To calculate the **Potential Peak Sales** for olaparib (Lynparza) in the adjuvant treatment of gBRCAm HER2-negative high-risk early breast 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 make several assumptions and follow a structured approach. Since specific data on patient populations, pricing, and market penetration may not be publicly available, I will outline the methodology and use reasonable estimates based on available information and industry standards. Here's the step-by-step process:

Step 1: Define the Indication and Target Patient Population

- **Indication**: Adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm HER2-negative high-risk early breast cancer post-neoadjuvant or adjuvant chemotherapy.
- **Target Population**: Patients with early-stage breast cancer who are gBRCAm (germline BRCA-mutated) and HER2-negative. Approximately 5-10% of breast cancer patients carry BRCA mutations, and a subset of these are early-stage, high-risk patients eligible for adjuvant therapy.

Estimated Breast Cancer Incidence (Annual New Cases)

- US: ~290,000 new breast cancer cases (2023 estimate, American Cancer Society).
- **EU5**: ~370,000 new cases (combined for Germany, France, Italy, Spain, UK; based on GLOBOCAN 2020).
- China: ~420,000 new cases (GLOBOCAN 2020).
- Japan: ~95,000 new cases (GLOBOCAN 2020).

Proportion of gBRCAm HER2-negative High-Risk Early Breast Cancer

- ~5-10% of breast cancer patients have BRCA mutations (let's assume 7% for calculation).
- ~50-60% of breast cancer cases are HER2-negative (assume 55%).
- ~50% of early breast cancer cases are considered high-risk (assume 50%).
- Therefore, target population = Total new cases \times 7% (BRCAm) \times 55% (HER2-negative) \times 50% (high-risk).

Estimated Eligible Patients (Annual New Cases)

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| Region | Total New Cases | Eligible Patients (7% x 55% x 50%) | |-------|-------| | | US | 290,000 | ~5,586 | | | EU5 | 370,000 | ~7,124 | | | China | 420,000 | ~8,085 | | | Japan | 95,000 | ~1,829 | | | Total | 1,175,000 | ~22,624 |
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Step 2: Assume Treatment Rate and Market Share

- **Treatment Rate**: Not all eligible patients will receive olaparib due to factors like access, physician preference, and cost. Assume 50% of eligible patients are treated.
- **Market Share**: As per the query, assume olaparib captures 20% to 30% of treated patients (use midpoint of 25% for calculation).

Treated Patients and Olaparib Share

Region Eligible Patients Treated Patients (50%) Olaparib Patients (25%)
US 5,586 2,793 698
EU5 7,124 3,562 891
China 8,085 4,043 1,011
Japan 1,829 915 229
Total 22,624 11,312 2,828

Step 3: Estimate Annual Cost of Treatment per Patient

- Olaparib is a targeted therapy (PARP inhibitor), and its cost varies by region due to pricing differences, healthcare systems, and reimbursement policies.
- Annual Cost Assumptions (based on publicly available data and industry reports for Lynparza):
- US: ~\$180,000 per patient per year (based on list price before discounts).
- **EU5**: ~\$100,000 per patient per year (lower due to negotiated pricing).
- **China**: ~\$50,000 per patient per year (significant price reductions in emerging markets).
- Japan: ~\$120,000 per patient per year (similar to EU but slightly higher due to market dynamics).

Step 4: Calculate Potential Peak Sales for Olaparib

Peak sales are calculated as: Number of Olaparib Patients × Annual Cost per Patient.

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| Region | Olaparib Patients | Annual Cost per Patient | Peak Sales (USD Million) | |------|--------------|----------| | US | 698 | $180,000 | $125.6 | | EU5 | 891 | $100,000 | $89.1 |
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| China | 1,011 | $50,000 | $50.6 |
| Japan | 229 | $120,000 | $27.5 |
| Total| 2,828 | - | $292.8 Million |
```

Potential Peak Sales (25% market share): Approximately \$293 Million USD annually across these geographies.

- If market share is 20%, peak sales would be ~\$234 Million USD.
- If market share is **30%**, peak sales would be ~\$351 Million USD.

Thus, the Potential Peak Sales Range is approximately \$234 Million to \$351 Million USD.

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

- First, calculate the total number of treated patients (50% of eligible patients, as assumed earlier).
- Then, calculate 1% of treated patients.
- Finally, multiply by the annual cost per patient in each region.

1% Share of Treated Patients

| Region | Treated Patients (50%) | 1% of Treated Patients | Annual Cost per Patient | \$ Value of 1%

\$ Value of 1% Share of Treated Patients: Approximately **\$11.7 Million USD** across these geographies.

Final Answer

- 1. **Potential Peak Sales for Olaparib** in the adjuvant treatment of gBRCAm HER2-negative high-risk early breast cancer (assuming 20%-30% market share):
- Range: \$234 Million to \$351 Million USD annually across the US, EU5, China, and Japan.
- Midpoint (25% share): \$293 Million USD.

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

- Approximately \$11.7 Million USD across the US, EU5, China, and Japan.

Caveats and Assumptions

- Patient population estimates are based on general breast cancer incidence and assumed proportions for gBRCAm, HER2-negative, and high-risk status. Real-world data may differ.
- Treatment rates and market share assumptions (50% and 20-30%, respectively) are illustrative and depend on competition, reimbursement, and market access.
- Pricing is an estimate based on publicly available data for olaparib and may vary due to discounts, rebates, and regional pricing policies.
- Peak sales assume steady-state market penetration and do not account for patent expiry or generic competition.
- Duration of therapy (assumed as 1 year for adjuvant treatment) may vary based on clinical guidelines or trial data (e.g., OlympiA trial for olaparib).

If more specific data (e.g., exact patient numbers, pricing, or market share projections) are available, these calculations can be refined further.