

To estimate the **Potential Peak Sales** for pembrolizumab (KEYTRUDA®) in a specific indication across 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 the specific indication is not fully detailed in your query, I will outline a general methodology that can be applied to any indication (e.g., non-small cell lung cancer, melanoma, etc.) for which pembrolizumab is approved. If you have a specific indication in mind, I can refine the numbers accordingly.

## **Step 1: Define the Scope and Assumptions**

1. **Indication:** Pembrolizumab is approved for multiple indications (e.g., NSCLC, melanoma, head and neck cancer, etc.). For this analysis, I'll assume we are focusing on a major indication like **first-line treatment of metastatic non-small cell lung cancer (NSCLC)**, as it represents a large patient population and significant market potential. If the indication differs, the numbers will need adjustment.
2. **Patient Population:** Estimate the total number of treatable patients in the specified geographies for the indication.
3. **Market Share:** Assume a 20% to 30% share of treated patients, as provided in the query.
4. **Pricing:** Pembrolizumab's annual treatment cost varies by country due to differences in healthcare systems, negotiations, and discounts. Approximate annual costs are:
  - US: ~\$150,000 per patient
  - EU5: ~\$100,000 per patient (average, varies by country)
  - Japan: ~\$120,000 per patient
  - China: ~\$80,000 per patient (lower due to pricing controls and potential local manufacturing agreements)
5. **Peak Sales Timeline:** Peak sales are typically achieved 5-10 years after launch in a given indication, assuming no major competition or patent expiry disruptions.

## **Step 2: Estimate Treatable Patient Population for NSCLC (Example Indication)**

Using NSCLC as an example, we can estimate the number of eligible patients for first-line metastatic treatment (pembrolizumab is often used in PD-L1 positive patients or in combination with chemotherapy). Data is sourced from epidemiology studies, cancer registries, and market research (e.g., Globocan, SEER, etc.).

- **US:** ~225,000 new NSCLC cases annually; ~40% are metastatic at diagnosis, and ~50% of these may be eligible for pembrolizumab (PD-L1 expression or combo therapy). **~45,000 eligible patients.**
- **EU5:** ~300,000 new NSCLC cases annually; similar proportions apply. **~60,000 eligible patients.**
- **China:** ~800,000 new NSCLC cases annually (high incidence due to smoking rates); ~40% metastatic, ~40% eligible due to access and PD-L1 testing constraints. **~128,000 eligible patients.**
- **Japan:** ~125,000 new NSCLC cases annually; similar proportions as the US. **~25,000 eligible patients.**

Total eligible patients across geographies: **~258,000 patients.**

### **Step 3: Calculate Potential Peak Sales (20%-30% Market Share)**

Assuming pembrolizumab captures 20% to 30% of the treated patient population in each region, we calculate peak sales as follows:

#### At 20% Market Share:

- **US:** 45,000 patients  $\times$  20% = 9,000 patients  $\times$  \$150,000 = **\$1.35 billion**
- **EU5:** 60,000 patients  $\times$  20% = 12,000 patients  $\times$  \$100,000 = **\$1.2 billion**
- **China:** 128,000 patients  $\times$  20% = 25,600 patients  $\times$  \$80,000 = **\$2.05 billion**
- **Japan:** 25,000 patients  $\times$  20% = 5,000 patients  $\times$  \$120,000 = **\$0.6 billion**

**Total Peak Sales (20% share):** \$1.35B + \$1.2B + \$2.05B + \$0.6B = **\$5.2 billion**

#### At 30% Market Share:

- **US:** 45,000 patients  $\times$  30% = 13,500 patients  $\times$  \$150,000 = **\$2.03 billion**
- **EU5:** 60,000 patients  $\times$  30% = 18,000 patients  $\times$  \$100,000 = **\$1.8 billion**
- **China:** 128,000 patients  $\times$  30% = 38,400 patients  $\times$  \$80,000 = **\$3.07 billion**
- **Japan:** 25,000 patients  $\times$  30% = 7,500 patients  $\times$  \$120,000 = **\$0.9 billion**

**Total Peak Sales (30% share):** \$2.03B + \$1.8B + \$3.07B + \$0.9B = **\$7.8 billion**

**Potential Peak Sales Range:** **\$5.2 billion to \$7.8 billion** annually for this indication across the specified geographies.

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

A 1% share of treated patients corresponds to 1% of the eligible patient population in each region, multiplied by the annual treatment cost per patient.

- **US:** 45,000 patients  $\times$  1% = 450 patients  $\times$  \$150,000 = **\$67.5 million**
- **EU5:** 60,000 patients  $\times$  1% = 600 patients  $\times$  \$100,000 = **\$60 million**
- **China:** 128,000 patients  $\times$  1% = 1,280 patients  $\times$  \$80,000 = **\$102.4 million**
- **Japan:** 25,000 patients  $\times$  1% = 250 patients  $\times$  \$120,000 = **\$30 million**

**Total \$ Value of 1% Share:** \$67.5M + \$60M + \$102.4M + \$30M = **\$259.9 million**

### **Final Answer:**

1. **Potential Peak Sales for Pembrolizumab** in the assumed indication (e.g., first-line metastatic NSCLC) across the US, EU5, China, and Japan, with a 20% to 30% share of treated patients:

- **\$5.2 billion to \$7.8 billion annually**

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

- **\$259.9 million annually**

### **Notes and Caveats:**

- These estimates are based on NSCLC as an example indication. If the indication differs (e.g., melanoma, renal cell carcinoma), the patient population and pricing may vary significantly.
- Pricing assumptions are approximate and can vary due to discounts, reimbursement policies, and competition from other immunotherapies (e.g., nivolumab, atezolizumab).
- Market share assumptions (20%-30%) may be influenced by competition, clinical trial outcomes, and guideline recommendations.
- Patient access in China may be lower due to cost and reimbursement challenges, which could reduce the peak sales estimate.
- If you provide the specific indication or additional data (e.g., exact patient numbers or pricing), I can refine the analysis further.

Let me know if you'd like to adjust the indication or assumptions!