

To calculate the **Potential Peak Sales** for pembrolizumab (KEYTRUDA) in the first-line treatment of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer 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 exact data (e.g., patient population, pricing, or market penetration) is not provided, I will outline the methodology with assumptions based on publicly available information and industry standards. You can adjust these assumptions with more specific data if available.

Step 1: Define Key Parameters

1. **Patient Population:** Estimate the number of eligible patients for pembrolizumab in the specified indication (first-line unresectable or metastatic MSI-H/dMMR colorectal cancer).
2. **Market Share:** Assume a 20% to 30% share of treated patients as given in the query.
3. **Annual Cost of Therapy:** Estimate the annual cost of pembrolizumab per patient in each geography (varies due to pricing differences).
4. **Peak Sales:** Calculate peak sales based on the number of treated patients and annual cost.
5. **1% Share Value:** Calculate the \$ value of 1% of treated patients.

Step 2: Estimate Patient Population

- **Colorectal Cancer Incidence:** According to various sources (e.g., GLOBOCAN 2020, American Cancer Society), colorectal cancer incidence and prevalence data are available for these regions.
- **MSI-H/dMMR Prevalence:** MSI-H/dMMR accounts for approximately 5% of metastatic colorectal cancer cases (based on literature).
- **First-Line Metastatic Patients:** Roughly 20-25% of colorectal cancer patients are diagnosed with metastatic disease at presentation, and a subset of these are unresectable.

Rough Estimates of Eligible Patients (Annual Incident Cases for First-Line Treatment)

- **US:** ~150,000 new colorectal cancer cases/year. ~25% metastatic (~37,500), 5% MSI-H/dMMR = ~1,875 eligible patients.
- **EU5:** ~250,000 new cases/year. ~25% metastatic (~62,500), 5% MSI-H/dMMR = ~3,125 eligible patients.
- **China:** ~550,000 new cases/year. ~25% metastatic (~137,500), 5% MSI-H/dMMR = ~6,875 eligible patients.
- **Japan:** ~150,000 new cases/year. ~25% metastatic (~37,500), 5% MSI-H/dMMR = ~1,875 eligible patients.
- **Total Eligible Patients:** ~1,875 (US) + 3,125 (EU5) + 6,875 (China) + 1,875 (Japan) = ~13,750 patients/year.

These numbers are rough and based on incidence. Adjustments for prevalence (existing patients) and treatment eligibility may increase the pool slightly.

Step 3: Estimate Annual Cost of Pembrolizumab per Patient

Pembrolizumab pricing varies by region due to healthcare systems, negotiations, and discounts. Approximate annual costs (based on historical data for KEYTRUDA and industry reports):

- **US:** ~\$150,000 per patient/year (list price, though discounts may apply).
- **EU5:** ~\$80,000–\$100,000 per patient/year (varies by country, lower due to negotiations).
- **China:** ~\$50,000 per patient/year (lower pricing due to market access programs and generics competition).
- **Japan:** ~\$100,000 per patient/year (similar to EU pricing).

For simplicity, use an average cost:

- US: \$150,000
- EU5: \$90,000
- China: \$50,000
- Japan: \$100,000

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

Peak sales assume pembrolizumab captures 20%-30% of the eligible patient population in each region.

Treated Patients (20%-30% Share)

- **US:** 1,875 patients × 20%-30% = 375-563 patients
- **EU5:** 3,125 patients × 20%-30% = 625-938 patients
- **China:** 6,875 patients × 20%-30% = 1,375-2,063 patients
- **Japan:** 1,875 patients × 20%-30% = 375-563 patients

Peak Sales Calculation (in \$ Millions)

- **US:**
 - 375 patients × \$150,000 = \$56.25M (20% share)
 - 563 patients × \$150,000 = \$84.45M (30% share)
- **EU5:**
 - 625 patients × \$90,000 = \$56.25M (20% share)
 - 938 patients × \$90,000 = \$84.42M (30% share)
- **China:**
 - 1,375 patients × \$50,000 = \$68.75M (20% share)
 - 2,063 patients × \$50,000 = \$103.15M (30% share)
- **Japan:**
 - 375 patients × \$100,000 = \$37.5M (20% share)
 - 563 patients × \$100,000 = \$56.3M (30% share)

Total Peak Sales Across Geographies

- **20% Share:** \$56.25M (US) + \$56.25M (EU5) + \$68.75M (China) + \$37.5M (Japan) = **\$218.75M**

- **30% Share:** \$84.45M (US) + \$84.42M (EU5) + \$103.15M (China) + \$56.3M (Japan) = **\$328.32M**

Thus, **Potential Peak Sales** for pembrolizumab in this indication across the US, EU5, China, and Japan range from **\$218.75M to \$328.32M annually**.

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

A 1% share corresponds to 1% of the eligible patient population in each region.

Treated Patients (1% Share)

- **US:** 1,875 patients × 1% = 18.75 patients

- **EU5:** 3,125 patients × 1% = 31.25 patients

- **China:** 6,875 patients × 1% = 68.75 patients

- **Japan:** 1,875 patients × 1% = 18.75 patients

\$ Value of 1% Share (in \$ Millions)

- **US:** 18.75 patients × \$150,000 = \$2.81M

- **EU5:** 31.25 patients × \$90,000 = \$2.81M

- **China:** 68.75 patients × \$50,000 = \$3.44M

- **Japan:** 18.75 patients × \$100,000 = \$1.88M

Total \$ Value of 1% Share Across Geographies

- \$2.81M (US) + \$2.81M (EU5) + \$3.44M (China) + \$1.88M (Japan) = **\$10.94M**

Thus, the **\$ value of a 1% share of treated patients** across the US, EU5, China, and Japan is approximately **\$10.94M**.

Final Answer

- **Potential Peak Sales** for pembrolizumab in this indication (20%-30% share): **\$218.75M to \$328.32M annually**.

- **\$ Value of 1% Share of Treated Patients:** **\$10.94M**.

Notes

- These calculations are based on rough estimates and assumptions for patient numbers, pricing, and market share. Real-world data may vary due to factors like competition, reimbursement, treatment duration, and patient access.

- Pembrolizumab's sales in this indication may also be influenced by its use in other indications, as it is a blockbuster drug with broad applications.
- If you have access to more precise data (e.g., exact patient numbers, real-world pricing, or market share forecasts), these figures can be refined.