To estimate the **Potential Peak Sales** for nivolumab (Opdivo) in the indication of completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease post-neoadjuvant chemoradiotherapy, as well as the \$ value of 1% share of treated patients in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, we need to follow a structured approach. Since specific data on patient population, pricing, and penetration rates may not be fully available, I will make reasonable assumptions based on publicly available information, oncology market trends, and the nature of the indication. Here's the step-by-step analysis:

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# \*\*Key Assumptions and Methodology\*\*

- 1. **Indication Scope**: Nivolumab is approved as an adjuvant therapy for esophageal or GEJ cancer patients with residual disease after neoadjuvant chemoradiotherapy. This is a niche indication within esophageal cancer, as it applies only to patients with completely resected tumors and residual pathologic disease.
- 2. **Patient Population**: Esophageal cancer incidence varies by region, with higher rates in East Asia (e.g., China) compared to the US and EU. Only a subset of patients will qualify for adjuvant therapy post-resection (estimated 20-30% of resected patients have residual disease and received neoadjuvant therapy).
- 3. Market Penetration: Assuming a 20-30% share of treated patients as given in the query.
- 4. **Pricing**: Nivolumab is a high-cost immunotherapy. Annual treatment cost per patient in the US is approximately \$100,000–\$150,000 (based on typical PD-1 inhibitor pricing). Pricing in EU5 is typically 60-80% of US prices, while in Japan and China, it may be 50-70% due to pricing controls and negotiations.
- 5. **Treatment Duration**: Adjuvant therapy is often given for 6-12 months, so we assume a 1-year treatment duration for peak sales estimation.
- 6. **Peak Sales Timing**: Peak sales are typically achieved 5-7 years post-launch after market penetration stabilizes.

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# \*\*Step 1: Estimate Eligible Patient Population\*\*

Esophageal cancer incidence and the proportion of patients eligible for adjuvant therapy vary by region. Below are rough estimates based on epidemiology data (e.g., GLOBOCAN, SEER, and regional cancer statistics):

- **US**: ~18,000 new cases/year. ~30% undergo resection, and of those, ~25% have residual disease post-neoadjuvant therapy. Eligible patients: ~1,350.
- EU5: ~45,000 new cases/year. Similar resection and residual disease rates. Eligible patients: ~3,375.
- **China**: ~300,000 new cases/year (highest global incidence). ~30% resection, ~25% residual disease. Eligible patients: ~22,500.
- Japan: ~25,000 new cases/year. ~30% resection, ~25% residual disease. Eligible patients: ~1,875.

Total eligible patients across regions: ~29,100.

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## \*\*Step 2: Estimate Treated Patients with 20-30% Market Share\*\*

Assuming nivolumab captures 20-30% of eligible patients:

- 20% share: ~5,820 treated patients.
- 30% share: ~8,730 treated patients.

### Regional breakdown:

- US: 270-405 patients (20-30% of 1,350).
- EU5: 675-1,013 patients (20-30% of 3,375).
- China: 4,500-6,750 patients (20-30% of 22,500).
- Japan: 375-563 patients (20-30% of 1,875).

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## \*\*Step 3: Estimate Annual Treatment Cost per Patient\*\*

Based on pricing benchmarks for PD-1 inhibitors like nivolumab:

- **US**: \$120,000/year.
- EU5: \$90,000/year (75% of US price).
- China: \$60,000/year (50% of US price, reflecting price negotiations and generics/biosimilars).
- Japan: \$80,000/year (67% of US price, reflecting pricing controls).

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

Peak sales are calculated as (Number of treated patients)  $\times$  (Annual treatment cost per patient) for each region.

### #### At 20% Market Share:

- **US**: 270 patients  $\times$  \$120,000 = **\$32.4M**.
- **EU5**: 675 patients  $\times$  \$90,000 = **\$60.8M**.
- **China**: 4,500 patients  $\times$  \$60,000 = **\$270.0M**.
- **Japan**: 375 patients  $\times$  \$80,000 = **\$30.0M**.
- Total Peak Sales (20%): \$393.2M.

#### #### At 30% Market Share:

- **US**: 405 patients  $\times$  \$120,000 = **\$48.6M**.
- **EU5**: 1,013 patients  $\times \$90,000 = \$91.2M$ .
- **China**: 6,750 patients  $\times$  \$60,000 = \$405.0**M**.
- Japan: 563 patients  $\times$  \$80,000 = \$45.0M.
- Total Peak Sales (30%): \$589.8M.

Thus, **Potential Peak Sales** for nivolumab in this indication across the US, EU5, China, and Japan range from **\$393M to \$590M**, depending on the 20-30% market share assumption.

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

1% of the eligible patient population is ~291 patients (1% of 29,100). Using the same regional distribution and pricing:

- **US**: 13.5 patients  $\times$  \$120,000 = **\$1.62M**.
- **EU5**: 33.75 patients  $\times$  \$90,000 = **\$3.04M**.
- China: 225 patients  $\times$  \$60,000 = \$13.50M.
- Japan: 18.75 patients  $\times$  \$80,000 = \$1.50M.
- Total \$ Value of 1% Share: \$19.66M.

Thus, the \$ value of 1% share of treated patients across these geographies is approximately \$19.7M.

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### \*\*Final Answer\*\*

- 1. Potential Peak Sales for Nivolumab in this Indication:
- At 20% market share: \$393 million.
- At 30% market share: \$590 million.
- Range: \$393M to \$590M across the US, EU5, China, and Japan.
- 2. \$ Value of 1% Share of Treated Patients: \$19.7 million across the US, EU5, China, and Japan.

**Note**: These estimates are based on assumptions about patient populations, pricing, and market penetration. Real-world data (e.g., exact patient numbers, competitive landscape, reimbursement policies, and treatment duration) could significantly alter these figures. For precise calculations, primary data from Bristol-Myers Squibb, market research reports, or regional health authorities would be required.