

To estimate the **Potential Peak Sales** for durvalumab (Imfinzi) in the indication of muscle-invasive bladder cancer (MIBC) in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since exact patient numbers, pricing, and penetration rates are not provided, I will make reasonable assumptions based on publicly available data, epidemiology, and market trends for oncology drugs. Let's break this down step by step.

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## **Step 1: Key Assumptions**

1. **Indication:** Durvalumab is approved for MIBC as neoadjuvant treatment with gemcitabine and cisplatin, followed by adjuvant treatment post-cystectomy.
2. **Market Share:** We are assuming a 20% to 30% share of treated patients for durvalumab in this indication.
3. **Geographies:** US, EU5 (combined), China, and Japan.
4. **Epidemiology:** MIBC accounts for approximately 25-30% of all bladder cancer cases. Incidence rates vary by region.
5. **Pricing:** Durvalumab's price varies by region. For simplicity, we will use approximate annual treatment costs based on typical pricing for immune checkpoint inhibitors (e.g., PD-L1 inhibitors).
6. **Treatment Duration:** Assuming a treatment duration of 1 year (neoadjuvant + adjuvant phases combined) for simplicity.
7. **Penetration Rate:** Not all eligible patients will receive treatment due to factors like access, cost, or clinical ineligibility.
8. **Peak Sales:** Peak sales are typically achieved 5-7 years after launch, assuming no major competition or patent cliffs during that time.

### #### Incidence of MIBC

- **US:** Bladder cancer incidence is ~81,000 cases/year (American Cancer Society, 2023). MIBC accounts for ~25-30%, so ~20,000-24,000 cases/year.
- **EU5:** Bladder cancer incidence is ~120,000 cases/year (combined for EU5). MIBC is ~30,000-36,000 cases/year.
- **China:** Bladder cancer incidence is ~80,000 cases/year (due to large population and rising cancer rates). MIBC is ~20,000-24,000 cases/year.
- **Japan:** Bladder cancer incidence is ~20,000 cases/year. MIBC is ~5,000-6,000 cases/year.

Total MIBC cases across geographies: ~75,000-90,000 cases/year.

### #### Eligible Patients

Not all MIBC patients are eligible for durvalumab due to comorbidities, advanced age, or lack of access to treatment. Assuming 60-70% eligibility:

- **US:** ~12,000-16,800 eligible patients.
- **EU5:** ~18,000-25,200 eligible patients.

- **China:** ~12,000-16,800 eligible patients.
- **Japan:** ~3,000-4,200 eligible patients.
- Total: ~45,000-63,000 eligible patients/year.

#### #### Pricing of Durvalumab

- **US:** ~\$150,000-\$180,000 per patient/year (based on typical pricing for PD-L1 inhibitors like Imfinzi).
- **EU5:** ~\$80,000-\$100,000 per patient/year (lower due to price negotiations and healthcare systems).
- **China:** ~\$50,000-\$70,000 per patient/year (lower pricing due to market access programs and local competition).
- **Japan:** ~\$100,000-\$120,000 per patient/year (similar to EU5 but with some variation).

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## **Step 2: Potential Peak Sales Calculation**

Assuming durvalumab captures **20%-30% market share** of eligible treated patients, we calculate peak sales for each region.

#### #### US

- Eligible patients: 12,000-16,800
- Treated patients (20%-30%): 2,400-5,040
- Price per patient: \$150,000-\$180,000
- Peak Sales:  $(2,400 * \$150,000)$  to  $(5,040 * \$180,000)$  = **\$360M to \$907M**

#### #### EU5

- Eligible patients: 18,000-25,200
- Treated patients (20%-30%): 3,600-7,560
- Price per patient: \$80,000-\$100,000
- Peak Sales:  $(3,600 * \$80,000)$  to  $(7,560 * \$100,000)$  = **\$288M to \$756M**

#### #### China

- Eligible patients: 12,000-16,800
- Treated patients (20%-30%): 2,400-5,040
- Price per patient: \$50,000-\$70,000
- Peak Sales:  $(2,400 * \$50,000)$  to  $(5,040 * \$70,000)$  = **\$120M to \$353M**

#### #### Japan

- Eligible patients: 3,000-4,200

- Treated patients (20%-30%): 600-1,260
- Price per patient: \$100,000-\$120,000
- Peak Sales:  $(600 * \$100,000)$  to  $(1,260 * \$120,000) = \text{\$60M to \$151M}$

#### #### Total Peak Sales Across Geographies

- Low end (20% share, lower price): \$360M (US) + \$288M (EU5) + \$120M (China) + \$60M (Japan) = **\$828M**
- High end (30% share, higher price): \$907M (US) + \$756M (EU5) + \$353M (China) + \$151M (Japan) = **\$2,167M (~\$2.17B)**

**Potential Peak Sales Range: \$828M to \$2.17B annually**

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### **Step 3: \$ Value of 1% Share of Treated Patients**

To calculate the value of a 1% share, we divide the total number of eligible patients by 100 and multiply by the price per patient.

#### #### US

- Eligible patients: 12,000-16,800
- 1% of patients: 120-168
- Price per patient: \$150,000-\$180,000
- Value of 1% share:  $(120 * \$150,000)$  to  $(168 * \$180,000) = \text{\$18M to \$30.2M}$

#### #### EU5

- Eligible patients: 18,000-25,200
- 1% of patients: 180-252
- Price per patient: \$80,000-\$100,000
- Value of 1% share:  $(180 * \$80,000)$  to  $(252 * \$100,000) = \text{\$14.4M to \$25.2M}$

#### #### China

- Eligible patients: 12,000-16,800
- 1% of patients: 120-168
- Price per patient: \$50,000-\$70,000
- Value of 1% share:  $(120 * \$50,000)$  to  $(168 * \$70,000) = \text{\$6M to \$11.8M}$

#### #### Japan

- Eligible patients: 3,000-4,200
- 1% of patients: 30-42

- Price per patient: \$100,000-\$120,000
- Value of 1% share:  $(30 * \$100,000)$  to  $(42 * \$120,000) = \text{\$3M to \$5M}$

#### Total Value of 1% Share Across Geographies

- Low end: \$18M (US) + \$14.4M (EU5) + \$6M (China) + \$3M (Japan) = **\$41.4M**
- High end: \$30.2M (US) + \$25.2M (EU5) + \$11.8M (China) + \$5M (Japan) = **\$72.2M**

**\$ Value of 1% Share of Treated Patients: \$41.4M to \$72.2M**

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## **Final Answer**

1. **Potential Peak Sales for Durvalumab in MIBC (20%-30% market share):**

- **US, EU5, China, Japan combined: \$828M to \$2.17B annually**

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

- **US, EU5, China, Japan combined: \$41.4M to \$72.2M**

**Note:** These estimates are based on assumptions regarding patient numbers, pricing, and market penetration. Real-world figures may vary due to competition (e.g., other PD-1/PD-L1 inhibitors), reimbursement policies, and changes in treatment paradigms. For more accurate data, primary market research or company-specific guidance from AstraZeneca would be required.