

To estimate the **Potential Peak Sales** for nivolumab (Opdivo) in the neoadjuvant setting for resectable 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 make several assumptions and follow a structured approach. Since specific data (e.g., exact patient numbers, pricing, or market penetration) is not provided, I will outline the methodology and use reasonable estimates based on publicly available information and industry trends. Please note that these are illustrative calculations and should be validated with real-world data for accuracy.

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

- **Indication:** Nivolumab in combination with platinum-doublet chemotherapy for resectable NSCLC in the neoadjuvant setting (pre-surgical treatment).

- **Target Population:** Patients with resectable NSCLC (typically stages IB to IIIA, depending on guidelines). Not all NSCLC patients are eligible for surgery, and neoadjuvant therapy is used in a subset of resectable cases to shrink tumors before surgery.

### #### Estimated Incidence of NSCLC and Resectable Cases

- **US:** ~235,000 new NSCLC cases/year; ~30% are resectable (~70,500 patients).

- **EU5:** ~320,000 new NSCLC cases/year; ~30% resectable (~96,000 patients).

- **China:** ~820,000 new NSCLC cases/year; ~25% resectable (~205,000 patients, lower due to late diagnosis trends).

- **Japan:** ~125,000 new NSCLC cases/year; ~35% resectable (~43,750 patients).

### #### Eligible for Neoadjuvant Therapy

Neoadjuvant therapy is typically used in ~20-30% of resectable cases (e.g., stage II-IIIa). Let's assume 25% of resectable patients are eligible:

- **US:**  $70,500 * 0.25 = \sim 17,625$  patients.

- **EU5:**  $96,000 * 0.25 = \sim 24,000$  patients.

- **China:**  $205,000 * 0.25 = \sim 51,250$  patients.

- **Japan:**  $43,750 * 0.25 = \sim 10,938$  patients.

**Total Eligible Patients Across Geographies:**  $17,625 + 24,000 + 51,250 + 10,938 = \mathbf{103,813}$  patients/year.

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## **Step 2: Market Share Assumption**

The problem states a **20% to 30% share of treated patients**. This implies nivolumab's penetration among eligible patients. Let's calculate peak sales for both ends of the range:

- **Low End:** 20% market share.

- **High End:** 30% market share.

#### Treated Patients with Nivolumab

- **20% Share:**

- US:  $17,625 * 0.2 = 3,525$  patients.

- EU5:  $24,000 * 0.2 = 4,800$  patients.

- China:  $51,250 * 0.2 = 10,250$  patients.

- Japan:  $10,938 * 0.2 = 2,188$  patients.

- **Total:** 20,763 patients.

- **30% Share:**

- US:  $17,625 * 0.3 = 5,288$  patients.

- EU5:  $24,000 * 0.3 = 7,200$  patients.

- China:  $51,250 * 0.3 = 15,375$  patients.

- Japan:  $10,938 * 0.3 = 3,281$  patients.

- **Total:** 31,144 patients.

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### **Step 3: Pricing of Nivolumab per Patient**

Nivolumab is typically administered in cycles, and in the neoadjuvant setting, treatment duration is shorter than in metastatic settings (e.g., 3-4 cycles before surgery). Let's estimate the cost per patient based on available data for Opdivo:

- **US:** ~\$150,000 per patient for a full course (based on ~\$12,000-\$15,000 per dose, 3-4 cycles).

- **EU5:** ~\$100,000 per patient (lower due to pricing negotiations).

- **Japan:** ~\$120,000 per patient (similar to EU but with some variation).

- **China:** ~\$50,000 per patient (lower due to pricing controls and local competition).

These are rough estimates and vary based on dosing, duration, and reimbursement policies.

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

Peak sales are calculated as (number of treated patients) \* (cost per patient) for each geography.

#### At 20% Market Share

- **US:**  $3,525 \text{ patients} * \$150,000 = \$528.8 \text{ million.}$

- **EU5:**  $4,800 \text{ patients} * \$100,000 = \$480.0 \text{ million.}$

- **China:** 10,250 patients \* \$50,000 = **\$512.5 million.**
- **Japan:** 2,188 patients \* \$120,000 = **\$262.6 million.**
- **Total Peak Sales (20%):** \$528.8M + \$480.0M + \$512.5M + \$262.6M = **\$1,784 million (~\$1.78 billion).**

#### At 30% Market Share

- **US:** 5,288 patients \* \$150,000 = **\$793.2 million.**
- **EU5:** 7,200 patients \* \$100,000 = **\$720.0 million.**
- **China:** 15,375 patients \* \$50,000 = **\$768.8 million.**
- **Japan:** 3,281 patients \* \$120,000 = **\$393.7 million.**
- **Total Peak Sales (30%):** \$793.2M + \$720.0M + \$768.8M + \$393.7M = **\$2,676 million (~\$2.68 billion).**

**Potential Peak Sales Range: \$1.78 billion to \$2.68 billion annually** across the US, EU5, China, and Japan for this indication.

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

A 1% share corresponds to 1% of the eligible patient population in each geography.

#### Eligible Patients (1% Share)

- **US:** 17,625 \* 0.01 = 176 patients.
- **EU5:** 24,000 \* 0.01 = 240 patients.
- **China:** 51,250 \* 0.01 = 513 patients.
- **Japan:** 10,938 \* 0.01 = 109 patients.
- **Total:** 1,038 patients.

#### Revenue for 1% Share

- **US:** 176 patients \* \$150,000 = **\$26.4 million.**
- **EU5:** 240 patients \* \$100,000 = **\$24.0 million.**
- **China:** 513 patients \* \$50,000 = **\$25.7 million.**
- **Japan:** 109 patients \* \$120,000 = **\$13.1 million.**
- **Total Value of 1% Share:** \$26.4M + \$24.0M + \$25.7M + \$13.1M = **\$89.2 million.**

**\$ Value of 1% Share of Treated Patients: \$89.2 million annually** across the US, EU5, China, and Japan.

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## **Final Answer**

- **Potential Peak Sales for Nivolumab** in the neoadjuvant setting for resectable NSCLC (assuming 20% to 30% market share):
- **Range: \$1.78 billion to \$2.68 billion annually** across the US, EU5, China, and Japan.
- **\$ Value of 1% Share of Treated Patients: \$89.2 million annually** across the same geographies.

**Note:** These estimates are based on assumptions about patient populations, pricing, and market penetration. Real-world data, including competition (e.g., other immunotherapies like pembrolizumab), reimbursement policies, and treatment adoption rates, could significantly alter these figures. For precise calculations, consult epidemiology data, pricing agreements, and market access reports specific to each region.