

To calculate the **Potential Peak Sales** for talazoparib (Talzenna) in the indication of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) 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 dynamics for talazoparib in this indication may not be fully public or up-to-date, I will outline the methodology and use reasonable assumptions based on available information and market trends for oncology drugs, particularly in prostate cancer. If you have specific data (e.g., exact patient numbers or pricing), I can refine the calculations.

Step 1: Define Key Parameters and Assumptions

1. Indication and Target Population:

- Talazoparib is approved for HRR gene-mutated mCRPC in combination with enzalutamide.
- HRR gene mutations (e.g., BRCA1/2) occur in approximately 20-30% of mCRPC patients, depending on the study and geography.
- mCRPC is an advanced stage of prostate cancer with a significant patient population globally.

2. Market Share:

- The problem assumes a 20-30% share of treated patients for talazoparib in this indication. We will calculate peak sales for both ends of this range.

3. Geographies:

- US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan.

4. Pricing:

- Talazoparib is a high-cost oncology drug. Pricing varies by region due to healthcare systems and reimbursement policies.
- Approximate annual cost per patient (based on similar PARP inhibitors like olaparib):
 - US: ~\$150,000–\$180,000 per year.
 - EU5: ~\$80,000–\$120,000 per year (lower due to negotiated pricing).
 - Japan: ~\$100,000–\$130,000 per year.
 - China: ~\$50,000–\$80,000 per year (lower due to pricing controls and generics/biosimilars competition).
- For simplicity, we'll use midpoint values: US (\$165,000), EU5 (\$100,000), Japan (\$115,000), China (\$65,000).

5. Treatment Duration:

- Average treatment duration for mCRPC with PARP inhibitors is approximately 8-12 months. We'll assume 10 months (0.83 years) for annual cost calculations.

6. Patient Population:

- We need the number of mCRPC patients eligible for talazoparib (i.e., HRR-mutated).
- Total prostate cancer incidence and prevalence vary by region. mCRPC represents a subset of advanced cases, and HRR mutations are a further subset (20-30%).
- Approximate annual mCRPC incidence (based on epidemiology data and reports like GlobalData or SEER):
- US: ~40,000–50,000 mCRPC patients; HRR-mutated (~25%): ~10,000–12,500.
- EU5: ~35,000–45,000 mCRPC patients; HRR-mutated (~25%): ~8,750–11,250.
- Japan: ~10,000–12,000 mCRPC patients; HRR-mutated (~25%): ~2,500–3,000.
- China: ~60,000–80,000 mCRPC patients (larger population but lower diagnosis rates); HRR-mutated (~25%): ~15,000–20,000.
- For calculations, we'll use midpoint values of HRR-mutated mCRPC patients:
- US: 11,250
- EU5: 10,000
- Japan: 2,750
- China: 17,500

7. Penetration and Diagnosis Rates:

- Not all eligible patients are diagnosed with HRR mutations or treated due to access, testing, and reimbursement issues.
- Assumed diagnosis and treatment access rates:
- US: 80%
- EU5: 70%
- Japan: 75%
- China: 50%
- Treated HRR-mutated mCRPC patients:
- US: $11,250 \times 80\% = 9,000$
- EU5: $10,000 \times 70\% = 7,000$
- Japan: $2,750 \times 75\% = 2,063$
- China: $17,500 \times 50\% = 8,750$

8. Peak Sales Timeline:

- Peak sales typically occur 5-7 years post-launch after market penetration stabilizes, assuming no major competition or patent expiry.

Step 2: Calculate Potential Peak Sales for Talazoparib

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

At 20% Market Share

- **US:** 9,000 patients × 20% × \$165,000 = **\$297 million**
- **EU5:** 7,000 patients × 20% × \$100,000 = **\$140 million**
- **Japan:** 2,063 patients × 20% × \$115,000 = **\$47 million**
- **China:** 8,750 patients × 20% × \$65,000 = **\$114 million**
- **Total Peak Sales (20% share):** \$297M + \$140M + \$47M + \$114M = **\$598 million**

At 30% Market Share

- **US:** 9,000 patients × 30% × \$165,000 = **\$446 million**
- **EU5:** 7,000 patients × 30% × \$100,000 = **\$210 million**
- **Japan:** 2,063 patients × 30% × \$115,000 = **\$71 million**
- **China:** 8,750 patients × 30% × \$65,000 = **\$171 million**
- **Total Peak Sales (30% share):** \$446M + \$210M + \$71M + \$171M = **\$898 million**

Range of Potential Peak Sales

- **Potential Peak Sales Range: \$598 million to \$898 million annually** across the US, EU5, Japan, and China for talazoparib in HRR-mutated mCRPC, assuming a 20-30% market share.

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

\$ Value of 1% share = (Number of treated patients) × (1%) × (Annual cost per patient)

- **US:** 9,000 patients × 1% × \$165,000 = **\$14.85 million**
- **EU5:** 7,000 patients × 1% × \$100,000 = **\$7.00 million**
- **Japan:** 2,063 patients × 1% × \$115,000 = **\$2.37 million**
- **China:** 8,750 patients × 1% × \$65,000 = **\$5.69 million**
- **Total \$ Value of 1% Share:** \$14.85M + \$7.00M + \$2.37M + \$5.69M = **\$29.91 million**

Summary of \$ Value of 1% Share of Treated Patients

- **US: \$14.85 million**
- **EU5: \$7.00 million**
- **Japan: \$2.37 million**
- **China: \$5.69 million**
- **Total across geographies: \$29.91 million**

Step 4: Key Considerations and Limitations

1. Competition:

- Talazoparib competes with other PARP inhibitors like olaparib (Lynparza) and rucaparib (Rubraca) in the HRR-mutated mCRPC space. Market share assumptions (20-30%) account for this, but competition could lower penetration.

2. Pricing Variability:

- Pricing is assumed based on benchmarks for PARP inhibitors. Actual net pricing may be lower due to discounts, rebates, or government negotiations, especially in EU5 and China.

3. Patient Population Estimates:

- The number of HRR-mutated mCRPC patients is an estimate based on epidemiology data. Genetic testing rates and diagnosis could impact the treated population.

4. Market Access:

- Access to talazoparib varies by region due to reimbursement policies, especially in China, where cost sensitivity is high.

5. Combination Therapy:

- Talazoparib is used with enzalutamide, which may influence treatment decisions and costs but is not factored into pricing here (only talazoparib's cost is considered).

Final Answer

- **Potential Peak Sales for Talazoparib in HRR-mutated mCRPC (20-30% market share):**

- **\$598 million to \$898 million annually** across the US, EU5, Japan, and China.

- **\$ Value of 1% Share of Treated Patients:**

- US: **\$14.85 million**

- EU5: **\$7.00 million**

- Japan: **\$2.37 million**

- China: **\$5.69 million**

- Total: **\$29.91 million**

If you have additional data (e.g., exact patient numbers, pricing, or market share forecasts), I can refine these estimates further.