

To estimate the **Potential Peak Sales** for elacestrant (Orserdu) in the specified indication (ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer) 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 data on patient populations, pricing, and market penetration may not be publicly available, I will outline the methodology and make reasonable assumptions based on available data and industry standards. If you have specific data (e.g., patient numbers or pricing), I can refine the calculations.

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

Elacestrant is approved for postmenopausal women or adult men with **ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer** who have progressed after at least one line of endocrine therapy. Key points to consider:

- **ER-positive, HER2-negative breast cancer** accounts for approximately 60-70% of all breast cancer cases.
- **ESR1 mutations** are present in about 20-40% of patients with ER-positive metastatic breast cancer who have progressed on endocrine therapy.
- **Advanced or metastatic breast cancer (Stage IV)** represents about 5-10% of breast cancer cases at diagnosis, but many early-stage patients progress to metastatic disease over time.

### **#### Estimated Eligible Patient Population**

Using prevalence and incidence data for breast cancer, along with the proportion of patients fitting the indication:

- **US:** ~3.8 million breast cancer survivors; ~150,000-200,000 with metastatic breast cancer. Of these, ~60-70% are ER+/HER2- (~90,000-140,000), and ~20-40% have ESR1 mutations (~18,000-56,000).
- **EU5:** Similar proportions, with a combined breast cancer prevalence of ~2.5-3 million. Metastatic cases are ~100,000-150,000, with ~60,000-105,000 ER+/HER2-, and ~12,000-42,000 with ESR1 mutations.
- **China:** Breast cancer prevalence is lower (~2-2.5 million), with ~80,000-120,000 metastatic cases. ER+/HER2- is ~50,000-84,000, and ESR1 mutations ~10,000-33,600.
- **Japan:** Prevalence ~500,000-600,000; metastatic cases ~20,000-30,000; ER+/HER2- ~12,000-21,000; ESR1 mutations ~2,400-8,400.

### **Midpoint Estimates of Eligible Patients (ESR1-mutated, post-endocrine therapy):**

- US: ~37,000
- EU5: ~27,000
- China: ~21,800
- Japan: ~5,400
- **Total:** ~91,200 patients

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

Assuming a **20-30% share of treated patients** among the eligible population (as per your query), we calculate:

- **20% Share:**  $91,200 \times 0.20 = \sim 18,240$  treated patients

- **30% Share:**  $91,200 \times 0.30 = \sim 27,360$  treated patients

#### **Breakdown by Geography (Midpoint Estimates):**

- **20% Share:**

- US:  $37,000 \times 0.20 = 7,400$

- EU5:  $27,000 \times 0.20 = 5,400$

- China:  $21,800 \times 0.20 = 4,360$

- Japan:  $5,400 \times 0.20 = 1,080$

- **30% Share:**

- US:  $37,000 \times 0.30 = 11,100$

- EU5:  $27,000 \times 0.30 = 8,100$

- China:  $21,800 \times 0.30 = 6,540$

- Japan:  $5,400 \times 0.30 = 1,620$

### **Step 3: Estimate Pricing for Elacestrant**

Pricing for targeted therapies in metastatic breast cancer varies by region. Elacestrant, being a novel oral SERD (selective estrogen receptor degrader), is likely priced similarly to other drugs in this class (e.g., fulvestrant, though it's injectable, or other oral therapies like CDK4/6 inhibitors).

- **US:** Annual cost for similar therapies is  $\sim \$100,000$ – $\$150,000$  per patient. Assume  $\sim \$120,000$ /year for elacestrant.

- **EU5:** Pricing is typically 50-70% of US prices due to healthcare system negotiations. Assume  $\sim \$60,000$ – $\$80,000$ /year (midpoint  $\$70,000$ ).

- **China:** Pricing is lower due to market access and affordability. Assume  $\sim \$30,000$ – $\$50,000$ /year (midpoint  $\$40,000$ ).

- **Japan:** Pricing is often closer to EU levels. Assume  $\sim \$60,000$ – $\$80,000$ /year (midpoint  $\$70,000$ ).

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

Peak sales are calculated as: **Number of Treated Patients  $\times$  Annual Cost per Patient.**

#### At 20% Market Share:

- **US:**  $7,400 \text{ patients} \times \$120,000 = \text{\$888 million}$

- **EU5:**  $5,400 \text{ patients} \times \$70,000 = \text{\$378 million}$

- **China:**  $4,360 \text{ patients} \times \$40,000 = \text{\$174.4 million}$

- **Japan:**  $1,080 \text{ patients} \times \$70,000 = \text{\$75.6 million}$

- **Total Peak Sales (20% share):**  $\$888\text{M} + \$378\text{M} + \$174.4\text{M} + \$75.6\text{M} = \sim\$1.516 \text{ billion}$

#### At 30% Market Share:

- **US:**  $11,100 \text{ patients} \times \$120,000 = \$1.332 \text{ billion}$

- **EU5:**  $8,100 \text{ patients} \times \$70,000 = \$567 \text{ million}$

- **China:**  $6,540 \text{ patients} \times \$40,000 = \$261.6 \text{ million}$

- **Japan:**  $1,620 \text{ patients} \times \$70,000 = \$113.4 \text{ million}$

- **Total Peak Sales (30% share):**  $\$1.332\text{B} + \$567\text{M} + \$261.6\text{M} + \$113.4\text{M} = \sim\$2.274 \text{ billion}$

**Potential Peak Sales Range: \$1.516 billion (20% share) to \$2.274 billion (30% share)** annually across the US, EU5, China, and Japan.

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

A 1% share of the eligible population (91,200 patients) is **912 patients**. Using the same pricing assumptions:

- **US:**  $(37,000 \times 0.01 = 370 \text{ patients}) \times \$120,000 = \$44.4 \text{ million}$

- **EU5:**  $(27,000 \times 0.01 = 270 \text{ patients}) \times \$70,000 = \$18.9 \text{ million}$

- **China:**  $(21,800 \times 0.01 = 218 \text{ patients}) \times \$40,000 = \$8.72 \text{ million}$

- **Japan:**  $(5,400 \times 0.01 = 54 \text{ patients}) \times \$70,000 = \$3.78 \text{ million}$

- **Total \$ Value of 1% Share:**  $\$44.4\text{M} + \$18.9\text{M} + \$8.72\text{M} + \$3.78\text{M} = \sim\$75.8 \text{ million}$

## **Final Answer**

1. **Potential Peak Sales for Elacestrant** in the specified indication across the US, EU5, China, and Japan:

- At 20% market share:  **$\sim\$1.516 \text{ billion}$**  annually

- At 30% market share:  **$\sim\$2.274 \text{ billion}$**  annually

2. **\$ Value of 1% Share of Treated Patients** across these geographies:  **$\sim\$75.8 \text{ million}$**  annually

## **Notes and Caveats**

- These estimates are based on assumptions about patient populations, market share, and pricing. Real-world figures may vary due to competition (e.g., other SERDs or therapies), reimbursement policies, and market access challenges, especially in China.

- Peak sales typically occur 5-10 years post-launch after market penetration stabilizes, assuming no major competitors or patent cliffs.

- If you have access to more specific data (e.g., exact patient numbers from clinical studies or pricing announcements), I can refine these calculations.