To estimate the **Potential Peak Sales** for tivozanib (Fotivda) in the indication of relapsed or refractory advanced renal cell carcinoma (RCC) 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 penetration) is not provided, I will make reasonable assumptions based on publicly available information, epidemiology data, and market dynamics for RCC and oncology drugs. Here's the step-by-step analysis:

Step 1: Define the Indication and Patient Population

Tivozanib is approved for adult patients with **relapsed or refractory advanced RCC** following two or more prior systemic therapies (third-line or later treatment). RCC is the most common type of kidney cancer, and advanced RCC refers to metastatic or stage IV disease. The target population is a subset of advanced RCC patients who have failed at least two prior therapies.

Epidemiology Assumptions:

- **Prevalence of RCC**: RCC accounts for ~2-3% of all cancers globally, with higher incidence in developed countries.

- **Advanced RCC**: Approximately 30-40% of RCC patients present with or progress to advanced/metastatic disease.

- **Relapsed/Refractory after 2+ Therapies**: Only a smaller subset (estimated 20-30% of advanced RCC patients) will reach third-line or later treatment due to disease progression or death before reaching this stage.

- **Annual Incidence** (new cases) and **Prevalence** (existing cases eligible for treatment) will be considered for peak sales estimation.

Estimated Annual Incident Cases of Advanced RCC (Relapsed/Refractory, 3L+):

Using approximate incidence rates and adjusting for advanced stage and 3L+ eligibility:

- **US**: ~74,000 new RCC cases/year; ~30% advanced = ~22,000; ~25% reach 3L+ = **5,500 patients/year**.

- **EU5**: ~60,000 new RCC cases/year; ~30% advanced = ~18,000; ~25% reach 3L+ = **4,500 patients/year**.

- **China**: ~66,000 new RCC cases/year; ~30% advanced = ~20,000; ~20% reach 3L+ (lower access to prior therapies) = **4,000 patients/year**.

- **Japan**: ~30,000 new RCC cases/year; ~30% advanced = ~9,000; ~25% reach 3L+ = **2,250 patients/year**.

- **Total 3L+ Eligible Patients**: ~5,500 (US) + 4,500 (EU5) + 4,000 (China) + 2,250 (Japan) = **16,250 patients/year**.

These numbers are rough estimates and may vary based on actual epidemiology data and healthcare access.

Step 2: Treatment Rate and Market Share Assumptions

- **Treatment Rate**: Not all eligible patients receive treatment due to factors like poor performance status, comorbidities, or lack of access. Assume **70-80% of eligible patients** are treated in the US, EU5, and Japan, and **50% in China**.

- US: 5,500 x 80% = **4,400 treated patients**.

- EU5: 4,500 x 80% = **3,600 treated patients**.

- China: 4,000 x 50% = **2,000 treated patients**.

- Japan: 2,250 x 80% = **1,800 treated patients**.

- **Total Treated Patients**: 4,400 + 3,600 + 2,000 + 1,800 = **11,800 patients/year**.

- **Market Share for Tivozanib**: The query assumes a **20-30% share of treated patients**. We'll use the midpoint of **25%** for peak sales estimation.

- US: 4,400 x 25% = **1,100 patients**.

- EU5: 3,600 x 25% = **900 patients**.

- China: 2,000 x 25% = **500 patients**.

- Japan: 1,800 x 25% = **450 patients**.

- **Total Tivozanib-Treated Patients**: 1,100 + 900 + 500 + 450 = **2,950 patients/year**.

Step 3: Pricing Assumptions

Oncology drugs for advanced RCC are expensive, especially in later lines of therapy. Pricing varies by region due to differences in healthcare systems and purchasing power.

- **US**: Annual cost of tivozanib (Fotivda) is approximately **$240,000 per patient** (based on reported list prices for similar kinase inhibitors like cabozantinib or lenvatinib, adjusted for tivozanib's pricing).

- **EU5**: Pricing is typically 40-50% lower than the US due to negotiations and health technology assessments. Assume **$120,000 per patient/year**.

- **Japan**: Pricing is similar to EU5, assume **$120,000 per patient/year**.

- **China**: Pricing is significantly lower due to market access challenges and local pricing policies. Assume **$40,000 per patient/year**.

Note: These are annual costs assuming continuous treatment. Actual treatment duration may be shorter (e.g., 6-12 months based on progression-free survival), but for peak sales, we assume full-year treatment.

Step 4: Calculate Potential Peak Sales for Tivozanib (25% Market Share)

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

- **US**: 1,100 patients x $240,000 = **$264 million**.

- **EU5**: 900 patients x $120,000 = **$108 million**.

- **China**: 500 patients x $40,000 = **$20 million**.

- **Japan**: 450 patients x $120,000 = **$54 million**.

- **Total Peak Sales**: $264M + $108M + $20M + $54M = **$446 million/year**.

Range for Peak Sales (20-30% Market Share):

- At **20% share**: Total treated patients = 2,360; Peak sales = **~$357 million**.

- At **30% share**: Total treated patients = 3,540; Peak sales = **~$535 million**.

- **Peak Sales Range**: **$357M to $535M per year**, with a midpoint of **$446M**.

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

A 1% share of treated patients corresponds to 1% of the total treated patient pool (11,800 patients) = **118 patients**.

- **US**: 4,400 x 1% = 44 patients; 44 x $240,000 = **$10.56 million**.

- **EU5**: 3,600 x 1% = 36 patients; 36 x $120,000 = **$4.32 million**.

- **China**: 2,000 x 1% = 20 patients; 20 x $40,000 = **$0.8 million**.

- **Japan**: 1,800 x 1% = 18 patients; 18 x $120,000 = **$2.16 million**.

- **Total $ Value of 1% Share**: $10.56M + $4.32M + $0.8M + $2.16M = **$17.84 million**.

Final Answer

1. **Potential Peak Sales for Tivozanib** (assuming 20-30% share of treated patients):

- Range: **$357 million to $535 million per year**.

- Midpoint (25% share): **$446 million per year**.

- Breakdown by region (at 25% share):

- US: $264M

- EU5: $108M

- China: $20M

- Japan: $54M

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

- Total: **$17.84 million per year**.

- Breakdown by region:

- US: $10.56M

- EU5: $4.32M

- China: $0.8M

- Japan: $2.16M

Caveats and Notes

- These estimates are based on assumptions for epidemiology, treatment rates, market share, and pricing. Real-world data may differ due to competition (e.g., other RCC drugs like cabozantinib, nivolumab), market access barriers, or payer restrictions.

- Peak sales typically occur 5-10 years after launch, depending on market penetration and patent exclusivity.

- Pricing in China is highly variable and may be lower if tivozanib is included in national reimbursement drug lists (NRDL) with price cuts.

- Treatment duration and patient compliance may reduce the effective annual cost per patient.

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