

To estimate the **Potential Peak Sales** for brexucabtagene autoleucel (Tecartus) in the indication of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) in the US, EU5 (France, Germany, 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 specific data on patient numbers, pricing, and market penetration may not be publicly available in full detail, I will outline the methodology and make reasonable assumptions based on available information about the drug, disease prevalence, and market dynamics.

## **Step 1: Key Assumptions and Inputs**

**1. Indication and Target Population:** Brexucabtagene autoleucel (Tecartus) is approved for adult patients with relapsed or refractory B-cell precursor ALL, a rare and aggressive hematologic malignancy.

**2. Epidemiology of Relapsed/Refractory ALL:**

- ALL incidence is relatively low, with a significant portion of patients achieving remission with first-line therapies. However, relapsed/refractory (R/R) ALL represents a smaller subset with high unmet need.
- Approximate annual incidence of ALL (adults) and R/R cases:
  - **US:** ~6,500 new ALL cases per year; ~30-40% are adults, and ~50% of these may relapse or be refractory (~1,000-1,300 R/R adult patients annually).
  - **EU5:** ~5,000-6,000 new ALL cases; similar adult and R/R proportions (~800-1,200 R/R adult patients).
  - **Japan:** ~1,000-1,500 new ALL cases; ~200-300 R/R adult patients.
  - **China:** Higher incidence due to population size, ~15,000-20,000 new ALL cases; ~2,500-3,500 R/R adult patients.
- These are rough estimates based on general leukemia epidemiology and relapse rates.

**3. Treatable Population:** Not all R/R ALL patients will be eligible for CAR-T therapies like Tecartus due to factors such as age, comorbidities, or access to treatment. Assume ~50-70% of R/R patients are eligible.

**4. Market Share:** Given the query specifies a 20-30% share of treated patients, we will use this range for peak sales estimation.

**5. Pricing of Tecartus:** CAR-T therapies are expensive. Tecartus is priced at approximately **\$373,000 per treatment** in the US (based on pricing for similar indications). Pricing in other regions may be lower due to healthcare system differences:

- **EU5:** ~\$300,000 per treatment.
- **Japan:** ~\$350,000 per treatment.
- **China:** ~\$200,000 per treatment (assuming lower pricing due to market access and affordability constraints).

**6. Peak Sales Timeline:** Peak sales are typically achieved 5-7 years post-launch after market penetration stabilizes.

## **Step 2: Estimate Eligible and Treated Patients**

Using the epidemiology data and eligibility assumptions:

| **Region** | **R/R Adult ALL Patients (Annual)** | **Eligible Patients (60% of R/R)** | **Treated Patients at 20-30% Market Share** |

US	1,200	720	144 - 216
EU5	1,000	600	120 - 180
Japan	250	150	30 - 45
China	3,000	1,800	360 - 540
<b>Total</b>	<b>5,450</b>	<b>3,270</b>	<b>654 - 981</b>

### **Step 3: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients by the price per treatment in each region.

| **Region** | **Treated Patients (20-30%)** | **Price per Treatment (\$)** | **Peak Sales at 20% (\$M)** | **Peak Sales at 30% (\$M)** |

US	144 - 216	373,000	53.7	80.6
EU5	120 - 180	300,000	36.0	54.0
Japan	30 - 45	350,000	10.5	15.8
China	360 - 540	200,000	72.0	108.0
<b>Total</b>	<b>654 - 981</b>	-	<b>172.2</b>	<b>258.4</b>

Thus, the **Potential Peak Sales** for brexucabtagene autoleucel in R/R ALL across the US, EU5, China, and Japan are estimated to be in the range of **\$172 million to \$258 million annually** at a 20-30% market share of treated patients.

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

To calculate the value of a 1% share of treated patients, we divide the peak sales at 20% and 30% by 20 and 30, respectively, to get the value per 1% share, or calculate based on total eligible patients.

| **Region** | **Eligible Patients** | **1% of Eligible Patients** | **Price per Treatment (\$)** | **\$ Value of 1% Share (\$M)** |

US	720	7.2	373,000	2.69
EU5	600	6.0	300,000	1.80
Japan	150	1.5	350,000	0.53
China	1,800	18.0	200,000	3.60

| Total | 3,270 | 32.7 | - | 8.62 |

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$8.62 million**.

## **Final Answer**

- **Potential Peak Sales** for brexucabtagene autoleucel in R/R ALL (assuming 20-30% market share of treated patients):

- **US, EU5, China, Japan combined: \$172 million to \$258 million annually.**

- **\$ Value of 1% Share of Treated Patients:**

- **US, EU5, China, Japan combined: \$8.62 million.**

## **Notes**

- These estimates are based on rough epidemiology data and assumptions about pricing and market penetration. Actual numbers may vary based on real-world access, reimbursement policies, competition (e.g., other CAR-T therapies or bispecific antibodies like blinatumomab), and patient outcomes.

- Pricing in China and other markets may be significantly lower or higher based on negotiations and local healthcare systems.

- If more precise data on patient numbers or pricing is available, the calculations can be refined accordingly.