

To estimate the **Potential Peak Sales** for olaparib (Lynparza) in the specified indication (first-line maintenance treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer with homologous recombination deficiency (HRD) positive status) 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. This will involve making assumptions based on epidemiology, market data, treatment rates, pricing, and market penetration. Since specific data might not be fully available, I'll outline the methodology and use reasonable estimates based on publicly available information and industry standards as of my last update (October 2023). If you have specific data, it can be incorporated for more precision.

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## **Step 1: Define the Indication and Target Population**

The indication is for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who:

- Are in complete or partial response to first-line platinum-based chemotherapy.
- Have HRD-positive status (defined by BRCA mutation or genomic instability).

#### Epidemiology of Ovarian Cancer (and related cancers):

- **US:** ~19,000-22,000 new cases of ovarian cancer annually (American Cancer Society).
- **EU5:** ~45,000-50,000 new cases annually (combined across France, Germany, Italy, Spain, UK; based on European Cancer Information System).
- **China:** ~50,000-55,000 new cases annually (due to large population and increasing incidence; GLOBOCAN data).
- **Japan:** ~13,000-15,000 new cases annually (GLOBOCAN data).

#### Advanced Cases (Stage III/IV):

- Approximately 70-80% of ovarian cancer cases are diagnosed at an advanced stage (Stage III/IV).

#### Response to First-Line Platinum-Based Chemotherapy:

- About 70-80% of advanced patients achieve a complete or partial response to first-line platinum-based chemotherapy.

#### HRD-Positive Status:

- Approximately 50% of advanced ovarian cancer patients are HRD-positive (including ~20-25% with BRCA mutations and additional patients with genomic instability).

#### Annual Eligible Patient Population (Incident Cases):

Using the above percentages, the approximate number of patients eligible for first-line maintenance with olaparib can be calculated as:

- Total new cases × % advanced stage (75%) × % response to chemo (75%) × % HRD-positive (50%).

| Region | New Cases (Annual) | Advanced (75%) | Response (75%) | HRD+ (50%) | Eligible Patients (Annual) |

|-----|-----|-----|-----|-----|-----|

| US | 20,000 | 15,000 | 11,250 | 5,625 | ~5,600 |

| EU5 | 47,500 | 35,625 | 26,719 | 13,359 | ~13,400 |

| China | 52,500 | 39,375 | 29,531 | 14,766 | ~14,800 |

| Japan | 14,000 | 10,500 | 7,875 | 3,938 | ~3,900 |

| **Total** | 134,000 | 100,500 | 75,375 | 37,688 | ~37,600 |

#### #### Treated Patients:

- Not all eligible patients receive maintenance therapy due to access, physician preference, or other factors. Assuming a treatment rate of 60-70% for maintenance therapy in this indication:
- US: ~3,400-3,900 treated patients.
- EU5: ~8,000-9,400 treated patients.
- China: ~8,900-10,400 treated patients (lower penetration due to access and cost barriers).
- Japan: ~2,300-2,700 treated patients.
- **Total Treated Patients:** ~22,600-26,400 annually.

#### #### Market Share for Olaparib:

- The problem assumes a 20-30% share of treated patients for olaparib. This accounts for competition from other PARP inhibitors (e.g., niraparib) and potential off-label or alternative therapies.
- US: 20-30% of 3,400-3,900 = ~680-1,170 patients.
- EU5: 20-30% of 8,000-9,400 = ~1,600-2,820 patients.
- China: 20-30% of 8,900-10,400 = ~1,780-3,120 patients.
- Japan: 20-30% of 2,300-2,700 = ~460-810 patients.
- **Total Patients on Olaparib:** ~4,500-7,900 annually.

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## **Step 2: Pricing and Treatment Duration**

#### #### Annual Cost of Olaparib:

- **US:** ~\$150,000-180,000 per patient per year (based on reported costs for Lynparza in oncology indications, adjusted for discounts/rebates).
- **EU5:** ~\$80,000-100,000 per patient per year (lower due to pricing negotiations and healthcare systems).
- **China:** ~\$40,000-60,000 per patient per year (significant price reductions due to market access programs and generics competition).

- **Japan:** ~\$100,000-120,000 per patient per year (aligned with developed markets but with some discounts).

#### Treatment Duration:

- Maintenance therapy with olaparib in ovarian cancer often lasts ~2 years (based on clinical trial data like SOLO-1, though real-world duration may vary). For simplicity, we calculate peak sales based on annual cost and assume steady-state patient numbers (incident cases treated annually).

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### **Step 3: Potential Peak Sales Calculation**

Peak sales are estimated based on the number of treated patients with olaparib (at 20-30% market share) multiplied by the annual cost per patient.

| Region | Patients (20-30% Share) | Annual Cost per Patient | Peak Sales (20% Share, \$M) | Peak Sales (30% Share, \$M) |

|-----|-----|-----|-----|-----|

| US | 680-1,170 | \$150,000-180,000 | ~102-122 | ~176-210 |

| EU5 | 1,600-2,820 | \$80,000-100,000 | ~128-160 | ~226-282 |

| China | 1,780-3,120 | \$40,000-60,000 | ~71-107 | ~125-187 |

| Japan | 460-810 | \$100,000-120,000 | ~46-55 | ~81-97 |

| **Total** | 4,500-7,900 | - | ~347-444 | ~608-776 |

**Potential Peak Sales Range:** Approximately **\$350M to \$780M annually** across the US, EU5, China, and Japan for this indication, assuming 20-30% market share.

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### **Step 4: \$ Value of 1% Share of Treated Patients**

To calculate the \$ value of a 1% share of treated patients, we use the total number of treated patients (not just olaparib's share) and multiply by the annual cost per patient.

| Region | Total Treated Patients (Annual) | 1% of Treated Patients | Annual Cost per Patient | \$ Value of 1% Share (\$M) |

|-----|-----|-----|-----|-----|

| US | 3,400-3,900 | 34-39 | \$150,000-180,000 | ~5.1-7.0 |

| EU5 | 8,000-9,400 | 80-94 | \$80,000-100,000 | ~6.4-9.4 |

| China | 8,900-10,400 | 89-104 | \$40,000-60,000 | ~3.6-6.2 |

| Japan | 2,300-2,700 | 23-27 | \$100,000-120,000 | ~2.3-3.2 |

| **Total** | 22,600-26,400 | 226-264 | - | ~17.4-25.8 |

**\$ Value of 1% Share of Treated Patients:** Approximately **\$17M to \$26M annually** across the US, EU5, China, and Japan.

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### **Key Assumptions and Caveats:**

1. **Epidemiology Data:** Incidence rates and patient segmentation (advanced stage, response rate, HRD status) are based on general oncology statistics and may vary by region or over time.
2. **Treatment Rate:** Assumed 60-70% of eligible patients receive maintenance therapy, which may be lower in emerging markets like China due to access barriers.
3. **Market Share:** 20-30% share for olaparib is a reasonable estimate given competition from other PARP inhibitors (e.g., niraparib, rucaparib) and potential future entrants.
4. **Pricing:** Costs are approximate and based on reported figures for olaparib in oncology; actual pricing may differ due to negotiations, rebates, or generic entry.
5. **Peak Sales Timing:** Peak sales assume a steady-state patient population and do not account for uptake curves or patent expiry (olaparib's patent protection extends into the late 2020s in many regions).

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### **Final Answer:**

- **Potential Peak Sales for Olaparib** in this indication (first-line maintenance for HRD-positive advanced ovarian cancer) across the US, EU5, China, and Japan, assuming a 20-30% market share: **\$350M to \$780M annually**.

- **\$ Value of 1% Share of Treated Patients** across these geographies: **\$17M to \$26M annually**.

If you have additional data (e.g., exact pricing, updated incidence figures, or market share projections), I can refine these estimates further.