

To estimate the **Potential Peak Sales** for **lisocabtagene maraleucel (Breyanzi)** in the indication of large B-cell lymphoma (LBCL) 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 vary and are often proprietary, I will base this analysis on reasonable assumptions derived from publicly available information, market research trends for CAR-T therapies, and the specific indication.

Step 1: Key Assumptions

1. **Indication:** Lisocabtagene maraleucel is approved for second-line treatment of LBCL in patients with refractory disease or relapse within 12 months of first-line chemoimmunotherapy, or those ineligible for HSCT due to comorbidities or age.
2. **Target Patient Population:** LBCL is a subset of non-Hodgkin lymphoma (NHL). Diffuse large B-cell lymphoma (DLBCL) is the most common subtype of LBCL, accounting for ~30-40% of NHL cases. We will estimate the eligible second-line population based on incidence, relapse rates, and ineligibility for HSCT.
3. **Market Share:** The query assumes a 20% to 30% share of treated patients. We will use this range for peak sales estimation.
4. **Pricing:** CAR-T therapies like Breyanzi are expensive. In the US, the list price for Breyanzi is approximately \$410,000 per treatment (based on available data as of 2023). Pricing in other regions is typically lower due to healthcare system differences (e.g., ~70-80% of US price in EU5 and Japan, and ~50% in China due to pricing pressures).
5. **Peak Sales Timeline:** Peak sales are typically achieved 5-7 years post-launch after market penetration stabilizes.

Step 2: Estimate Target Patient Population

Incidence and Eligible Population for Second-Line LBCL

- US:

- NHL incidence: ~80,000 new cases/year.
- DLBCL/LBCL: ~30-40% of NHL → ~24,000-32,000 new cases/year.
- Second-line eligible (relapse/refractory within 12 months or ineligible for HSCT): ~30-40% of LBCL patients → ~7,200-12,800 patients/year.

- EU5:

- NHL incidence: ~100,000 new cases/year.
- LBCL: ~30-40% → ~30,000-40,000 new cases/year.
- Second-line eligible: ~30-40% → ~9,000-16,000 patients/year.

- Japan:

- NHL incidence: ~30,000 new cases/year.
- LBCL: ~30-40% → ~9,000-12,000 new cases/year.
- Second-line eligible: ~30-40% → ~2,700-4,800 patients/year.

- **China:**

- NHL incidence: ~90,000 new cases/year (higher population but lower diagnosis rates).
- LBCL: ~30-40% → ~27,000-36,000 new cases/year.
- Second-line eligible: ~30-40% → ~8,100-14,400 patients/year.

Total Eligible Patients Across Geographies

- US: ~10,000 patients/year (midpoint of range).
- EU5: ~12,500 patients/year.
- Japan: ~3,750 patients/year.
- China: ~11,250 patients/year.
- **Total:** ~37,500 patients/year.

Step 3: Estimate Pricing per Patient

- **US:** \$410,000 per treatment.
- **EU5:** ~\$320,000 per treatment (assuming ~78% of US price due to negotiated discounts).
- **Japan:** ~\$320,000 per treatment (similar to EU5).
- **China:** ~\$205,000 per treatment (assuming ~50% of US price due to market access and affordability constraints).

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

Treated Patients with 20%-30% Market Share

- Total eligible patients: 37,500.
- At 20% share: 7,500 patients treated.
- At 30% share: 11,250 patients treated.

Peak Sales Calculation by Region

- **US:**

- Eligible patients: 10,000.
- 20% share: 2,000 patients × \$410,000 = **\$820 million**.
- 30% share: 3,000 patients × \$410,000 = **\$1,230 million**.

- **EU5:**

- Eligible patients: 12,500.
- 20% share: 2,500 patients × \$320,000 = **\$800 million**.
- 30% share: 3,750 patients × \$320,000 = **\$1,200 million**.

- **Japan:**

- Eligible patients: 3,750.
- 20% share: 750 patients × \$320,000 = **\$240 million**.
- 30% share: 1,125 patients × \$320,000 = **\$360 million**.

- China:

- Eligible patients: 11,250.
- 20% share: 2,250 patients × \$205,000 = **\$461 million**.
- 30% share: 3,375 patients × \$205,000 = **\$692 million**.

Total Peak Sales Across Geographies

- At 20% share: \$820M (US) + \$800M (EU5) + \$240M (Japan) + \$461M (China) = **\$2,321 million (~\$2.3 billion)**.
- At 30% share: \$1,230M (US) + \$1,200M (EU5) + \$360M (Japan) + \$692M (China) = **\$3,482 million (~\$3.5 billion)**.

Potential Peak Sales Range: \$2.3 billion to \$3.5 billion annually.

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

- Total eligible patients: 37,500.
- 1% share: 375 patients treated.

Value of 1% Share by Region

- US:

- Eligible patients: 10,000.
- 1% share: 100 patients × \$410,000 = **\$41 million**.

- EU5:

- Eligible patients: 12,500.
- 1% share: 125 patients × \$320,000 = **\$40 million**.

- Japan:

- Eligible patients: 3,750.
- 1% share: 37.5 patients × \$320,000 = **\$12 million**.

- China:

- Eligible patients: 11,250.
- 1% share: 112.5 patients × \$205,000 = **\$23 million**.

Total Value of 1% Share Across Geographies

- \$41M (US) + \$40M (EU5) + \$12M (Japan) + \$23M (China) = **\$116 million**.

\$ Value of 1% Share of Treated Patients: \$116 million.

Final Answer

- **Potential Peak Sales for Lisocabtagene Maraleucel** (20%-30% market share): **\$2.3 billion to \$3.5 billion annually** across the US, EU5, China, and Japan.
- **\$ Value of 1% Share of Treated Patients: \$116 million** across the same geographies.

Caveats

- These estimates are based on assumptions and may vary due to real-world factors such as competition (e.g., other CAR-T therapies like axicabtagene ciloleucel or tisagenlecleucel), reimbursement policies, manufacturing capacity, and actual market penetration.
- Pricing and patient access in China are particularly uncertain due to evolving healthcare policies and affordability challenges.
- Adjustments may be needed based on updated epidemiology data, pricing negotiations, or clinical trial outcomes affecting eligible patient definitions.