

To estimate the **Potential Peak Sales** for the combination of nivolumab (Opdivo) plus ipilimumab (Yervoy) and 2 cycles of platinum-doublet chemotherapy in the first-line treatment of metastatic or recurrent 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 follow a structured approach. This involves estimating the eligible patient population, treatment costs, market share, and peak sales potential. Since exact data may not be publicly available, I will outline the methodology and provide reasonable assumptions based on industry standards, epidemiology, and market trends as of my last update (October 2023). Please note that these are illustrative calculations and should be validated with up-to-date market research or proprietary data.

Step 1: Define the Indication and Eligible Patient Population

The indication is first-line treatment for metastatic or recurrent NSCLC patients without EGFR or ALK genomic aberrations. NSCLC accounts for approximately 85% of lung cancer cases, and a significant portion of these are diagnosed at an advanced stage (Stage IIIB/IV or recurrent).

Epidemiology of NSCLC (Estimated Annual Incidence of Advanced NSCLC):

- **US:** ~230,000 new lung cancer cases annually, of which ~85% are NSCLC (~195,500). Approximately 60% are advanced or metastatic at diagnosis (~117,300). About 80-85% of these do not have EGFR/ALK mutations (~94,000–100,000 eligible patients).

- **EU5:** Combined incidence of lung cancer is ~320,000 annually, with ~85% NSCLC (~272,000). About 60% are advanced (~163,200), and ~80-85% lack EGFR/ALK mutations (~130,000–140,000 eligible patients).

- **China:** ~735,000 new lung cancer cases annually, ~85% NSCLC (~625,000). About 60% are advanced (~375,000), and ~80-85% lack EGFR/ALK mutations (~300,000–320,000 eligible patients). (Note: EGFR mutation rates are higher in China, so we lean toward the lower end.)

- **Japan:** ~125,000 new lung cancer cases annually, ~85% NSCLC (~106,000). About 60% are advanced (~63,600), and ~80-85% lack EGFR/ALK mutations (~51,000–54,000 eligible patients).

Total Eligible Patients (Approximate Midpoint):

- US: 97,000

- EU5: 135,000

- China: 310,000

- Japan: 52,500

- **Total:** ~594,500 patients annually across these geographies.

Step 2: Estimate Treated Patient Share

Not all eligible patients receive treatment due to factors like comorbidities, access to healthcare, or patient/physician preferences. We assume:

- **US/EU5/Japan:** ~70-80% of eligible patients receive systemic therapy in first-line (midpoint: 75%).
- **China:** ~50-60% due to access and affordability constraints (midpoint: 55%).

Treated Patients:

- US: $97,000 \times 75\% = \sim 72,750$
- EU5: $135,000 \times 75\% = \sim 101,250$
- China: $310,000 \times 55\% = \sim 170,500$
- Japan: $52,500 \times 75\% = \sim 39,375$
- **Total Treated Patients:** ~383,875 annually.

The problem assumes a **20% to 30% share of treated patients** for this combination therapy. We will use the midpoint of **25%** for peak sales calculation.

- Patients Treated with Nivolumab + Ipilimumab Combo (25% Share):

- US: $72,750 \times 25\% = \sim 18,188$
- EU5: $101,250 \times 25\% = \sim 25,313$
- China: $170,500 \times 25\% = \sim 42,625$
- Japan: $39,375 \times 25\% = \sim 9,844$
- **Total:** ~96,000 patients annually.

1% Share of Treated Patients (for \$ value calculation):

- US: $72,750 \times 1\% = 728$
- EU5: $101,250 \times 1\% = 1,013$
- China: $170,500 \times 1\% = 1,705$
- Japan: $39,375 \times 1\% = 394$
- **Total:** ~3,840 patients.

Step 3: Estimate Annual Treatment Cost per Patient

The cost of therapy varies by region due to pricing differences, healthcare systems, and reimbursement policies. The combination includes nivolumab, ipilimumab, and 2 cycles of platinum-doublet chemotherapy. We focus primarily on the immunotherapy component as it dominates the cost.

- **Nivolumab (Opdivo):** Often dosed at 240 mg every 2 weeks or 480 mg every 4 weeks. Annual cost in the US is ~\$150,000–\$180,000 (assuming full-year treatment).

- **Ipilimumab (Yervoy):** Typically dosed less frequently in combination (e.g., 1 mg/kg every 6 weeks). Annual cost in the US is ~\$80,000–\$100,000.

- **Chemotherapy (2 cycles):** Platinum-doublet chemo (e.g., cisplatin/carboplatin + pemetrexed) costs ~\$5,000–\$10,000 in the US for 2 cycles.
- **Total US Cost per Patient:** ~\$235,000–\$290,000 annually (midpoint: \$262,500).

Regional Cost Adjustments (as a % of US pricing, approximate):

- EU5: ~60-70% of US pricing due to negotiations and discounts (midpoint: 65% = ~\$170,625 per patient).
- Japan: ~70-80% of US pricing (midpoint: 75% = ~\$196,875 per patient).
- China: ~30-40% of US pricing due to significant discounts and access programs (midpoint: 35% = ~\$91,875 per patient).

Annual Cost per Patient by Region:

- US: \$262,500
- EU5: \$170,625
- China: \$91,875
- Japan: \$196,875

Step 4: Calculate Potential Peak Sales (25% Share)

Peak sales are calculated by multiplying the number of treated patients (25% share) by the annual cost per patient in each region.

- **US:** 18,188 patients × \$262,500 = ~\$4.77 billion
- **EU5:** 25,313 patients × \$170,625 = ~\$4.32 billion
- **China:** 42,625 patients × \$91,875 = ~\$3.92 billion
- **Japan:** 9,844 patients × \$196,875 = ~\$1.94 billion
- **Total Potential Peak Sales (25% Share):** ~\$14.95 billion annually.

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

Using the number of patients corresponding to a 1% share of treated patients and multiplying by the annual cost per patient:

- **US:** 728 patients × \$262,500 = ~\$191 million
- **EU5:** 1,013 patients × \$170,625 = ~\$173 million
- **China:** 1,705 patients × \$91,875 = ~\$157 million
- **Japan:** 394 patients × \$196,875 = ~\$78 million

- **Total \$ Value of 1% Share:** ~\$599 million annually.

Final Answer

1. Potential Peak Sales for the Combination of Nivolumab + Ipilimumab in this Indication (25% Share of Treated Patients):

- US: ~\$4.77 billion
- EU5: ~\$4.32 billion
- China: ~\$3.92 billion
- Japan: ~\$1.94 billion
- **Total:** ~\$14.95 billion annually

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

- US: ~\$191 million
- EU5: ~\$173 million
- China: ~\$157 million
- Japan: ~\$78 million
- **Total:** ~\$599 million annually

Notes and Caveats

- These estimates are based on assumptions for epidemiology, treatment rates, market share, and pricing as of general industry knowledge up to October 2023. Actual figures may differ due to competition (e.g., other immunotherapies like pembrolizumab), pricing negotiations, or changes in treatment guidelines.

- Peak sales typically occur 5-10 years after launch, factoring in market penetration and patent exclusivity (nivolumab's patent expires around 2028-2030 in major markets, though extensions or biosimilars may impact this).

- Costs in China are highly variable due to government-driven price reductions and inclusion in the National Reimbursement Drug List (NRDL).

- These calculations assume a full year of treatment, though real-world duration may be shorter due to progression or toxicity.

For precise figures, consult market research reports (e.g., EvaluatePharma, GlobalData) or Bristol-Myers Squibb's financial disclosures.