

To estimate the **Potential Peak Sales** for **nivolumab and relatlimab-rmbw (Opdualag)** in the indication of unresectable or metastatic melanoma across the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to make a series of assumptions and calculations based on available data. Since specific patient numbers, pricing, and penetration rates may not be publicly available for this drug in all regions, I will outline a structured approach using reasonable estimates and industry benchmarks. The results will be approximate and should be validated with more precise data if available.

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## **Step 1: Define Key Parameters**

1. **Target Population:** Patients with unresectable or metastatic melanoma (Stage III/IV) eligible for systemic therapy.
2. **Treated Patient Share:** Assuming 20% to 30% of treated patients in this indication will use Opdualag.
3. **Annual Cost of Therapy:** Pricing for Opdualag or similar immunotherapies (e.g., nivolumab or pembrolizumab) will be used as a benchmark.
4. **Peak Sales:** Estimated as the maximum annual revenue after market penetration stabilizes (typically 5-7 years post-launch).
5. **Geographies:** US, EU5, China, Japan.

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

Using epidemiology data for melanoma and the proportion of unresectable or metastatic cases (Stage III/IV), we estimate the eligible patient population. Incidence rates and prevalence of advanced melanoma vary by region due to differences in skin cancer prevalence (higher in Western countries) and healthcare access.

- **US:** ~100,000 new melanoma cases annually; ~10% are unresectable/metastatic at diagnosis, with additional progression. Estimated eligible patients: ~15,000-20,000 annually.

- **EU5:** ~60,000 new melanoma cases annually; ~10% unresectable/metastatic. Estimated eligible patients: ~8,000-12,000.

- **Japan:** ~2,000-3,000 new melanoma cases annually; ~10% unresectable/metastatic. Estimated eligible patients: ~300-500.

- **China:** Lower incidence due to population demographics (~5,000-7,000 new cases annually); ~10% unresectable/metastatic. Estimated eligible patients: ~500-1,000.

**Total Eligible Patients (Approximate):** ~24,000-33,500 across all regions.

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

Assuming systemic therapy is used in most unresectable/metastatic melanoma cases (due to limited alternatives), nearly all eligible patients are treated. With a **20%-30% share of treated patients** for Opdualag, the number of patients on Opdualag would be:

- **US:** 3,000-6,000 patients (20%-30% of 15,000-20,000)
- **EU5:** 1,600-3,600 patients (20%-30% of 8,000-12,000)
- **Japan:** 60-150 patients (20%-30% of 300-500)
- **China:** 100-300 patients (20%-30% of 500-1,000)

**Total Patients on Opdualag:** ~4,760-10,050 annually at peak.

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### **Step 4: Estimate Annual Cost of Therapy**

Opdualag is a combination of nivolumab (anti-PD-1) and relatlimab (anti-LAG-3). Nivolumab (Opdivo) costs approximately **\$150,000-\$180,000 per year** in the US for melanoma. As a combination therapy, Opdualag may be priced higher, potentially **\$200,000-\$250,000 per year** in the US. Pricing in other regions is typically lower due to healthcare systems and negotiations:

- **US:** \$200,000-\$250,000 per patient/year
- **EU5:** \$120,000-\$150,000 per patient/year (discounts due to payer negotiations)
- **Japan:** \$100,000-\$130,000 per patient/year
- **China:** \$50,000-\$80,000 per patient/year (lower due to pricing controls and limited reimbursement)

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

Peak sales are calculated as (Number of Patients) x (Annual Cost per Patient) at the assumed market share (20%-30%).

#### At 20% Market Share:

- **US:** 3,000 patients x \$225,000 (midpoint) = **\$675M**
- **EU5:** 1,600 patients x \$135,000 (midpoint) = **\$216M**
- **Japan:** 60 patients x \$115,000 (midpoint) = **\$7M**
- **China:** 100 patients x \$65,000 (midpoint) = **\$6.5M**
- **Total Peak Sales (20% share): ~\$904.5M**

#### At 30% Market Share:

- **US:** 6,000 patients x \$225,000 = **\$1,350M**

- **EU5:** 3,600 patients x \$135,000 = **\$486M**
- **Japan:** 150 patients x \$115,000 = **\$17.25M**
- **China:** 300 patients x \$65,000 = **\$19.5M**
- **Total Peak Sales (30% share):** ~\$1,873M

**Potential Peak Sales Range: \$900M - \$1.9B annually** across the US, EU5, China, and Japan.

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

To calculate the value of 1% share, divide the number of treated patients by 100 and multiply by the annual cost per patient.

#### Total Eligible Patients:

- US: 17,500 (midpoint) x 1% = 175 patients x \$225,000 = **\$39.4M**
- EU5: 10,000 (midpoint) x 1% = 100 patients x \$135,000 = **\$13.5M**
- Japan: 400 (midpoint) x 1% = 4 patients x \$115,000 = **\$0.46M**
- China: 750 (midpoint) x 1% = 7.5 patients x \$65,000 = **\$0.49M**
- **Total Value of 1% Share:** ~\$53.85M

**\$ Value of 1% Share of Treated Patients:** Approximately **\$54M** across these geographies.

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## **Final Answer**

1. **Potential Peak Sales for Opdualag** in unresectable or metastatic melanoma (20%-30% market share):

- **\$900M to \$1.9B annually** across the US, EU5, China, and Japan.

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

- Approximately **\$54M** across the same geographies.

## **Notes and Caveats**

- These estimates are based on assumptions about patient numbers, pricing, and market share. Real-world data may differ due to competition (e.g., Keytruda, other immunotherapies), reimbursement policies, and regional access.
- Peak sales may be influenced by duration of therapy (e.g., if patients respond well and stay on treatment longer or shorter than assumed).
- China and Japan have lower melanoma incidence and may have slower adoption due to pricing and access challenges.

- Validation with primary market research or company guidance (e.g., Bristol Myers Squibb investor reports) is recommended for precision.