

To estimate the **Potential Peak Sales** for pembrolizumab (Keytruda) in the indication of high-risk, early-stage triple-negative breast cancer (TNBC) 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 exact data (e.g., patient population, pricing, or market penetration specifics) are not provided, I will outline the methodology and use reasonable assumptions based on publicly available information and industry standards. You can adjust these assumptions with specific data if available.

Step 1: Define Key Parameters

1. **Target Patient Population:** High-risk, early-stage TNBC patients eligible for neoadjuvant and adjuvant therapy.
2. **Market Share:** Assuming 20% to 30% of treated patients will receive pembrolizumab.
3. **Pricing:** Annual cost of pembrolizumab therapy per patient.
4. **Geographies:** US, EU5, China, Japan.
5. **Peak Sales:** The maximum annual revenue achieved after market penetration stabilizes (typically 5-7 years post-launch).

Step 2: Estimate TNBC Patient Population

TNBC accounts for ~10-15% of all breast cancer cases, with a subset being high-risk, early-stage patients. Incidence rates and treatment eligibility vary by region due to differences in healthcare access, screening, and diagnosis.

Approximate Annual Incidence of Breast Cancer and TNBC:

- **US:** ~280,000 new breast cancer cases/year; TNBC ~10-15% (~28,000-42,000). High-risk, early-stage TNBC eligible for neoadjuvant/adjuvant therapy might be ~50% of TNBC cases (~14,000-21,000).
- **EU5:** ~250,000 new breast cancer cases/year; TNBC ~10-15% (~25,000-37,500). High-risk, early-stage TNBC ~50% (~12,500-18,750).
- **China:** ~300,000 new breast cancer cases/year; TNBC ~10-15% (~30,000-45,000). High-risk, early-stage TNBC ~50% (~15,000-22,500), though access to advanced therapies may be lower.
- **Japan:** ~90,000 new breast cancer cases/year; TNBC ~10-15% (~9,000-13,500). High-risk, early-stage TNBC ~50% (~4,500-6,750).

Total Eligible Patients (High-Risk, Early-Stage TNBC):

- US: ~14,000-21,000
- EU5: ~12,500-18,750
- China: ~15,000-22,500
- Japan: ~4,500-6,750
- **Total Across Geographies:** ~46,000-69,000 patients annually.

Step 3: Estimate Treated Patients with Pembrolizumab

Assuming a **20%-30% market share** of treated patients:

- **US:** 2,800-6,300 patients (20%-30% of 14,000-21,000)
- **EU5:** 2,500-5,625 patients (20%-30% of 12,500-18,750)
- **China:** 3,000-6,750 patients (20%-30% of 15,000-22,500; assuming similar penetration despite access barriers)
- **Japan:** 900-2,025 patients (20%-30% of 4,500-6,750)
- **Total Treated Patients:** 9,200-20,700 patients annually.

Step 4: Estimate Annual Cost of Pembrolizumab per Patient

Pembrolizumab pricing varies by region due to healthcare systems, negotiations, and discounts. For TNBC, treatment includes neoadjuvant (pre-surgery) and adjuvant (post-surgery) phases, typically spanning ~1 year.

- **US:** ~\$150,000-\$200,000 per patient/year (based on Keytruda's pricing for other indications like melanoma or lung cancer).
- **EU5:** ~\$100,000-\$150,000 per patient/year (lower due to price negotiations and public healthcare systems).
- **China:** ~\$50,000-\$100,000 per patient/year (significant discounts and access programs; pricing varies widely).
- **Japan:** ~\$100,000-\$150,000 per patient/year (similar to EU5, with structured pricing).

For simplicity, I'll use a midpoint estimate for each region:

- US: \$175,000
- EU5: \$125,000
- China: \$75,000
- Japan: \$125,000

Step 5: Calculate Potential Peak Sales

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

At 20% Market Share:

- **US:** 2,800 patients × \$175,000 = **\$490 million**
- **EU5:** 2,500 patients × \$125,000 = **\$312.5 million**
- **China:** 3,000 patients × \$75,000 = **\$225 million**

- **Japan:** 900 patients × \$125,000 = **\$112.5 million**
- **Total Peak Sales (20%):** **\$1,140 million (~\$1.14 billion)**

At 30% Market Share:

- **US:** 6,300 patients × \$175,000 = **\$1,102.5 million**
- **EU5:** 5,625 patients × \$125,000 = **\$703.1 million**
- **China:** 6,750 patients × \$75,000 = **\$506.3 million**
- **Japan:** 2,025 patients × \$125,000 = **\$253.1 million**
- **Total Peak Sales (30%):** **\$2,565 million (~\$2.57 billion)**

Range of Potential Peak Sales:

- **\$1.14 billion to \$2.57 billion annually** across the US, EU5, China, and Japan for this indication.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the eligible patient population being treated with pembrolizumab.

Eligible Patients per Geography:

- **US:** 14,000-21,000 → 1% = 140-210 patients
- **EU5:** 12,500-18,750 → 1% = 125-187.5 patients
- **China:** 15,000-22,500 → 1% = 150-225 patients
- **Japan:** 4,500-6,750 → 1% = 45-67.5 patients

\$ Value of 1% Share (Using Midpoint of Patient Range and Annual Cost):

- **US:** 175 patients × \$175,000 = **\$30.6 million**
- **EU5:** 156 patients × \$125,000 = **\$19.5 million**
- **China:** 187.5 patients × \$75,000 = **\$14.1 million**
- **Japan:** 56 patients × \$125,000 = **\$7.0 million**
- **Total \$ Value of 1% Share:** **\$71.2 million annually**

Final Answer:

1. Potential Peak Sales for Pembrolizumab in High-Risk, Early-Stage TNBC:

- At 20% market share: **\$1.14 billion annually**
- At 30% market share: **\$2.57 billion annually**
- Range: **\$1.14 billion to \$2.57 billion annually** across the US, EU5, China, and Japan.

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

- Approximately **\$71.2 million annually** across the US, EU5, China, and Japan.

Notes:

- These estimates are based on assumptions about patient populations, pricing, and market penetration. Real-world data (e.g., exact TNBC epidemiology, pricing agreements, or competitive landscape) could alter these figures.
- Pembrolizumab faces competition from other therapies (e.g., chemotherapy, other immunotherapies), which may impact market share.
- Access and reimbursement policies, especially in China, could significantly affect sales.
- If you have specific data (e.g., exact patient numbers or pricing), I can refine these calculations.