

To estimate the **Potential Peak Sales** for durvalumab (Imfinzi) in the indication of primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) 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 make several assumptions and follow a structured approach. Since specific data such as exact patient numbers, pricing, and market penetration may not be publicly available, I will outline the methodology and provide illustrative calculations based on reasonable estimates. If you have access to specific data (e.g., epidemiology, pricing, or market reports), I can refine the calculations.

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## **Step 1: Define the Target Population**

- **Indication:** Primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

- **Epidemiology:** Endometrial cancer is one of the most common gynecologic cancers. Approximately 20-30% of endometrial cancer cases are dMMR, which is associated with a poorer prognosis and eligibility for immunotherapy like durvalumab.

- **Geographies:** US, EU5, China, Japan.

### #### Estimated Incidence of Endometrial Cancer (Annual New Cases)

- **US:** ~66,000 new cases per year (based on American Cancer Society data).

- **EU5:** ~100,000 new cases per year (combined estimate based on European cancer statistics).

- **China:** ~80,000 new cases per year (based on global cancer statistics and population size).

- **Japan:** ~15,000 new cases per year (based on Japanese cancer statistics).

### #### Proportion of dMMR Cases

- Approximately 25% of endometrial cancer cases are dMMR (midpoint of 20-30% range).

#### - **Eligible Population (dMMR cases):**

- US:  $66,000 * 0.25 = \sim 16,500$  patients.

- EU5:  $100,000 * 0.25 = \sim 25,000$  patients.

- China:  $80,000 * 0.25 = \sim 20,000$  patients.

- Japan:  $15,000 * 0.25 = \sim 3,750$  patients.

- **Total Eligible Population:**  $16,500 + 25,000 + 20,000 + 3,750 = \sim 65,250$  patients annually.

### #### Proportion of Treated Patients

- Not all eligible patients will receive treatment due to factors like late diagnosis, comorbidities, or access to care. Assuming ~70% of eligible patients are treated:

- US:  $16,500 * 0.7 = \sim 11,550$  treated patients.

- EU5:  $25,000 * 0.7 = \sim 17,500$  treated patients.

- China:  $20,000 * 0.7 = \sim 14,000$  treated patients.

- Japan:  $3,750 * 0.7 = \sim 2,625$  treated patients.
- **Total Treated Population:**  $11,550 + 17,500 + 14,000 + 2,625 = \sim 45,675$  patients annually.

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## **Step 2: Market Share Assumption**

- The query assumes a **20% to 30% share of treated patients** for durvalumab in this indication.
- For peak sales estimation, we'll take the midpoint of **25% market share**.
- **Durvalumab Treated Patients:**
- US:  $11,550 * 0.25 = \sim 2,888$  patients.
- EU5:  $17,500 * 0.25 = \sim 4,375$  patients.
- China:  $14,000 * 0.25 = \sim 3,500$  patients.
- Japan:  $2,625 * 0.25 = \sim 656$  patients.
- **Total Durvalumab Treated Patients:**  $2,888 + 4,375 + 3,500 + 656 = \sim 11,419$  patients annually.

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## **Step 3: Pricing Assumption**

Durvalumab (Imfinzi) is a PD-L1 inhibitor, and pricing for such immunotherapies is high, though it varies by geography due to healthcare systems and pricing negotiations.

- **Annual Cost per Patient** (illustrative estimates for a full treatment course):
- US:  $\sim \$150,000$  per year (based on typical pricing for checkpoint inhibitors like pembrolizumab or nivolumab).
- EU5:  $\sim \$100,000$  per year (lower due to price negotiations and reimbursement policies).
- China:  $\sim \$50,000$  per year (reflecting lower pricing in emerging markets and potential local manufacturing or discounts).
- Japan:  $\sim \$120,000$  per year (similar to US but slightly lower due to pricing controls).
- These are rough estimates and may vary based on treatment duration, dosing, and local pricing agreements.

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

Peak sales are calculated as the number of treated patients multiplied by the annual cost per patient in each geography.

- **US:**  $2,888 \text{ patients} * \$150,000 = \sim \$433.2 \text{ million}$ .

- **EU5:** 4,375 patients \* \$100,000 = ~\$437.5 million.
- **China:** 3,500 patients \* \$50,000 = ~\$175.0 million.
- **Japan:** 656 patients \* \$120,000 = ~\$78.7 million.
- **Total Potential Peak Sales:** \$433.2M + \$437.5M + \$175.0M + \$78.7M = **~\$1,124.4 million (or ~\$1.12 billion)** annually at 25% market share.

#### Range of Peak Sales (20% to 30% Market Share)

- **At 20% Market Share:** Total treated patients = ~9,135; Peak Sales = ~\$900 million.
- **At 30% Market Share:** Total treated patients = ~13,703; Peak Sales = ~\$1.35 billion.
- **Range: \$900 million to \$1.35 billion annually.**

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

A 1% share of treated patients corresponds to 1% of the total treated population (~45,675 patients) = ~457 patients annually.

- **US:** 11,550 \* 0.01 = 115.5 patients \* \$150,000 = ~\$17.3 million.
- **EU5:** 17,500 \* 0.01 = 175 patients \* \$100,000 = ~\$17.5 million.
- **China:** 14,000 \* 0.01 = 140 patients \* \$50,000 = ~\$7.0 million.
- **Japan:** 2,625 \* 0.01 = 26.25 patients \* \$120,000 = ~\$3.2 million.
- **Total \$ Value of 1% Share:** \$17.3M + \$17.5M + \$7.0M + \$3.2M = **~\$45.0 million annually.**

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## **Final Answer**

1. **Potential Peak Sales for Durvalumab** in the indication of dMMR endometrial cancer (assuming 20% to 30% market share):

- Range: **\$900 million to \$1.35 billion annually.**
- Midpoint (25% share): **~\$1.12 billion annually.**
- Breakdown by geography (at 25% share):
- US: ~\$433 million.
- EU5: ~\$438 million.
- China: ~\$175 million.
- Japan: ~\$79 million.

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

- Total: **~\$45 million annually.**

- Breakdown by geography:

- US: ~\$17.3 million.

- EU5: ~\$17.5 million.

- China: ~\$7.0 million.

- Japan: ~\$3.2 million.

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## **Notes and Caveats**

- These calculations are based on illustrative assumptions for epidemiology, treatment rates, market share, and pricing. Real-world data may differ due to factors like competition (e.g., other PD-1/PD-L1 inhibitors), reimbursement policies, and patient access.

- Peak sales typically occur several years after launch as market penetration increases, and sales may decline post-patent expiry.

- If you have specific data on patient numbers, pricing, or market dynamics, I can adjust the calculations accordingly.