To estimate the **Potential Peak Sales** for capivasertib (Truqap) in the specified indication (HR-positive, HER2-negative locally advanced or metastatic breast cancer with PIK3CA/AKT1/PTEN alterations) 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 involves estimating the addressable patient population, treatment rates, pricing, market share, and peak sales potential.

Since specific data on patient numbers, pricing, and market penetration for capivasertib are not publicly available in this format, I will use reasonable assumptions based on general oncology market trends, breast cancer epidemiology, and the drug's target population. Please note that these are illustrative calculations and should be validated with real-world data or proprietary market research for accuracy.

Step 1: Define the Target Indication and Patient Population

- **Indication**: HR-positive, HER2-negative locally advanced or metastatic breast cancer with PIK3CA/AKT1/PTEN alterations.

- **Prevalence of Subtype**: HR-positive, HER2-negative breast cancer accounts for ~60-70% of all breast cancer cases. Of these, ~40-50% of patients have PIK3CA/AKT1/PTEN alterations (based on literature and clinical trial data for similar drugs like alpelisib).

- **Stage**: Focus is on locally advanced or metastatic breast cancer (Stage III/IV), which represents ~30-40% of breast cancer cases at diagnosis or progression.

- **Eligible Patients**: Patients who have progressed on at least one endocrine-based regimen or recurred within 12 months of adjuvant therapy.

Estimated Incidence and Prevalence of Breast Cancer (Annual New Cases + Prevalent Metastatic Cases)

Using approximate breast cancer incidence and prevalence data for 2023:

- **US**: ~300,000 new cases/year; ~500,000 prevalent metastatic cases.

- **EU5**: ~350,000 new cases/year; ~600,000 prevalent metastatic cases.

- **China**: ~400,000 new cases/year; ~700,000 prevalent metastatic cases.

- **Japan**: ~90,000 new cases/year; ~150,000 prevalent metastatic cases.

Proportion of Target Population (HR+/HER2-, Metastatic, with PIK3CA/AKT1/PTEN Alterations)

- HR+/HER2-: ~65% of breast cancer cases.

- Metastatic (Stage IV or progression to metastatic): ~30% of total breast cancer population.

- PIK3CA/AKT1/PTEN alterations: ~45% of HR+/HER2- metastatic patients.

- Progression on endocrine therapy: ~80% of metastatic HR+/HER2- patients.

Thus, the target population as a percentage of total breast cancer cases is roughly:

- 65% (HR+/HER2-) x 30% (metastatic) x 45% (alterations) x 80% (progressed on endocrine therapy) = ~5.3% of total breast cancer cases.

Addressable Patient Population (Annual Treated Patients)

Assuming a mix of incident and prevalent cases eligible for treatment each year:

- **US**: ~500,000 prevalent metastatic cases x 5.3% = ~26,500 patients.

- **EU5**: ~600,000 prevalent metastatic cases x 5.3% = ~31,800 patients.

- **China**: ~700,000 prevalent metastatic cases x 5.3% = ~37,100 patients.

- **Japan**: ~150,000 prevalent metastatic cases x 5.3% = ~7,950 patients.

Total addressable patients across geographies: ~103,350 patients.

Step 2: Estimate Treatment Rate and Market Share

- **Treatment Rate**: Not all eligible patients will receive capivasertib due to factors like access, physician preference, and competing therapies (e.g., alpelisib for PIK3CA mutations, CDK4/6 inhibitors, etc.). Assuming a treatment rate of ~50% of eligible patients.

- **Market Share**: The query assumes a 20-30% share of treated patients for capivasertib. We will use the midpoint of 25% for calculations.

Treated Patients with Capivasertib

- **US**: 26,500 x 50% treatment rate x 25% market share = ~3,313 patients.

- **EU5**: 31,800 x 50% x 25% = ~3,975 patients.

- **China**: 37,100 x 50% x 25% = ~4,638 patients.

- **Japan**: 7,950 x 50% x 25% = ~994 patients.

Total treated patients with capivasertib: ~12,920 patients.

Step 3: Estimate Annual Drug Pricing per Patient

Capivasertib is a targeted oral therapy for metastatic breast cancer, likely priced in line with similar drugs like alpelisib (Piqray) or everolimus (Afinitor). Pricing varies by geography due to healthcare systems and purchasing power:

- **US**: ~$180,000 per patient per year (based on pricing for similar targeted therapies).

- **EU5**: ~$90,000 per patient per year (lower due to negotiated pricing and reimbursement).

- **Japan**: ~$100,000 per patient per year (similar to EU5 but with specific pricing controls).

- **China**: ~$30,000 per patient per year (significantly lower due to market access programs and generics competition).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as: (Number of treated patients) x (Annual cost per patient).

- **US**: 3,313 patients x $180,000 = ~$596 million.
- **EU5**: 3,975 patients x $90,000 = ~$358 million.
- **China**: 4,638 patients x $30,000 = ~$139 million.
- **Japan**: 994 patients x $100,000 = ~$99 million.

Total Potential Peak Sales: $596M (US) + $358M (EU5) + $139M (China) + $99M (Japan) = **~$1,192 million (or ~$1.2 billion)**.

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

First, calculate the total number of treated patients (50% of addressable patients) and the revenue per 1% share.

Total Treated Patients (50% of Addressable Population)

- **US**: 26,500 x 50% = 13,250 patients.
- **EU5**: 31,800 x 50% = 15,900 patients.
- **China**: 37,100 x 50% = 18,550 patients.
- **Japan**: 7,950 x 50% = 3,975 patients.

Total treated patients across geographies: ~51,675 patients.

1% of Treated Patients

- **US**: 13,250 x 1% = 133 patients.
- **EU5**: 15,900 x 1% = 159 patients.
- **China**: 18,550 x 1% = 186 patients.
- **Japan**: 3,975 x 1% = 40 patients.

Revenue for 1% Share

- **US**: 133 patients x $180,000 = ~$23.9 million.
- **EU5**: 159 patients x $90,000 = ~$14.3 million.
- **China**: 186 patients x $30,000 = ~$5.6 million.
- **Japan**: 40 patients x $100,000 = ~$4.0 million.

Total $ Value of 1% Share: $23.9M (US) + $14.3M (EU5) + $5.6M (China) + $4.0M (Japan) = **~$47.8 million**.

Final Answer

1. **Potential Peak Sales for Capivasertib** (assuming 20-30% market share, midpoint 25%):

- **Total**: ~$1.2 billion across US, EU5, China, and Japan.

- **Breakdown**:

- US: ~$596 million

- EU5: ~$358 million

- China: ~$139 million

- Japan: ~$99 million

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

- **Total**: ~$47.8 million across US, EU5, China, and Japan.

- **Breakdown**:

- US: ~$23.9 million

- EU5: ~$14.3 million

- China: ~$5.6 million

- Japan: ~$4.0 million

Note: These estimates are based on assumptions about patient population, treatment rates, market share, and pricing. Actual figures may vary depending on real-world data, competition, reimbursement policies, and market access. For precise calculations, consult primary market research or financial reports from AstraZeneca.