

To estimate the **Potential Peak Sales** for lisocabtagene maraleucel (Breyanzi) in the indication of relapsed or refractory follicular lymphoma (FL) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients**, 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 the methodology and provide a reasonable estimate based on publicly available data, industry benchmarks, and logical assumptions. If you have access to specific data (e.g., exact patient numbers or pricing), I can refine the calculations.

Lisocabtagene maraleucel (liso-cel, marketed as Breyanzi) is a CAR-T cell therapy approved for adults with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy. This is a niche indication with a relatively small patient population compared to other cancers, but the high cost of CAR-T therapies can lead to significant revenue potential.

Step 1: Key Assumptions

1. Patient Population:

- Follicular lymphoma (FL) is a subtype of non-Hodgkin lymphoma (NHL). Relapsed or refractory FL patients who have failed ≥ 2 lines of therapy represent a smaller subset of the total FL population.
- Estimated incidence and prevalence of FL vary by geography. We will focus on the addressable patient population (relapsed/refractory after ≥ 2 lines of therapy).
- Based on literature and reports, the addressable population for third-line or later FL therapies is roughly estimated as follows (these are approximations and may need validation with specific epidemiology data):
 - **US:** ~3,000–5,000 eligible patients annually.
 - **EU5:** ~3,000–5,000 eligible patients annually (combined across the 5 countries, adjusted for smaller populations vs. US).
 - **Japan:** ~1,000–1,500 eligible patients annually.
 - **China:** ~5,000–8,000 eligible patients annually (larger population but lower diagnosis and treatment access rates).
- Total addressable patients across these geographies: ~12,000–19,500 annually.

2. Market Penetration:

- Given the query assumes a 20% to 30% share of treated patients, we will use this range for peak sales calculation.
- CAR-T therapies face logistical challenges (e.g., manufacturing, hospital infrastructure) and competition from other therapies (e.g., bispecific antibodies, other CAR-Ts), so penetration may be limited to this range even at peak.

3. Pricing:

- CAR-T therapies are expensive. Breyanzi's list price in the US for other indications (e.g., large B-cell lymphoma) is approximately \$410,000 per treatment (based on publicly available data as of 2023). For FL, we assume a similar price.
- Pricing in other geographies is typically lower due to healthcare system differences:

- **EU5:** ~\$300,000–\$350,000 per treatment (adjusted for European pricing norms).
- **Japan:** ~\$350,000 per treatment (similar to EU due to regulated pricing).
- **China:** ~\$200,000–\$250,000 per treatment (lower due to affordability and market access constraints).
- These are rough estimates and may vary based on negotiations with payers and reimbursement policies.

4. Peak Sales Timeline:

- Peak sales are typically achieved 5–7 years post-launch in a given indication, assuming no major competitive disruptions or patent cliffs.

Step 2: Estimate Addressable Patients and Treated Patients

Using the mid-point of the patient population ranges:

- **US:** 4,000 patients
- **EU5:** 4,000 patients
- **Japan:** 1,250 patients
- **China:** 6,500 patients
- **Total:** 15,750 patients annually

With a 20% to 30% share of treated patients:

- **20% share:** 3,150 patients treated annually
- **30% share:** 4,725 patients treated annually

Step 3: Calculate Potential Peak Sales

Peak sales are calculated as:

Peak Sales = (Number of Treated Patients) × (Price per Treatment)

At 20% Share:

- **US:** $4,000 \times 20\% = 800 \text{ patients} \times \$410,000 = \text{\$328 million}$
- **EU5:** $4,000 \times 20\% = 800 \text{ patients} \times \$325,000 \text{ (mid-point)} = \text{\$260 million}$
- **Japan:** $1,250 \times 20\% = 250 \text{ patients} \times \$350,000 = \text{\$87.5 million}$
- **China:** $6,500 \times 20\% = 1,300 \text{ patients} \times \$225,000 \text{ (mid-point)} = \text{\$292.5 million}$
- **Total Peak Sales at 20% Share:** $\text{\$328M} + \text{\$260M} + \text{\$87.5M} + \text{\$292.5M} = \text{\$968 million}$

At 30% Share:

- **US:** $4,000 \times 30\% = 1,200 \text{ patients} \times \$410,000 = \text{\$492 million}$
- **EU5:** $4,000 \times 30\% = 1,200 \text{ patients} \times \$325,000 = \text{\$390 million}$

- **Japan:** $1,250 \times 30\% = 375$ patients $\times \$350,000 =$ **\$131.25 million**
- **China:** $6,500 \times 30\% = 1,950$ patients $\times \$225,000 =$ **\$438.75 million**
- **Total Peak Sales at 30% Share:** $\$492\text{M} + \$390\text{M} + \$131.25\text{M} + \$438.75\text{M} =$ **~\$1,452 million (~\$1.45 billion)**

Step 4: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total addressable patient population:

- **Total patients:** 15,750
- **1% share:** 157.5 patients

Using the same pricing assumptions:

- **US:** $(4,000 \times 1\%) = 40$ patients $\times \$410,000 =$ **\$16.4 million**
- **EU5:** $(4,000 \times 1\%) = 40$ patients $\times \$325,000 =$ **\$13.0 million**
- **Japan:** $(1,250 \times 1\%) = 12.5$ patients $\times \$350,000 =$ **\$4.375 million**
- **China:** $(6,500 \times 1\%) = 65$ patients $\times \$225,000 =$ **\$14.625 million**
- **Total \$ Value of 1% Share:** $\$16.4\text{M} + \$13.0\text{M} + \$4.375\text{M} + \$14.625\text{M} =$ **~\$48.4 million**

Final Answer

1. Potential Peak Sales for lisocabtagene maraleucel (Breyanzi) in relapsed/refractory FL
(assuming 20% to 30% share of treated patients):

- At 20% share: **~\$968 million annually**
- At 30% share: **~\$1.45 billion annually**

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

- **~\$48.4 million annually**

Caveats and Notes

- These estimates are based on assumptions about patient numbers, pricing, and market penetration. Real-world data may differ due to factors like reimbursement challenges, competition (e.g., from other CAR-T therapies or bispecific antibodies like mosunetuzumab), and access barriers (especially in China).

- The follicular lymphoma indication is smaller compared to other approved indications for Breyanzi (e.g., large B-cell lymphoma), so peak sales in this specific indication are limited by the addressable population.

- If you have access to more precise epidemiology data, pricing details, or market research reports (e.g., from EvaluatePharma, GlobalData, or company filings), the numbers can be refined further.

Let me know if you'd like to adjust any assumptions or focus on a specific geography or aspect of the analysis!

