

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of primary advanced or recurrent endometrial carcinoma 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, or market penetration may not be fully available, I will make reasonable assumptions based on available epidemiology data, treatment rates, drug pricing trends, and market dynamics. Here's the step-by-step analysis:

Step 1: Indication and Epidemiology Overview

- **Indication:** Pembrolizumab is approved for primary advanced or recurrent endometrial carcinoma in combination with carboplatin and paclitaxel, followed by single-agent therapy.

- **Epidemiology:** Endometrial carcinoma is a common gynecologic cancer. The incidence and prevalence of advanced or recurrent cases vary by geography due to differences in healthcare systems, screening, and population demographics.

- Approximate annual incidence of endometrial cancer (all stages):

- **US:** ~66,000 new cases (American Cancer Society, 2023), with ~20-30% being advanced or recurrent (~13,000–20,000 patients).

- **EU5:** ~100,000 new cases annually (combined), with ~20-30% advanced or recurrent (~20,000–30,000 patients).

- **Japan:** ~15,000 new cases, with ~20-30% advanced or recurrent (~3,000–4,500 patients).

- **China:** ~80,000 new cases (due to large population), with ~20-30% advanced or recurrent (~16,000–24,000 patients).

- **Eligible Patients:** Not all advanced/recurrent patients will be eligible for pembrolizumab due to factors like comorbidities, prior treatments, or biomarker status (e.g., PD-L1 expression). Let's assume ~50% of advanced/recurrent patients are eligible for pembrolizumab-based therapy.

- **US:** ~6,500–10,000 eligible patients.

- **EU5:** ~10,000–15,000 eligible patients.

- **Japan:** ~1,500–2,250 eligible patients.

- **China:** ~8,000–12,000 eligible patients.

- **Treatment Rate:** Assuming 20-30% of eligible patients are treated with pembrolizumab (as per the query), we can calculate the treated patient population:

- **US:** 1,300–3,000 patients.

- **EU5:** 2,000–4,500 patients.

- **Japan:** 300–675 patients.

- **China:** 1,600–3,600 patients.

Step 2: Pricing Assumptions for Pembrolizumab

Pembrolizumab is a high-cost immunotherapy. Pricing varies by region due to healthcare systems, negotiations, and reimbursement policies. Annual cost per patient (based on standard dosing and duration of therapy) is estimated as follows (2023 data or approximations):

- **US:** ~\$150,000–\$180,000 per patient per year.
- **EU5:** ~\$100,000–\$120,000 per patient per year (lower due to price negotiations and discounts).
- **Japan:** ~\$120,000–\$140,000 per patient per year.
- **China:** ~\$60,000–\$80,000 per patient per year (lower due to market access programs, generics/biosimilars, and government pricing controls).

For simplicity, we'll use the midpoint of these ranges for calculations:

- **US:** \$165,000/patient/year.
- **EU5:** \$110,000/patient/year.
- **Japan:** \$130,000/patient/year.
- **China:** \$70,000/patient/year.

Step 3: Potential Peak Sales Calculation

Peak sales are calculated by multiplying the number of treated patients (using the midpoint of the 20-30% range, i.e., 25%) by the annual cost per patient.

- **US:**
 - Treated patients (25% of eligible): $(6,500 + 10,000)/2 * 0.25 = 2,062$ patients.
 - Peak Sales: $2,062 * \$165,000 = \text{\$340 million}$.
- **EU5:**
 - Treated patients: $(10,000 + 15,000)/2 * 0.25 = 3,125$ patients.
 - Peak Sales: $3,125 * \$110,000 = \text{\$344 million}$.
- **Japan:**
 - Treated patients: $(1,500 + 2,250)/2 * 0.25 = 469$ patients.
 - Peak Sales: $469 * \$130,000 = \text{\$61 million}$.
- **China:**
 - Treated patients: $(8,000 + 12,000)/2 * 0.25 = 2,500$ patients.
 - Peak Sales: $2,500 * \$70,000 = \text{\$175 million}$.
- **Total Peak Sales Across Geographies:** \$340M (US) + \$344M (EU5) + \$61M (Japan) + \$175M (China) = **\$920 million**.

Step 4: \$ Value of 1% Share of Treated Patients

To calculate the \$ value of a 1% share of treated patients, we divide the peak sales by 25 (since 25% share was used for peak sales calculation), to get the value per 1% share.

- **US:**

- 1% share value: $\$340\text{M} / 25 = \text{\$13.6 million}$.

- **EU5:**

- 1% share value: $\$344\text{M} / 25 = \text{\$13.8 million}$.

- **Japan:**

- 1% share value: $\$61\text{M} / 25 = \text{\$2.4 million}$.

- **China:**

- 1% share value: $\$175\text{M} / 25 = \text{\$7.0 million}$.

- **Total \$ Value of 1% Share Across Geographies:** $\$13.6\text{M (US)} + \$13.8\text{M (EU5)} + \$2.4\text{M (Japan)} + \$7.0\text{M (China)} = \text{\$36.8 million}$.

Final Answer

1. Potential Peak Sales for Pembrolizumab in Primary Advanced or Recurrent Endometrial Carcinoma (assuming 25% share of treated patients):

- **US:** \$340 million

- **EU5:** \$344 million

- **Japan:** \$61 million

- **China:** \$175 million

- **Total:** \$920 million

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

- **US:** \$13.6 million

- **EU5:** \$13.8 million

- **Japan:** \$2.4 million

- **China:** \$7.0 million

- **Total:** \$36.8 million

Notes and Caveats

- These estimates are based on assumptions regarding patient numbers, eligibility, treatment rates, and pricing. Real-world data may differ due to market access, competition, reimbursement, or changes in treatment guidelines.
- Pembrolizumab's sales may be influenced by combination therapy costs (carboplatin/paclitaxel) and duration of treatment.
- China's lower pricing reflects market-specific dynamics, including government negotiations and potential biosimilar competition.
- Peak sales assume steady-state market penetration and do not account for patent cliffs or future competitors in the PD-1/PD-L1 space.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market share forecasts), I can refine these calculations further.