To estimate the **Potential Peak Sales** for durvalumab (IMFINZI) in the indication of extensive-stage small cell lung cancer (ES-SCLC) 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 such as exact patient numbers, pricing, or market penetration may not be fully available, I will outline the methodology and provide a reasonable estimate based on publicly available information, assumptions, and typical market dynamics for oncology drugs. Please note that these are rough estimates and should be validated with more precise data if available.

Step 1: Define Key Parameters and Assumptions

- 1. **Indication**: Durvalumab is approved for first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) in combination with chemotherapy.
- 2. **Market Share Assumption**: The problem assumes a 20% to 30% share of treated patients for durvalumab in this indication.
- 3. Geographies: US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan.
- 4. **Pricing**: Drug pricing varies by region due to healthcare systems, reimbursement policies, and purchasing power. For oncology drugs like durvalumab (a PD-L1 inhibitor), annual treatment costs are typically high.
- US: ~\$150,000–\$180,000 per patient per year (based on similar immunotherapies like pembrolizumab or nivolumab).
- EU5: ~\$80,000–\$120,000 per patient per year (lower due to negotiated pricing and public health systems).
- Japan: ~\$100,000–\$130,000 per patient per year (similar to EU but slightly higher due to market dynamics).
- China: ~\$50,000–\$70,000 per patient per year (lower due to pricing controls and generics competition, though durvalumab may have premium pricing).
- 5. **Patient Population**: We need to estimate the number of ES-SCLC patients eligible for first-line treatment in each region. SCLC accounts for ~15% of all lung cancer cases, and ~70% of SCLC cases are extensive-stage at diagnosis. Incidence of lung cancer varies by region due to smoking prevalence and other factors.
- 6. **Treatment Duration**: Assume an average treatment duration of ~1 year for durvalumab (based on clinical trial data like the CASPIAN trial, where patients receive durvalumab until disease progression or unacceptable toxicity, often around 12 months).

Step 2: Estimate Eligible Patient Population for ES-SCLC

Using approximate lung cancer incidence data and the proportion of ES-SCLC cases:

- **US**: ~230,000 new lung cancer cases/year; ~15% SCLC = ~34,500 SCLC cases; ~70% ES-SCLC = ~24,000 eligible patients.

- **EU5**: \sim 300,000 new lung cancer cases/year; \sim 15% SCLC = \sim 45,000 SCLC cases; \sim 70% ES-SCLC = \sim 31,500 eligible patients.
- China: ~800,000 new lung cancer cases/year (highest incidence due to smoking rates); ~15% SCLC = ~120,000 SCLC cases; ~70% ES-SCLC = ~84,000 eligible patients.
- Japan: ~120,000 new lung cancer cases/year; ~15% SCLC = ~18,000 SCLC cases; ~70% ES-SCLC = ~12,600 eligible patients.

Total Eligible Patients Across Geographies: \sim 24,000 (US) + \sim 31,500 (EU5) + \sim 84,000 (China) + \sim 12,600 (Japan) = \sim 152,100 patients.

<u>Step 3: Estimate Treated Patients with Durvalumab (20%-30% Market Share)</u>

- 20% Market Share:
- US: 24,000 * 0.2 = **4,800 patients**.
- EU5: 31,500 * 0.2 = **6,300 patients**.
- China: 84,000 * 0.2 = 16,800 patients.
- Japan: 12,600 * 0.2 = **2,520 patients**.
- Total: 30,420 patients.
- 30% Market Share:
- US: 24,000 * 0.3 = 7,200 patients.
- EU5: 31,500 * 0.3 = 9,450 patients.
- China: 84,000 * 0.3 = 25,200 patients.
- Japan: 12,600 * 0.3 = 3,780 patients.
- Total: **45,630 patients**.

Step 4: Estimate Peak Sales Based on Pricing and Treated Patients

Using the midpoint of pricing ranges for simplicity:

- US: \$165,000/patient/year.
- EU5: \$100,000/patient/year.
- China: \$60,000/patient/year.
- Japan: \$115,000/patient/year.

Peak Sales at 20% Market Share:

- US: 4,800 patients * \$165,000 = **\$792 million**.

- EU5: 6,300 patients * \$100,000 = **\$630 million**.
- China: 16,800 patients * \$60,000 = **\$1,008 million**.
- Japan: 2,520 patients * \$115,000 = **\$290 million**.
- Total Peak Sales (20% share): \$792M + \$630M + \$1,008M + \$290M = ~\$2,720 million (~\$2.72 billion).

Peak Sales at 30% Market Share:

- US: 7,200 patients * \$165,000 = **\$1,188 million**.
- EU5: 9,450 patients * \$100,000 = **\$945 million**.
- China: 25,200 patients * \$60,000 = **\$1,512 million**.
- Japan: 3,780 patients * \$115,000 = \$435 million.
- Total Peak Sales (30% share): \$1,188M + \$945M + \$1,512M + \$435M = ~\$4,080 million (~\$4.08 billion).

Potential Peak Sales Range for Durvalumab in ES-SCLC: \$2.72 billion to \$4.08 billion annually across the specified geographies for a 20% to 30% market share.

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

A 1% share of treated patients corresponds to 1% of the eligible patient population in each region.

- **US**: 24,000 patients * 0.01 = 240 patients * \$165,000 = **\$39.6 million**.
- **EU5**: 31,500 patients * 0.01 = 315 patients * \$100,000 = **\$31.5 million**.
- China: 84,000 patients * 0.01 = 840 patients * \$60,000 = \$50.4 million.
- **Japan**: 12,600 patients * 0.01 = 126 patients * \$115,000 = **\$14.5 million**.
- Total \$ Value of 1% Share: \$39.6M + \$31.5M + \$50.4M + \$14.5M = ~\$136 million.

\$ Value of 1% Share of Treated Patients: **~\$136 million annually** across the US, EU5, China, and Japan.

Final Answer

- 1. Potential Peak Sales for Durvalumab in ES-SCLC (20%-30% market share):
- Range: \$2.72 billion to \$4.08 billion annually across the US, EU5, China, and Japan.
- 2. \$ Value of 1% Share of Treated Patients:
- ~\$136 million annually across the same geographies.

Notes and Caveats

- These estimates are based on assumptions for pricing, patient population, and market share. Actual figures may vary due to competition (e.g., other PD-1/PD-L1 inhibitors), reimbursement policies, and real-world treatment adoption rates.
- Pricing in China may be lower if durvalumab is included in the National Reimbursement Drug List (NRDL) with significant discounts.
- Peak sales may take several years to achieve post-launch as market penetration grows.
- If more precise data (e.g., exact incidence, pricing, or trial uptake rates) is available, these numbers can be refined.

Let me know if you'd like me to adjust any assumptions or dive deeper into a specific region or factor!