

To calculate the **Potential Peak Sales** for **cemiplimab-rwlc (Libtayo)** in the indication of advanced non-small cell lung cancer (NSCLC) 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 such as exact patient numbers, pricing, or market penetration rates are not provided, I will outline a methodology using reasonable estimates based on publicly available information and industry standards.

Step 1: Key Assumptions and Data Points

1. Indication: Advanced NSCLC with no EGFR, ALK, or ROS1 aberrations.

- This represents approximately 85-90% of NSCLC cases, as EGFR, ALK, and ROS1 mutations/aberrations account for about 10-15% of cases in Western populations and slightly higher in Asian populations.

2. Patient Population:

- NSCLC accounts for ~85% of all lung cancer cases.
- We will estimate the number of advanced NSCLC patients (Stage IIIB/IV) eligible for systemic therapy.
- Incidence rates and eligible patient populations will be estimated for each geography.

3. Market Share:

- Assuming a 20% to 30% share of treated patients for cemiplimab-rwlc in combination with platinum-based chemotherapy.

4. Pricing:

- Cemiplimab-rwlc (Libtayo) pricing is based on its current cost in the US for other indications (e.g., cutaneous squamous cell carcinoma or basal cell carcinoma). The annual cost is approximately **\$150,000–\$180,000 per patient** in the US. For other regions, pricing is typically lower due to healthcare system differences (e.g., 50-70% of US price in EU5, and further discounts in China and Japan).

5. Treatment Duration:

- Assuming an average treatment duration of **6–12 months** for advanced NSCLC, depending on progression-free survival (PFS) and overall survival (OS) data from clinical trials (e.g., EMPOWER-Lung 3 trial for cemiplimab + chemo).

6. Peak Sales Timing:

- Peak sales are typically reached 5–7 years post-launch after market penetration stabilizes.

Step 2: Estimate Eligible Patient Population

Using approximate lung cancer incidence rates and adjusting for NSCLC (85%) and advanced stage (60-70% of NSCLC cases), we estimate the number of patients eligible for systemic therapy (advanced NSCLC without EGFR/ALK/ROS1 aberrations, ~85-90% of advanced NSCLC).

- US:

- Lung cancer incidence: ~230,000 cases/year.
- NSCLC: ~195,000 cases (85%).

- Advanced NSCLC (Stage IIIB/IV): ~117,000–136,000 (60-70%).
- Eligible (no aberrations): ~100,000–122,000 (85-90%).
- **EU5** (France, Germany, Italy, Spain, UK):
- Lung cancer incidence: ~300,000 cases/year.
- NSCLC: ~255,000 cases (85%).
- Advanced NSCLC: ~153,000–178,000 (60-70%).
- Eligible: ~130,000–160,000 (85-90%).
- **China:**
- Lung cancer incidence: ~800,000 cases/year.
- NSCLC: ~680,000 cases (85%).
- Advanced NSCLC: ~408,000–476,000 (60-70%).
- Eligible: ~347,000–428,000 (85-90%, though EGFR mutations are higher in Asia, ~30-40%, so adjust to ~60-70% eligible: ~245,000–333,000).
- **Japan:**
- Lung cancer incidence: ~130,000 cases/year.
- NSCLC: ~110,000 cases (85%).
- Advanced NSCLC: ~66,000–77,000 (60-70%).
- Eligible: ~46,000–54,000 (adjust for higher EGFR mutations, ~60-70% eligible: ~40,000–46,000).

Total Eligible Patients (Approximate Midpoint):

- US: 110,000
- EU5: 145,000
- China: 290,000
- Japan: 43,000
- **Total:** ~588,000 patients across these geographies.

Step 3: Estimate Treated Patients with Cemiplimab-rwlc

Assuming a market share of **20% to 30%** of eligible patients:

- **US:** 22,000–33,000 patients.
- **EU5:** 29,000–43,500 patients.
- **China:** 58,000–87,000 patients.
- **Japan:** 8,600–12,900 patients.
- **Total Treated:** ~117,600–176,400 patients at 20-30% share.

Step 4: Estimate Pricing per Patient

- **US:** \$150,000–\$180,000/year.
- **EU5:** \$75,000–\$100,000/year (50-60% of US price due to negotiated pricing).
- **China:** \$30,000–\$50,000/year (20-30% of US price due to significant discounts and local policies).
- **Japan:** \$60,000–\$80,000/year (40-50% of US price).

Step 5: Calculate Potential Peak Sales

Using midpoint patient numbers and pricing for simplicity:

- **US:** 27,500 patients × \$165,000 = **\$4.54 billion**.
- **EU5:** 36,250 patients × \$87,500 = **\$3.17 billion**.
- **China:** 72,500 patients × \$40,000 = **\$2.90 billion**.
- **Japan:** 10,750 patients × \$70,000 = **\$0.75 billion**.
- **Total Peak Sales (Midpoint):** **\$11.36 billion** annually at ~25% market share.

Range of Peak Sales (based on 20-30% market share and pricing ranges):

- Low end (20% share, lower pricing): ~\$7.5–\$8.0 billion.
- High end (30% share, higher pricing): ~\$13.5–\$14.0 billion.

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

1% of eligible patients (total ~588,000) = ~5,880 patients.

- **US:** 1% = 1,100 patients × \$165,000 = **\$181.5 million**.
- **EU5:** 1% = 1,450 patients × \$87,500 = **\$126.9 million**.
- **China:** 1% = 2,900 patients × \$40,000 = **\$116.0 million**.
- **Japan:** 1% = 430 patients × \$70,000 = **\$30.1 million**.
- **Total Value of 1% Share:** **\$454.5 million**.

Final Answer

- **Potential Peak Sales for Cemiplimab-rwlc** in advanced NSCLC (US, EU5, China, Japan):
- **Range:** \$7.5 billion to \$14.0 billion annually.
- **Midpoint Estimate:** ~\$11.4 billion annually (at ~25% market share).
- **\$ Value of 1% Share of Treated Patients:**
- US: \$181.5 million
- EU5: \$126.9 million

- China: \$116.0 million
- Japan: \$30.1 million
- **Total:** \$454.5 million.

Notes

- These estimates are based on assumptions and should be refined with actual clinical trial data (e.g., EMPOWER-Lung 3 results for PFS/OS), real-world pricing, reimbursement policies, and competitive landscape (e.g., Keytruda, Opdivo, and other PD-1/PD-L1 inhibitors dominate NSCLC).
- Market share assumptions (20-30%) account for competition from established players like pembrolizumab (Keytruda), which has a strong foothold in NSCLC.
- China's lower pricing reflects government-driven price negotiations and volume-based procurement policies.
- Peak sales may vary based on adoption rates, label expansions, or combination therapy outcomes.

If you have access to specific data (e.g., exact patient numbers, trial results, or pricing), I can refine these calculations further.