To estimate the **Potential Peak Sales** for the combination of nivolumab (Opdivo) and ipilimumab (Yervoy) in the indication of first-line treatment for metastatic non-small cell lung cancer (NSCLC) with PD-L1 expression ≥1% 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 exact data on patient numbers, pricing, and market penetration may not be publicly available or up-to-date, I will outline the methodology and make reasonable assumptions based on available information and industry standards. The final figures will be illustrative and based on these assumptions.

Step 1: Define the Target Patient Population

The indication is for first-line treatment of metastatic NSCLC patients with PD-L1 expression ≥1% and no EGFR or ALK aberrations. We need to estimate the eligible patient population in each geography.

Incidence of NSCLC and Eligible Population:

- **NSCLC** accounts for approximately 85% of all lung cancer cases.

- **Metastatic NSCLC (Stage IV)** represents about 40-50% of NSCLC cases at diagnosis.

- **PD-L1 expression ≥1%**: Studies suggest that approximately 60-70% of NSCLC patients have PD-L1 expression ≥1%.

- **No EGFR/ALK aberrations**: Around 85-90% of NSCLC patients do not have these mutations (as EGFR mutations occur in ~10-15% and ALK in ~3-5% of patients, with some overlap).

Using global cancer statistics (e.g., GLOBOCAN 2020) and regional data:

- **US**: ~235,000 new lung cancer cases annually; ~85% NSCLC (~200,000); ~45% metastatic (~90,000); ~65% PD-L1 ≥1% (~58,500); ~85% no EGFR/ALK (~50,000 eligible patients).

- **EU5**: ~320,000 new lung cancer cases; ~85% NSCLC (~272,000); ~45% metastatic (~122,000); ~65% PD-L1 ≥1% (~79,300); ~85% no EGFR/ALK (~67,400 eligible patients).

- **China**: ~820,000 new lung cancer cases; ~85% NSCLC (~697,000); ~45% metastatic (~313,650); ~65% PD-L1 ≥1% (~203,900); ~85% no EGFR/ALK (~173,300 eligible patients). (Note: EGFR mutation rates are higher in Asia, but we assume 85% for simplicity.)

- **Japan**: ~130,000 new lung cancer cases; ~85% NSCLC (~110,500); ~45% metastatic (~49,700); ~65% PD-L1 ≥1% (~32,300); ~85% no EGFR/ALK (~27,500 eligible patients).

Total Eligible Patients (approximate):

- US: 50,000

- EU5: 67,400

- China: 173,300

- Japan: 27,500

- **Total**: ~318,200 patients annually.

Step 2: Estimate Market Share of Treated Patients

The problem assumes a **20-30% share of treated patients** for this combination therapy. This accounts for competition from other therapies (e.g., pembrolizumab, atezolizumab, chemotherapy regimens) and market access barriers.

- **Low-end (20%)**: 318,200 * 0.2 = ~63,640 treated patients.

- **High-end (30%)**: 318,200 * 0.3 = ~95,460 treated patients.

Step 3: Estimate Annual Treatment Cost per Patient

The combination of nivolumab and ipilimumab is expensive, and costs vary by region due to pricing differences, healthcare systems, and reimbursement policies.

- **US**: Annual cost of nivolumab + ipilimumab combination is approximately $150,000–$200,000 per patient (based on reported costs for Opdivo ~$12,000/month and Yervoy ~$30,000 per dose, with treatment duration of ~1 year or until progression).

- **EU5**: Costs are lower due to price negotiations; assume ~$80,000–$120,000 per patient annually.

- **Japan**: Similar to EU5, ~$80,000–$120,000 per patient annually.

- **China**: Significantly lower due to pricing controls and local competition; assume ~$30,000–$50,000 per patient annually.

For simplicity, we'll use midpoint values:

- US: $175,000 per patient/year

- EU5: $100,000 per patient/year

- Japan: $100,000 per patient/year

- China: $40,000 per patient/year

Step 4: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients (at 20% and 30% market share) by the annual treatment cost per patient in each geography.

Distribution of Eligible Patients by Geography:

- US: 50,000 / 318,200 = ~15.7%

- EU5: 67,400 / 318,200 = ~21.2%

- China: 173,300 / 318,200 = ~54.5%

- Japan: 27,500 / 318,200 = ~8.6%

At 20% Market Share (63,640 treated patients):

- US: 63,640 * 0.157 = ~10,000 patients * $175,000 = **$1.75 billion**

- EU5: 63,640 * 0.212 = ~13,500 patients * $100,000 = **$1.35 billion**

- China: 63,640 * 0.545 = ~34,700 patients * $40,000 = **$1.39 billion**

- Japan: 63,640 * 0.086 = ~5,500 patients * $100,000 = **$0.55 billion**

- **Total Peak Sales (20% share)**: $1.75B + $1.35B + $1.39B + $0.55B = **$5.04 billion**

At 30% Market Share (95,460 treated patients):

- US: 95,460 * 0.157 = ~15,000 patients * $175,000 = **$2.63 billion**

- EU5: 95,460 * 0.212 = ~20,200 patients * $100,000 = **$2.02 billion**

- China: 95,460 * 0.545 = ~52,000 patients * $40,000 = **$2.08 billion**

- Japan: 95,460 * 0.086 = ~8,200 patients * $100,000 = **$0.82 billion**

- **Total Peak Sales (30% share)**: $2.63B + $2.02B + $2.08B + $0.82B = **$7.55 billion**

Potential Peak Sales Range: **$5.0 billion to $7.6 billion annually** across the US, EU5, China, and Japan.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population (318,200 patients) being treated with this combination therapy.

- **1% of eligible patients** = 318,200 * 0.01 = **3,182 patients**

Value of 1% Share by Geography:

- US: 3,182 * 0.157 = ~500 patients * $175,000 = **$87.5 million**

- EU5: 3,182 * 0.212 = ~675 patients * $100,000 = **$67.5 million**

- China: 3,182 * 0.545 = ~1,735 patients * $40,000 = **$69.4 million**

- Japan: 3,182 * 0.086 = ~275 patients * $100,000 = **$27.5 million**

- **Total Value of 1% Share**: $87.5M + $67.5M + $69.4M + $27.5M = **$251.9 million**

$ Value of 1% Share of Treated Patients: **~$252 million annually** across the US, EU5, China, and Japan.

Final Answer:

1. **Potential Peak Sales** for the combination of nivolumab and ipilimumab in first-line metastatic NSCLC (PD-L1 ≥1%, no EGFR/ALK aberrations) with a 20-30% share of treated patients:

- **Range**: **$5.0 billion to $7.6 billion annually** across the US, EU5, China, and Japan.

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

- **~$252 million annually** across the US, EU5, China, and Japan.

Note: These figures are estimates based on assumptions about patient populations, market share, and pricing. Actual figures may vary due to competition, pricing negotiations, reimbursement policies, treatment duration, and market dynamics. For precise calculations, primary data from market research reports (e.g., EvaluatePharma, GlobalData) or company disclosures would be required.