

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the adjuvant treatment of renal cell carcinoma (RCC) in the specified geographies (US, EU5, China, and Japan) and calculate the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since exact patient numbers, pricing, and market penetration data are not provided, I will use reasonable assumptions based on publicly available data, epidemiology, and market trends for RCC and pembrolizumab. Here's the step-by-step process:

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## **Step 1: Key Assumptions**

1. **Indication:** Adjuvant treatment for RCC patients at intermediate-high or high risk of recurrence post-nephrectomy or resection of metastatic lesions.
2. **Market Share:** Assuming 20% to 30% of treated patients in this indication will use pembrolizumab.
3. **Geographies:** US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan.
4. **Pricing:** Pembrolizumab's annual cost of treatment varies by country due to healthcare systems, discounts, and negotiations. Approximate costs (based on historical data and reports) are:
  - US: ~\$150,000 per patient per year
  - EU5: ~\$100,000 per patient per year (average, adjusted for discounts)
  - China: ~\$50,000 per patient per year (lower due to pricing controls and generics)
  - Japan: ~\$120,000 per patient per year (closer to US pricing but with some discounts)
5. **Treatment Duration:** Adjuvant therapy for RCC with pembrolizumab is typically 1 year (based on clinical trial designs like KEYNOTE-564).
6. **Peak Sales Timing:** Peak sales are typically reached 5-7 years after launch in a new indication, assuming market penetration and adoption.

## **Step 2: Epidemiology of RCC and Eligible Patient Population**

RCC incidence and the proportion of patients eligible for adjuvant therapy (intermediate-high or high risk of recurrence) need to be estimated. Based on cancer statistics and clinical guidelines:

- **US:** ~76,000 new RCC cases annually (American Cancer Society, 2023). ~50% are localized or regional at diagnosis, and of those, ~60% are at intermediate-high or high risk of recurrence post-nephrectomy. Thus, ~22,800 eligible patients.
- **EU5:** ~68,000 new RCC cases annually (combined estimate from GLOBOCAN). Using similar proportions, ~20,400 eligible patients.
- **China:** ~66,000 new RCC cases annually (GLOBOCAN). Due to differences in healthcare access, assume ~30% eligible, or ~19,800 patients.
- **Japan:** ~13,000 new RCC cases annually (GLOBOCAN). ~50% eligible, or ~6,500 patients.

Total eligible patients across geographies: ~69,500.

## **Step 3: Treated Patient Population**

Not all eligible patients receive adjuvant therapy due to access, cost, physician preference, or patient choice. Assume:

- US: 80% of eligible patients treated (~18,240 patients).
- EU5: 70% of eligible patients treated (~14,280 patients).
- China: 40% of eligible patients treated (~7,920 patients).
- Japan: 75% of eligible patients treated (~4,875 patients).

Total treated patients: ~45,315.

### **Step 4: Pembrolizumab Market Share (20%-30%)**

Assuming pembrolizumab captures 20%-30% of treated patients:

- **Low end (20%):** ~9,063 patients.
- **High end (30%):** ~13,595 patients.

Breakdown by geography (using mid-point 25% for simplicity in distribution):

- US: ~4,560 patients (25% of 18,240).
- EU5: ~3,570 patients (25% of 14,280).
- China: ~1,980 patients (25% of 7,920).
- Japan: ~1,219 patients (25% of 4,875).

### **Step 5: Potential Peak Sales Calculation**

Using annual treatment cost per patient and number of patients treated with pembrolizumab (mid-point of 25% market share for calculation):

- **US:** 4,560 patients × \$150,000 = **\$684 million.**
- **EU5:** 3,570 patients × \$100,000 = **\$357 million.**
- **China:** 1,980 patients × \$50,000 = **\$99 million.**
- **Japan:** 1,219 patients × \$120,000 = **\$146 million.**

**Total Peak Sales (25% market share):** \$684M + \$357M + \$99M + \$146M = **~\$1,286 million (or ~\$1.29 billion).**

- **Range at 20% market share:** ~\$1.03 billion.
- **Range at 30% market share:** ~\$1.54 billion.

Thus, **Potential Peak Sales for pembrolizumab in adjuvant RCC** across US, EU5, China, and Japan is approximately **\$1.03 billion to \$1.54 billion.**

### **Step 6: \$ Value of 1% Share of Treated Patients**

1% of total treated patients (45,315) is ~453 patients. Using the per-patient annual cost:

- **US:** 1% of 18,240 = 182 patients × \$150,000 = **\$27.3 million.**

- **EU5:** 1% of 14,280 = 143 patients × \$100,000 = **\$14.3 million.**

- **China:** 1% of 7,920 = 79 patients × \$50,000 = **\$4.0 million.**

- **Japan:** 1% of 4,875 = 49 patients × \$120,000 = **\$5.9 million.**

**Total \$ Value of 1% Share:** \$27.3M + \$14.3M + \$4.0M + \$5.9M = **~\$51.5 million.**

## **Final Answer**

- **Potential Peak Sales for pembrolizumab in adjuvant RCC** (20%-30% market share) in the US, EU5, China, and Japan: **\$1.03 billion to \$1.54 billion.**

- **\$ Value of 1% Share of Treated Patients** in these geographies: **~\$51.5 million.**

**Note:** These estimates are based on assumptions and should be validated with real-world data on patient access, pricing agreements, and competitive landscape (e.g., other therapies like nivolumab or combination therapies). Adjustments may also be needed for currency fluctuations, healthcare policy changes, or patent expirations. If you have specific data (e.g., exact pricing or patient numbers), I can refine the calculations further.