatments.

Epidemiology of DLBCL (Estimated Annual Incidence):

- **US:** ~25,000 new DLBCL cases per year (based on NHL incidence of ~80,000 and DLBCL as ~30% of NHL).
- **EU5:** ~30,000 new DLBCL cases per year (based on population and NHL incidence rates similar to the US).
- **China:** ~40,000 new DLBCL cases per year (higher population, but lower diagnosis rates compared to the US/EU).
- **Japan:** ~10,000 new DLBCL cases per year (smaller population, but high diagnosis rates).

R/R DLBCL Population:

Approximately 30-40% of DLBCL patients relapse or become refractory after first-line treatment. Of these, a significant portion (50-60%) are not eligible for ASCT due to age, comorbidities, or other factors. Thus, the target population for tafasitamab-cxix is roughly **15-20% of total DLBCL incident cases**.

Treated Patient Population (Eligible for Tafasitamab-cxix):

- **US:** ~4,000–5,000 patients/year (15-20% of 25,000).
- **EU5:** ~4,500–6,000 patients/year (15-20% of 30,000).
- **China:** ~6,000–8,000 patients/year (15-20% of 40,000).
- **Japan:** ~1,500–2,000 patients/year (15-20% of 10,000).

Total target population across these geographies: ~16,000–21,000 patients/year.

Step 2: Market Share Assumption

The problem states a **20% to 30% share of treated patients**. This accounts for competition from other therapies for R/R DLBCL, such as CAR-T therapies (e.g., Yescarta, Kymriah), antibody-drug conjugates (e.g., Polivy), and other emerging treatments. Tafasitamab-cxix, used in combination with lenalidomide, targets a specific niche (non-ASCT eligible patients) and has shown promising efficacy in clinical trials (e.g., L-MIND study).

- **Assumed market share:** 25% (midpoint of 20-30%).

Treated Patients with Tafasitamab-cxix (25% Share):

- **US:** ~1,000–1,250 patients/year.

- **EU5:** ~1,125–1,500 patients/year.

- **China:** ~1,500–2,000 patients/year.

- **Japan:** ~375–500 patients/year.

Total treated patients: ~4,000–5,250 patients/year.

Step 3: Pricing and Treatment Cost

Tafasitamab-cxix pricing varies by region due to differences in healthcare systems, reimbursement, and market access. Based on available data:

- **US:** Annual cost of therapy (tafasitamab + lenalidomide) is estimated at ~\$200,000–\$250,000 per patient (based on US oncology drug pricing trends and MorphoSys reports).

- **EU5:** Annual cost is lower due to price negotiations, estimated at ~\$150,000–\$200,000 per patient.

- **China:** Pricing is significantly lower due to market dynamics and government negotiations, estimated at ~\$50,000–\$75,000 per patient.

- **Japan:** Pricing is similar to EU5, estimated at ~\$150,000–\$200,000 per patient.

Average Annual Cost per Patient (Assumed Midpoint):

- **US:** \$225,000.

- **EU5:** \$175,000.

- **China:** \$62,500.

- **Japan:** \$175,000.

Step 4: Potential Peak Sales Calculation

Peak sales are calculated by multiplying the number of treated patients (at 25% market share) by the average annual cost per patient in each geography.

Peak Sales by Region (25% Market Share):

- **US:** 1,125 patients × \$225,000 = **~\$253 million.**
- **EU5:** 1,312 patients × \$175,000 = **~\$229 million.**
- **China:** 1,750 patients × \$62,500 = **~\$109 million.**
- **Japan:** 437 patients × \$175,000 = **~\$76 million.**

Total Potential Peak Sales: ~\$253M (US) + \$229M (EU5) + \$109M (China) + \$76M (Japan) = **~\$667 million/year.**

Range of Peak Sales (20% to 30% Market Share):

- At 20% share: ~\$534 million/year.
- At 30% share: ~\$801 million/year.
- **Midpoint (25% share):** ~\$667 million/year.

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

To calculate the value of 1% share of treated patients, we divide the total peak sales by 25 (since 25% market share was used for the peak sales calculation).

- **Total treated patients at 1% share:** ~160–210 patients/year (1% of 16,000–21,000).
- **\$ Value of 1% share** = Total Peak Sales at 25% share ÷ 25 = \$667 million ÷ 25 = **~\$26.7 million/year.**

Breakdown by Region (1% Share):

- **US:** ~40–50 patients × \$225,000 = **~\$10.1 million.**
- **EU5:** ~45–60 patients × \$175,000 = **~\$9.2 million.**
- **China:** ~60–80 patients × \$62,500 = **~\$4.4 million.**
- **Japan:** ~15–20 patients × \$175,000 = **~\$3.0 million.**

Total \$ Value of 1% Share: ~\$10.1M (US) + \$9.2M (EU5) + \$4.4M (China) + \$3.0M (Japan) = **~\$26.7 million/year.**

Final Answer

1. **Potential Peak Sales for Tafasitamab-cxix** (at 20% to 30% market share):

- Range: **\$534 million to \$801 million per year.**
- Midpoint (25% share): **~\$667 million per year.**
- Breakdown:

- US: ~\$253 million.
- EU5: ~\$229 million.
- China: ~\$109 million.
- Japan: ~\$76 million.

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

- Total: **~\$26.7 million per year.**
- Breakdown:
- US: ~\$10.1 million.
- EU5: ~\$9.2 million.
- China: ~\$4.4 million.
- Japan: ~\$3.0 million.

Notes and Assumptions

- These estimates are based on approximate epidemiology data, assumed market share, and pricing. Actual numbers may vary based on real-world uptake, competition (e.g., CAR-T therapies), reimbursement policies, and market access challenges, especially in China.

- Peak sales are assumed to be reached within 5-7 years post-launch, depending on regulatory approvals and market penetration.

- The pricing in China is assumed to be lower due to government-driven price negotiations and local manufacturing/competition.

- These figures do not account for discounts, rebates, or patient assistance programs that may reduce net sales.

For more accurate figures, consult market research reports, company earnings calls, or primary data on patient numbers and pricing.