

To estimate the **Potential Peak Sales** for niraparib (Zejvula) in the indication of maintenance treatment for advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer 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 (e.g., exact patient numbers, pricing, or market share) is not provided, I will outline the methodology and make reasonable assumptions based on publicly available information and market trends for oncology drugs, particularly PARP inhibitors like niraparib.

Step 1: Define the Target Patient Population

Niraparib is approved for maintenance treatment in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who have responded to first-line platinum-based chemotherapy. We need to estimate the number of eligible patients in each geography.

- **Incidence of ovarian cancer:** According to the World Cancer Research Fund and other sources, ovarian cancer incidence (which includes epithelial ovarian, fallopian tube, and primary peritoneal cancers) varies by region. Approximately 60-70% of ovarian cancer cases are diagnosed at an advanced stage (Stage III/IV), and a significant proportion of these patients respond to first-line platinum-based chemotherapy, making them eligible for maintenance therapy.

- **Eligible patient population:** Not all diagnosed patients will be eligible for maintenance therapy. We assume that ~50-60% of advanced-stage patients achieve a complete or partial response to first-line therapy and are candidates for niraparib.

Using approximate annual incidence rates for ovarian cancer:

- **US:** ~22,000 new cases; ~70% advanced stage = ~15,400; ~55% eligible for maintenance = ~8,500 patients.

- **EU5:** ~34,000 new cases (combined); ~70% advanced = ~23,800; ~55% eligible = ~13,100 patients.

- **China:** ~52,000 new cases; ~70% advanced = ~36,400; ~55% eligible = ~20,000 patients (access to advanced therapies may be lower, but we assume full potential for peak sales).

- **Japan:** ~13,000 new cases; ~70% advanced = ~9,100; ~55% eligible = ~5,000 patients.

Total eligible patients across geographies: ~8,500 (US) + 13,100 (EU5) + 20,000 (China) + 5,000 (Japan) = **46,600 patients annually**.

Step 2: Market Penetration (Share of Treated Patients)

The problem assumes a **20% to 30% share of treated patients** for niraparib. This accounts for competition from other PARP inhibitors (e.g., olaparib, rucaparib) and other therapies, as well as market access and reimbursement challenges.

- **Low-end penetration (20%):** $46,600 * 0.20 = \sim 9,320$ patients treated with niraparib annually.

- **High-end penetration (30%):** $46,600 * 0.30 = \sim 13,980$ patients treated with niraparib annually.

Step 3: Pricing and Annual Cost per Patient

Niraparib is a high-cost oncology drug. The annual cost of treatment varies by region due to differences in healthcare systems, pricing negotiations, and reimbursement policies. Based on available data for PARP inhibitors:

- **US:** Annual cost ~\$150,000–\$180,000 per patient (list price before discounts).
- **EU5:** Annual cost ~\$80,000–\$100,000 per patient (lower due to price negotiations and universal healthcare systems).
- **China:** Annual cost ~\$40,000–\$60,000 per patient (emerging market pricing, limited reimbursement, but growing access).
- **Japan:** Annual cost ~\$90,000–\$110,000 per patient (similar to EU5, with strong reimbursement systems).

For simplicity, we will use the midpoint of these ranges:

- US: \$165,000/year
- EU5: \$90,000/year
- China: \$50,000/year
- Japan: \$100,000/year

Step 4: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients (at 20% and 30% penetration) by the annual cost per patient in each geography.

Low-End Penetration (20% Share of Treated Patients)

- **US:** $8,500 * 0.20 = 1,700$ patients * \$165,000 = **\$280.5 million**
- **EU5:** $13,100 * 0.20 = 2,620$ patients * \$90,000 = **\$235.8 million**
- **China:** $20,000 * 0.20 = 4,000$ patients * \$50,000 = **\$200.0 million**
- **Japan:** $5,000 * 0.20 = 1,000$ patients * \$100,000 = **\$100.0 million**
- **Total Peak Sales (20%):** \$280.5M + \$235.8M + \$200.0M + \$100.0M = **\$816.3 million annually**

High-End Penetration (30% Share of Treated Patients)

- **US:** $8,500 * 0.30 = 2,550$ patients * \$165,000 = **\$420.8 million**
- **EU5:** $13,100 * 0.30 = 3,930$ patients * \$90,000 = **\$353.7 million**
- **China:** $20,000 * 0.30 = 6,000$ patients * \$50,000 = **\$300.0 million**
- **Japan:** $5,000 * 0.30 = 1,500$ patients * \$100,000 = **\$150.0 million**
- **Total Peak Sales (30%):** \$420.8M + \$353.7M + \$300.0M + \$150.0M = **\$1,224.5 million annually**

Potential Peak Sales Range: \$816 million to \$1.22 billion annually across the US, EU5, China, and Japan for this indication.

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

A 1% share of treated patients corresponds to 1% of the eligible patient population (46,600 patients) = **466 patients annually**.

Using the same annual cost per patient:

- **US:** $8,500 * 0.01 = 85 \text{ patients} * \$165,000 = \text{\$14.0 million}$

- **EU5:** $13,100 * 0.01 = 131 \text{ patients} * \$90,000 = \text{\$11.8 million}$

- **China:** $20,000 * 0.01 = 200 \text{ patients} * \$50,000 = \text{\$10.0 million}$

- **Japan:** $5,000 * 0.01 = 50 \text{ patients} * \$100,000 = \text{\$5.0 million}$

- **Total \$ Value of 1% Share:** $\$14.0\text{M} + \$11.8\text{M} + \$10.0\text{M} + \$5.0\text{M} = \text{\$40.8 million annually}$

Final Answer

- **Potential Peak Sales for Niraparib** in the indication of maintenance treatment for advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (assuming 20% to 30% share of treated patients):

- **\$816 million to \$1.22 billion annually** across the US, EU5, China, and Japan.

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

- **\$40.8 million annually** across the US, EU5, China, and Japan.

Notes and Caveats

1. These estimates are based on assumptions about patient populations, pricing, and market penetration. Actual figures may vary due to competition, reimbursement policies, and real-world treatment duration (patients may not remain on therapy for a full year).
2. Pricing in China and other emerging markets may be lower due to access challenges, but I assumed a conservative estimate to reflect potential growth.
3. Peak sales typically occur several years after launch, factoring in market uptake and expanded access.
4. This analysis focuses solely on the specified indication (first-line maintenance). Niraparib may have additional indications (e.g., recurrent ovarian cancer), which would increase overall sales potential but are outside the scope of this question.

If more specific data (e.g., exact patient numbers, real-world pricing, or competitor market shares) is available, these estimates can be refined further.