

To estimate the **Potential Peak Sales** for nivolumab (Opdivo) in the adjuvant treatment of urothelial carcinoma (UC) 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 penetration may vary, I'll outline the methodology and provide reasonable assumptions based on publicly available data and industry standards. If you have specific data or assumptions (e.g., patient numbers or pricing), I can refine the calculations accordingly.

## **Step 1: Key Assumptions and Methodology**

1. **Indication:** Adjuvant treatment of urothelial carcinoma (UC) in patients at high risk of recurrence after radical resection.
2. **Market Share:** Assuming 20% to 30% share of treated patients as per the query.
3. **Geographies:** US, EU5, China, and Japan.
4. **Patient Population:** Estimate the number of eligible patients based on incidence of UC, proportion of patients undergoing radical resection, and proportion at high risk of recurrence.
5. **Pricing:** Use approximate annual treatment costs for nivolumab, which can vary by region due to healthcare systems, negotiations, and discounts.
6. **Peak Sales:** Assume peak sales occur after a few years of market penetration (typically 5-7 years post-launch) with stable market share.
7. **Treatment Duration:** Assume 1 year of adjuvant therapy, as per common practice in oncology for adjuvant settings.

## **Step 2: Estimate Eligible Patient Population**

Urothelial carcinoma (bladder cancer being the most common form) incidence varies by region. We focus on patients undergoing radical resection (e.g., cystectomy for bladder cancer) and at high risk of recurrence (typically Stage II/III or node-positive disease). Below are rough estimates of annual incidence and eligible patients:

### **- US:**

- Incidence of bladder cancer: ~80,000 new cases/year.
- ~20-25% undergo radical resection (15,000-20,000 patients).
- ~50% at high risk of recurrence: ~7,500-10,000 eligible patients.

### **- EU5:**

- Incidence: ~120,000 new cases/year (combined for EU5).
- ~20-25% undergo resection: ~24,000-30,000 patients.
- ~50% high risk: ~12,000-15,000 eligible patients.

### **- China:**

- Incidence: ~80,000 new cases/year.
- ~15-20% undergo resection (lower due to access to surgery): ~12,000-16,000 patients.
- ~50% high risk: ~6,000-8,000 eligible patients.

- **Japan:**

- Incidence: ~20,000 new cases/year.
- ~20-25% undergo resection: ~4,000-5,000 patients.
- ~50% high risk: ~2,000-2,500 eligible patients.

**Total Eligible Patients (midpoint estimate):**

- US: 8,750
- EU5: 13,500
- China: 7,000
- Japan: 2,250
- **Total:** 31,500 patients/year across all geographies.

### **Step 3: Pricing Assumptions**

Nivolumab pricing varies by region due to healthcare systems and negotiations. Approximate annual costs (based on historical data for oncology drugs like Opdivo) are:

- **US:** ~\$150,000 per patient/year (list price, though discounts may apply).
- **EU5:** ~\$80,000-\$100,000 per patient/year (average, varies by country due to negotiations).
- **China:** ~\$50,000 per patient/year (lower due to pricing controls and generics competition).
- **Japan:** ~\$100,000 per patient/year (similar to EU pricing).

For simplicity, we'll use midpoint pricing:

- US: \$150,000
- EU5: \$90,000
- China: \$50,000
- Japan: \$100,000

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

Assuming 20%-30% of eligible patients are treated with nivolumab, we calculate peak sales as follows:

#### At 20% Market Share:

- **US:** 8,750 patients \* 20% = 1,750 patients \* \$150,000 = **\$262.5M**
- **EU5:** 13,500 patients \* 20% = 2,700 patients \* \$90,000 = **\$243M**
- **China:** 7,000 patients \* 20% = 1,400 patients \* \$50,000 = **\$70M**
- **Japan:** 2,250 patients \* 20% = 450 patients \* \$100,000 = **\$45M**
- **Total Peak Sales (20%):** \$262.5M + \$243M + \$70M + \$45M = **\$620.5M**

#### At 30% Market Share:

- **US:** 8,750 patients \* 30% = 2,625 patients \* \$150,000 = **\$393.75M**
- **EU5:** 13,500 patients \* 30% = 4,050 patients \* \$90,000 = **\$364.5M**
- **China:** 7,000 patients \* 30% = 2,100 patients \* \$50,000 = **\$105M**
- **Japan:** 2,250 patients \* 30% = 675 patients \* \$100,000 = **\$67.5M**
- **Total Peak Sales (30%):** \$393.75M + \$364.5M + \$105M + \$67.5M = **\$930.75M**

**Potential Peak Sales Range: \$620M to \$931M annually** across all geographies for this indication.

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

A 1% share corresponds to 1% of the eligible patient population in each region. Using the same pricing:

- **US:** 8,750 patients \* 1% = 87.5 patients \* \$150,000 = **\$13.13M**
- **EU5:** 13,500 patients \* 1% = 135 patients \* \$90,000 = **\$12.15M**
- **China:** 7,000 patients \* 1% = 70 patients \* \$50,000 = **\$3.5M**
- **Japan:** 2,250 patients \* 1% = 22.5 patients \* \$100,000 = **\$2.25M**
- **Total \$ Value of 1% Share:** \$13.13M + \$12.15M + \$3.5M + \$2.25M = **\$31.03M**

### **Final Answer:**

1. **Potential Peak Sales for Nivolumab in Adjuvant UC (20%-30% market share):**

- **Range:** \$620 million to \$931 million annually across the US, EU5, China, and Japan.

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

- **Total:** \$31.03 million across the US, EU5, China, and Japan.

### **Notes:**

- These estimates are based on rough approximations of patient numbers and pricing. Actual figures may differ due to real-world access, reimbursement policies, competition (e.g., other immunotherapies), and treatment duration.
- Peak sales could be influenced by market dynamics, such as the entry of biosimilars or new therapies.
- If you have specific data on patient numbers, pricing, or market share assumptions, I can adjust the calculations accordingly.