

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of advanced renal cell carcinoma (RCC) in the US, EU5 (France, Germany, 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 (e.g., exact patient numbers, pricing, or market penetration) is not provided, I will outline the methodology using reasonable assumptions based on publicly available information and industry standards. The final numbers will be illustrative and can be adjusted with precise data.

Step 1: Key Assumptions

1. **Indication:** Pembrolizumab in combination with lenvatinib for first-line treatment of advanced renal cell carcinoma (RCC).
2. **Market Share:** Assuming 20% to 30% of treated patients in this indication will use pembrolizumab.
3. **Geographies:** US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan.
4. **Pricing:** Pembrolizumab's annual cost per patient varies by region due to healthcare systems 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, varies by country)
 - Japan: ~\$120,000 per patient per year
 - China: ~\$50,000 per patient per year (lower due to pricing controls and generics/biosimilars competition)
5. **Patient Population:** Estimated number of advanced RCC patients eligible for first-line treatment (based on incidence and prevalence data from cancer registries and reports like Globocan or SEER). Approximate annual new cases of advanced RCC (first-line eligible) are:
 - US: ~15,000 patients
 - EU5: ~20,000 patients (combined)
 - China: ~25,000 patients (higher population base)
 - Japan: ~5,000 patients
6. **Treatment Penetration:** Assuming 80% of eligible patients receive systemic therapy (some may not due to comorbidities or other factors).

Step 2: Estimate Treated Patient Population

Using the above assumptions, the number of treated patients per geography (80% of eligible patients) is:

- US: $15,000 \times 80\% = 12,000$ patients
- EU5: $20,000 \times 80\% = 16,000$ patients

- China: $25,000 \times 80\% = 20,000$ patients
- Japan: $5,000 \times 80\% = 4,000$ patients
- **Total Treated Patients:** $12,000 + 16,000 + 20,000 + 4,000 = 52,000$ patients

Step 3: Estimate Pembrolizumab's Treated Patients (20%-30% Market Share)

- At 20% market share:
 - US: $12,000 \times 20\% = 2,400$ patients
 - EU5: $16,000 \times 20\% = 3,200$ patients
 - China: $20,000 \times 20\% = 4,000$ patients
 - Japan: $4,000 \times 20\% = 800$ patients
 - **Total:** $2,400 + 3,200 + 4,000 + 800 = 10,400$ patients
- At 30% market share:
 - US: $12,000 \times 30\% = 3,600$ patients
 - EU5: $16,000 \times 30\% = 4,800$ patients
 - China: $20,000 \times 30\% = 6,000$ patients
 - Japan: $4,000 \times 30\% = 1,200$ patients
 - **Total:** $3,600 + 4,800 + 6,000 + 1,200 = 15,600$ patients

Step 4: Calculate Potential Peak Sales for Pembrolizumab

Peak sales are calculated as (number of treated patients) \times (annual cost per patient).

- At 20% market share:
 - US: $2,400 \times \$150,000 = \360 million
 - EU5: $3,200 \times \$100,000 = \320 million
 - China: $4,000 \times \$50,000 = \200 million
 - Japan: $800 \times \$120,000 = \96 million
 - **Total Peak Sales (20%):** $\$360M + \$320M + \$200M + \$96M = \$976$ million
- At 30% market share:
 - US: $3,600 \times \$150,000 = \540 million
 - EU5: $4,800 \times \$100,000 = \480 million

- China: $6,000 \times \$50,000 = \300 million
- Japan: $1,200 \times \$120,000 = \144 million
- **Total Peak Sales (30%):** $\$540\text{M} + \$480\text{M} + \$300\text{M} + \$144\text{M} = \$1,464 \text{ million } (\$1.464 \text{ billion})$

Potential Peak Sales Range: \$976 million to \$1.464 billion annually across the specified geographies for this indication.

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

A 1% share corresponds to 1% of the treated patient population in each geography. Using the treated patient numbers from Step 2 and the annual cost per patient:

- US: $12,000 \times 1\% = 120 \text{ patients} \times \$150,000 = \$18 \text{ million}$
- EU5: $16,000 \times 1\% = 160 \text{ patients} \times \$100,000 = \$16 \text{ million}$
- China: $20,000 \times 1\% = 200 \text{ patients} \times \$50,000 = \$10 \text{ million}$
- Japan: $4,000 \times 1\% = 40 \text{ patients} \times \$120,000 = \$4.8 \text{ million}$
- **Total \$ Value of 1% Share:** $\$18\text{M} + \$16\text{M} + \$10\text{M} + \$4.8\text{M} = \$48.8 \text{ million}$

Final Answer

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

- Range: **\$976 million to \$1.464 billion annually** across the US, EU5, China, and Japan.
- Breakdown by geography (at 20% / 30%):
- US: $\$360\text{M} / \540M
- EU5: $\$320\text{M} / \480M
- China: $\$200\text{M} / \300M
- Japan: $\$96\text{M} / \144M

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

- Total: **\$48.8 million annually**
- Breakdown by geography:
- US: $\$18\text{M}$
- EU5: $\$16\text{M}$
- China: $\$10\text{M}$
- Japan: $\$4.8\text{M}$

Notes

- These estimates are based on assumptions and should be refined with actual epidemiology data, real-world pricing, market access conditions, and competition (e.g., other immunotherapies or targeted therapies for RCC like nivolumab, axitinib, etc.).
- Pembrolizumab's sales may also be impacted by combination therapy dynamics (e.g., revenue sharing with lenvatinib's manufacturer, Eisai).
- Peak sales may take a few years to achieve post-launch due to gradual market penetration and physician adoption.
- China's lower pricing reflects government negotiations and potential inclusion in the National Reimbursement Drug List (NRDL), which could further impact revenue.

If you have specific data (e.g., exact patient numbers, pricing, or market share projections), I can update the calculations accordingly.