

To estimate the **Potential Peak Sales** for abemaciclib (Verzenio) in the adjuvant treatment of HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence 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 exact data on patient numbers, pricing, and penetration rates may not be publicly available, I will outline the methodology and make reasonable assumptions based on available market data and trends. This will provide an illustrative estimate.

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

- **Indication:** Adjuvant treatment of HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence.

- **Epidemiology:**

- Breast cancer is the most common cancer globally, with HR-positive, HER2-negative subtype representing ~60-70% of cases.

- Early breast cancer (stages I-III) accounts for ~90% of diagnosed cases, and node-positive patients with high risk of recurrence are a subset of this group (estimated at ~20-30% of early breast cancer cases).

- Using breast cancer incidence data and refining it for this specific indication, we can estimate the eligible patient population.

### **Estimated Annual Incidence of Breast Cancer (2023, approximate figures):**

- US: ~290,000 new cases

- EU5: ~260,000 new cases (combined)

- China: ~420,000 new cases

- Japan: ~95,000 new cases

### **Refining for Target Population (assumptions):**

- HR-positive, HER2-negative: 65% of total cases.

- Early breast cancer: 90% of total cases.

- Node-positive, high risk of recurrence: 25% of early breast cancer cases.

- Therefore, target population = Total incidence  $\times$  0.65  $\times$  0.9  $\times$  0.25.

### **Calculated Target Population (Annual New Cases):**

- US:  $290,000 \times 0.65 \times 0.9 \times 0.25 = \sim 42,400$  patients

- EU5:  $260,000 \times 0.65 \times 0.9 \times 0.25 = \sim 38,000$  patients

- China:  $420,000 \times 0.65 \times 0.9 \times 0.25 = \sim 61,400$  patients

- Japan:  $95,000 \times 0.65 \times 0.9 \times 0.25 = \sim 13,900$  patients

- **Total Target Population:** ~155,700 patients annually across these geographies.

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## **Step 2: Estimate Treated Patient Share**

- The problem assumes a **20% to 30% share of treated patients** for abemaciclib in this indication.
- This share accounts for market penetration, competition (e.g., other CDK4/6 inhibitors like palbociclib and ribociclib), physician adoption, and patient access.
- For peak sales calculation, we will use the midpoint of **25% share**.

### **Treated Patients with Abemaciclib (25% share):**

- US:  $42,400 \times 0.25 = \sim 10,600$  patients
- EU5:  $38,000 \times 0.25 = \sim 9,500$  patients
- China:  $61,400 \times 0.25 = \sim 15,350$  patients
- Japan:  $13,900 \times 0.25 = \sim 3,475$  patients
- **Total Treated Patients:**  $\sim 38,925$  patients annually.

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## **Step 3: Estimate Annual Treatment Cost per Patient**

- Abemaciclib is a premium-priced drug as a CDK4/6 inhibitor.
- **US Pricing:**  $\sim \$12,000$ – $\$15,000$  per month (based on metastatic breast cancer pricing). For adjuvant therapy (typically 2 years), annual cost  $\sim \$144,000$ – $\$180,000$ . Assume  $\$160,000$  per year.
- **EU5 Pricing:** Typically 40-60% lower than US due to price controls. Assume  $\sim \$80,000$  per year.
- **Japan Pricing:** Similar to EU5, assume  $\sim \$80,000$  per year.
- **China Pricing:** Significantly lower due to market access negotiations and generics pressure. Assume  $\sim \$30,000$  per year.

**Note:** Adjuvant therapy duration is often shorter (e.g., 2 years for abemaciclib per clinical trials like monarchE). For simplicity, we calculate annual cost and assume peak sales reflect annualized revenue at steady state (patients on therapy in a given year).

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

### **Peak Sales = Treated Patients $\times$ Annual Cost per Patient**

- **US:**  $10,600 \text{ patients} \times \$160,000 = \sim \$1.70 \text{ billion}$
- **EU5:**  $9,500 \text{ patients} \times \$80,000 = \sim \$0.76 \text{ billion}$
- **China:**  $15,350 \text{ patients} \times \$30,000 = \sim \$0.46 \text{ billion}$

- **Japan:**  $3,475 \text{ patients} \times \$80,000 = \sim\$0.28 \text{ billion}$
- **Total Peak Sales:**  $\$1.70\text{B} + \$0.76\text{B} + \$0.46\text{B} + \$0.28\text{B} = \sim\$3.20 \text{ billion annually}$

**Range for Peak Sales (based on 20-30% share):**

- At 20% share:  $\sim\$2.56 \text{ billion}$
- At 30% share:  $\sim\$3.84 \text{ billion}$

Thus, **Potential Peak Sales** for abemaciclib in this indication across the specified geographies is approximately **\$2.56B to \$3.84B**, with a midpoint of **\$3.20B**.

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

**1% of Treated Patients = 1% of Total Target Population  $\times$  Annual Cost per Patient**

- **US:**  $42,400 \times 0.01 = 424 \text{ patients} \times \$160,000 = \sim\$67.8 \text{ million}$
- **EU5:**  $38,000 \times 0.01 = 380 \text{ patients} \times \$80,000 = \sim\$30.4 \text{ million}$
- **China:**  $61,400 \times 0.01 = 614 \text{ patients} \times \$30,000 = \sim\$18.4 \text{ million}$
- **Japan:**  $13,900 \times 0.01 = 139 \text{ patients} \times \$80,000 = \sim\$11.1 \text{ million}$
- **Total Value of 1% Share:**  $\$67.8\text{M} + \$30.4\text{M} + \$18.4\text{M} + \$11.1\text{M} = \sim\$127.7 \text{ million}$

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$127.7 million**.

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## **Summary of Results**

**1. Potential Peak Sales for Abemaciclib (20-30% share):**

- US:  $\$1.36\text{B}$  to  $\$2.04\text{B}$  (midpoint  $\$1.70\text{B}$ )
- EU5:  $\$0.61\text{B}$  to  $\$0.91\text{B}$  (midpoint  $\$0.76\text{B}$ )
- China:  $\$0.37\text{B}$  to  $\$0.55\text{B}$  (midpoint  $\$0.46\text{B}$ )
- Japan:  $\$0.22\text{B}$  to  $\$0.33\text{B}$  (midpoint  $\$0.28\text{B}$ )
- **Total:**  **$\$2.56\text{B}$  to  $\$3.84\text{B}$**  (midpoint  $\$3.20\text{B}$ )

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

- US:  $\$67.8\text{M}$
- EU5:  $\$30.4\text{M}$
- China:  $\$18.4\text{M}$

- Japan: \$11.1M

- **Total: \$127.7M**

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## **Caveats and Assumptions**

- **Epidemiology:** Patient population estimates are based on approximate incidence rates and subtype distributions. Real-world data may vary.

- **Pricing:** Costs are assumed based on public data for metastatic indications and adjusted for adjuvant use and regional pricing differences. Actual negotiated prices may differ.

- **Market Share:** The 20-30% range is as per the query, but competition and access barriers (e.g., reimbursement in China) may impact penetration.

- **Treatment Duration:** Peak sales assume annualized revenue; actual sales may depend on the number of patients completing the 2-year adjuvant therapy.

These estimates are illustrative and should be validated with primary market research or company-provided guidance for more precision. If you have additional data (e.g., exact pricing or patient numbers), I can refine the calculations further.