To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the specified indication—neoadjuvant and adjuvant treatment for resectable non-small cell lung cancer (NSCLC) with tumors ≥4 cm or node-positive—in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **$ value of a 1% share of treated patients**, we need to follow a structured approach. Since exact data on patient populations, pricing, and market dynamics may not be fully available, I will outline the methodology and provide reasonable assumptions based on publicly available information and industry trends. The final numbers are illustrative and should be validated with up-to-date market research or proprietary data.

Step 1: Define the Target Indication and Patient Population

- **Indication**: Pembrolizumab is approved for neoadjuvant treatment (with platinum-containing chemotherapy) and adjuvant treatment (as a single agent) for resectable NSCLC with tumors ≥4 cm or node-positive.

- **Patient Population**: We need to estimate the number of patients eligible for this treatment in the specified geographies. NSCLC accounts for ~85% of lung cancer cases, and resectable cases (stages IB-IIIA, where surgery is feasible) represent a subset. Tumors ≥4 cm or node-positive typically correspond to stages II and IIIA.

Estimated Incidence and Eligible Patients:

- **US**: Lung cancer incidence is ~230,000 cases/year. NSCLC is ~195,500 cases. Resectable NSCLC (stages IB-IIIA) is ~20-25% of cases (~39,000-49,000 patients). Tumors ≥4 cm or node-positive may narrow this to ~50-60% of resectable cases, so ~20,000-29,000 patients.

- **EU5**: Combined lung cancer incidence is ~320,000 cases/year. NSCLC is ~272,000. Resectable cases (~20-25%) are ~54,000-68,000. Eligible subset (~50-60%) is ~27,000-41,000 patients.

- **China**: Lung cancer incidence is ~820,000 cases/year. NSCLC is ~697,000. Resectable cases (~20-25%) are ~139,000-174,000. Eligible subset (~50-60%) is ~70,000-104,000 patients.

- **Japan**: Lung cancer incidence is ~130,000 cases/year. NSCLC is ~110,500. Resectable cases (~20-25%) are ~22,000-27,500. Eligible subset (~50-60%) is ~11,000-16,500 patients.

Total Eligible Patients (midpoint estimate):

- US: ~24,500 patients

- EU5: ~34,000 patients

- China: ~87,000 patients

- Japan: ~13,750 patients

- **Total**: ~159,250 patients

Treated Patients:

Not all eligible patients receive treatment due to access, cost, or clinical decisions. Assuming a treatment rate of 70-80%:

- US: ~17,000-19,500 (midpoint: 18,250)

- EU5: ~24,000-27,000 (midpoint: 25,500)

- China: ~61,000-70,000 (midpoint: 65,500)

- Japan: ~9,500-11,000 (midpoint: 10,250)

- **Total Treated Patients**: ~119,500

Step 2: Market Share Assumption

The query assumes a 20-30% share of treated patients for pembrolizumab in this indication. This is reasonable given Keytruda's established position in NSCLC and its first-mover advantage in this specific setting.

- Midpoint share: 25%

- **Treated Patients on Pembrolizumab**: 25% of 119,500 = ~29,875 patients

Breakdown by Geography (at 25% share):

- US: 25% of 18,250 = ~4,560 patients

- EU5: 25% of 25,500 = ~6,375 patients

- China: 25% of 65,500 = ~16,375 patients

- Japan: 25% of 10,250 = ~2,565 patients

Step 3: Pricing and Treatment Duration

Pembrolizumab pricing varies by region due to healthcare systems, negotiations, and discounts. Treatment duration for neoadjuvant (pre-surgery) and adjuvant (post-surgery) settings in NSCLC is typically up to 1 year (based on clinical trial designs like KEYNOTE-671).

Annual Cost per Patient (Estimated):

- **US**: ~$150,000/year (list price, though discounts may apply)

- **EU5**: ~$100,000/year (lower due to negotiations and health system pricing)

- **China**: ~$50,000/year (significantly discounted due to National Reimbursement Drug List inclusion and local competition)

- **Japan**: ~$120,000/year (closer to US pricing but with some discounts)

Total Annual Revenue per Patient:

- US: $150,000 x 4,560 patients = $684 million

- EU5: $100,000 x 6,375 patients = $637.5 million

- China: $50,000 x 16,375 patients = $818.75 million

- Japan: $120,000 x 2,565 patients = $307.8 million

- **Total Potential Peak Sales (at 25% share)**: ~$2,448 million (~$2.45 billion)

Range for Peak Sales (20-30% Share):

- At 20% share (23,900 patients): ~$1.96 billion

- At 30% share (35,850 patients): ~$2.94 billion

- **Midpoint (25%) Peak Sales**: ~$2.45 billion

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

1% of total treated patients = 1% of 119,500 = ~1,195 patients

Revenue for 1% Share:

- US: 1% of 18,250 = 182.5 patients x $150,000 = $27.375 million

- EU5: 1% of 25,500 = 255 patients x $100,000 = $25.5 million

- China: 1% of 65,500 = 655 patients x $50,000 = $32.75 million

- Japan: 1% of 10,250 = 102.5 patients x $120,000 = $12.3 million

- **Total $ Value of 1% Share**: ~$97.925 million (~$98 million)

Final Answers

1. **Potential Peak Sales for Pembrolizumab in this Indication (20-30% Share)**:

- US, EU5, China, and Japan combined: **$1.96 billion to $2.94 billion**, with a midpoint of **$2.45 billion** at 25% market share.

- Breakdown (at 25% share):

- US: ~$684 million

- EU5: ~$637.5 million

- China: ~$818.75 million

- Japan: ~$307.8 million

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

- US, EU5, China, and Japan combined: **~$98 million**

- Breakdown:

- US: ~$27.4 million

- EU5: ~$25.5 million

- China: ~$32.75 million

- Japan: ~$12.3 million

Caveats and Assumptions

- Patient population estimates are based on general epidemiology data for NSCLC and assumptions about resectability and eligibility criteria.

- Pricing is approximate and varies by country due to discounts, reimbursement policies, and local competition.

- Market share (20-30%) assumes pembrolizumab maintains a strong position, though competition from other PD-1/PD-L1 inhibitors (e.g., nivolumab, atezolizumab) could impact this.

- Peak sales assume steady-state adoption and do not account for market entry delays or patent expiry (pembrolizumab's patent is expected to expire around 2028 in the US, though biosimilars may take time to impact sales).

These estimates should be refined with primary market research, clinical trial data, and updated pricing/access information for accuracy.