

To estimate the **Potential Peak Sales** for epcoritamab-bysp (Epkinly) in the indication of relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy in the US, EU5 (Germany, France, 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 exact data on patient populations, pricing, and market penetration may not be publicly available, I will outline the methodology and use reasonable assumptions based on available data for oncology drugs and follicular lymphoma epidemiology. The results will be approximate and should be validated with more specific market research or proprietary data.

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

Follicular lymphoma (FL) is a common type of non-Hodgkin lymphoma (NHL). We are focusing on relapsed or refractory (R/R) FL patients who have received two or more lines of systemic therapy (third-line or later, 3L+). The patient population in this segment is smaller than the total FL population due to attrition after each line of therapy.

### **#### Estimated Incidence and Prevalence of R/R FL (3L+)**

- **US:** FL accounts for ~20-25% of NHL cases. NHL incidence in the US is ~80,000 cases/year (American Cancer Society). Of these, ~16,000-20,000 are FL. Approximately 20-30% of FL patients progress to 3L+ therapy (based on historical data and treatment patterns). Thus, ~3,200-6,000 patients/year in the US.

- **EU5:** NHL incidence in Europe is ~100,000 cases/year. FL accounts for ~20-25% (~20,000-25,000 cases/year). Adjusting for EU5 population (~60% of EU total), ~12,000-15,000 FL cases/year. About 20-30% reach 3L+, so ~2,400-4,500 patients/year.

- **China:** NHL incidence in China is ~90,000 cases/year (due to large population). FL is less common (~10-15% of NHL due to higher T-cell lymphoma prevalence), so ~9,000-13,500 FL cases/year. Assuming 20-30% reach 3L+, ~1,800-4,000 patients/year.

- **Japan:** NHL incidence is ~30,000 cases/year. FL accounts for ~20-25% (~6,000-7,500 cases/year). About 20-30% reach 3L+, so ~1,200-2,250 patients/year.

### **Total Addressable 3L+ R/R FL Patients (Annual Incident Cases):**

- US: ~3,200-6,000

- EU5: ~2,400-4,500

- China: ~1,800-4,000

- Japan: ~1,200-2,250

- **Total:** ~8,600-16,750 patients/year

Since FL is an indolent disease, we also consider **prevalent patients** (existing patients eligible for treatment over time). Prevalence is typically 3-5x incidence for FL due to its chronic nature. For simplicity, we'll use incident cases for peak sales calculation, assuming steady-state annual treatment demand at peak.

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

The query assumes a **20-30% share of treated patients** for epcoritamab-bysp. This accounts for competition from other therapies (e.g., CAR-T therapies like tisagenlecleucel or axicabtagene ciloleucel, other bispecifics, or novel agents) and market access barriers.

### **Treated Patients Captured by Epcoritamab-bysp (20-30% of Total Addressable):**

- US: 640-1,800 patients/year (20-30% of 3,200-6,000)
- EU5: 480-1,350 patients/year (20-30% of 2,400-4,500)
- China: 360-1,200 patients/year (20-30% of 1,800-4,000)
- Japan: 240-675 patients/year (20-30% of 1,200-2,250)
- **Total:** 1,720-5,025 patients/year

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## **Step 3: Estimate Drug Pricing**

Epcoritamab-bysp is a bispecific antibody, and pricing for such therapies in oncology (e.g., blinatumomab for ALL or other bispecifics) typically ranges from **\$100,000 to \$200,000 per patient per year** in the US, depending on dosing regimen and treatment duration. For other regions, pricing is generally lower due to healthcare system negotiations and cost controls:

- **US:** ~\$150,000/patient/year (midpoint of range)
- **EU5:** ~\$80,000-\$100,000/patient/year (discount due to payer negotiations)
- **Japan:** ~\$80,000-\$100,000/patient/year (similar to EU5)
- **China:** ~\$30,000-\$50,000/patient/year (significant discount due to pricing controls and market access challenges)

For simplicity, let's use average pricing:

- US: \$150,000/patient/year
- EU5: \$90,000/patient/year
- Japan: \$90,000/patient/year
- China: \$40,000/patient/year

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

Peak sales are calculated as: **Number of Treated Patients x Annual Price per Patient.**

#### Peak Sales at 20-30% Market Share

- **US:** (640-1,800 patients) x \$150,000 = **\$96M - \$270M/year**

- **EU5:** (480-1,350 patients) x \$90,000 = **\$43M - \$121M/year**
- **Japan:** (240-675 patients) x \$90,000 = **\$22M - \$61M/year**
- **China:** (360-1,200 patients) x \$40,000 = **\$14M - \$48M/year**
- **Total Peak Sales: \$175M - \$500M/year**

**Potential Peak Sales Range for Epcoritamab-bysp:** Approximately **\$175 million to \$500 million per year** across the US, EU5, China, and Japan at 20-30% market share.

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

A 1% share of treated patients corresponds to 1% of the total addressable 3L+ R/R FL patients in each geography.

### **Total Addressable Patients (from Step 1):**

- US: 3,200-6,000 → 1% = 32-60 patients
- EU5: 2,400-4,500 → 1% = 24-45 patients
- Japan: 1,200-2,250 → 1% = 12-22.5 patients
- China: 1,800-4,000 → 1% = 18-40 patients

### **Revenue for 1% Share (Patients x Price):**

- **US:** (32-60) x \$150,000 = **\$4.8M - \$9.0M/year**
- **EU5:** (24-45) x \$90,000 = **\$2.2M - \$4.1M/year**
- **Japan:** (12-22.5) x \$90,000 = **\$1.1M - \$2.0M/year**
- **China:** (18-40) x \$40,000 = **\$0.7M - \$1.6M/year**
- **Total \$ Value of 1% Share: \$8.8M - \$16.7M/year**

**\$ Value of 1% Share of Treated Patients:** Approximately **\$9 million to \$17 million per year** across the US, EU5, China, and Japan.

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## **Summary of Results**

### **1. Potential Peak Sales for Epcoritamab-bysp (20-30% Market Share):**

- US: \$96M - \$270M/year
- EU5: \$43M - \$121M/year
- Japan: \$22M - \$61M/year
- China: \$14M - \$48M/year

- **Total: \$175M - \$500M/year**

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

- US: \$4.8M - \$9.0M/year

- EU5: \$2.2M - \$4.1M/year

- Japan: \$1.1M - \$2.0M/year

- China: \$0.7M - \$1.6M/year

- **Total: \$8.8M - \$16.7M/year**

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## **Caveats and Assumptions**

- **Patient Population:** Estimates are based on general epidemiology data for FL and assumptions about progression to 3L+ therapy. Real-world data may differ.

- **Pricing:** Pricing assumptions are based on comparable oncology therapies. Actual pricing for epcoritamab-bysp may vary by region and over time due to negotiations, rebates, and market access.

- **Market Share:** The 20-30% share assumption does not account for specific competitive dynamics or future entrants in the R/R FL space.

- **Treatment Duration:** Assumes one year of treatment per patient; actual duration may be shorter or longer based on clinical guidelines or trial data.

- **Peak Sales Timing:** Peak sales are assumed to occur after full market penetration (typically 3-5 years post-launch), ignoring initial ramp-up or patent expiry.

These estimates should be refined with more granular data on patient numbers, competitive landscape, and pricing from sources like company filings, market research reports, or clinical trial outcomes for epcoritamab-bysp. If you have access to specific data (e.g., trial results, pricing announcements, or market forecasts), I can adjust the calculations accordingly.