

To estimate the **Potential Peak Sales** for enzalutamide (Xtandi) in the indication of non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific patient numbers, pricing, and market penetration data are not provided, I will outline the methodology and use reasonable assumptions based on publicly available data and market trends for prostate cancer treatments. I will also note where data is assumed or requires further validation.

## **Step 1: Define Key Parameters**

1. **Target Patient Population:** Estimate the number of nmCSPC patients with high-risk BCR in each geography.
2. **Market Share:** Assume a 20% to 30% share of treated patients as given in the query.
3. **Pricing:** Estimate the annual cost of enzalutamide treatment per patient in each region.
4. **Peak Sales:** Calculate potential peak sales based on the above parameters.
5. **Value of 1% Share:** Derive the monetary value of a 1% share of treated patients.

## **Step 2: Estimate Target Patient Population**

Prostate cancer is one of the most common cancers in men. The nmCSPC with high-risk BCR population is a subset of prostate cancer patients who have undergone primary treatment (e.g., surgery or radiation) and show rising PSA levels (biochemical recurrence) but no detectable metastases. Below are rough estimates of the target population, based on incidence, prevalence, and proportion of nmCSPC with high-risk BCR.

- **US:** Prostate cancer incidence is ~268,000 new cases/year (American Cancer Society, 2023). Approximately 20-30% of patients experience biochemical recurrence after primary treatment, and of those, ~50% are at high risk for metastasis. Assuming a prevalent population, the nmCSPC high-risk BCR population could be ~30,000–50,000 patients annually (eligible for treatment).
- **EU5:** Prostate cancer incidence in EU5 is ~350,000 new cases/year. Using similar proportions, the nmCSPC high-risk BCR population might be ~40,000–60,000 patients.
- **China:** Prostate cancer incidence is lower (~115,000 new cases/year), but growing due to an aging population. The target population might be ~10,000–20,000 patients.
- **Japan:** Incidence is ~92,000 new cases/year. The target population might be ~10,000–15,000 patients.

### **Total Target Population (Approximate):**

- US: 40,000 patients
- EU5: 50,000 patients
- China: 15,000 patients
- Japan: 12,500 patients
- **Total:** 117,500 patients

\*Note\*: These numbers are rough estimates and should be validated with epidemiology data specific to nmCSPC with high-risk BCR.

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

Enzalutamide (Xtandi) pricing varies by region due to differences in healthcare systems, negotiations, and purchasing power. Below are approximate annual costs per patient (based on historical data and general pricing trends for oncology drugs):

- **US**: ~\$120,000–\$150,000 per year (high due to lack of price controls).
- **EU5**: ~\$50,000–\$80,000 per year (lower due to price negotiations and public health systems).
- **China**: ~\$30,000–\$50,000 per year (reflecting lower pricing and potential generics competition or government negotiations).
- **Japan**: ~\$60,000–\$90,000 per year (similar to EU5, with some variation).

**Assumed Average Annual Cost per Patient** (midpoint for simplicity):

- US: \$135,000
- EU5: \$65,000
- China: \$40,000
- Japan: \$75,000

### **Step 4: Calculate Potential Peak Sales (20%–30% Market Share)**

Peak sales are calculated as:

**Peak Sales = Target Population × Market Share × Annual Cost per Patient**

#### At 20% Market Share:

- **US**:  $40,000 \times 20\% \times \$135,000 = \$1.08 \text{ billion}$
- **EU5**:  $50,000 \times 20\% \times \$65,000 = \$0.65 \text{ billion}$
- **China**:  $15,000 \times 20\% \times \$40,000 = \$0.12 \text{ billion}$
- **Japan**:  $12,500 \times 20\% \times \$75,000 = \$0.1875 \text{ billion}$
- **Total**: **\$2.0375 billion**

#### At 30% Market Share:

- **US**:  $40,000 \times 30\% \times \$135,000 = \$1.62 \text{ billion}$
- **EU5**:  $50,000 \times 30\% \times \$65,000 = \$0.975 \text{ billion}$
- **China**:  $15,000 \times 30\% \times \$40,000 = \$0.18 \text{ billion}$
- **Japan**:  $12,500 \times 30\% \times \$75,000 = \$0.28125 \text{ billion}$
- **Total**: **\$3.05625 billion**

**Potential Peak Sales Range: \$2.04 billion to \$3.06 billion annually** across these geographies for this indication.

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

The value of a 1% share is calculated as:

**Value of 1% Share = Target Population × 1% × Annual Cost per Patient**

- **US:**  $40,000 \times 1\% \times \$135,000 = \$5.4 \text{ million}$
- **EU5:**  $50,000 \times 1\% \times \$65,000 = \$3.25 \text{ million}$
- **China:**  $15,000 \times 1\% \times \$40,000 = \$0.6 \text{ million}$
- **Japan:**  $12,500 \times 1\% \times \$75,000 = \$0.9375 \text{ million}$
- **Total Value of 1% Share: \$10.1875 million**

## **Final Answer**

1. **Potential Peak Sales for Enzalutamide** in nmCSPC with high-risk BCR (assuming 20%–30% market share):

- **US:** \$1.08 billion to \$1.62 billion
- **EU5:** \$0.65 billion to \$0.975 billion
- **China:** \$0.12 billion to \$0.18 billion
- **Japan:** \$0.1875 billion to \$0.28125 billion
- **Total: \$2.04 billion to \$3.06 billion annually**

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

- **US:** \$5.4 million
- **EU5:** \$3.25 million
- **China:** \$0.6 million
- **Japan:** \$0.9375 million
- **Total: \$10.1875 million**

## **Caveats and Notes**

- **Epidemiology Data:** The patient population estimates are rough and should be replaced with precise data on nmCSPC with high-risk BCR prevalence/incidence.
- **Pricing Variability:** Drug pricing can vary widely due to rebates, discounts, and regional policies (e.g., China's volume-based procurement could lower costs further).
- **Market Dynamics:** Competition from other therapies (e.g., apalutamide, darolutamide) could impact market share.

- **Treatment Duration:** Peak sales assume patients are treated for a full year; actual treatment duration may vary based on clinical guidelines or progression.

- **Regulatory and Access Delays:** Peak sales assume full market access, which may be delayed in some regions (e.g., China).

If more specific data on patient numbers, pricing, or market penetration is available, these estimates can be refined. Would you like me to adjust any assumptions or focus on a specific region or parameter?