

To estimate the **Potential Peak Sales** for ribociclib (Kisqali) in the adjuvant treatment of HR-positive, HER2-negative stage II and III 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 patient numbers, pricing, and market penetration data are not provided, I will make reasonable assumptions based on available epidemiology data, market trends, and typical pricing for oncology drugs. Here's the step-by-step process:

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

Ribociclib is approved for HR-positive, HER2-negative stage II and III early breast cancer at high risk of recurrence. We need to estimate the number of eligible patients in each geography.

- **US:** Approximately 290,000 new breast cancer cases are diagnosed annually (American Cancer Society). About 70% are HR-positive, HER2-negative (~203,000). Of these, ~40% are stage II/III (~81,200). Assuming 50% are at high risk of recurrence, the target population is ~40,600 patients annually.
- **EU5:** Combined breast cancer incidence is ~250,000 annually (ECIS data). Using similar proportions (70% HR+/HER2-, 40% stage II/III, 50% high risk), the target population is ~35,000 patients.
- **China:** Breast cancer incidence is ~420,000 annually (GLOBOCAN). Using the same proportions, the target population is ~58,800 patients.
- **Japan:** Breast cancer incidence is ~95,000 annually (GLOBOCAN). Using the same proportions, the target population is ~13,300 patients.

### **Total Target Population (Annual Incident Cases):**

- US: 40,600
- EU5: 35,000
- China: 58,800
- Japan: 13,300
- **Total: 147,700 patients annually**

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## **Step 2: Estimate Treated Patients (Market Penetration)**

Assuming a 20% to 30% share of treated patients for ribociclib in this indication (as given in the query), we calculate the number of treated patients:

- **20% Share:**  $147,700 * 0.2 = 29,540$  patients
- **30% Share:**  $147,700 * 0.3 = 44,310$  patients

### **Breakdown by Geography (20% Share):**

- US:  $40,600 * 0.2 = 8,120$

- EU5:  $35,000 * 0.2 = 7,000$
- China:  $58,800 * 0.2 = 11,760$
- Japan:  $13,300 * 0.2 = 2,660$

**Breakdown by Geography (30% Share):**

- US:  $40,600 * 0.3 = 12,180$
- EU5:  $35,000 * 0.3 = 10,500$
- China:  $58,800 * 0.3 = 17,640$
- Japan:  $13,300 * 0.3 = 3,990$

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

Ribociclib is a high-cost oncology drug. Pricing varies by region due to differences in healthcare systems and negotiations:

- **US:** ~\$15,000 per month for ribociclib (based on reported costs). Assuming a 12-month treatment duration in the adjuvant setting (common for CDK4/6 inhibitors), annual cost = \$180,000 per patient.
- **EU5:** Pricing is lower due to negotiations. Assume ~\$100,000 per patient annually.
- **Japan:** Similar to EU5, assume ~\$100,000 per patient annually.
- **China:** Pricing is significantly lower due to market access programs and generics. Assume ~\$30,000 per patient annually.

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

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each region.

#### At 20% Market Share:

- **US:**  $8,120 \text{ patients} * \$180,000 = \$1.462 \text{ billion}$
- **EU5:**  $7,000 \text{ patients} * \$100,000 = \$0.700 \text{ billion}$
- **China:**  $11,760 \text{ patients} * \$30,000 = \$0.353 \text{ billion}$
- **Japan:**  $2,660 \text{ patients} * \$100,000 = \$0.266 \text{ billion}$
- **Total Peak Sales (20% Share):**  $\$1.462\text{B} + \$0.700\text{B} + \$0.353\text{B} + \$0.266\text{B} = \$2.781 \text{ billion}$

#### At 30% Market Share:

- **US:**  $12,180 \text{ patients} * \$180,000 = \$2.192 \text{ billion}$

- **EU5:** 10,500 patients \* \$100,000 = \$1.050 billion
- **China:** 17,640 patients \* \$30,000 = \$0.529 billion
- **Japan:** 3,990 patients \* \$100,000 = \$0.399 billion
- **Total Peak Sales (30% Share):** \$2.192B + \$1.050B + \$0.529B + \$0.399B = **\$4.170 billion**

**Potential Peak Sales Range: \$2.78 billion to \$4.17 billion annually** across the US, EU5, China, and Japan.

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

A 1% share corresponds to 1% of the total target population (147,700 \* 0.01 = 1,477 patients).

### **Breakdown by Geography (1% Share):**

- US: 40,600 \* 0.01 = 406 patients
- EU5: 35,000 \* 0.01 = 350 patients
- China: 58,800 \* 0.01 = 588 patients
- Japan: 13,300 \* 0.01 = 133 patients

### **Revenue from 1% Share:**

- **US:** 406 patients \* \$180,000 = \$73.08 million
- **EU5:** 350 patients \* \$100,000 = \$35.00 million
- **China:** 588 patients \* \$30,000 = \$17.64 million
- **Japan:** 133 patients \* \$100,000 = \$13.30 million
- **Total Value of 1% Share:** \$73.08M + \$35.00M + \$17.64M + \$13.30M = **\$139.02 million**

**\$ Value of 1% Share of Treated Patients: \$139 million annually**

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## **Final Answer:**

1. **Potential Peak Sales for Ribociclib** in the adjuvant treatment of HR-positive, HER2-negative stage II and III early breast cancer at high risk of recurrence (assuming 20% to 30% market share):

- **Range: \$2.78 billion to \$4.17 billion annually** across the US, EU5, China, and Japan.
- **Breakdown by Region (20% Share):**
  - US: \$1.462 billion
  - EU5: \$0.700 billion
  - China: \$0.353 billion

- Japan: \$0.266 billion
- **Breakdown by Region (30% Share):**
- US: \$2.192 billion
- EU5: \$1.050 billion
- China: \$0.529 billion
- Japan: \$0.399 billion

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

- **Total: \$139 million annually**
- **Breakdown by Region:**
- US: \$73.08 million
- EU5: \$35.00 million
- China: \$17.64 million
- Japan: \$13.30 million

**Note:** These estimates are based on assumptions regarding patient population, market share, treatment duration, and pricing. Actual figures may vary depending on real-world data, competition (e.g., other CDK4/6 inhibitors like palbociclib and abemaciclib), reimbursement policies, and market access challenges. For more precise estimates, detailed market research or proprietary data would be required.