

To estimate the **Potential Peak Sales** for darolutamide (Nubeqa) in the indication of metastatic hormone-sensitive prostate cancer (mHSPC) 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 specific data on patient numbers, pricing, and market penetration may vary and are not provided, I will outline the methodology and use reasonable assumptions based on publicly available information and typical market dynamics for oncology drugs. Please note that these are illustrative calculations, and real-world figures may differ based on proprietary data, pricing negotiations, and market access.

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## **Step 1: Key Assumptions and Methodology**

1. **Indication:** Darolutamide is approved for mHSPC in combination with docetaxel. mHSPC represents a significant portion of prostate cancer patients, often treated with androgen deprivation therapy (ADT) and increasingly with novel hormonal therapies like darolutamide.
2. **Patient Population:** Estimate the number of mHSPC patients eligible for treatment in each geography.
3. **Treated Patient Share:** Assume 20% to 30% of mHSPC patients are treated with darolutamide, as per the query.
4. **Pricing:** Use an approximate annual cost of treatment for darolutamide. Pricing varies by region due to healthcare systems and negotiations (e.g., higher in the US, lower in EU5/China/Japan).
5. **Peak Sales:** Peak sales are typically achieved 5-7 years post-launch after maximum market penetration.
6. **Market Size:** Use epidemiology data for prostate cancer and mHSPC prevalence/incidence.

### #### Epidemiology Estimates for mHSPC

- **US:** ~180,000 new prostate cancer cases annually; ~10-15% are metastatic at diagnosis (mHSPC or mCRPC). Assume ~20,000-25,000 mHSPC patients eligible annually.
- **EU5:** ~200,000 new cases annually across EU5; ~10-15% metastatic. Assume ~20,000-30,000 mHSPC patients.
- **China:** ~115,000 new cases annually; higher metastatic rate due to late diagnosis (~20%). Assume ~20,000-25,000 mHSPC patients.
- **Japan:** ~80,000 new cases annually; ~10-15% metastatic. Assume ~8,000-12,000 mHSPC patients.
- Total eligible patients across regions: ~68,000-92,000 annually (midpoint ~80,000).

### #### Pricing Assumptions (Annual Cost per Patient)

- **US:** ~\$100,000/year (based on typical pricing for novel hormonal therapies like enzalutamide or abiraterone).
- **EU5:** ~\$50,000/year (lower due to price controls and negotiations).
- **China:** ~\$30,000/year (emerging market pricing with potential generics competition).
- **Japan:** ~\$60,000/year (similar to EU but with higher reimbursement rates).

#### #### Market Share

- As per the query, assume darolutamide captures **20% to 30%** of treated mHSPC patients in each region.
- Assume all eligible patients are treated (realistically, treatment rates may be lower due to access or cost, but we simplify for calculation).

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## **Step 2: Estimate Treated Patients and Peak Sales**

#### #### Total Eligible Patients (Midpoint Estimate)

- US: 22,500 patients
- EU5: 25,000 patients
- China: 22,500 patients
- Japan: 10,000 patients
- Total: 80,000 patients

#### #### Treated Patients with Darolutamide (20%-30% Share)

##### - **20% Share:**

- US: 4,500 patients
- EU5: 5,000 patients
- China: 4,500 patients
- Japan: 2,000 patients
- Total: 16,000 patients

##### - **30% Share:**

- US: 6,750 patients
- EU5: 7,500 patients
- China: 6,750 patients
- Japan: 3,000 patients
- Total: 24,000 patients

#### #### Peak Sales Calculation

Peak sales = (Number of treated patients) × (Annual cost per patient)

##### - **At 20% Share:**

- US:  $4,500 \times \$100,000 = \text{\$450 million}$
- EU5:  $5,000 \times \$50,000 = \text{\$250 million}$

- China:  $4,500 \times \$30,000 = \$135 \text{ million}$
- Japan:  $2,000 \times \$60,000 = \$120 \text{ million}$
- Total Peak Sales: **\$955 million**
- **At 30% Share:**
- US:  $6,750 \times \$100,000 = \$675 \text{ million}$
- EU5:  $7,500 \times \$50,000 = \$375 \text{ million}$
- China:  $6,750 \times \$30,000 = \$202.5 \text{ million}$
- Japan:  $3,000 \times \$60,000 = \$180 \text{ million}$
- Total Peak Sales: **\$1,432.5 million (or ~\$1.43 billion)**

Thus, **Potential Peak Sales** for darolutamide in mHSPC across the US, EU5, China, and Japan range from **\$955 million to \$1.43 billion** annually, assuming a 20%-30% share of treated patients.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient pool (80,000 patients) = **800 patients**.

- **US** (1% = 225 patients):
- $225 \times \$100,000 = \$22.5 \text{ million}$
- **EU5** (1% = 250 patients):
- $250 \times \$50,000 = \$12.5 \text{ million}$
- **China** (1% = 225 patients):
- $225 \times \$30,000 = \$6.75 \text{ million}$
- **Japan** (1% = 100 patients):
- $100 \times \$60,000 = \$6 \text{ million}$
- **Total for 1% Share Across All Regions:**
- $\$22.5\text{M} + \$12.5\text{M} + \$6.75\text{M} + \$6\text{M} = \$47.75 \text{ million}$

Thus, the **\$ value of a 1% share of treated patients** across the US, EU5, China, and Japan is approximately **\$47.75 million** annually.

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### **Final Answer**

1. **Potential Peak Sales for Darolutamide in mHSPC** (20%-30% share of treated patients):

- **US:** \$450M - \$675M
- **EU5:** \$250M - \$375M
- **China:** \$135M - \$202.5M
- **Japan:** \$120M - \$180M
- **Total: \$955M - \$1.43B** annually

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

- **US:** \$22.5M
- **EU5:** \$12.5M
- **China:** \$6.75M
- **Japan:** \$6M
- **Total: \$47.75M** annually

## **Caveats**

- These figures are based on assumptions for patient numbers, pricing, and market share. Real-world data may vary due to competition (e.g., from enzalutamide, abiraterone), access barriers, and reimbursement policies.
- Peak sales may also depend on duration of therapy, patient compliance, and potential label expansions or generic entry.
- For precise figures, primary market research or proprietary data from Bayer or industry reports (e.g., EvaluatePharma, GlobalData) would be required.