To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of persistent, recurrent, or metastatic cervical cancer with PD-L1 expression (CPS ≥1) 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. Since specific data (e.g., exact patient numbers, pricing, or market penetration) isn't provided, I'll make reasonable assumptions based on publicly available data, epidemiology, and market trends for oncology drugs. I'll outline the methodology and provide illustrative numbers.

Step 1: Define the Target Patient Population

- **Indication**: Pembrolizumab is approved for persistent, recurrent, or metastatic cervical cancer with PD-L1 expression (CPS ≥1).

- **Epidemiology of Cervical Cancer**:

- Cervical cancer incidence varies by region due to differences in screening and HPV vaccination rates.

- Persistent, recurrent, or metastatic cases typically represent advanced-stage patients, which are a subset of total cervical cancer cases (approximately 20-30% of diagnosed cases progress to advanced stages).

- PD-L1 expression (CPS ≥1) is present in ~80-85% of cervical cancer patients based on clinical trial data for pembrolizumab (e.g., KEYNOTE-826 trial).

- **Estimated Annual Incidence of Cervical Cancer** (2023 estimates based on GLOBOCAN and other sources):

- US: ~13,000 new cases; ~30% advanced = ~3,900; ~85% PD-L1+ = ~3,300 eligible patients.

- EU5: ~34,000 new cases; ~30% advanced = ~10,200; ~85% PD-L1+ = ~8,700 eligible patients.

- China: ~110,000 new cases; ~30% advanced = ~33,000; ~85% PD-L1+ = ~28,000 eligible patients.

- Japan: ~13,000 new cases; ~30% advanced = ~3,900; ~85% PD-L1+ = ~3,300 eligible patients.

- **Total Eligible Patients**: ~3,300 (US) + 8,700 (EU5) + 28,000 (China) + 3,300 (Japan) = ~43,300 patients annually.

Step 2: Estimate Treated Patient Share

- The question assumes a **20% to 30% share of treated patients** for pembrolizumab in this indication.

- Factors influencing share include:

- Competition (e.g., other immunotherapies, chemotherapy regimens).

- Market access, reimbursement, and physician adoption.

- For calculation, let’s use the midpoint of **25% treated patient share**.

- **Treated Patients**:

- US: 3,300 * 25% = 825 patients.

- EU5: 8,700 * 25% = 2,175 patients.

- China: 28,000 * 25% = 7,000 patients.

- Japan: 3,300 * 25% = 825 patients.

- **Total Treated Patients**: 825 + 2,175 + 7,000 + 825 = ~10,825 patients annually.

Step 3: Estimate Annual Cost per Patient

- Pembrolizumab pricing varies by region due to healthcare systems, negotiations, and discounts.

- **Annual Cost per Patient** (based on typical dosing for advanced cancers, e.g., 200 mg every 3 weeks, and published list prices or estimates):

- US: ~$150,000–$180,000 per year.

- EU5: ~$100,000–$120,000 per year (lower due to negotiated pricing).

- China: ~$50,000–$70,000 per year (lower pricing due to market access programs and generics competition).

- Japan: ~$120,000–$140,000 per year (similar to EU5 but with specific pricing structures).

- For simplicity, use midpoint estimates:

- US: $165,000.

- EU5: $110,000.

- China: $60,000.

- Japan: $130,000.

Step 4: Calculate Potential Peak Sales

- **Peak Sales** = (Number of Treated Patients) * (Annual Cost per Patient) for each region.

- US: 825 patients * $165,000 = **$136.1 million**.

- EU5: 2,175 patients * $110,000 = **$239.3 million**.

- China: 7,000 patients * $60,000 = **$420.0 million**.

- Japan: 825 patients * $130,000 = **$107.3 million**.

- **Total Peak Sales**: $136.1M (US) + $239.3M (EU5) + $420.0M (China) + $107.3M (Japan) = **~$902.7 million annually**.

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

- First, calculate the total eligible patients per region (from Step 1).

- Then, calculate revenue for 1% of treated patients using the annual cost per patient.

- US: 3,300 patients * 1% = 33 patients; 33 * $165,000 = **$5.4 million**.

- EU5: 8,700 patients * 1% = 87 patients; 87 * $110,000 = **$9.6 million**.

- China: 28,000 patients * 1% = 280 patients; 280 * $60,000 = **$16.8 million**.

- Japan: 3,300 patients * 1% = 33 patients; 33 * $130,000 = **$4.3 million**.

- **Total $ Value of 1% Share**: $5.4M (US) + $9.6M (EU5) + $16.8M (China) + $4.3M (Japan) = **~$36.1 million**.

Final Answer

- **Potential Peak Sales for Pembrolizumab** (at 25% treated patient share) in the specified indication across the US, EU5, China, and Japan: **~$902.7 million annually**.

- US: $136.1 million.

- EU5: $239.3 million.

- China: $420.0 million.

- Japan: $107.3 million.

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

- US: $5.4 million.

- EU5: $9.6 million.

- China: $16.8 million.

- Japan: $4.3 million.

- Total: **~$36.1 million**.

Notes and Caveats

- These estimates are based on assumptions for patient numbers, PD-L1 positivity rates, treatment share, and pricing. Real-world figures may vary due to competition, reimbursement policies, and actual market uptake.

- Peak sales assume steady-state market penetration, which may take several years post-approval to achieve.

- Pricing in China is particularly variable due to government negotiations and volume-based procurement policies.

- If more specific data (e.g., exact patient numbers or trial data) is available, these estimates can be refined.