

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma in 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 follow a structured approach. Since specific data on patient populations, pricing, and market dynamics may not be fully available, I will outline the methodology and provide a reasonable estimation based on publicly available information, assumptions, and industry benchmarks as of my last update (October 2023). Please note that actual figures may vary based on real-time data, pricing changes, and market access.

Step 1: Define the Target Patient Population

The indication is for first-line treatment of HER2-positive gastric or GEJ adenocarcinoma (locally advanced unresectable or metastatic). We need to estimate the number of eligible patients in each geography.

1. US:

- Incidence of gastric cancer: ~27,000 new cases annually (American Cancer Society).
- ~20% are HER2-positive (based on literature).
- ~60-70% are advanced or metastatic at diagnosis.
- Eligible patients: $\sim 27,000 \times 20\% \times 65\% \approx \mathbf{3,500 \text{ patients/year}}$.

2. EU5:

- Incidence of gastric cancer: ~130,000 new cases annually across Europe (EU5 accounts for ~70% of Europe).
- EU5 incidence: ~91,000.
- HER2-positive: $20\% \approx 18,200$.
- Advanced/metastatic: $65\% \approx \mathbf{11,800 \text{ patients/year}}$.

3. China:

- Incidence of gastric cancer: ~680,000 new cases annually (highest globally).
- HER2-positive: $20\% \approx 136,000$.
- Advanced/metastatic: $65\% \approx \mathbf{88,400 \text{ patients/year}}$.

4. Japan:

- Incidence of gastric cancer: ~130,000 new cases annually.
- HER2-positive: $20\% \approx 26,000$.
- Advanced/metastatic: $65\% \approx \mathbf{16,900 \text{ patients/year}}$.

Total eligible patients across geographies: $\sim 3,500 \text{ (US)} + 11,800 \text{ (EU5)} + 88,400 \text{ (China)} + 16,900 \text{ (Japan)} \approx \mathbf{120,600 \text{ patients/year}}$.

Step 2: Estimate Treatment Rate and Market Share

- Assuming 20-30% of eligible patients are treated with pembrolizumab (as per the query).
- This accounts for factors like physician adoption, reimbursement, competition (e.g., trastuzumab-based therapies), and patient access.

Treated patients (midpoint of 25%):

- US: $3,500 \times 25\% \approx 875$ patients.
- EU5: $11,800 \times 25\% \approx 2,950$ patients.
- China: $88,400 \times 25\% \approx 22,100$ patients.
- Japan: $16,900 \times 25\% \approx 4,225$ patients.
- **Total treated patients:** ~30,150 patients/year.

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 typical dosing for a year, often 200 mg every 3 weeks, and publicly reported figures as of 2023) are:

- **US:** ~\$150,000–\$180,000/year (list price before discounts).
- **EU5:** ~\$80,000–\$120,000/year (varies by country due to negotiations).
- **China:** ~\$40,000–\$60,000/year (lower due to pricing controls and inclusion in National Reimbursement Drug List).
- **Japan:** ~\$100,000–\$130,000/year (aligned with developed markets but with negotiated pricing).

Using midpoint estimates:

- US: \$165,000/year.
- EU5: \$100,000/year.
- China: \$50,000/year.
- Japan: \$115,000/year.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients multiplied by the annual cost per patient in each geography.

- **US:** $875 \text{ patients} \times \$165,000 = \$144.4 \text{ million}$.
- **EU5:** $2,950 \text{ patients} \times \$100,000 = \$295 \text{ million}$.
- **China:** $22,100 \text{ patients} \times \$50,000 = \$1,105 \text{ million}$.
- **Japan:** $4,225 \text{ patients} \times \$115,000 = \$485.9 \text{ million}$.
- **Total Peak Sales:** $\$144.4\text{M (US)} + \$295\text{M (EU5)} + \$1,105\text{M (China)} + \$485.9\text{M (Japan)} = \sim\$2,030.3 \text{ million or } \sim\$2.03 \text{ billion/year}$.

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

A 1% share of treated patients corresponds to 1% of the total eligible patients treated with pembrolizumab (i.e., 1% of $120,600 \times 25\% = 301.5$ patients total across geographies). We calculate the value based on the proportion of patients in each region and their respective annual treatment costs.

- **US:** 1% of total treated patients = $301.5 \times (875/30,150) \approx 8.75$ patients; Value = $8.75 \times \$165,000 \approx$ **\$1.44 million.**

- **EU5:** $301.5 \times (2,950/30,150) \approx 29.5$ patients; Value = $29.5 \times \$100,000 \approx$ **\$2.95 million.**

- **China:** $301.5 \times (22,100/30,150) \approx 221$ patients; Value = $221 \times \$50,000 \approx$ **\$11.05 million.**

- **Japan:** $301.5 \times (4,225/30,150) \approx 42.25$ patients; Value = $42.25 \times \$115,000 \approx$ **\$4.86 million.**

- **Total \$ Value of 1% Share:** \$1.44M (US) + \$2.95M (EU5) + \$11.05M (China) + \$4.86M (Japan) = **~\$20.3 million.**

Final Answer

- **Potential Peak Sales for Pembrolizumab** in this indication (assuming 20-30% market share, midpoint 25%) across the US, EU5, China, and Japan: **~\$2.03 billion/year.**

- **\$ Value of 1% Share of Treated Patients** across these geographies: **~\$20.3 million.**

Caveats and Assumptions

1. Patient population estimates are based on incidence data and literature on HER2-positivity and advanced disease prevalence.
2. Pricing is approximate and may vary due to discounts, rebates, and regional policies.
3. Market share (25%) is an assumption based on the query range; actual penetration may differ due to competition (e.g., trastuzumab, biosimilars) and payer dynamics.
4. Peak sales assume steady-state adoption and do not account for time to peak or patent expiry (pembrolizumab's patent extends to ~2028 in key markets).
5. Access in China may be influenced by reimbursement and local manufacturing agreements, potentially affecting pricing and uptake.

For more precise figures, primary market research, updated epidemiology data, and current pricing agreements would be necessary. If you have specific data or additional parameters, I can refine the analysis further.