

To estimate the **Potential Peak Sales** for rucaparib (Rubraca) in the indication of metastatic castration-resistant prostate cancer (mCRPC) with deleterious BRCA mutations in the US, EU5 (France, Germany, 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 (e.g., exact patient numbers, pricing, or market penetration) may not be fully available, I will outline the methodology and make reasonable assumptions based on publicly available information and typical market dynamics for oncology drugs. If you have specific data points, they can be incorporated for more precision.

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

Rucaparib is approved for mCRPC patients with deleterious BRCA mutations (germline and/or somatic) who have been treated with androgen receptor-directed therapy and taxane-based chemotherapy. Key considerations:

- **Prevalence of mCRPC:** mCRPC represents a subset of prostate cancer patients with advanced, resistant disease. In the US, prostate cancer incidence is ~250,000 new cases annually, with ~10-15% progressing to mCRPC (~25,000-37,500 patients). In EU5, Japan, and China, the numbers vary based on population and healthcare access.
- **BRCA Mutation Rate:** Approximately 10-12% of mCRPC patients have BRCA mutations (germline or somatic), so the eligible population is a subset of mCRPC patients.
- **Prior Treatment:** The indication specifies prior treatment with androgen receptor-directed therapy and taxane-based chemotherapy, further narrowing the population (assume ~50-60% of mCRPC patients reach this stage).

### **Rough Estimates of Eligible Patients (Annual Incident Cases):**

- **US:** ~25,000-37,500 mCRPC patients \* 10-12% BRCA mutation \* 50-60% prior treatment = ~1,250-2,700 patients.
- **EU5:** Similar to US, but adjusted for population (~60% of US incidence due to smaller combined population) = ~750-1,600 patients.
- **Japan:** Smaller population, high healthcare access (~20% of US incidence) = ~250-550 patients.
- **China:** Large population but lower diagnosis rates and access to advanced therapies (~50% of US incidence) = ~625-1,350 patients.

**Total Eligible Patients (Annual):** ~2,875-6,200 across all geographies.

## **Step 2: Estimate Market Penetration (20%-30% Share of Treated Patients)**

Assuming rucaparib captures 20%-30% of the eligible treated population:

- **US:** 250-810 patients treated.
- **EU5:** 150-480 patients treated.
- **Japan:** 50-165 patients treated.
- **China:** 125-405 patients treated.
- **Total Treated Patients:** 575-1,860 patients annually at peak.

### **Step 3: Estimate Pricing and Treatment Duration**

- **Pricing:** Rucaparib's annual cost in the US is approximately \$150,000-\$200,000 per patient (based on typical oral PARP inhibitor pricing, e.g., olaparib). In EU5 and Japan, pricing is often 60-80% of US prices due to negotiations (~\$90,000-\$160,000). In China, pricing may be lower due to market access challenges (~\$50,000-\$100,000).

- **Treatment Duration:** mCRPC patients on PARP inhibitors like rucaparib typically remain on therapy for ~6-12 months (average ~9 months). For simplicity, assume full annual cost as a proxy for peak sales calculation.

#### **Annual Revenue per Patient (Assumed Average):**

- **US:** \$175,000
- **EU5:** \$125,000
- **Japan:** \$125,000
- **China:** \$75,000

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

Peak sales are calculated as: (Number of treated patients) \* (Annual revenue per patient).

- **US:** 250-810 patients \* \$175,000 = **\$43.8M - \$141.8M**
- **EU5:** 150-480 patients \* \$125,000 = **\$18.8M - \$60.0M**
- **Japan:** 50-165 patients \* \$125,000 = **\$6.3M - \$20.6M**
- **China:** 125-405 patients \* \$75,000 = **\$9.4M - \$30.4M**
- **Total Peak Sales:** **\$78.3M - \$252.8M** annually at 20%-30% market share.

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

First, estimate the total eligible patient population and calculate 1% of that population, then apply the per-patient revenue.

- **Total Eligible Patients:** ~2,875-6,200
- **1% of Eligible Patients:** ~29-62 patients
- Using the same per-patient revenue as above, calculate for each geography:
- **US:** 1% of 1,250-2,700 = 12.5-27 patients \* \$175,000 = **\$2.2M - \$4.7M**
- **EU5:** 1% of 750-1,600 = 7.5-16 patients \* \$125,000 = **\$0.9M - \$2.0M**
- **Japan:** 1% of 250-550 = 2.5-5.5 patients \* \$125,000 = **\$0.3M - \$0.7M**
- **China:** 1% of 625-1,350 = 6.25-13.5 patients \* \$75,000 = **\$0.5M - \$1.0M**
- **Total \$ Value of 1% Share:** **\$3.9M - \$8.4M**

## **Final Answer**

- **Potential Peak Sales for Rucaparib in mCRPC (20%-30% market share): \$78.3M - \$252.8M annually** across the US, EU5, Japan, and China.

- **\$ Value of 1% Share of Treated Patients: \$3.9M - \$8.4M** across the same geographies.

## **Caveats and Assumptions**

1. Patient population estimates are based on general epidemiology data for prostate cancer and mCRPC, adjusted for BRCA mutation prevalence and prior treatment. Actual numbers may vary.

2. Pricing is assumed based on typical PARP inhibitor costs and may differ by country due to negotiations, reimbursement, or generics/biosimilars.

3. Market share (20%-30%) assumes competition from other PARP inhibitors (e.g., olaparib) and emerging therapies.

4. Peak sales assume steady-state adoption, which may take several years post-approval.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market research), I can refine these calculations further.