

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of unresectable advanced or metastatic malignant pleural mesothelioma (MPM) 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 exact data on patient populations, pricing, and penetration rates may not be publicly available in real-time, I will outline the methodology and make reasonable assumptions based on available data and industry trends. Please note that these are hypothetical calculations and should be validated with current market research or proprietary data.

Step 1: Define the Target Population (Treated Patients with MPM)

Malignant pleural mesothelioma (MPM) is a rare cancer, primarily caused by asbestos exposure, with a poor prognosis. The incidence and prevalence of MPM vary by geography due to differences in asbestos use and regulations.

- **US:** Annual incidence of MPM is approximately 3,000 new cases. Assuming a prevalence of advanced or metastatic cases (around 70-80% of diagnoses), and factoring in first-line treatment eligibility, we estimate ~2,000-2,500 patients eligible for first-line treatment annually.
- **EU5:** Annual incidence in Europe is higher due to historical asbestos exposure, with ~5,000-6,000 new cases across EU5. Assuming a similar proportion of advanced/metastatic cases, ~3,500-4,500 patients may be eligible for first-line treatment.
- **Japan:** Incidence is lower, with ~1,500-2,000 new cases annually. Eligible first-line patients are estimated at ~1,000-1,500.
- **China:** Incidence is less well-documented but likely higher due to industrial exposure. Estimates suggest ~5,000-7,000 new cases annually, with ~3,500-5,000 eligible for first-line treatment.

Total Eligible Patients (Annual, First-Line Treatment):

- US: ~2,250
- EU5: ~4,000
- Japan: ~1,250
- China: ~4,250
- **Total:** ~11,750 patients annually

Step 2: Market Share Assumption (20%-30% of Treated Patients)

Pembrolizumab is approved as a first-line treatment in combination with pemetrexed and platinum chemotherapy for MPM. Given its efficacy (as demonstrated in trials like KEYNOTE-189 for other indications and likely similar benefits in MPM), and considering competition (e.g., Opdivo/Yervoy in some markets), we assume a market share of **20%-30%** of eligible treated patients.

Treated Patients with Pembrolizumab (20%-30% share):

- US: 450-675 patients

- EU5: 800-1,200 patients
- Japan: 250-375 patients
- China: 850-1,275 patients
- **Total:** 2,350-3,525 patients annually

Step 3: Pricing of Pembrolizumab

Pembrolizumab's pricing varies by region due to healthcare systems, negotiations, and market access dynamics. The annual cost per patient is based on a typical regimen (e.g., 200 mg every 3 weeks). Below are approximate annual costs (pre-discounts/negotiations):

- **US:** ~\$150,000-\$180,000 per patient per year (based on list price; actual net price may be lower due to rebates).
- **EU5:** ~\$80,000-\$120,000 per patient per year (varies by country due to pricing negotiations).
- **Japan:** ~\$100,000-\$130,000 per patient per year.
- **China:** ~\$50,000-\$80,000 per patient per year (lower due to pricing controls and potential inclusion in national reimbursement drug lists).

Average Annual Cost per Patient (Assumed Midpoint):

- US: \$165,000
- EU5: \$100,000
- Japan: \$115,000
- China: \$65,000

Step 4: Calculate Potential Peak Sales (20%-30% Market Share)

Peak sales are calculated as the number of treated patients multiplied by the annual cost per patient.

- **US:**
 - 450 patients (20%) x \$165,000 = **\$74.25M**
 - 675 patients (30%) x \$165,000 = **\$111.38M**
- **EU5:**
 - 800 patients (20%) x \$100,000 = **\$80M**
 - 1,200 patients (30%) x \$100,000 = **\$120M**
- **Japan:**

- 250 patients (20%) x \$115,000 = **\$28.75M**

- 375 patients (30%) x \$115,000 = **\$43.13M**

- **China:**

- 850 patients (20%) x \$65,000 = **\$55.25M**

- 1,275 patients (30%) x \$65,000 = **\$82.88M**

Total Potential Peak Sales (20%-30% Share):

- 20% Share: \$74.25M (US) + \$80M (EU5) + \$28.75M (Japan) + \$55.25M (China) = **\$238.25M**

- 30% Share: \$111.38M (US) + \$120M (EU5) + \$43.13M (Japan) + \$82.88M (China) = **\$357.39M**

Range of Potential Peak Sales: \$238M to \$357M annually

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population in each geography.

- **Total Eligible Patients (from Step 1):**

- US: 2,250 → 1% = 22.5 patients

- EU5: 4,000 → 1% = 40 patients

- Japan: 1,250 → 1% = 12.5 patients

- China: 4,250 → 1% = 42.5 patients

- **Revenue for 1% Share (Patients x Annual Cost per Patient):**

- US: 22.5 patients x \$165,000 = **\$3.71M**

- EU5: 40 patients x \$100,000 = **\$4M**

- Japan: 12.5 patients x \$115,000 = **\$1.44M**

- China: 42.5 patients x \$65,000 = **\$2.76M**

Total \$ Value of 1% Share Across Geographies: \$3.71M (US) + \$4M (EU5) + \$1.44M (Japan) + \$2.76M (China) = **\$11.91M**

Final Summary

1. Potential Peak Sales for Pembrolizumab in MPM (20%-30% Market Share):

- **US:** \$74M to \$111M

- **EU5:** \$80M to \$120M
- **Japan:** \$29M to \$43M
- **China:** \$55M to \$83M
- **Total: \$238M to \$357M annually**

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

- **US:** \$3.71M
- **EU5:** \$4M
- **Japan:** \$1.44M
- **China:** \$2.76M
- **Total: \$11.91M**

Caveats and Assumptions

- **Patient Population:** Incidence and eligibility estimates are based on general epidemiology data for MPM and may vary with updated studies or real-world data.
- **Pricing:** Costs are approximate and do not account for discounts, rebates, or payer negotiations, which can significantly lower net prices, especially in the EU5 and China.
- **Market Share:** The 20%-30% assumption reflects pembrolizumab's strong position as an immunotherapy, but competition (e.g., nivolumab/ipilimumab) and market access barriers could impact this.
- **Treatment Duration:** Assumes a full year of treatment, though actual duration may be shorter due to disease progression or toxicity.
- **Peak Sales Timing:** Peak sales may take a few years post-launch to achieve, depending on uptake and reimbursement.

For precise figures, consult recent market research reports (e.g., from EvaluatePharma, GlobalData) or proprietary data from Merck or healthcare databases.