

To estimate the **Potential Peak Sales** for epcoritamab-bysp (Epkinly) in the indication of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data such as exact patient numbers, pricing, or market penetration may not be fully available, I will outline the methodology and use reasonable assumptions based on publicly available information and typical market dynamics for oncology drugs.

Step 1: Define Key Parameters

1. **Target Patient Population:** Relapsed or refractory DLBCL patients after two or more lines of systemic therapy.
2. **Market Share Assumption:** 20% to 30% of treated patients.
3. **Geographies:** US, EU5, China, Japan.
4. **Pricing:** Oncology drugs like epcoritamab-bysp (a bispecific antibody) often have high annual treatment costs, typically ranging from \$100,000 to \$300,000 per patient in the US, with lower costs in other regions due to pricing regulations.
5. **Treatment Duration:** Assume an average treatment duration of 6-12 months per patient.

Step 2: Estimate Target Patient Population

DLBCL is the most common type of non-Hodgkin lymphoma (NHL), and relapsed/refractory cases after two or more lines of therapy represent a smaller subset of the total DLBCL population. Below are rough estimates based on epidemiology data and incidence rates (sourced from general oncology reports and publications like SEER, GLOBOCAN, etc.):

- US:

- DLBCL incidence: ~25,000 new cases/year.
- Relapsed/refractory after 2+ lines: ~20-30% of cases progress to this stage (~5,000-7,500 patients/year).

- EU5:

- DLBCL incidence: ~30,000 new cases/year (combined across EU5).
- Relapsed/refractory after 2+ lines: ~6,000-9,000 patients/year.

- China:

- DLBCL incidence: ~50,000 new cases/year (higher population base).
- Relapsed/refractory after 2+ lines: ~10,000-15,000 patients/year.

- Japan:

- DLBCL incidence: ~10,000 new cases/year.
- Relapsed/refractory after 2+ lines: ~2,000-3,000 patients/year.

Total Addressable Patient Population (annual incident cases):

- US: ~6,250 patients (midpoint).

- EU5: ~7,500 patients.
- China: ~12,500 patients.
- Japan: ~2,500 patients.
- **Total across geographies:** ~28,750 patients/year.

Assumption on Treated Patients: Not all eligible patients receive treatment due to access, cost, or clinical ineligibility. Assume 70-80% of eligible patients are treated.

- Treated patients: ~20,125 to 23,000 patients/year across all geographies.

Step 3: Estimate Pricing per Patient

Pricing for bispecific antibodies like epcoritamab-bysp varies by region due to healthcare systems and pricing negotiations. Below are assumptions for annual treatment cost per patient:

- **US:** \$200,000/year (midpoint of typical oncology drug pricing range).
- **EU5:** \$120,000/year (lower due to pricing controls).
- **China:** \$50,000/year (significantly lower due to market access and pricing policies).
- **Japan:** \$150,000/year (similar to US but slightly lower due to regulations).

Step 4: Calculate Potential Peak Sales (20%-30% Market Share)

Assuming epcoritamab-bysp captures 20% to 30% of treated patients, we calculate the number of patients treated with the drug and multiply by the annual cost per patient.

US:

- Treated patients (total): ~4,375 to 5,000 (70-80% of 6,250).
- Patients on epcoritamab (20%-30%): ~875 to 1,500 patients.
- Annual cost: \$200,000.
- **Peak Sales:** \$175M (875 x \$200K) to \$300M (1,500 x \$200K).

EU5:

- Treated patients (total): ~5,250 to 6,000 (70-80% of 7,500).
- Patients on epcoritamab (20%-30%): ~1,050 to 1,800 patients.
- Annual cost: \$120,000.
- **Peak Sales:** \$126M (1,050 x \$120K) to \$216M (1,800 x \$120K).

China:

- Treated patients (total): ~8,750 to 10,000 (70-80% of 12,500).
- Patients on epcoritamab (20%-30%): ~1,750 to 3,000 patients.
- Annual cost: \$50,000.

- **Peak Sales:** \$87.5M (1,750 x \$50K) to \$150M (3,000 x \$50K).

Japan:

- Treated patients (total): ~1,750 to 2,000 (70-80% of 2,500).

- Patients on epcoritamab (20%-30%): ~350 to 600 patients.

- Annual cost: \$150,000.

- **Peak Sales:** \$52.5M (350 x \$150K) to \$90M (600 x \$150K).

Total Peak Sales Across Geographies:

- **Low End (20% share):** \$175M (US) + \$126M (EU5) + \$87.5M (China) + \$52.5M (Japan) = **\$441M**.

- **High End (30% share):** \$300M (US) + \$216M (EU5) + \$150M (China) + \$90M (Japan) = **\$756M**.

Potential Peak Sales Range: Approximately **\$441M to \$756M** annually.

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

Using the total treated patients and annual cost per patient, we calculate the value of a 1% share of treated patients in each geography.

- **US:**

- Treated patients: ~4,375 to 5,000.

- 1% of treated patients: ~44 to 50 patients.

- Value: 44 x \$200K = **\$8.8M** (low end); 50 x \$200K = **\$10M** (high end).

- **EU5:**

- Treated patients: ~5,250 to 6,000.

- 1% of treated patients: ~53 to 60 patients.

- Value: 53 x \$120K = **\$6.36M** (low end); 60 x \$120K = **\$7.2M** (high end).

- **China:**

- Treated patients: ~8,750 to 10,000.

- 1% of treated patients: ~88 to 100 patients.

- Value: 88 x \$50K = **\$4.4M** (low end); 100 x \$50K = **\$5M** (high end).

- **Japan:**

- Treated patients: ~1,750 to 2,000.

- 1% of treated patients: ~18 to 20 patients.

- Value: 18 x \$150K = **\$2.7M** (low end); 20 x \$150K = **\$3M** (high end).

Total \$ Value of 1% Share Across Geographies:

- **Low End:** \$8.8M (US) + \$6.36M (EU5) + \$4.4M (China) + \$2.7M (Japan) = **\$22.26M**.

- **High End:** \$10M (US) + \$7.2M (EU5) + \$5M (China) + \$3M (Japan) = **\$25.2M**.

\$ Value of 1% Share Range: Approximately **\$22.3M to \$25.2M**.

Final Answer

1. **Potential Peak Sales for epcoritamab-bysp** (20%-30% market share) in the US, EU5, China, and Japan for relapsed/refractory DLBCL: **\$441M to \$756M annually**.

2. **\$ Value of 1% Share of Treated Patients** in these geographies: **\$22.3M to \$25.2M**.

Notes and Caveats

- These estimates are based on assumptions for patient populations, treatment rates, pricing, and market share. Real-world data may differ due to competition (e.g., other therapies like CAR-T, polatuzumab, etc.), reimbursement policies, and market access challenges.

- Peak sales typically occur several years after launch as market penetration increases.

- Pricing in China and EU5 may be lower than assumed due to government negotiations or biosimilar/generic competition over time.

- The analysis assumes annual incident cases; prevalent cases (existing patients) could increase the total addressable market but are harder to estimate without specific data.