

To estimate the **Potential Peak Sales** for cemiplimab-rwlc (Libtayo) in the first-line treatment of advanced non-small cell lung cancer (NSCLC) with high PD-L1 expression (TPS > 50%) in the US, EU5 (Germany, France, 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 numbers, pricing, and market penetration may not be publicly available in real-time, I will outline the methodology and use reasonable assumptions based on publicly available data, historical trends for NSCLC treatments, and market dynamics for PD-1/PD-L1 inhibitors.

Key Assumptions and Methodology

1. Indication and Target Population:

- Cemiplimab-rwlc is approved for first-line treatment of advanced NSCLC patients with high PD-L1 expression (TPS > 50%) and no EGFR, ALK, or ROS1 aberrations.
- Approximately 25-30% of NSCLC patients have high PD-L1 expression (TPS > 50%).
- We will estimate the total number of eligible patients based on NSCLC incidence, proportion of advanced cases, and PD-L1 expression rates.

2. Market Share:

- The question assumes a 20-30% share of treated patients for cemiplimab-rwlc. This accounts for competition with other PD-1/PD-L1 inhibitors like pembrolizumab (Keytruda), which dominates the first-line NSCLC market for high PD-L1 expressors.
- We will calculate peak sales based on this range of market share.

3. Pricing:

- Annual treatment cost for PD-1/PD-L1 inhibitors like cemiplimab is typically in the range of \$100,000–\$150,000 per patient in the US. Pricing in other regions is generally lower due to healthcare system differences (e.g., ~50-70% of US price in EU5 and Japan, and significantly lower in China due to price negotiations and generics).
- Assumed annual costs (per patient):
 - US: \$120,000
 - EU5: \$80,000 (aggregate average)
 - Japan: \$80,000
 - China: \$30,000 (due to lower pricing and potential inclusion in the National Reimbursement Drug List)

4. Geographic Incidence of NSCLC:

- Total new NSCLC cases annually (based on historical data and epidemiology reports like GLOBOCAN):
 - US: ~200,000
 - EU5: ~300,000 (combined)
 - China: ~800,000

- Japan: ~120,000
- Proportion of advanced NSCLC (Stage IIIB/IV, not candidates for surgery or chemoradiation): ~60-70%.
- Proportion with high PD-L1 (TPS > 50%): ~25-30%.
- Proportion without EGFR/ALK/ROS1 aberrations: ~70-80% (since these mutations are mutually exclusive with high PD-L1 in many cases).

5. Treatment Rate:

- Not all eligible patients receive immunotherapy due to comorbidities, access issues, or physician preference. Assumed treatment rate: 70% in the US/EU5/Japan, 50% in China.

6. Peak Sales Timeline:

- Peak sales are typically achieved 5-7 years after launch in a given indication, assuming no major changes in competitive landscape or patent expiry.

Step 1: Estimate Eligible Patient Population

Using the above assumptions, let's calculate the number of eligible patients for first-line cemiplimab-rwlc in each geography.

- US:

- Total NSCLC cases: 200,000
- Advanced NSCLC (65%): 130,000
- High PD-L1 (TPS > 50%, 27.5%): 35,750
- No EGFR/ALK/ROS1 aberrations (75%): 26,813
- Treated patients (70%): ~18,770

- EU5:

- Total NSCLC cases: 300,000
- Advanced NSCLC (65%): 195,000
- High PD-L1 (27.5%): 53,625
- No aberrations (75%): 40,219
- Treated patients (70%): ~28,153

- China:

- Total NSCLC cases: 800,000
- Advanced NSCLC (65%): 520,000

- High PD-L1 (27.5%): 143,000
- No aberrations (75%): 107,250
- Treated patients (50%): ~53,625

- Japan:

- Total NSCLC cases: 120,000
- Advanced NSCLC (65%): 78,000
- High PD-L1 (27.5%): 21,450
- No aberrations (75%): 16,088
- Treated patients (70%): ~11,262

Total Treated Patients Across Geographies:

18,770 (US) + 28,153 (EU5) + 53,625 (China) + 11,262 (Japan) = **111,810**

Step 2: Estimate Potential Peak Sales for 20-30% Market Share

Now, calculate the number of patients treated with cemiplimab-rwlc assuming a 20-30% market share, and multiply by the annual treatment cost per geography.

- US:

- Treated patients at 20% share: $18,770 * 0.2 = 3,754$
- Treated patients at 30% share: $18,770 * 0.3 = 5,631$
- Peak sales at 20% share: $3,754 * \$120,000 = \textbf{\$450.5 million}$
- Peak sales at 30% share: $5,631 * \$120,000 = \textbf{\$675.7 million}$

- EU5:

- Treated patients at 20% share: $28,153 * 0.2 = 5,631$
- Treated patients at 30% share: $28,153 * 0.3 = 8,446$
- Peak sales at 20% share: $5,631 * \$80,000 = \textbf{\$450.5 million}$
- Peak sales at 30% share: $8,446 * \$80,000 = \textbf{\$675.7 million}$

- China:

- Treated patients at 20% share: $53,625 * 0.2 = 10,725$
- Treated patients at 30% share: $53,625 * 0.3 = 16,088$
- Peak sales at 20% share: $10,725 * \$30,000 = \textbf{\$321.8 million}$
- Peak sales at 30% share: $16,088 * \$30,000 = \textbf{\$482.6 million}$

- Japan:

- Treated patients at 20% share: $11,262 * 0.2 = 2,252$
- Treated patients at 30% share: $11,262 * 0.3 = 3,379$
- Peak sales at 20% share: $2,252 * \$80,000 = \text{\$180.2 million}$
- Peak sales at 30% share: $3,379 * \$80,000 = \text{\$270.3 million}$

Total Peak Sales Across Geographies:

- At 20% market share: $\$450.5\text{M (US)} + \$450.5\text{M (EU5)} + \$321.8\text{M (China)} + \$180.2\text{M (Japan)} = \text{\$1,403.0 million (~\$1.40 billion)}$
- At 30% market share: $\$675.7\text{M (US)} + \$675.7\text{M (EU5)} + \$482.6\text{M (China)} + \$270.3\text{M (Japan)} = \text{\$2,104.3 million (~\$2.10 billion)}$

Potential Peak Sales Range for Cemiplimab-rwlc in this Indication: \$1.40 billion to \$2.10 billion annually

Step 3: Estimate \$ Value of 1% Share of Treated Patients

A 1% market share corresponds to 1% of the total treated patients in each geography, multiplied by the annual treatment cost.

- US:

- Total treated patients: 18,770
- 1% share: $18,770 * 0.01 = 188$
- Value of 1% share: $188 * \$120,000 = \text{\$22.5 million}$

- EU5:

- Total treated patients: 28,153
- 1% share: $28,153 * 0.01 = 282$
- Value of 1% share: $282 * \$80,000 = \text{\$22.5 million}$

- China:

- Total treated patients: 53,625
- 1% share: $53,625 * 0.01 = 536$
- Value of 1% share: $536 * \$30,000 = \text{\$16.1 million}$

- Japan:

- Total treated patients: 11,262
- 1% share: $11,262 * 0.01 = 113$

- Value of 1% share: $113 * \$80,000 = \9.0 million

Total \$ Value of 1% Share Across Geographies:

$\$22.5\text{M (US)} + \$22.5\text{M (EU5)} + \$16.1\text{M (China)} + \$9.0\text{M (Japan)} = \mathbf{\$70.1 \text{ million}}$

Final Answer

1. Potential Peak Sales for Cemiplimab-rwlc in this Indication (assuming 20-30% market share):

- **US, EU5, China, and Japan Combined: \$1.40 billion to \$2.10 billion annually**

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

- **US:** \$22.5 million

- **EU5:** \$22.5 million

- **China:** \$16.1 million

- **Japan:** \$9.0 million

- **Total Across Geographies: \$70.1 million**

Caveats and Notes

- These estimates are based on assumptions for patient numbers, pricing, and treatment rates. Real-world data may differ due to competitive dynamics (e.g., dominance of pembrolizumab in this space), reimbursement policies, and regional access challenges.

- Peak sales could be impacted by future competitors, biosimilars, or changes in standard of care.

- Pricing in China is particularly variable due to government negotiations and potential local manufacturing agreements.

- The analysis assumes a steady-state market without significant disruptions (e.g., new therapies or loss of exclusivity).

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