

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of FIGO 2014 Stage III-IVA cervical cancer 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 make several assumptions and follow a structured approach. Since exact data on patient populations, pricing, and penetration rates may not be publicly available, this analysis will use reasonable estimates based on available epidemiology data, market trends, and typical pricing for oncology drugs like pembrolizumab. Let's break this down step by step.

Step 1: Define the Indication and Patient Population

- **Indication:** Pembrolizumab is approved for FIGO 2014 Stage III-IVA cervical cancer in combination with chemoradiotherapy (CRT).

- **Target Population:** Patients with locally advanced cervical cancer (Stage III-IVA). This is a subset of cervical cancer patients, typically representing ~30-40% of all cervical cancer cases, as earlier stages (I-II) are often treated with surgery and later stages (IVB) are metastatic and may not qualify for CRT.

Epidemiology of Cervical Cancer

- **US:** ~13,820 new cases of cervical cancer annually (American Cancer Society, 2023). ~30-40% are Stage III-IVA, so approximately **4,150-5,500 patients**.

- **EU5:** Incidence varies by country, with ~30,000 new cases annually across EU5 (based on GLOBOCAN 2020). ~30-40% are Stage III-IVA, so **9,000-12,000 patients**.

- **China:** ~109,000 new cases annually (GLOBOCAN 2020). ~30-40% are Stage III-IVA, so **32,700-43,600 patients**.

- **Japan:** ~12,800 new cases annually (GLOBOCAN 2020). ~30-40% are Stage III-IVA, so **3,840-5,120 patients**.

Total **eligible patient population** (Stage III-IVA):

- US: ~4,800 (midpoint)

- EU5: ~10,500 (midpoint)

- China: ~38,150 (midpoint)

- Japan: ~4,480 (midpoint)

- **Total:** ~58,000 patients annually across these geographies.

Treated Patients

Not all eligible patients receive treatment due to access, comorbidities, or other factors. Assuming ~80-90% of Stage III-IVA patients receive treatment (CRT as standard of care):

- US: ~4,320 patients

- EU5: ~9,450 patients

- China: ~34,335 patients (lower access assumed due to healthcare disparities)

- Japan: ~4,032 patients

- **Total Treated Patients:** ~52,137 patients annually.

Market Share Assumption

The query assumes a **20-30% share of treated patients** for pembrolizumab. This accounts for competition (e.g., other therapies, emerging immunotherapies) and adoption rates. We will use the midpoint of **25%** for peak sales calculation.

- **Treated Patients Receiving Pembrolizumab:**

- US: $4,320 * 25\% = \sim 1,080$ patients
- EU5: $9,450 * 25\% = \sim 2,363$ patients
- China: $34,335 * 25\% = \sim 8,584$ patients
- Japan: $4,032 * 25\% = \sim 1,008$ patients
- **Total:** ~13,035 patients annually at peak.

Step 2: Pricing of Pembrolizumab

Pembrolizumab pricing varies by geography due to healthcare systems, negotiations, and discounts. The drug is typically administered every 3 weeks (Q3W) at 200 mg or 400 mg every 6 weeks (Q6W). For simplicity, we assume an annual cost based on typical regimens (e.g., ~8-12 cycles per year depending on response and tolerability).

- **US:** Annual cost ~\$150,000-\$180,000 per patient (based on list price; real-world net price may be lower due to discounts).
- **EU5:** Annual cost ~\$80,000-\$100,000 per patient (lower due to negotiated pricing in national health systems).
- **China:** Annual cost ~\$40,000-\$60,000 per patient (lower due to pricing controls and generics/biosimilars competition).
- **Japan:** Annual cost ~\$90,000-\$110,000 per patient (similar to EU5 but with specific pricing mechanisms).

Using midpoint estimates:

- US: \$165,000/year
- EU5: \$90,000/year
- China: \$50,000/year
- Japan: \$100,000/year

Step 3: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients receiving pembrolizumab multiplied by the annual cost per patient in each geography.

- **US:** 1,080 patients * \$165,000 = **\$178.2 million**
- **EU5:** 2,363 patients * \$90,000 = **\$212.7 million**
- **China:** 8,584 patients * \$50,000 = **\$429.2 million**
- **Japan:** 1,008 patients * \$100,000 = **\$100.8 million**
- **Total Peak Sales:** \$178.2M + \$212.7M + \$429.2M + \$100.8M = **~\$920.9 million annually**

Potential Peak Sales for Pembrolizumab in Stage III-IVA Cervical Cancer: Approximately **\$921 million** per year across the US, EU5, China, and Japan, assuming a 25% market share.

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

A 1% share of treated patients corresponds to 1% of the total treated patient population in each geography. Using the treated patient numbers from Step 1:

- **US:** 4,320 patients * 1% = 43.2 patients * \$165,000 = **\$7.13 million**
- **EU5:** 9,450 patients * 1% = 94.5 patients * \$90,000 = **\$8.51 million**
- **China:** 34,335 patients * 1% = 343.35 patients * \$50,000 = **\$17.17 million**
- **Japan:** 4,032 patients * 1% = 40.32 patients * \$100,000 = **\$4.03 million**
- **Total Value of 1% Share:** \$7.13M + \$8.51M + \$17.17M + \$4.03M = **\$36.84 million**

\$ Value of 1% Share of Treated Patients: Approximately **\$36.8 million** annually across the US, EU5, China, and Japan.

Summary of Results

1. Potential Peak Sales for Pembrolizumab (assuming 25% market share):

- US: \$178.2 million
- EU5: \$212.7 million
- China: \$429.2 million
- Japan: \$100.8 million
- **Total:** ~\$921 million annually

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

- US: \$7.13 million

- EU5: \$8.51 million
- China: \$17.17 million
- Japan: \$4.03 million
- **Total:** ~\$36.8 million annually

Key Assumptions and Caveats

- **Epidemiology:** Patient numbers are estimates based on GLOBOCAN and other public data. Actual numbers may vary.

- **Pricing:** Pricing is approximated and may differ due to discounts, payer negotiations, and local policies.

- **Market Share:** A 20-30% share (midpoint 25%) is assumed, but actual penetration depends on competition, clinical guidelines, and reimbursement.

- **Treatment Duration:** Assumes a full year of treatment; actual duration may vary based on response or progression.

- **Access:** Treatment access in China is assumed lower; actual numbers may differ based on healthcare reforms.

This analysis provides a high-level estimate. For more precise figures, detailed market research, real-world data, and proprietary pricing information would be required.