

To estimate the **Potential Peak Sales** for pembrolizumab (KEYTRUDA) in the indication of recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation 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 make several assumptions and follow a structured approach. Since specific data on patient numbers, pricing, and market penetration for this indication may not be publicly available in real-time, I will outline the methodology and provide a reasonable estimate based on general oncology market data and pembrolizumab's established profile.

Step 1: Define Key Assumptions and Methodology

1. Target Patient Population:

- cSCC is a relatively rare cancer compared to other indications for pembrolizumab (e.g., non-small cell lung cancer or melanoma). The indication specified is for recurrent or metastatic cSCC not curable by surgery or radiation, which narrows the patient pool further.
- Incidence of cSCC varies by region due to differences in sun exposure, skin types, and aging populations. We will estimate the eligible patient population using available epidemiology data and assume a fraction of patients are in the recurrent/metastatic stage.

2. Market Share:

- The problem assumes a 20% to 30% share of treated patients for pembrolizumab in this indication. This range seems reasonable given pembrolizumab's strong position in immuno-oncology and the lack of many competing therapies for advanced cSCC prior to its approval.

3. Pricing:

- Pembrolizumab's annual cost per patient in the US is approximately \$150,000–\$180,000 (based on standard dosing for oncology indications). Pricing in other regions like EU5, Japan, and China may be lower due to healthcare system negotiations and local pricing policies (e.g., 60–80% of US price in EU5 and Japan, and potentially lower in China).

4. Peak Sales:

- Peak sales are typically achieved 5–10 years after approval in a given indication, assuming market penetration and no major competitive disruptions.

5. Geographic Focus:

- US, EU5 (aggregate), China, and Japan are the key markets. We will estimate patient populations and sales for each region.

Step 2: Estimate Eligible Patient Population

Based on epidemiology data and oncology reports, the incidence of cSCC and the proportion of recurrent/metastatic cases can be approximated as follows (these are rough estimates and may need adjustment with more precise data):

- **US:**

- Annual incidence of cSCC: ~1 million cases (high due to sun exposure and aging population).
- Proportion with recurrent/metastatic cSCC not curable by surgery/radiation: ~1–2% (i.e., 10,000–20,000 patients annually).
- Treatable population (factoring diagnosis and access): ~10,000 patients.

- **EU5:**

- Annual incidence of cSCC: ~500,000–600,000 cases (lower per capita than US but significant aging population).
- Recurrent/metastatic not curable: ~1–2% (i.e., 5,000–12,000 patients).
- Treatable population: ~8,000 patients.

- **Japan:**

- Annual incidence of cSCC: ~10,000–15,000 cases (lower incidence due to skin type and less UV exposure).
- Recurrent/metastatic not curable: ~1–2% (i.e., 100–300 patients).
- Treatable population: ~200 patients.

- **China:**

- Annual incidence of cSCC: ~50,000–100,000 cases (lower incidence due to skin type, but large population).
- Recurrent/metastatic not curable: ~1–2% (i.e., 500–2,000 patients).
- Treatable population: ~1,000 patients (factoring lower access to advanced therapies).

Total Treatable Population Across Regions: ~10,000 (US) + 8,000 (EU5) + 200 (Japan) + 1,000 (China) = **19,200 patients**.

Step 3: Estimate Pricing Per Patient

Pembrolizumab pricing varies by region:

- **US:** \$150,000 per patient per year.
- **EU5:** ~\$100,000 per patient per year (assuming ~65–70% of US price due to negotiated discounts).
- **Japan:** ~\$100,000 per patient per year (similar to EU5).
- **China:** ~\$50,000 per patient per year (lower due to pricing controls and limited reimbursement).

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

Using the treatable population, assumed market share, and pricing, we calculate peak sales as follows:

US:

- Treatable patients: 10,000
- Market share (20–30%): 2,000–3,000 patients
- Price per patient: \$150,000
- **Peak Sales:** $2,000 \times \$150,000 = \300M (20% share) to $3,000 \times \$150,000 = \450M (30% share)

EU5:

- Treatable patients: 8,000
- Market share (20–30%): 1,600–2,400 patients
- Price per patient: \$100,000
- **Peak Sales:** $1,600 \times \$100,000 = \160M (20% share) to $2,400 \times \$100,000 = \240M (30% share)

Japan:

- Treatable patients: 200
- Market share (20–30%): 40–60 patients
- Price per patient: \$100,000
- **Peak Sales:** $40 \times \$100,000 = \4M (20% share) to $60 \times \$100,000 = \6M (30% share)

China:

- Treatable patients: 1,000
- Market share (20–30%): 200–300 patients
- Price per patient: \$50,000
- **Peak Sales:** $200 \times \$50,000 = \10M (20% share) to $300 \times \$50,000 = \15M (30% share)

Total Peak Sales Across Regions:

- At 20% market share: $\$300\text{M (US)} + \$160\text{M (EU5)} + \$4\text{M (Japan)} + \$10\text{M (China)} = \$474\text{M}$
- At 30% market share: $\$450\text{M (US)} + \$240\text{M (EU5)} + \$6\text{M (Japan)} + \$15\text{M (China)} = \$711\text{M}$

Potential Peak Sales Range: \$474M to \$711M annually.

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

A 1% share corresponds to 1% of the treatable population in each region, multiplied by the price per patient.

US:

- 1% of 10,000 patients = 100 patients
- Price per patient: \$150,000
- **Value of 1% share:** $100 \times \$150,000 = \15M

EU5:

- 1% of 8,000 patients = 80 patients
- Price per patient: \$100,000
- **Value of 1% share:** $80 \times \$100,000 = \8M

Japan:

- 1% of 200 patients = 2 patients
- Price per patient: \$100,000
- **Value of 1% share:** $2 \times \$100,000 = \0.2M

China:

- 1% of 1,000 patients = 10 patients
- Price per patient: \$50,000
- **Value of 1% share:** $10 \times \$50,000 = \0.5M

Total Value of 1% Share Across Regions: \$15M (US) + \$8M (EU5) + \$0.2M (Japan) + \$0.5M (China)
= \$23.7M

Final Answer

- **Potential Peak Sales for Pembrolizumab in cSCC (20–30% market share):**

- US: \$300M–\$450M
- EU5: \$160M–\$240M
- Japan: \$4M–\$6M
- China: \$10M–\$15M
- **Total: \$474M–\$711M annually**

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

- US: \$15M
- EU5: \$8M
- Japan: \$0.2M

- China: \$0.5M

- **Total: \$23.7M**

Notes and Caveats

1. These estimates are based on rough approximations of patient populations and pricing. Real-world data may differ due to access barriers, competition (e.g., other immunotherapies or generics post-patent expiry), and reimbursement policies.

2. Pembrolizumab's sales in cSCC are a small fraction of its total revenue (which exceeds \$20B annually across all indications), as cSCC is a niche indication compared to lung cancer or melanoma.

3. If more precise data on patient numbers or regional pricing is available, these estimates can be refined. For now, this provides a reasonable range based on industry standards.