

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the adjuvant treatment of stage IIB or IIC melanoma in the specified geographies (US, EU5, China, and Japan) and the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since specific data such as patient population, treatment rates, pricing, and market penetration might not be publicly available or provided in the query, I will outline the methodology and assumptions to arrive at an estimate. You can adjust the numbers based on more precise data if available.

****Step 1: Define the Indication and Patient Population****

- **Indication:** Adjuvant treatment of stage IIB or IIC melanoma following complete resection in patients ≥ 12 years of age.

- **Geographies:** US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan.

- **Epidemiology:** Melanoma incidence varies by region, with higher rates in Western countries (US, EU5) due to higher UV exposure and lighter skin types, and lower rates in China and Japan.

- **Stage Distribution:** Stage IIB and IIC melanoma represent a subset of melanoma cases. According to general oncology data, early-stage melanoma (Stage I-II) accounts for ~70-80% of cases at diagnosis, with Stage IIB/IIC being a smaller fraction (estimated ~10-20% of total melanoma cases).

Estimated Incidence of Melanoma (Annual New Cases)

Using approximate incidence rates (per 100,000 population) and population sizes:

- **US:** Incidence ~25/100,000; Population ~330M \rightarrow ~82,500 new cases/year. Stage IIB/IIC (~15%) \rightarrow ~12,375 patients.

- **EU5:** Incidence ~20/100,000; Population ~320M \rightarrow ~64,000 new cases/year. Stage IIB/IIC (~15%) \rightarrow ~9,600 patients.

- **China:** Incidence ~0.5/100,000; Population ~1,400M \rightarrow ~7,000 new cases/year. Stage IIB/IIC (~15%) \rightarrow ~1,050 patients.

- **Japan:** Incidence ~1.5/100,000; Population ~125M \rightarrow ~1,875 new cases/year. Stage IIB/IIC (~15%) \rightarrow ~280 patients.

- **Total Eligible Patients (Annual):** ~12,375 (US) + 9,600 (EU5) + 1,050 (China) + 280 (Japan) = ~23,305 patients/year.

Adjust for Treatment Eligibility

- Only patients with complete resection are eligible for adjuvant therapy. Assume ~80% of Stage IIB/IIC patients undergo complete resection.

- **Treated Population (Annual):** $23,305 \times 80\% = \sim 18,644$ patients/year.

****Step 2: Market Share Assumption****

- The query assumes a **20% to 30% share of treated patients** for pembrolizumab in this indication.

- For calculation, use the midpoint of **25% market share**.
- **Pembrolizumab Treated Patients (Annual):** $18,644 \times 25\% = \sim 4,661$ patients/year.

Breakdown by Geography (at 25% Market Share)

- US: $12,375 \times 80\% \times 25\% = \sim 2,475$ patients/year.
- EU5: $9,600 \times 80\% \times 25\% = \sim 1,920$ patients/year.
- China: $1,050 \times 80\% \times 25\% = \sim 210$ patients/year.
- Japan: $280 \times 80\% \times 25\% = \sim 56$ patients/year.

****Step 3: Pricing and Treatment Duration****

- **Pricing:** Pembrolizumab pricing varies by region due to healthcare systems and negotiations.
- US: $\sim \$10,000$ per dose (every 3 weeks); Annual cost for 1 year of treatment (17 cycles) $\approx \$170,000$.
- EU5: $\sim \$6,000$ - $\$8,000$ per dose; Annual cost $\approx \$100,000$ - $\$130,000$ (assume $\$120,000$).
- China: Lower due to pricing controls; Annual cost $\approx \$50,000$ (post-negotiation via NRDL inclusion).
- Japan: Similar to EU5; Annual cost $\approx \$120,000$.
- **Treatment Duration:** Adjuvant therapy for melanoma is typically 1 year (as per clinical guidelines and trial data like KEYNOTE-054).

Annual Revenue per Patient

- US: $\$170,000$.
- EU5: $\$120,000$.
- China: $\$50,000$.
- Japan: $\$120,000$.

****Step 4: Calculate Potential Peak Sales (at 25% Market Share)****

Peak sales assume steady-state market penetration, which may take a few years post-approval to achieve.

- **US:** $2,475 \text{ patients} \times \$170,000 = \mathbf{\$420.8M}$.
- **EU5:** $1,920 \text{ patients} \times \$120,000 = \mathbf{\$230.4M}$.
- **China:** $210 \text{ patients} \times \$50,000 = \mathbf{\$10.5M}$.
- **Japan:** $56 \text{ patients} \times \$120,000 = \mathbf{\$6.7M}$.
- **Total Peak Sales (Annual):** $\$420.8M + \$230.4M + \$10.5M + \$6.7M = \mathbf{\sim \$668.4M}$.

Range for 20%-30% Market Share

- At 20% share: Total treated patients = $18,644 \times 20\% = 3,729 \rightarrow$ Peak Sales \approx **\$534.7M**.
- At 30% share: Total treated patients = $18,644 \times 30\% = 5,593 \rightarrow$ Peak Sales \approx **\$802.1M**.
- **Peak Sales Range: \$535M to \$802M annually.**

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

- **Total Treated Patients (Annual):** 18,644.
- **1% of Treated Patients:** $18,644 \times 1\% = 186$ patients/year.

Revenue per 1% Share by Geography

- US: $(12,375 \times 80\% \times 1\%) \times \$170,000 = 99$ patients $\times \$170,000 =$ **\$16.8M**.
- EU5: $(9,600 \times 80\% \times 1\%) \times \$120,000 = 77$ patients $\times \$120,000 =$ **\$9.2M**.
- China: $(1,050 \times 80\% \times 1\%) \times \$50,000 = 8$ patients $\times \$50,000 =$ **\$0.4M**.
- Japan: $(280 \times 80\% \times 1\%) \times \$120,000 = 2$ patients $\times \$120,000 =$ **\$0.3M**.
- **Total \$ Value of 1% Share:** $\$16.8M + \$9.2M + \$0.4M + \$0.3M =$ **\$26.7M**.

****Final Answer****

1. Potential Peak Sales for Pembrolizumab in Stage IIB/IIC Melanoma (Adjuvant Setting):

- At 20% market share: **~\$535M annually.**
- At 30% market share: **~\$802M annually.**
- Midpoint (25% share): **~\$668M annually.**

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

- Total across US, EU5, China, and Japan: **~\$26.7M annually.**

****Caveats and Assumptions****

- **Epidemiology:** Incidence rates and stage distribution are approximations based on general melanoma data (e.g., SEER, GLOBOCAN). Actual numbers may vary.
- **Pricing:** Drug pricing is subject to change due to negotiations, discounts, and access programs. China's pricing reflects inclusion in the National Reimbursement Drug List (NRDL), which significantly lowers costs.

- **Market Share:** The 20%-30% range is as per the query. Actual penetration depends on competition (e.g., nivolumab/Opdivo in melanoma), guideline adoption, and reimbursement.

- **Treatment Duration:** Assumed 1 year based on current guidelines; real-world data may show shorter durations or non-compliance.

- **Population Growth:** Static population numbers are used; actual growth or demographic shifts are not accounted for.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market share forecasts), these estimates can be refined further.