

To estimate the **Potential Peak Sales** for durvalumab (Imfinzi) in the indication of limited-stage small cell lung cancer (LS-SCLC) 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 based on available data, assumptions, and market analysis. Since exact figures may not be publicly available, I will outline a methodology using reasonable assumptions and provide illustrative calculations.

## **Key Indication: Limited-Stage Small Cell Lung Cancer (LS-SCLC)**

- **Durvalumab** is approved for LS-SCLC patients whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- This approval positions durvalumab as an adjuvant or maintenance therapy in this setting.

## **Step 1: Estimate the Target Patient Population**

LS-SCLC accounts for approximately 30% of all small cell lung cancer (SCLC) cases, with the majority being extensive-stage SCLC (ES-SCLC). We will estimate the number of LS-SCLC patients eligible for durvalumab in each geography.

#### Incidence of SCLC and LS-SCLC:

- **US:** ~30,000 new SCLC cases annually; ~30% are LS-SCLC = ~9,000 patients.
- **EU5:** ~35,000 new SCLC cases annually (combined); ~30% are LS-SCLC = ~10,500 patients.
- **China:** ~120,000 new SCLC cases annually (higher smoking rates); ~30% are LS-SCLC = ~36,000 patients.
- **Japan:** ~15,000 new SCLC cases annually; ~30% are LS-SCLC = ~4,500 patients.

#### Eligibility for Durvalumab:

- Durvalumab is indicated for patients who have not progressed after chemoradiation. Assuming ~60-70% of LS-SCLC patients achieve stable disease or response post-chemoradiation, the eligible population is:

- **US:**  $\sim 9,000 \times 0.65 = \sim 5,850$  patients.
- **EU5:**  $\sim 10,500 \times 0.65 = \sim 6,825$  patients.
- **China:**  $\sim 36,000 \times 0.65 = \sim 23,400$  patients.
- **Japan:**  $\sim 4,500 \times 0.65 = \sim 2,925$  patients.

#### Total Eligible Patients Across Geographies:

- **Total:** 5,850 (US) + 6,825 (EU5) + 23,400 (China) + 2,925 (Japan) = ~39,000 patients.

## **Step 2: Market Penetration (20% to 30% Share of Treated Patients)**

Assuming durvalumab captures **20% to 30%** of the eligible treated patient population:

- **Low end (20%):**  $39,000 \times 0.20 = \sim 7,800$  patients.

- **High end (30%):**  $39,000 * 0.30 = \sim 11,700$  patients.

#### Breakdown by Geography (20% to 30% Penetration):

- **US:**  $5,850 * 0.20$  to  $0.30 = 1,170$  to  $1,755$  patients.

- **EU5:**  $6,825 * 0.20$  to  $0.30 = 1,365$  to  $2,048$  patients.

- **China:**  $23,400 * 0.20$  to  $0.30 = 4,680$  to  $7,020$  patients.

- **Japan:**  $2,925 * 0.20$  to  $0.30 = 585$  to  $878$  patients.

### **Step 3: Pricing of Durvalumab**

Durvalumab's pricing varies by region due to differences in healthcare systems, reimbursement, and purchasing power. Based on publicly available data and assumptions:

- **US:** Annual cost per patient  $\sim \$150,000$  (based on pricing for other indications like ES-SCLC or NSCLC).

- **EU5:** Annual cost per patient  $\sim \$100,000$  (lower due to negotiated pricing and discounts).

- **China:** Annual cost per patient  $\sim \$50,000$  (significantly lower due to pricing controls and local competition).

- **Japan:** Annual cost per patient  $\sim \$120,000$  (similar to the US but with some discounts).

### **Step 4: Calculate Potential Peak Sales**

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

#### Peak Sales at 20% Penetration:

- **US:**  $1,170$  patients  $* \$150,000 = \sim \$175.5$  million.

- **EU5:**  $1,365$  patients  $* \$100,000 = \sim \$136.5$  million.

- **China:**  $4,680$  patients  $* \$50,000 = \sim \$234.0$  million.

- **Japan:**  $585$  patients  $* \$120,000 = \sim \$70.2$  million.

- **Total (20%):**  $\$175.5M + \$136.5M + \$234.0M + \$70.2M = \sim \$616.2$  million.

#### Peak Sales at 30% Penetration:

- **US:**  $1,755$  patients  $* \$150,000 = \sim \$263.3$  million.

- **EU5:**  $2,048$  patients  $* \$100,000 = \sim \$204.8$  million.

- **China:**  $7,020$  patients  $* \$50,000 = \sim \$351.0$  million.

- **Japan:**  $878$  patients  $* \$120,000 = \sim \$105.4$  million.

- **Total (30%):**  $\$263.3M + \$204.8M + \$351.0M + \$105.4M = \sim \$924.5$  million.

#### Potential Peak Sales Range:

- **Potential Peak Sales: \$616 million to \$925 million** annually across the US, EU5, China, and Japan for LS-SCLC at 20% to 30% market penetration.

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

A 1% share of treated patients corresponds to 1% of the eligible patient population (39,000 patients) = 390 patients.

#### Value of 1% Share by Geography:

- **US:**  $5,850 * 0.01 = 58.5 \text{ patients} * \$150,000 = \sim \$8.8 \text{ million.}$

- **EU5:**  $6,825 * 0.01 = 68.25 \text{ patients} * \$100,000 = \sim \$6.8 \text{ million.}$

- **China:**  $23,400 * 0.01 = 234 \text{ patients} * \$50,000 = \sim \$11.7 \text{ million.}$

- **Japan:**  $2,925 * 0.01 = 29.25 \text{ patients} * \$120,000 = \sim \$3.5 \text{ million.}$

- **Total Value of 1% Share:**  $\$8.8\text{M} + \$6.8\text{M} + \$11.7\text{M} + \$3.5\text{M} = \sim \$30.8 \text{ million.}$

## **Final Answers:**

1. **Potential Peak Sales for Durvalumab in LS-SCLC** (assuming 20% to 30% market share of treated patients):

- **Range: \$616 million to \$925 million annually** across the US, EU5, China, and Japan.

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

- **Total: ~\$30.8 million annually** across the US, EU5, China, and Japan.

## **Notes and Assumptions:**

- Patient population estimates are based on approximate SCLC incidence rates and the proportion of LS-SCLC.

- Pricing assumptions are illustrative and may vary based on negotiations, reimbursement policies, and market access.

- Market penetration (20%-30%) assumes competition from other therapies and adoption rates in different regions.

- Peak sales assume stable pricing and patient numbers over time, which may fluctuate due to generic competition, new entrants, or changes in treatment paradigms.

- These figures are rough estimates and should be validated with primary market research or updated data from AstraZeneca or healthcare databases.

If you have additional data (e.g., exact pricing, patient numbers, or penetration rates), I can refine these calculations further.