

To estimate the **Potential Peak Sales** for cemiplimab-rwlc (Libtayo) in the indication of locally advanced basal cell carcinoma (laBCC) and metastatic basal cell carcinoma (mBCC) 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. This involves estimating the addressable patient population, treatment rates, market share, pricing, and other relevant factors. Since exact data may not be publicly available, I will outline the methodology and provide reasonable assumptions based on industry standards and publicly available information.

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## **Step 1: Define the Indication and Target Population**

Cemiplimab-rwlc (Libtayo) is approved for:

- **Locally advanced basal cell carcinoma (laBCC)** in patients previously treated with a hedgehog pathway inhibitor (HHI) or for whom HHI is not appropriate (regular approval).
- **Metastatic basal cell carcinoma (mBCC)** in patients previously treated with a HHI or for whom HHI is not appropriate (accelerated approval).

Basal cell carcinoma (BCC) is the most common type of skin cancer. While most cases are early-stage and treatable with surgery, a small percentage progress to laBCC or mBCC, which are more challenging to treat.

## **Step 2: Estimate the Addressable Patient Population**

We need to estimate the number of patients with laBCC and mBCC who are eligible for cemiplimab-rwlc (i.e., previously treated with HHI or ineligible for HHI). Below are approximate incidence and prevalence figures based on available epidemiology data:

### **- US:**

- BCC incidence: ~3.6 million cases per year.
- laBCC/mBCC: ~1-2% of BCC cases (~36,000–72,000 patients).
- Eligible for cemiplimab (post-HHI or HHI-ineligible): ~20-30% of laBCC/mBCC (~7,200–21,600 patients).

### **- EU5:**

- BCC incidence: ~1.5–2 million cases per year.
- laBCC/mBCC: ~1-2% (~15,000–40,000 patients).
- Eligible for cemiplimab: ~20-30% (~3,000–12,000 patients).

### **- China:**

- BCC incidence: Lower than in Western countries due to lower UV exposure and different skin types; estimated at ~500,000–700,000 cases per year.
- laBCC/mBCC: ~1-2% (~5,000–14,000 patients).
- Eligible for cemiplimab: ~20-30% (~1,000–4,200 patients).

- **Japan:**

- BCC incidence: ~100,000–150,000 cases per year.
- laBCC/mBCC: ~1-2% (~1,000–3,000 patients).
- Eligible for cemiplimab: ~20-30% (~200–900 patients).

**Total Eligible Patients Across Geographies:** ~11,400–38,700 patients.

### **Step 3: Estimate Treatment Rate and Market Share**

- **Treatment Rate:** Not all eligible patients will receive systemic therapy. Assuming a treatment rate of 50-70% for advanced BCC patients who fail or are ineligible for HHI, the treated population is ~5,700–27,090 patients.

- **Market Share:** The query assumes a 20-30% share of treated patients for cemiplimab-rwlc. This translates to:

- Low end (20%): ~1,140–5,418 patients.
- High end (30%): ~1,710–8,127 patients.

### **Step 4: Estimate Pricing and Annual Cost per Patient**

Cemiplimab-rwlc is a PD-1 inhibitor, and its pricing is aligned with other immunotherapies like pembrolizumab or nivolumab. The annual cost per patient is typically in the range of \$100,000–\$150,000 in the US, with lower prices in other geographies due to healthcare system differences and negotiations.

- **US:** ~\$120,000 per patient per year.
- **EU5:** ~\$80,000 per patient per year (discounted due to pricing controls).
- **China:** ~\$50,000 per patient per year (lower due to market access challenges and pricing pressures).
- **Japan:** ~\$90,000 per patient per year (similar to EU5 but with some variation).

### **Step 5: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients (based on market share) by the annual cost per patient in each geography.

#### Low-End Estimate (20% Market Share)

- **US:** 1,140–4,320 patients × \$120,000 = **\$137M–\$518M.**
- **EU5:** 600–2,400 patients × \$80,000 = **\$48M–\$192M.**
- **China:** 200–840 patients × \$50,000 = **\$10M–\$42M.**
- **Japan:** 40–180 patients × \$90,000 = **\$3.6M–\$16.2M.**
- **Total Peak Sales (Low End):** **\$198.6M–\$768.2M.**

#### High-End Estimate (30% Market Share)

- **US:** 1,710–6,480 patients × \$120,000 = **\$205M–\$778M.**
- **EU5:** 900–3,600 patients × \$80,000 = **\$72M–\$288M.**
- **China:** 300–1,260 patients × \$50,000 = **\$15M–\$63M.**
- **Japan:** 60–270 patients × \$90,000 = **\$5.4M–\$24.3M.**
- **Total Peak Sales (High End):** **\$297.4M–\$1,153.3M.**

**Potential Peak Sales Range:** **\$198.6M–\$1,153.3M annually.**

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

A 1% share of treated patients corresponds to 1% of the treated population (5,700–27,090 patients), i.e., ~57–271 patients globally.

- **US:** 28–136 patients × \$120,000 = **\$3.4M–\$16.3M.**
- **EU5:** 12–48 patients × \$80,000 = **\$1.0M–\$3.8M.**
- **China:** 4–17 patients × \$50,000 = **\$0.2M–\$0.9M.**
- **Japan:** 1–3 patients × \$90,000 = **\$0.1M–\$0.3M.**
- **Total \$ Value of 1% Share:** **\$4.7M–\$21.3M.**

**\$ Value of 1% Share of Treated Patients:** **\$4.7M–\$21.3M.**

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## **Key Assumptions and Limitations**

1. **Epidemiology Data:** Exact numbers for laBCC and mBCC patients eligible for cemiplimab are not publicly available and are based on approximations. Real-world data may vary.
2. **Treatment Rate:** The assumption of a 50-70% treatment rate may overestimate or underestimate actual uptake.
3. **Pricing:** Pricing varies significantly by country and is subject to negotiations, rebates, and access programs.
4. **Market Share:** The 20-30% market share assumes competition from other therapies (e.g., other PD-1 inhibitors or novel treatments) and physician/patient preferences.
5. **Duration of Therapy:** Peak sales assume patients are treated for a full year, but actual treatment duration may vary based on response, progression, or adverse events.

## **Final Answer**

- **Potential Peak Sales for Cemiplimab-rwlc (20-30% Market Share):** **\$198.6M–\$1,153.3M annually** across the US, EU5, China, and Japan.

- **\$ Value of 1% Share of Treated Patients: \$4.7M–\$21.3M** across the same geographies.

These estimates are rough and should be validated with more precise epidemiology, pricing, and market access data if available. If you have additional specific data or context, I can refine the calculations further.