

To estimate the **Potential Peak Sales** for nivolumab (Opdivo) in the adjuvant treatment of completely resected Stage IIB/C melanoma 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 specific data such as exact patient numbers, pricing, and market penetration may not be publicly available, I will outline the methodology and provide a reasonable estimation based on available data and assumptions. Please note that these are illustrative figures and should be validated with up-to-date market research or proprietary data.

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

Nivolumab is approved for the adjuvant treatment of completely resected Stage IIB/C melanoma in patients aged 12 years and older. Adjuvant therapy is given after surgical resection to reduce the risk of recurrence. Stage IIB/C melanoma represents a subset of early-stage melanoma patients with a higher risk of recurrence.

- **Epidemiology of Melanoma:** Melanoma incidence varies by region, with higher rates in Western countries (US, EU5) compared to Asia (China, Japan). Stage IIB/C typically accounts for ~15-20% of melanoma cases at diagnosis.
- **Eligible Patients:** Only patients with completely resected melanoma are eligible for adjuvant therapy. We assume that ~80-90% of Stage IIB/C patients undergo complete resection and are candidates for adjuvant therapy.
- **Treated Patients:** Not all eligible patients receive adjuvant therapy due to factors like patient/physician preference, comorbidities, or access to treatment. We assume a treatment rate of ~50-70% of eligible patients.

## **Step 2: Estimate the Number of Treated Patients**

Using approximate melanoma incidence rates and assumptions about the proportion of Stage IIB/C patients, resection rates, and treatment rates, we estimate the number of treated patients in each geography.

### **- US:**

- Incidence of melanoma: ~100,000 new cases/year.
- Stage IIB/C: ~15-20% → 15,000-20,000 patients.
- Resected: ~85% → 12,750-17,000 patients.
- Treated with adjuvant therapy: ~60% → **7,650-10,200 patients.**

### **- EU5:**

- Incidence: ~150,000 new cases/year (combined).
- Stage IIB/C: ~15-20% → 22,500-30,000 patients.
- Resected: ~85% → 19,125-25,500 patients.
- Treated: ~60% → **11,475-15,300 patients.**

- **China:**

- Incidence: ~20,000 new cases/year (lower incidence in Asia).
- Stage IIB/C: ~15-20% → 3,000-4,000 patients.
- Resected: ~80% → 2,400-3,200 patients.
- Treated: ~50% → **1,200-1,600 patients.**

- **Japan:**

- Incidence: ~5,000 new cases/year.
- Stage IIB/C: ~15-20% → 750-1,000 patients.
- Resected: ~80% → 600-800 patients.
- Treated: ~60% → **360-480 patients.**

**Total Treated Patients Across Geographies:**

- Low estimate: 7,650 (US) + 11,475 (EU5) + 1,200 (China) + 360 (Japan) = **20,685 patients.**
- High estimate: 10,200 (US) + 15,300 (EU5) + 1,600 (China) + 480 (Japan) = **27,580 patients.**

### **Step 3: Estimate Market Share and Treated Patients for Nivolumab**

The problem assumes a **20% to 30% share of treated patients** for nivolumab. This accounts for competition from other adjuvant therapies (e.g., pembrolizumab, another PD-1 inhibitor approved in this setting).

- **Nivolumab-treated patients (20-30% share):**

- Low estimate (20% of 20,685): ~4,137 patients.
- High estimate (30% of 27,580): ~8,274 patients.

### **Step 4: Estimate Pricing and Treatment Duration**

Nivolumab pricing varies by region due to differences in healthcare systems, negotiations, and purchasing power. Adjuvant treatment for melanoma typically involves a fixed duration (e.g., 1 year of therapy).

- **US Pricing:** ~\$150,000 per patient per year (based on list prices for PD-1 inhibitors).
- **EU5 Pricing:** ~\$80,000-\$100,000 per patient per year (lower due to negotiations).
- **China Pricing:** ~\$50,000 per patient per year (discounted due to market access programs).
- **Japan Pricing:** ~\$100,000 per patient per year (similar to EU5).

### **Step 5: Calculate Potential Peak Sales for Nivolumab**

Using the number of treated patients, market share, and regional pricing, we calculate peak sales.

#### Low Estimate (20% share, low patient numbers):

- **US:** 4,137 patients \* 20% \* \$150,000 = ~\$124 million.
- **EU5:** 11,475 patients \* 20% \* \$90,000 (avg.) = ~\$206 million.
- **China:** 1,200 patients \* 20% \* \$50,000 = ~\$12 million.
- **Japan:** 360 patients \* 20% \* \$100,000 = ~\$7 million.
- **Total Peak Sales (Low):** \$124M + \$206M + \$12M + \$7M = ~\$349 million.

#### High Estimate (30% share, high patient numbers):

- **US:** 10,200 patients \* 30% \* \$150,000 = ~\$459 million.
- **EU5:** 15,300 patients \* 30% \* \$90,000 = ~\$413 million.
- **China:** 1,600 patients \* 30% \* \$50,000 = ~\$24 million.
- **Japan:** 480 patients \* 30% \* \$100,000 = ~\$14 million.
- **Total Peak Sales (High):** \$459M + \$413M + \$24M + \$14M = ~\$910 million.

**Potential Peak Sales Range for Nivolumab: \$349 million to \$910 million annually** across the US, EU5, China, and Japan for this indication.

## **Step 6: Calculate \$ Value of 1% Share of Treated Patients**

Using the total treated patient numbers (low to high estimates) and regional pricing, we calculate the value of a 1% share.

#### Low Estimate (20,685 total treated patients):

- **US:** 7,650 patients \* 1% \* \$150,000 = ~\$11.5 million.
- **EU5:** 11,475 patients \* 1% \* \$90,000 = ~\$10.3 million.
- **China:** 1,200 patients \* 1% \* \$50,000 = ~\$0.6 million.
- **Japan:** 360 patients \* 1% \* \$100,000 = ~\$0.4 million.
- **Total Value of 1% Share (Low):** \$11.5M + \$10.3M + \$0.6M + \$0.4M = ~\$22.8 million.

#### High Estimate (27,580 total treated patients):

- **US:** 10,200 patients \* 1% \* \$150,000 = ~\$15.3 million.
- **EU5:** 15,300 patients \* 1% \* \$90,000 = ~\$13.8 million.
- **China:** 1,600 patients \* 1% \* \$50,000 = ~\$0.8 million.
- **Japan:** 480 patients \* 1% \* \$100,000 = ~\$0.5 million.
- **Total Value of 1% Share (High):** \$15.3M + \$13.8M + \$0.8M + \$0.5M = ~\$30.4 million.

**\$ Value of 1% Share of Treated Patients: \$22.8 million to \$30.4 million annually** across these geographies.

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## **Final Answer**

1. **Potential Peak Sales for Nivolumab** in the adjuvant treatment of Stage IIB/C melanoma (20%-30% market share):

- **\$349 million to \$910 million annually** across the US, EU5, China, and Japan.

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

- **\$22.8 million to \$30.4 million annually** across the US, EU5, China, and Japan.

## **Notes**

- These estimates are based on assumptions about patient numbers, treatment rates, market share, and pricing. Actual figures may vary based on real-world data, competition (e.g., pembrolizumab), market access, and health technology assessments.

- Peak sales typically occur a few years after launch, depending on uptake and penetration.

- For more accurate figures, consult proprietary databases (e.g., IQVIA, GlobalData) or company reports from Bristol-Myers Squibb.