

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the adjuvant treatment of stage IB (T2a  $\geq$  4 cm), II, or IIIA non-small cell lung cancer (NSCLC) 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 exact data on patient numbers, pricing, and market penetration may not be publicly available in real-time, I will outline the methodology and use reasonable assumptions based on available data and market trends up to my knowledge cutoff in October 2023. Please note that these are illustrative calculations and should be validated with current market data.

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## **Step 1: Define the Indication and Target Patient Population**

Pembrolizumab is approved for adjuvant treatment following resection and platinum-based chemotherapy for stage IB (T2a  $\geq$  4 cm), II, or IIIA NSCLC. This is a specific subset of NSCLC patients who are eligible for adjuvant therapy post-surgery.

- **NSCLC Epidemiology:** NSCLC accounts for ~85% of all lung cancer cases. Stages IB, II, and IIIA represent early to locally advanced stages, with a significant proportion of patients eligible for surgical resection followed by adjuvant therapy.

- **Target Population:** We need to estimate the number of patients in these stages who undergo resection and are eligible for adjuvant therapy in the US, EU5, China, and Japan.

#### Approximate Incidence and Eligible Patients

- **US:** ~193,000 new lung cancer cases annually (SEER data); ~85% NSCLC (~164,000). Stages IB-IIIa account for ~30-40% of NSCLC (~49,000-65,000). Assuming 50-60% are eligible for resection and adjuvant therapy, ~25,000-39,000 patients.

- **EU5:** Combined lung cancer incidence ~250,000 annually; ~85% NSCLC (~212,500). Stages IB-IIIa ~30-40% (~64,000-85,000). Assuming 50-60% eligibility, ~32,000-51,000 patients.

- **China:** ~820,000 new lung cancer cases annually; ~85% NSCLC (~697,000). Stages IB-IIIa ~30-40% (~209,000-279,000). Assuming 40-50% eligibility (lower surgery rates), ~84,000-139,000 patients.

- **Japan:** ~125,000 new lung cancer cases annually; ~85% NSCLC (~106,000). Stages IB-IIIa ~30-40% (~32,000-42,000). Assuming 50-60% eligibility, ~16,000-25,000 patients.

**Total Eligible Patients (Midpoint Estimates):**

- US: ~32,000

- EU5: ~41,500

- China: ~111,500

- Japan: ~20,500

- **Total:** ~205,500 patients

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## **Step 2: Estimate Market Penetration (20%-30% Share of Treated Patients)**

The problem assumes a 20%-30% share of treated patients for pembrolizumab in this indication. This accounts for competition (e.g., other immunotherapies like atezolizumab in adjuvant NSCLC) and treatment preferences.

- **Low-End (20%):**  $205,500 * 0.2 = \sim 41,100$  patients treated with pembrolizumab.

- **High-End (30%):**  $205,500 * 0.3 = \sim 61,650$  patients treated with pembrolizumab.

#### Breakdown by Geography (Midpoint of 25% Penetration for Simplicity):

- US:  $32,000 * 0.25 = 8,000$  patients

- EU5:  $41,500 * 0.25 = 10,375$  patients

- China:  $111,500 * 0.25 = 27,875$  patients

- Japan:  $20,500 * 0.25 = 5,125$  patients

- **Total:**  $\sim 51,375$  patients

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### **Step 3: Estimate Treatment Cost per Patient**

Pembrolizumab pricing varies by region due to differences in healthcare systems, negotiations, and discounts. Adjuvant therapy typically involves a defined treatment duration (e.g., 1 year or until disease progression). Based on clinical trial data (e.g., KEYNOTE-091), assume treatment for  $\sim 1$  year.

- **US:** Annual cost  $\sim \$150,000$ -\$200,000 (list price before discounts; assume \$175,000 for calculation).

- **EU5:** Annual cost  $\sim \$80,000$ -\$120,000 (lower due to negotiated pricing; assume \$100,000).

- **China:** Annual cost  $\sim \$30,000$ -\$50,000 (significant discounts via National Reimbursement Drug List; assume \$40,000).

- **Japan:** Annual cost  $\sim \$100,000$ -\$130,000 (assume \$115,000).

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### **Step 4: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each geography.

#### Using Midpoint Penetration (25% Share):

- **US:**  $8,000 \text{ patients} * \$175,000 = \text{\$1.4 billion}$

- **EU5:**  $10,375 \text{ patients} * \$100,000 = \text{\$1.04 billion}$

- **China:**  $27,875 \text{ patients} * \$40,000 = \text{\$1.11 billion}$

- **Japan:**  $5,125 \text{ patients} * \$115,000 = \text{\$0.59 billion}$

- **Total Peak Sales (25% Share):**  $\text{\$4.14 billion}$

#### Range for 20%-30% Share:

- **20% Share:** Total patients = 41,100

- US:  $6,400 * \$175,000 = \$1.12\text{B}$

- EU5:  $8,300 * \$100,000 = \$0.83\text{B}$

- China:  $22,300 * \$40,000 = \$0.89\text{B}$

- Japan:  $4,100 * \$115,000 = \$0.47\text{B}$

- **Total: \$3.31 billion**

- **30% Share:** Total patients = 61,650

- US:  $9,600 * \$175,000 = \$1.68\text{B}$

- EU5:  $12,450 * \$100,000 = \$1.25\text{B}$

- China:  $33,450 * \$40,000 = \$1.34\text{B}$

- Japan:  $6,150 * \$115,000 = \$0.71\text{B}$

- **Total: \$4.98 billion**

**Potential Peak Sales Range: \$3.31 billion to \$4.98 billion annually.**

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population (205,500 patients) = **2,055 patients**.

#### Value of 1% Share by Geography:

- **US:**  $32,000 * 0.01 = 320 \text{ patients} * \$175,000 = \$56 \text{ million}$

- **EU5:**  $41,500 * 0.01 = 415 \text{ patients} * \$100,000 = \$41.5 \text{ million}$

- **China:**  $111,500 * 0.01 = 1,115 \text{ patients} * \$40,000 = \$44.6 \text{ million}$

- **Japan:**  $20,500 * 0.01 = 205 \text{ patients} * \$115,000 = \$23.6 \text{ million}$

- **Total Value of 1% Share: \$165.7 million**

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## **Final Answer**

- **Potential Peak Sales for Pembrolizumab** in adjuvant treatment of stage IB-IIIa NSCLC (20%-30% share of treated patients) in the US, EU5, China, and Japan: **\$3.31 billion to \$4.98 billion annually.**

- **\$ Value of 1% Share of Treated Patients** in these geographies: **\$165.7 million annually.**

**Note:** These estimates are based on assumptions about patient numbers, pricing, and market penetration. Real-world figures may differ due to competition, reimbursement policies, and evolving treatment guidelines. For precise forecasts, consult recent market research reports or financial analyses from sources like EvaluatePharma, GlobalData, or Merck's investor reports.