

To estimate the **Potential Peak Sales** for cosibelimab-ipdl in the indication of metastatic cutaneous squamous cell carcinoma (mCSCC) and locally advanced CSCC (laCSCC) 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 specific data on patient populations, pricing, and market dynamics for cosibelimab-ipdl may not be publicly available, I will base the analysis on reasonable assumptions derived from market research, epidemiology data for CSCC, and benchmarks for similar oncology drugs (e.g., other PD-1/PD-L1 inhibitors like pembrolizumab or cemiplimab, which is already approved for CSCC).

Step 1: Key Assumptions

1. Indication and Patient Population:

- Cosibelimab-ipdl is approved for mCSCC and laCSCC in patients not eligible for curative surgery or radiation.
- CSCC is the second most common skin cancer, with a subset progressing to advanced stages (mCSCC or laCSCC). Approximately 5-10% of CSCC cases are advanced.
- Incidence of CSCC varies by geography due to differences in UV exposure, aging populations, and healthcare access.

2. Market Share:

- Assuming a 20-30% share of treated patients for cosibelimab-ipdl, as provided in the query. This accounts for competition from existing therapies like cemiplimab (Libtayo) and other systemic therapies.

3. Pricing:

- PD-1/PD-L1 inhibitors for oncology indications typically have an annual cost per patient in the range of \$100,000–\$150,000 in the US. Costs are lower in other markets due to pricing regulations and negotiations (e.g., 50-70% of US price in EU5, and even lower in China and Japan).

4. Treatment Duration:

- Patients with advanced CSCC on immunotherapy are often treated for 6-12 months or until disease progression/toxicity. We assume an average of 9 months of treatment for peak sales calculation.

5. Penetration and Diagnosis Rates:

- Not all eligible patients receive treatment due to access, cost, or late diagnosis. Penetration rates are assumed to be 60-80% in the US and EU5, 40-50% in Japan, and 20-30% in China.

Step 2: Estimate Eligible Patient Population

Using epidemiology data and published estimates for CSCC:

- **US:** ~1 million CSCC cases annually; ~5-7% advanced (mCSCC/laCSCC) = ~50,000–70,000 patients. Assuming 60% are ineligible for surgery/radiation and 70% treated = ~25,000–30,000 treated patients.
- **EU5:** ~300,000–400,000 CSCC cases annually (combined); ~5-7% advanced = ~15,000–28,000 patients. Assuming 60% ineligible and 70% treated = ~6,000–12,000 treated patients.

- **China:** ~200,000–300,000 CSCC cases annually (lower incidence due to skin type and UV exposure); ~5% advanced = ~10,000–15,000 patients. Assuming 50% ineligible and 25% treated = ~1,250–1,875 treated patients.

- **Japan:** ~30,000–50,000 CSCC cases annually; ~5-7% advanced = ~1,500–3,500 patients. Assuming 60% ineligible and 60% treated = ~500–1,250 treated patients.

Total Treated Patients Across Geographies: ~32,750–45,125 patients.

Step 3: Estimate Annual Cost per Patient

- **US:** \$120,000 per patient (average for PD-1/PD-L1 therapies).

- **EU5:** \$80,000 per patient (lower due to pricing negotiations).

- **China:** \$40,000 per patient (significant discounts and local pricing pressures).

- **Japan:** \$70,000 per patient (regulated pricing, slightly lower than EU5).

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

- **US:**

- Treated patients: 25,000–30,000

- 20-30% share: 5,000–9,000 patients

- Peak Sales: $5,000-9,000 \times \$120,000 = \$600\text{M}-\$1,080\text{M}$

- **EU5:**

- Treated patients: 6,000–12,000

- 20-30% share: 1,200–3,600 patients

- Peak Sales: $1,200-3,600 \times \$80,000 = \$96\text{M}-\$288\text{M}$

- **China:**

- Treated patients: 1,250–1,875

- 20-30% share: 250–563 patients

- Peak Sales: $250-563 \times \$40,000 = \$10\text{M}-\$22.5\text{M}$

- **Japan:**

- Treated patients: 500–1,250

- 20-30% share: 100–375 patients

- Peak Sales: $100-375 \times \$70,000 = \$7\text{M}-\$26.3\text{M}$

Total Peak Sales Across Geographies (20-30% Share): \$713M–\$1,417M

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

- **US:**

- Treated patients: 25,000–30,000
- 1% share: 250–300 patients
- Value: $250-300 \times \$120,000 = \$30\text{M}-\$36\text{M}$

- **EU5:**

- Treated patients: 6,000–12,000
- 1% share: 60–120 patients
- Value: $60-120 \times \$80,000 = \$4.8\text{M}-\$9.6\text{M}$

- **China:**

- Treated patients: 1,250–1,875
- 1% share: 12.5–18.75 patients
- Value: $12.5-18.75 \times \$40,000 = \$0.5\text{M}-\$0.75\text{M}$

- **Japan:**

- Treated patients: 500–1,250
- 1% share: 5–12.5 patients
- Value: $5-12.5 \times \$70,000 = \$0.35\text{M}-\$0.875\text{M}$

Total \$ Value of 1% Share Across Geographies: \$35.65M–\$47.225M

Final Answer

- **Potential Peak Sales for cosibelimab-ipdl (20-30% share)** in the US, EU5, China, and Japan: **\$713 million to \$1,417 million** annually.

- **\$ Value of 1% Share of Treated Patients** in these geographies: **\$35.65 million to \$47.23 million** annually.

Note: These estimates are based on assumptions and should be refined with more precise data on patient numbers, pricing, market access, and competitive dynamics specific to cosibelimab-ipdl. Factors such as reimbursement policies, generic competition, and clinical differentiation could significantly impact these figures. If you have additional data (e.g., specific pricing or trial outcomes), I can adjust the analysis accordingly.