

To estimate the **Potential Peak Sales** for axicabtagene ciloleucel (Yescarta) in the indication of relapsed or refractory large B-cell lymphoma (LBCL) 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 specific data on patient populations, pricing, and market penetration may not be publicly available in real-time, I will outline a methodology using reasonable assumptions based on available data, industry standards, and market dynamics for CAR-T therapies like Yescarta.

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

Axicabtagene ciloleucel (Yescarta) is approved for adult patients with LBCL that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line treatment (second-line setting). LBCL is a subtype of non-Hodgkin lymphoma (NHL), and the target population includes patients with diffuse large B-cell lymphoma (DLBCL) and other high-grade B-cell lymphomas in this specific setting.

### **#### Incidence and Eligible Patient Population**

- **US:** Approximately 80,000 new cases of NHL are diagnosed annually, with DLBCL accounting for ~30-40% (24,000-32,000 cases). Of these, ~30-40% fail first-line therapy (refractory or relapse within 12 months), leading to ~7,200-12,800 eligible patients annually.
- **EU5:** NHL incidence is ~93,000 annually across Europe, with DLBCL at ~30-40% (28,000-37,200 cases). Assuming a similar failure rate, ~8,400-14,880 patients are eligible in EU5.
- **China:** NHL incidence is ~88,000 annually, with DLBCL at ~30-40% (26,400-35,200 cases). Failure rate yields ~7,920-14,080 eligible patients.
- **Japan:** NHL incidence is ~30,000 annually, with DLBCL at ~30-40% (9,000-12,000 cases). Failure rate yields ~2,700-4,800 eligible patients.

### **#### Total Eligible Patients (Midpoint Estimate)**

- US: ~10,000 patients
- EU5: ~11,640 patients
- China: ~11,000 patients
- Japan: ~3,750 patients
- **Total:** ~36,390 patients annually across these geographies.

## **Step 2: Estimate Market Penetration (20%-30% Share of Treated Patients)**

As per the query, we assume Yescarta captures **20%-30%** of the eligible treated patients. Using the midpoint of 25%:

- US:  $10,000 * 25\% = 2,500$  patients
- EU5:  $11,640 * 25\% = 2,910$  patients
- China:  $11,000 * 25\% = 2,750$  patients
- Japan:  $3,750 * 25\% = 938$  patients

- **Total Treated Patients:** ~9,098 patients annually at peak penetration.

### **Step 3: Pricing of Yescarta**

Yescarta is a one-time CAR-T therapy with high pricing due to its personalized nature and manufacturing costs:

- **US:** List price is ~\$373,000 per treatment (based on historical data for Yescarta in LBCL).
- **EU5:** Pricing is typically lower due to healthcare negotiations; assume ~\$300,000 per treatment.
- **China:** Pricing may be significantly lower due to market dynamics and local policies; assume ~\$150,000 per treatment.
- **Japan:** Pricing is closer to EU levels due to advanced healthcare systems; assume ~\$300,000 per treatment.

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

Using the number of treated patients and pricing per geography:

- **US:** 2,500 patients \* \$373,000 = **\$932.5 million**
- **EU5:** 2,910 patients \* \$300,000 = **\$873 million**
- **China:** 2,750 patients \* \$150,000 = **\$412.5 million**
- **Japan:** 938 patients \* \$300,000 = **\$281.4 million**
- **Total Peak Sales:** **\$2,499.4 million (~\$2.5 billion)** annually at 25% market share.

#### Range Based on 20%-30% Market Share

- At 20% share: Total patients = 7,278; Peak Sales = **~\$2.0 billion**
- At 30% share: Total patients = 10,917; Peak Sales = **~\$3.0 billion**

Thus, **Potential Peak Sales** for Yescarta in this indication across the US, EU5, China, and Japan range from **\$2.0 billion to \$3.0 billion**, with a midpoint of **\$2.5 billion**.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient pool:

- Total eligible patients = 36,390
- 1% share = 363.9 patients

Using the same pricing per geography and proportional patient distribution:

- **US:**  $(10,000 / 36,390) * 363.9 \approx 100$  patients \* \$373,000 = **\$37.3 million**
- **EU5:**  $(11,640 / 36,390) * 363.9 \approx 116$  patients \* \$300,000 = **\$34.8 million**
- **China:**  $(11,000 / 36,390) * 363.9 \approx 110$  patients \* \$150,000 = **\$16.5 million**
- **Japan:**  $(3,750 / 36,390) * 363.9 \approx 37$  patients \* \$300,000 = **\$11.1 million**

- **Total \$ Value of 1% Share: \$99.7 million**

## **Final Answer**

1. **Potential Peak Sales for Axicabtagene Ciloleucel (Yescarta)** in relapsed/refractory LBCL (assuming 20%-30% market share):

- Range: **\$2.0 billion to \$3.0 billion** annually

- Midpoint (25% share): **\$2.5 billion** annually

2. **\$ Value of 1% Share of Treated Patients** across US, EU5, China, and Japan:

- **\$99.7 million** annually

## **Notes and Assumptions**

- Patient population estimates are based on general NHL and DLBCL incidence rates and relapse/refractory proportions from literature.

- Pricing assumptions reflect historical data for CAR-T therapies and regional pricing differences.

- Market penetration (20%-30%) accounts for competition from other CAR-T therapies (e.g., tisagenlecleucel, lisocabtagene maraleucel) and alternative treatments.

- Peak sales assume steady-state market share, likely achieved 3-5 years post-launch in the second-line LBCL setting.

- Real-world data may vary based on reimbursement, access, manufacturing capacity, and local healthcare policies. If specific data or updates are available, these estimates can be refined.