

To estimate the **Potential Peak Sales** for the drug combination of **niraparib and abiraterone acetate (Akeega)** for the indication of BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC) 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 such as exact patient numbers, pricing, or market penetration rates are not provided, I will outline the methodology and use reasonable assumptions based on publicly available information and industry standards. The final numbers will be illustrative and should be validated with real-world data.

Step 1: Define the Target Patient Population

The indication is for adult patients with **BRCA-mutated mCRPC**. We need to estimate the number of eligible patients in each geography.

- **Prevalence of mCRPC:** mCRPC represents a subset of prostate cancer patients who have progressed to metastatic disease and are resistant to androgen deprivation therapy. According to various studies, mCRPC patients make up approximately 10-20% of advanced prostate cancer cases.

- **BRCA Mutations:** Around 10-15% of mCRPC patients have BRCA1/2 mutations (deleterious or suspected deleterious), which is the target population for Akeega.

- **Total Prostate Cancer Incidence:** We will use approximate incidence rates and population data for each region to estimate the mCRPC BRCA-mutated population.

Estimated mCRPC BRCA-mutated Patient Population (Annual Incidence)

- **US:** Prostate cancer incidence is ~248,000 new cases per year (SEER data). Assuming 15% progress to mCRPC and 12% of those have BRCA mutations, the eligible population is ~4,500-5,000 patients per year.

- **EU5:** Combined prostate cancer incidence is ~400,000 new cases per year. Using similar proportions, the eligible population is ~7,000-8,000 patients per year.

- **China:** Prostate cancer incidence is lower (~115,000 new cases per year due to lower screening rates), but with a large population, the eligible mCRPC BRCA-mutated population is ~2,000-2,500 patients per year.

- **Japan:** Prostate cancer incidence is ~92,000 new cases per year. The eligible population is ~1,500-2,000 patients per year.

Total estimated annual incident patients across geographies: **~15,000-17,500 patients**.

Treated Patient Population

Not all eligible patients will receive treatment due to access, diagnosis rates, or other barriers. Assuming 60-80% of eligible patients are treated:

- Total treated patients annually: **~9,000-14,000 patients**.

Step 2: Market Share Assumption

The query assumes a **20-30% share of treated patients** for Akeega. Using the midpoint of 25% for calculation:

- Treated patients on Akeega: **~2,250-3,500 patients annually**.

Step 3: Drug Pricing and Treatment Duration

- **Pricing:** Akeega is a combination of niraparib (a PARP inhibitor) and abiraterone acetate (an androgen receptor inhibitor). Based on pricing for similar drugs:
 - Niraparib (Zejula) costs ~\$10,000-15,000 per month in the US.
 - Abiraterone (Zytiga) costs ~\$3,000-5,000 per month in the US.
 - Combined pricing for Akeega might be discounted but is likely in the range of **\$12,000-18,000 per month** in the US. For EU5, pricing is typically 30-50% lower (~\$6,000-9,000/month). In China and Japan, pricing may be further reduced due to negotiations and market dynamics (~\$3,000-6,000/month).
- **Treatment Duration:** mCRPC patients on targeted therapies like this combination typically remain on treatment for **6-12 months** (average ~9 months) based on progression-free survival data from clinical trials (e.g., MAGNITUDE trial for niraparib + abiraterone).

Annual Cost per Patient

- US: \$12,000-\$18,000/month x 9 months = **\$108,000-\$162,000/year**.
- EU5: \$6,000-\$9,000/month x 9 months = **\$54,000-\$81,000/year**.
- China/Japan: \$3,000-\$6,000/month x 9 months = **\$27,000-\$54,000/year**.

Step 4: Potential Peak Sales Calculation

Using the number of treated patients on Akeega (25% market share) and annual cost per patient, we calculate peak sales. We'll assume a proportional distribution of patients across geographies (based on earlier estimates: US ~30%, EU5 ~50%, China ~15%, Japan ~5%).

Peak Sales Estimate

- **US:** 2,250-3,500 patients x 30% = ~675-1,050 patients x \$135,000 (midpoint) = **\$91M-\$142M**.
- **EU5:** 2,250-3,500 patients x 50% = ~1,125-1,750 patients x \$67,500 (midpoint) = **\$76M-\$118M**.
- **China:** 2,250-3,500 patients x 15% = ~340-525 patients x \$40,500 (midpoint) = **\$14M-\$21M**.
- **Japan:** 2,250-3,500 patients x 5% = ~115-175 patients x \$40,500 (midpoint) = **\$5M-\$7M**.

Total Peak Sales: \$186M-\$288M annually across all geographies at 20-30% market share (midpoint ~\$237M at 25% share).

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

A 1% share of treated patients corresponds to 1% of the total treated population (9,000-14,000 patients) = **90-140 patients annually**.

Revenue per 1% Share

- **US:** 90-140 patients x 30% = 27-42 patients x \$135,000 = **\$3.6M-\$5.7M**.

- **EU5:** 90-140 patients x 50% = 45-70 patients x \$67,500 = **\$3.0M-\$4.7M**.
- **China:** 90-140 patients x 15% = 14-21 patients x \$40,500 = **\$0.6M-\$0.9M**.
- **Japan:** 90-140 patients x 5% = 5-7 patients x \$40,500 = **\$0.2M-\$0.3M**.

Total \$ Value of 1% Share: \$7.4M-\$11.6M annually (midpoint ~\$9.5M).

Final Answers

1. Potential Peak Sales for Niraparib and Abiraterone Acetate (Akeega) in BRCA-mutated mCRPC at 20-30% market share:

- **US, EU5, China, and Japan Combined: \$186M-\$288M annually** (midpoint ~\$237M at 25% share).
- Breakdown:
 - US: \$91M-\$142M
 - EU5: \$76M-\$118M
 - China: \$14M-\$21M
 - Japan: \$5M-\$7M

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

- **US, EU5, China, and Japan Combined: \$7.4M-\$11.6M annually** (midpoint ~\$9.5M).
- Breakdown:
 - US: \$3.6M-\$5.7M
 - EU5: \$3.0M-\$4.7M
 - China: \$0.6M-\$0.9M
 - Japan: \$0.2M-\$0.3M

Caveats

- These estimates are based on assumptions for patient population, pricing, treatment duration, and market share. Real-world data may differ due to competition (e.g., olaparib, another PARP inhibitor for BRCA-mutated mCRPC), reimbursement policies, and diagnostic testing rates.
- Peak sales typically occur 5-10 years after launch, assuming no major patent cliffs or generic competition.
- Adjustments may be needed based on actual trial outcomes, market access, and regional pricing negotiations.

For more accurate estimates, detailed epidemiology data, competitive landscape analysis, and primary market research would be required.