To estimate the **Potential Peak Sales** for tisagenlecleucel (Kymriah) in the indication of relapsed or refractory follicular lymphoma (FL) 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 exact data on patient populations, pricing, and penetration rates may not be publicly available, I will outline the methodology and make reasonable assumptions based on available information and industry standards.

Key Steps for Estimation:

1. **Define the Target Patient Population**: Estimate the number of patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy in each geography.

2. **Estimate Market Share**: Use the provided range of 20% to 30% share of treated patients.

3. **Determine Pricing**: Estimate the cost of tisagenlecleucel per patient in each region.

4. **Calculate Potential Peak Sales**: Multiply the treated patient population by the price per patient.

5. **Calculate Value of 1% Share**: Determine the monetary value of treating 1% of the eligible patient population.

Step 1: Estimate Target Patient Population

Follicular lymphoma (FL) is a subtype of non-Hodgkin lymphoma (NHL). Relapsed or refractory FL after two or more lines of therapy represents a smaller subset of the total FL population. We will estimate the eligible patient population based on epidemiology data and treatment patterns.

Incidence and Prevalence of FL:

- **US**: Approximately 74,000 new cases of NHL annually, with FL accounting for ~20-25% (14,800-18,500 cases). Of these, ~20-30% become relapsed/refractory after 2+ lines of therapy (~3,000-5,500 patients annually).

- **EU5**: Combined NHL incidence is ~100,000 annually. FL accounts for ~20-25% (20,000-25,000 cases). Relapsed/refractory after 2+ lines: ~4,000-7,500 patients annually.

- **China**: NHL incidence is ~90,000 annually. FL proportion is lower (~10-15%) due to higher prevalence of aggressive lymphomas (9,000-13,500 cases). Relapsed/refractory after 2+ lines: ~1,800-4,000 patients annually.

- **Japan**: NHL incidence is ~30,000 annually. FL accounts for ~20-25% (6,000-7,500 cases). Relapsed/refractory after 2+ lines: ~1,200-2,250 patients annually.

Total estimated eligible patients (relapsed/refractory FL after 2+ lines):

- US: ~4,250 (midpoint of 3,000-5,500)

- EU5: ~5,750 (midpoint of 4,000-7,500)

- China: ~2,900 (midpoint of 1,800-4,000)

- Japan: ~1,725 (midpoint of 1,200-2,250)

- **Total across geographies**: ~14,625 patients annually.

Step 2: Estimate Market Share

The problem assumes a 20% to 30% share of treated patients. We will calculate peak sales for both ends of this range and use the midpoint (25%) for a single-point estimate where needed.

- **20% share**: 14,625 * 0.20 = 2,925 patients treated annually.

- **30% share**: 14,625 * 0.30 = 4,388 patients treated annually.

- **25% share (midpoint)**: 14,625 * 0.25 = 3,656 patients treated annually.

Breakdown by geography (using 25% share for simplicity):

- US: 4,250 * 0.25 = 1,063 patients

- EU5: 5,750 * 0.25 = 1,438 patients

- China: 2,900 * 0.25 = 725 patients

- Japan: 1,725 * 0.25 = 431 patients

Step 3: Estimate Pricing per Patient

Tisagenlecleucel (Kymriah) is a CAR-T cell therapy with high pricing due to its personalized nature and manufacturing costs. Pricing varies by region due to healthcare systems and reimbursement structures:

- **US**: Kymriah is priced at ~$475,000 per patient for other indications (e.g., DLBCL). We assume a similar price for FL.

- **EU5**: Pricing is typically lower due to negotiations with health authorities. Assume ~$350,000 per patient.

- **China**: Pricing is significantly lower due to cost sensitivities and local policies. Assume ~$200,000 per patient (if approved and reimbursed).

- **Japan**: Pricing is closer to EU levels due to advanced healthcare system. Assume ~$350,000 per patient.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as: (Number of treated patients) * (Price per patient). We will calculate for 20%, 25%, and 30% market shares.

At 20% Market Share (2,925 treated patients):

- US: 850 patients (4,250 * 0.20) * $475,000 = **$403.8 million**

- EU5: 1,150 patients (5,750 * 0.20) * $350,000 = **$402.5 million**

- China: 580 patients (2,900 * 0.20) * $200,000 = **$116.0 million**

- Japan: 345 patients (1,725 * 0.20) * $350,000 = **$120.8 million**

- **Total Peak Sales (20%)**: $403.8M + $402.5M + $116.0M + $120.8M = **$1,043.1 million (~$1.04 billion)**

At 25% Market Share (3,656 treated patients):

- US: 1,063 patients * $475,000 = **$504.9 million**

- EU5: 1,438 patients * $350,000 = **$503.3 million**

- China: 725 patients * $200,000 = **$145.0 million**

- Japan: 431 patients * $350,000 = **$150.9 million**

- **Total Peak Sales (25%)**: $504.9M + $503.3M + $145.0M + $150.9M = **$1,304.1 million (~$1.30 billion)**

At 30% Market Share (4,388 treated patients):

- US: 1,275 patients (4,250 * 0.30) * $475,000 = **$605.6 million**

- EU5: 1,725 patients (5,750 * 0.30) * $350,000 = **$603.8 million**

- China: 870 patients (2,900 * 0.30) * $200,000 = **$174.0 million**

- Japan: 518 patients (1,725 * 0.30) * $350,000 = **$181.3 million**

- **Total Peak Sales (30%)**: $605.6M + $603.8M + $174.0M + $181.3M = **$1,564.7 million (~$1.56 billion)**

Potential Peak Sales Range: **$1.04 billion to $1.56 billion**, with a midpoint of **$1.30 billion** at 25% market share.

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

A 1% share corresponds to 1% of the total eligible patient population (14,625 patients) = 146 patients annually.

- US: 4,250 * 0.01 = 42.5 patients * $475,000 = **$20.2 million**

- EU5: 5,750 * 0.01 = 57.5 patients * $350,000 = **$20.1 million**

- China: 2,900 * 0.01 = 29 patients * $200,000 = **$5.8 million**

- Japan: 1,725 * 0.01 = 17.25 patients * $350,000 = **$6.0 million**

- **Total $ Value of 1% Share**: $20.2M + $20.1M + $5.8M + $6.0M = **$52.1 million**

Final Answer:

1. **Potential Peak Sales for Tisagenlecleucel in Relapsed/Refractory FL** (20% to 30% market share):

- Range: **$1.04 billion to $1.56 billion**

- Midpoint (25% share): **$1.30 billion**

Breakdown by geography (at 25% share):

- US: **$504.9 million**

- EU5: **$503.3 million**

- China: **$145.0 million**

- Japan: **$150.9 million**

2. **$ Value of 1% Share of Treated Patients**:

- Total: **$52.1 million**

- Breakdown by geography:

- US: **$20.2 million**

- EU5: **$20.1 million**

- China: **$5.8 million**

- Japan: **$6.0 million**

Notes and Assumptions:

- Patient population estimates are based on general NHL and FL epidemiology data and may vary with more precise data.

- Pricing assumptions are based on Kymriah's pricing in other indications and adjusted for regional differences.

- Market share of 20-30% assumes competition from other therapies (e.g., other CAR-T therapies, bispecific antibodies).

- These calculations assume full market access and reimbursement in all regions, which may not yet be the case (especially in China).

- Peak sales are annual figures at steady-state market penetration, typically 5-7 years post-launch in each region.

If you have access to more specific data (e.g., exact patient numbers or pricing), these estimates can be refined further.