

To estimate the **Potential Peak Sales** for nivolumab (Opdivo) in the indication of advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma in the US, EU5 (France, Germany, 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 patient numbers, pricing, and market penetration data are not provided, I will outline the methodology and make reasonable assumptions based on publicly available data and industry standards as of 2023. Please note that these are illustrative calculations and should be validated with up-to-date market research or proprietary data.

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## **Step 1: Define the Target Patient Population**

The indication is for **advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma**. We will estimate the number of eligible patients in each geography based on incidence rates and prevalence of advanced/metastatic cases.

### #### Incidence and Prevalence Estimates (Approximate)

- **Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma:** These cancers are often grouped together in epidemiological data. According to global cancer statistics (e.g., GLOBOCAN 2020), the incidence of gastric and esophageal cancers varies by region, with higher rates in East Asia (e.g., China, Japan) compared to Western countries.

- **Stage Distribution:** Approximately 30-40% of patients are diagnosed at an advanced or metastatic stage (Stage III/IV), making them eligible for systemic therapies like nivolumab.

### #### Estimated Annual New Cases (Advanced/Metastatic) in 2023:

- **US:** ~27,000 new cases of gastric/esophageal cancer; ~40% advanced/metastatic = ~10,800 patients.

- **EU5:** ~60,000 new cases (combined across 5 countries); ~40% advanced/metastatic = ~24,000 patients.

- **China:** ~500,000 new cases (highest incidence globally); ~40% advanced/metastatic = ~200,000 patients.

- **Japan:** ~130,000 new cases; ~40% advanced/metastatic = ~52,000 patients.

- **Total:** ~286,800 advanced/metastatic patients annually across these geographies.

### #### Treated Patient Population:

Not all diagnosed patients receive treatment due to factors like comorbidities, access to care, or late diagnosis. Assuming ~70-80% of advanced/metastatic patients receive systemic therapy:

- **US:** ~8,600 treated patients.

- **EU5:** ~19,200 treated patients.

- **China:** ~160,000 treated patients (lower treatment rate due to access issues, assumed ~80%).

- **Japan:** ~41,600 treated patients.

- **Total Treated Patients:** ~229,400.

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

The query assumes a **20-30% share of treated patients** for nivolumab. This is reasonable for a novel immunotherapy like nivolumab, especially in combination with chemotherapy, given its efficacy (e.g., based on trials like CheckMate-649, which showed improved overall survival). We'll use the midpoint of **25%** for calculations.

#### Estimated Treated Patients on Nivolumab:

- **US:** 25% of 8,600 = ~2,150 patients.
- **EU5:** 25% of 19,200 = ~4,800 patients.
- **China:** 25% of 160,000 = ~40,000 patients.
- **Japan:** 25% of 41,600 = ~10,400 patients.
- **Total:** ~57,350 patients.

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## **Step 3: Pricing and Treatment Duration**

Nivolumab is an expensive immunotherapy. Pricing varies by region due to healthcare systems, negotiations, and access programs. Annual treatment cost estimates are based on typical pricing for PD-1 inhibitors:

- **US:** ~\$150,000 per patient per year (based on list price, though discounts may apply).
- **EU5:** ~\$80,000–\$100,000 per patient per year (varies by country, averaged at \$90,000).
- **China:** ~\$30,000–\$50,000 per patient per year (lower due to pricing controls and generics/biosimilars, averaged at \$40,000).
- **Japan:** ~\$80,000–\$100,000 per patient per year (similar to EU, averaged at \$90,000).

**Treatment Duration:** Patients with advanced/metastatic disease may receive treatment for ~6-12 months on average (depending on response, progression, or toxicity). For simplicity, assume an average of 1 year of treatment for peak sales calculation.

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

Peak sales are calculated as: **Number of Treated Patients on Nivolumab × Annual Cost per Patient.**

#### Peak Sales by Geography (at 25% Market Share):

- **US:** 2,150 patients × \$150,000 = **\$322.5 million.**
- **EU5:** 4,800 patients × \$90,000 = **\$432 million.**

- **China:** 40,000 patients × \$40,000 = **\$1,600 million** (or \$1.6 billion).
- **Japan:** 10,400 patients × \$90,000 = **\$936 million**.
- **Total Peak Sales:** **\$3,290.5 million** (or ~\$3.3 billion).

#### Range Based on 20-30% Market Share:

- **20% Share:** Total treated patients = ~45,880; Peak Sales = ~\$2.63 billion.
- **30% Share:** Total treated patients = ~68,820; Peak Sales = ~\$3.95 billion.
- **Range:** **\$2.6–\$4.0 billion** annually at peak.

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

A 1% share of treated patients corresponds to 1% of the total treated population (~229,400 patients) = **2,294 patients**.

#### Revenue from 1% Share by Geography:

- **US:** 1% of 8,600 = 86 patients × \$150,000 = **\$12.9 million**.
- **EU5:** 1% of 19,200 = 192 patients × \$90,000 = **\$17.3 million**.
- **China:** 1% of 160,000 = 1,600 patients × \$40,000 = **\$64.0 million**.
- **Japan:** 1% of 41,600 = 416 patients × \$90,000 = **\$37.4 million**.
- **Total \$ Value of 1% Share:** **\$131.6 million**.

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## **Final Answer**

1. **Potential Peak Sales for Nivolumab** in the indication (advanced/metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma) across the US, EU5, China, and Japan, assuming a 20-30% market share:

- Range: **\$2.6 billion to \$4.0 billion annually**.
- Midpoint (25% share): **\$3.3 billion annually**.

Breakdown by Geography (at 25% share):

- US: **\$322.5 million**.
- EU5: **\$432 million**.
- China: **\$1,600 million**.
- Japan: **\$936 million**.

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

- Total: **\$131.6 million.**
- Breakdown:
- US: **\$12.9 million.**
- EU5: **\$17.3 million.**
- China: **\$64.0 million.**
- Japan: **\$37.4 million.**

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## **Caveats and Assumptions**

- **Patient Numbers:** Incidence and treatment rates are approximated based on global cancer statistics and may vary by country or year.
- **Pricing:** Costs are estimated and may differ due to discounts, reimbursement policies, or biosimilar competition.
- **Market Share:** 20-30% is assumed based on immunotherapy adoption; actual penetration depends on competition (e.g., pembrolizumab, other PD-1/PD-L1 inhibitors), guideline recommendations, and payer access.
- **Treatment Duration:** Assumed as 1 year; real-world duration may be shorter or longer based on clinical outcomes.

For more accurate estimates, consult market research reports (e.g., EvaluatePharma, GlobalData), clinical trial data, or Bristol Myers Squibb's financial guidance.