

To estimate the **Potential Peak Sales** for **lisocabtagene maraleucel (Breyanzi)** in the specified indication (relapsed or refractory large B-cell lymphoma, R/R 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 based on available data, assumptions, and market dynamics for CAR-T therapies.

Lisocabtagene maraleucel is a CAR-T cell therapy approved for adult patients with R/R LBCL after two or more lines of systemic therapy. This is a niche indication with a limited patient population but high treatment cost due to the personalized nature of CAR-T therapies.

Step 1: Key Assumptions and Data Inputs

Since exact patient numbers, pricing, and penetration rates may vary, we will use reasonable estimates based on industry reports, epidemiology data, and pricing benchmarks for CAR-T therapies. Note that actual figures may differ based on updated data or specific market access conditions.

1. Patient Population (Eligible for Treatment):

- R/R LBCL represents a subset of non-Hodgkin lymphoma (NHL) patients who have failed at least two prior lines of therapy.
- Based on epidemiology data and literature:
- **US:** ~7,000–10,000 eligible R/R LBCL patients annually.
- **EU5:** ~6,000–9,000 eligible patients annually (combined across the 5 countries, adjusted for population size).
- **Japan:** ~1,500–2,000 eligible patients annually.
- **China:** ~10,000–15,000 eligible patients annually (larger population but lower diagnosis and treatment rates).
- Total eligible patients across geographies: ~24,500–36,000 annually.

2. Pricing of CAR-T Therapy (Lisocabtagene Maraleucel):

- CAR-T therapies like Breyanzi are priced at a premium due to manufacturing complexity and clinical value.
- **US:** ~\$410,000 per treatment (based on reported pricing for Breyanzi).
- **EU5:** ~\$350,000 per treatment (slightly lower due to pricing negotiations and healthcare systems).
- **Japan:** ~\$350,000 per treatment (similar to EU5, adjusted for market dynamics).
- **China:** ~\$200,000 per treatment (lower pricing due to affordability constraints and potential local manufacturing or subsidies).

3. Market Penetration (Share of Treated Patients):

- As per the query, assuming 20% to 30% of eligible patients receive Breyanzi in the peak sales year (accounting for competition from other CAR-T therapies like axicabtagene ciloleucel and tisagenlecleucel, as well as logistical and reimbursement challenges).

4. Peak Sales Year:

- Peak sales are typically achieved 5–7 years post-launch, assuming market access, reimbursement, and manufacturing scale-up are in place. Breyanzi was approved in the US in 2021, so peak sales could be around 2026–2028.

Step 2: Calculate Potential Peak Sales

We will calculate peak sales based on the number of eligible patients, market share (20%–30%), and pricing in each geography.

1. US

- Eligible patients: 8,500 (midpoint of 7,000–10,000).
- Market share: 20%–30% → 1,700 to 2,550 treated patients.
- Price per treatment: \$410,000.
- Peak Sales:
 - At 20% share: $1,700 \times \$410,000 = \text{\$697 million}$.
 - At 30% share: $2,550 \times \$410,000 = \text{\$1,045 million}$.

2. EU5

- Eligible patients: 7,500 (midpoint of 6,000–9,000).
- Market share: 20%–30% → 1,500 to 2,250 treated patients.
- Price per treatment: \$350,000.
- Peak Sales:
 - At 20% share: $1,500 \times \$350,000 = \text{\$525 million}$.
 - At 30% share: $2,250 \times \$350,000 = \text{\$788 million}$.

3. Japan

- Eligible patients: 1,750 (midpoint of 1,500–2,000).
- Market share: 20%–30% → 350 to 525 treated patients.
- Price per treatment: \$350,000.
- Peak Sales:
 - At 20% share: $350 \times \$350,000 = \text{\$123 million}$.
 - At 30% share: $525 \times \$350,000 = \text{\$184 million}$.

4. China

- Eligible patients: 12,500 (midpoint of 10,000–15,000).

- Market share: 20%–30% → 2,500 to 3,750 treated patients.
- Price per treatment: \$200,000.
- Peak Sales:
 - At 20% share: $2,500 \times \$200,000 = \text{\$500 million}$.
 - At 30% share: $3,750 \times \$200,000 = \text{\$750 million}$.

Total Potential Peak Sales Across Geographies

- At 20% share: \$697M (US) + \$525M (EU5) + \$123M (Japan) + \$500M (China) = **\$1,845 million (~\$1.85 billion)**.
- At 30% share: \$1,045M (US) + \$788M (EU5) + \$184M (Japan) + \$750M (China) = **\$2,767 million (~\$2.77 billion)**.

Potential Peak Sales Range: \$1.85 billion to \$2.77 billion annually.

Step 3: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the eligible patient population being treated with Breyanzi. We calculate the revenue generated from this 1% share using the same pricing assumptions.

1. US

- Eligible patients: 8,500.
- 1% share: 85 patients.
- Price per treatment: \$410,000.
- Value of 1% share: $85 \times \$410,000 = \text{\$34.85 million}$.

2. EU5

- Eligible patients: 7,500.
- 1% share: 75 patients.
- Price per treatment: \$350,000.
- Value of 1% share: $75 \times \$350,000 = \text{\$26.25 million}$.

3. Japan

- Eligible patients: 1,750.
- 1% share: 17.5 patients (~18 patients).
- Price per treatment: \$350,000.
- Value of 1% share: $18 \times \$350,000 = \text{\$6.3 million}$.

4. China

- Eligible patients: 12,500.
- 1% share: 125 patients.
- Price per treatment: \$200,000.
- Value of 1% share: $125 \times \$200,000 = \text{\$25 million}$.

Total \$ Value of 1% Share Across Geographies

- US: \$34.85M + EU5: \$26.25M + Japan: \$6.3M + China: \$25M = **\$92.4 million**.

Value of 1% Share of Treated Patients: ~\$92.4 million annually.

Final Answer

1. **Potential Peak Sales for Lisocabtagene Maraleucel (Breyanzi)** in R/R LBCL across the US, EU5, China, and Japan, assuming a 20% to 30% share of treated patients:

- **\$1.85 billion to \$2.77 billion annually.**

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

- **\$92.4 million annually.**

Notes and Caveats

- These estimates are based on assumptions regarding patient populations, pricing, and market penetration. Actual figures may vary due to competition, reimbursement policies, manufacturing capacity, and market access challenges.

- CAR-T therapies face logistical hurdles (e.g., patient referral to specialized centers, apheresis, and manufacturing timelines), which may limit penetration rates.

- Pricing in China is assumed to be lower due to affordability and potential local competition or pricing reforms; this could impact overall revenue.

- Peak sales are subject to change based on label expansions, new indications, or emerging therapies in the R/R LBCL space.