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:

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

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) |

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) |

| 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.