

To estimate the **Potential Peak Sales** for nivolumab (Opdivo) in the specified indication (neoadjuvant and adjuvant treatment 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**, we need to follow a structured approach. Since specific data on patient numbers, pricing, and market penetration may not be fully available, I will outline the methodology and use reasonable assumptions based on publicly available data and industry standards. 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:** Neoadjuvant treatment with nivolumab + platinum-doublet chemotherapy, followed by adjuvant nivolumab, for resectable NSCLC (tumors  $\geq 4$  cm and/or node-positive) without EGFR mutations or ALK rearrangements.

- **Eligible Patients:** This applies to early-stage NSCLC patients (Stage IB-IIIa) who are candidates for surgery. Approximately 20-30% of NSCLC patients are diagnosed at an early stage, and a subset of these will meet the specific criteria (resectable, specific tumor size/node status, no EGFR/ALK mutations).

## **Step 2: Estimate the Addressable Patient Population**

Using approximate incidence rates for NSCLC and adjusting for the specific indication:

- **US:** ~230,000 new NSCLC cases/year. ~25% are early-stage (resectable), and ~80% lack EGFR/ALK mutations. So, ~46,000 patients may be eligible.

- **EU5:** ~260,000 new NSCLC cases/year. Applying similar proportions, ~52,000 eligible patients.

- **China:** ~800,000 new NSCLC cases/year. ~25% early-stage, 80% no mutations, ~160,000 eligible patients.

- **Japan:** ~125,000 new NSCLC cases/year. ~25% early-stage, 80% no mutations, ~25,000 eligible patients.

**Total Eligible Patients:** ~283,000 across all geographies.

Given the 20-30% share of treated patients:

- **Treated Patients (20-30%):** ~56,600 to ~84,900 patients annually.

## **Step 3: Estimate Treatment Cost and Duration**

- **Nivolumab Pricing:** Pricing varies by region due to healthcare systems and negotiations.

- **US:** ~\$15,000/month (based on typical immunotherapy costs).

- **EU5:** ~\$8,000-\$10,000/month (discounts due to payer negotiations).

- **China:** ~\$5,000/month (lower due to pricing controls and local competition).

- **Japan:** ~\$10,000/month (similar to EU5).

- **Treatment Duration:** Neoadjuvant (pre-surgery) and adjuvant (post-surgery) treatment may span 6-12 months total, depending on protocol. Assume an average of 9 months of treatment.

**Annual Cost per Patient ( illustrative):**

- US:  $\$15,000 \times 9 = \$135,000$
- EU5:  $\$9,000 \times 9 = \$81,000$
- China:  $\$5,000 \times 9 = \$45,000$
- Japan:  $\$10,000 \times 9 = \$90,000$

**Step 4: Calculate Potential Peak Sales (20-30% Market Share)**

Using the estimated number of treated patients and per-patient cost:

##### At 20% Market Share (~56,600 patients):

- **US:** 9,200 patients x \$135,000 = \$1.24 billion
- **EU5:** 10,400 patients x \$81,000 = \$0.84 billion
- **China:** 32,000 patients x \$45,000 = \$1.44 billion
- **Japan:** 5,000 patients x \$90,000 = \$0.45 billion
- **Total Peak Sales (20%):** ~\$4.0 billion

##### At 30% Market Share (~84,900 patients):

- **US:** 13,800 patients x \$135,000 = \$1.86 billion
- **EU5:** 15,600 patients x \$81,000 = \$1.26 billion
- **China:** 48,000 patients x \$45,000 = \$2.16 billion
- **Japan:** 7,500 patients x \$90,000 = \$0.68 billion
- **Total Peak Sales (30%):** ~\$6.0 billion

**Potential Peak Sales Range: \$4.0 billion to \$6.0 billion** annually across these geographies.

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

1% of the total eligible patients (~283,000) is ~2,830 patients. Using the same per-patient cost:

- **US:** 460 patients x \$135,000 = \$62.1 million
- **EU5:** 520 patients x \$81,000 = \$42.1 million
- **China:** 1,600 patients x \$45,000 = \$72.0 million
- **Japan:** 250 patients x \$90,000 = \$22.5 million
- **Total Value of 1% Share:** ~\$198.7 million

**\$ Value of 1% Share of Treated Patients: ~\$200 million** annually.

**Key Assumptions and Caveats**

1. **Patient Population:** Incidence rates and eligibility criteria are based on general NSCLC epidemiology. Exact numbers for resectable, node-positive, or specific tumor size patients may vary.
2. **Market Share:** Assumes 20-30% penetration, which depends on competition (e.g., other immunotherapies like pembrolizumab), physician adoption, and payer reimbursement.
3. **Pricing:** Costs are illustrative and may differ based on negotiations, discounts, and regional policies. Duration of therapy (9 months) is an estimate.
4. **Peak Sales Timing:** Peak sales may take several years post-approval to achieve, depending on market access and uptake.

## **Final Answer**

- **Potential Peak Sales for Nivolumab in this Indication:** Approximately **\$4.0 billion to \$6.0 billion** annually across the US, EU5, China, and Japan, assuming a 20-30% share of treated patients.
- **\$ Value of 1% Share of Treated Patients:** Approximately **\$200 million** annually across these geographies.

For more precise figures, access to specific market research reports (e.g., from EvaluatePharma, GlobalData) or Bristol Myers Squibb's guidance would be necessary. Would you like me to refine this further with additional data or focus on a specific region?