

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of advanced endometrial carcinoma with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since specific data on patient numbers, pricing, and market penetration may not be publicly available in real-time, I'll outline the methodology and provide reasonable assumptions based on available oncology market trends and epidemiology data as of my last update (October 2023). For precise figures, you would need access to proprietary databases like IQVIA, GlobalData, or company reports.

Step 1: Define the Target Patient Population

- **Indication:** Advanced endometrial carcinoma (EC) that is MSI-H or dMMR, post-systemic therapy, not candidates for surgery or radiation.

- **Epidemiology:**

- Endometrial cancer is one of the most common gynecologic cancers. In the US, there are ~66,000 new cases annually (American Cancer Society, 2023). In EU5, the incidence is roughly similar per capita, totaling ~100,000 cases annually. In China, with a larger population, incidence is ~130,000 cases, and in Japan, ~15,000 cases annually.

- Advanced or recurrent cases account for ~20-30% of total cases.

- MSI-H/dMMR status is present in ~20-30% of endometrial cancers (depending on stage and region).

- Of these, patients failing prior systemic therapy and ineligible for surgery/radiation might represent ~50-60% of advanced cases (a conservative estimate for second-line or later treatment).

Using these assumptions:

- **US:** 66,000 total cases → ~15,000 advanced → ~4,000 MSI-H/dMMR → ~2,000-2,400 eligible patients.

- **EU5:** 100,000 total cases → ~25,000 advanced → ~6,000 MSI-H/dMMR → ~3,000-3,600 eligible patients.

- **China:** 130,000 total cases → ~30,000 advanced → ~7,500 MSI-H/dMMR → ~3,750-4,500 eligible patients.

- **Japan:** 15,000 total cases → ~3,500 advanced → ~900 MSI-H/dMMR → ~450-540 eligible patients.

Total eligible patients across geographies: **~9,200-11,000 patients annually.**

Step 2: Estimate Treatment Rate and Market Share

- **Treatment Rate:** Not all eligible patients will receive pembrolizumab due to factors like access, cost, physician preference, or competing therapies (e.g., other immunotherapies or chemotherapy). Assume a treatment rate of 50-70% of eligible patients.

- **Market Share:** Given the query's assumption of 20-30% share of treated patients for pembrolizumab, we apply this to the treated population.

Treated patients (60% treatment rate midpoint):

- US: 2,200 eligible → ~1,320 treated.
- EU5: 3,300 eligible → ~1,980 treated.
- China: 4,125 eligible → ~2,475 treated.
- Japan: 495 eligible → ~297 treated.
- Total treated: ~6,072 patients.

Pembrolizumab-treated patients (25% share midpoint):

- US: $1,320 \times 25\% = \sim 330$ patients.
- EU5: $1,980 \times 25\% = \sim 495$ patients.
- China: $2,475 \times 25\% = \sim 619$ patients.
- Japan: $297 \times 25\% = \sim 74$ patients.
- Total pembrolizumab-treated: ~1,518 patients annually.

Step 3: Estimate Annual Cost of Therapy per Patient

- Pembrolizumab pricing varies by region due to healthcare systems, negotiations, and discounts.
- **US:** ~\$150,000-\$175,000 per patient per year (based on list price for Keytruda, ~\$10,000 per dose, dosed every 3 weeks).
- **EU5:** ~\$80,000-\$100,000 per patient per year (lower due to negotiated pricing).
- **Japan:** ~\$90,000-\$110,000 per patient per year (similar to EU5).
- **China:** ~\$50,000-\$70,000 per patient per year (lower due to market access programs and generics competition).

Using midpoint estimates:

- US: \$162,500.
- EU5: \$90,000.
- Japan: \$100,000.
- China: \$60,000.

Step 4: Calculate Potential Peak Sales

Peak sales = (Number of pembrolizumab-treated patients) × (Annual cost per patient).

- **US:** 330 patients × \$162,500 = ~\$53.6 million.
- **EU5:** 495 patients × \$90,000 = ~\$44.6 million.
- **China:** 619 patients × \$60,000 = ~\$37.1 million.
- **Japan:** 74 patients × \$100,000 = ~\$7.4 million.
- **Total Peak Sales:** \$53.6M + \$44.6M + \$37.1M + \$7.4M = ~\$142.7 million annually.

This assumes a 25% market share. For a range of 20-30%:

- 20% share: ~\$114 million.
- 30% share: ~\$171 million.

Thus, **Potential Peak Sales** range: **\$114 million to \$171 million annually.**

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

1% share of treated patients = 1% of total treated patients across geographies (~6,072 patients) = ~61 patients.

Value of 1% share (using weighted average cost per patient by region):

- US: $1,320/6,072 \times 61 \times \$162,500$ = ~\$2.16 million.
- EU5: $1,980/6,072 \times 61 \times \$90,000$ = ~\$1.79 million.
- China: $2,475/6,072 \times 61 \times \$60,000$ = ~\$1.49 million.
- Japan: $297/6,072 \times 61 \times \$100,000$ = ~\$0.30 million.
- **Total \$ Value of 1% Share:** \$2.16M + \$1.79M + \$1.49M + \$0.30M = ~\$5.74 million.

Final Answer

- **Potential Peak Sales for Pembrolizumab** (20-30% market share) in the US, EU5, China, and Japan for advanced endometrial carcinoma (MSI-H/dMMR): **\$114 million to \$171 million annually.**

- **\$ Value of 1% Share of Treated Patients:** ~\$5.74 million.

Note: These figures are estimates based on assumptions about patient populations, treatment rates, market share, and pricing. Real-world values may differ due to evolving market dynamics, competition (e.g., dostarlimab from GSK), pricing negotiations, and updated epidemiology data. For precise calculations, consult recent market research reports or financial disclosures from Merck & Co.