

To estimate the **Potential Peak Sales** for durvalumab (Imfinzi) in the specified indication (resectable NSCLC with tumors ≥ 4 cm and/or node positive, without EGFR mutations or ALK rearrangements) 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 specific data on patient numbers, pricing, and market penetration might not be fully available, I will outline the methodology and use reasonable assumptions based on publicly available information and industry standards.

Step 1: Define the Target Patient Population

- **Indication:** Resectable NSCLC (Stage II-IIIa, tumors ≥ 4 cm and/or node positive, without EGFR mutations or ALK rearrangements).
- **Geographies:** US, EU5, China, Japan.
- **Epidemiology:**
 - NSCLC accounts for ~85% of all lung cancer cases.
 - Resectable NSCLC (Stage II-IIIa) represents approximately 20-30% of NSCLC cases.
 - Of these, tumors ≥ 4 cm and/or node-positive cases are a subset, estimated at ~60-70% of resectable cases.
 - EGFR mutations (~15-20% in Western populations, ~40-50% in Asian populations) and ALK rearrangements (~5%) will be excluded.

Using approximate NSCLC incidence data (2023 estimates from sources like GLOBOCAN, American Cancer Society, and industry reports):

- **US:** ~200,000 new NSCLC cases/year; ~25% resectable (~50,000); ~65% of these meet criteria (~32,500); exclude ~20% with EGFR/ALK (~26,000 eligible patients).
- **EU5:** ~250,000 new NSCLC cases/year; ~25% resectable (~62,500); ~65% meet criteria (~40,625); exclude ~20% with EGFR/ALK (~32,500 eligible patients).
- **China:** ~800,000 new NSCLC cases/year; ~25% resectable (~200,000); ~65% meet criteria (~130,000); exclude ~45% with EGFR/ALK (~71,500 eligible patients).
- **Japan:** ~100,000 new NSCLC cases/year; ~25% resectable (~25,000); ~65% meet criteria (~16,250); exclude ~40% with EGFR/ALK (~9,750 eligible patients).

Total Eligible Patients (approx.):

- US: 26,000
- EU5: 32,500
- China: 71,500
- Japan: 9,750
- **Total across geographies:** ~139,750 patients/year.

Step 2: Market Share Assumption

- The problem states a **20% to 30% share of treated patients**. This assumes durvalumab captures this percentage of the eligible patient population in this indication.
- For calculation, we'll use the midpoint of **25% market share** as a base case for peak sales estimation.

Treated Patients with Durvalumab (at 25% share):

- US: $26,000 * 25\% = 6,500$
- EU5: $32,500 * 25\% = 8,125$
- China: $71,500 * 25\% = 17,875$
- Japan: $9,750 * 25\% = 2,438$
- **Total:** ~34,938 patients/year.

Step 3: Pricing Assumptions

Durvalumab pricing varies by region due to differences in healthcare systems, reimbursement, and purchasing power. Based on industry reports and public data:

- **US:** ~\$180,000 per patient/year (based on typical immunotherapy pricing for NSCLC).
- **EU5:** ~\$100,000 per patient/year (discounted due to price negotiations and public health systems).
- **China:** ~\$50,000 per patient/year (lower pricing due to market access programs and generics competition).
- **Japan:** ~\$120,000 per patient/year (slightly lower than the US, aligned with developed market pricing).

Note: These are rough estimates for a full treatment course (neoadjuvant + adjuvant durvalumab). Actual costs may vary based on treatment duration (e.g., 1 year or more) and specific pricing agreements.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as: **Number of treated patients * Annual cost per patient.**

- **US:** 6,500 patients * \$180,000 = **\$1,170 million** (~\$1.17 billion)
- **EU5:** 8,125 patients * \$100,000 = **\$812.5 million** (~\$0.81 billion)
- **China:** 17,875 patients * \$50,000 = **\$893.75 million** (~\$0.89 billion)
- **Japan:** 2,438 patients * \$120,000 = **\$292.56 million** (~\$0.29 billion)

- **Total Peak Sales (at 25% share): \$3,168.81 million** (~\$3.17 billion)

Range for 20% to 30% Share:

- At 20% share: ~\$2.54 billion

- At 30% share: ~\$3.80 billion

Thus, **Potential Peak Sales** for durvalumab in this indication across the specified geographies is approximately **\$2.5 to \$3.8 billion**, with a midpoint of ~\$3.17 billion at 25% market share.

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

A 1% share of treated patients means 1% of the eligible patient population in each geography.

Eligible Patients per 1% Share:

- US: $26,000 * 1\% = 260$ patients

- EU5: $32,500 * 1\% = 325$ patients

- China: $71,500 * 1\% = 715$ patients

- Japan: $9,750 * 1\% = 98$ patients

- **Total: 1,398 patients**

Revenue per 1% Share (using the same pricing assumptions):

- US: $260 * \$180,000 = \46.8 million

- EU5: $325 * \$100,000 = \32.5 million

- China: $715 * \$50,000 = \35.75 million

- Japan: $98 * \$120,000 = \11.76 million

- **Total Value of 1% Share: \$126.81 million**

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$127 million**.

Final Answer

1. **Potential Peak Sales for Durvalumab** in this indication (resectable NSCLC) across the US, EU5, China, and Japan, assuming a 20% to 30% share of treated patients:

- Range: **\$2.5 billion to \$3.8 billion**

- Midpoint (at 25% share): **\$3.17 billion**

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

- **\$127 million**

Caveats: These estimates are based on assumptions about patient populations, market share, and pricing. Real-world figures may differ due to competition (e.g., other immunotherapies like pembrolizumab), reimbursement policies, treatment duration, and market access challenges. For precise figures, primary market research or company-specific data would be required.