To estimate the **Potential Peak Sales** for sirolimus protein-bound particles for injectable suspension (albumin-bound) (Fyarro) in the indication of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) 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 on patient numbers, pricing, and market penetration may not be publicly available in full detail, I will outline the methodology and make reasonable assumptions based on available information about the drug, indication, and market dynamics.

Step 1: Background on PEComa and Fyarro

- **PEComa** (Perivascular Epithelioid Cell Tumor) is a rare type of sarcoma, with an estimated incidence of less than 1 per million people annually. It often affects adults and can be aggressive in its locally advanced or metastatic forms.

- **Fyarro** (sirolimus protein-bound particles for injectable suspension, albumin-bound) was approved by the FDA in November 2021 for adult patients with locally advanced unresectable or metastatic malignant PEComa. It is the first and only approved therapy specifically for this indication, giving it an orphan drug status and potential for high pricing due to the rarity of the disease.

- The drug is administered intravenously, typically in a clinical setting, and is likely to have a high cost per treatment cycle (similar to other orphan drugs for rare cancers, often in the range of $10,000–$20,000 per month or more).

Step 2: Key Assumptions

Since exact data on patient numbers, treatment costs, and market penetration are not publicly specified, we will make the following assumptions:

1. **Prevalence of PEComa**: Given its rarity, we estimate an incidence of ~0.5–1 case per million population annually, with a prevalence of treatable patients (locally advanced unresectable or metastatic) being slightly higher due to the chronic nature of the disease in some patients. For simplicity, we assume a prevalence of ~2–3 cases per million population for the target patient population.

2. **Market Share**: The problem specifies a 20% to 30% share of treated patients. Since Fyarro is the only approved therapy for this indication, we will assume a **25% average market share** for peak sales calculations.

3. **Treatment Cost**: Orphan drugs for rare cancers often have annual treatment costs ranging from $100,000 to $300,000 per patient. We assume an **annual cost of $200,000 per patient** for Fyarro, reflecting high pricing due to rarity and lack of competition.

4. **Population Data**: Using approximate 2023 population figures for the geographies:

- US: 330 million

- EU5 (Germany, France, Italy, Spain, UK): 320 million combined

- China: 1,400 million

- Japan: 125 million

- Total Population: ~2,175 million

5. **Diagnosis and Treatment Rates**: Not all prevalent cases will be diagnosed or treated due to underdiagnosis in rare diseases, especially in less developed healthcare systems. We assume a **diagnosis and treatment rate of 70% in the US and EU5, 60% in Japan, and 40% in China**.

Step 3: Estimate Target Patient Population

Using the prevalence assumption of **2.5 cases per million population** (midpoint of 2–3):

- **US**: 330 million × 2.5 / 1,000,000 = ~825 patients
- **EU5**: 320 million × 2.5 / 1,000,000 = ~800 patients
- **China**: 1,400 million × 2.5 / 1,000,000 = ~3,500 patients
- **Japan**: 125 million × 2.5 / 1,000,000 = ~313 patients
- **Total**: ~5,438 patients

Adjusting for diagnosis and treatment rates:

- **US**: 825 × 70% = ~578 treated patients
- **EU5**: 800 × 70% = ~560 treated patients
- **China**: 3,500 × 40% = ~1,400 treated patients
- **Japan**: 313 × 60% = ~188 treated patients
- **Total Treated Patients**: ~2,726 patients

Step 4: Estimate Patients Treated with Fyarro (25% Market Share)

- **US**: 578 × 25% = ~145 patients
- **EU5**: 560 × 25% = ~140 patients
- **China**: 1,400 × 25% = ~350 patients
- **Japan**: 188 × 25% = ~47 patients
- **Total Treated with Fyarro**: ~682 patients

Step 5: Calculate Potential Peak Sales

Assuming an annual treatment cost of **$200,000 per patient** (note: this may vary by region due to pricing differences, but for simplicity, we use a uniform figure):

- **US**: 145 patients × $200,000 = **$29 million**
- **EU5**: 140 patients × $200,000 = **$28 million**
- **China**: 350 patients × $200,000 = **$70 million**
- **Japan**: 47 patients × $200,000 = **$9.4 million**
- **Total Peak Sales**: **$136.4 million annually**

Step 6: Calculate $ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treated patient population (~2,726 patients), which is **27.26 patients**.

- **Value per patient**: $200,000

- **Value of 1% share**: 27.26 patients × $200,000 = **$5.45 million annually**

Breaking it down by geography (1% of treated patients in each region):

- **US**: 578 × 1% = 5.78 patients × $200,000 = **$1.16 million**

- **EU5**: 560 × 1% = 5.6 patients × $200,000 = **$1.12 million**

- **China**: 1,400 × 1% = 14 patients × $200,000 = **$2.8 million**

- **Japan**: 188 × 1% = 1.88 patients × $200,000 = **$0.38 million**

- **Total for 1% Share**: **$5.46 million** (matches the earlier calculation, with slight rounding differences)

Final Answer

1. **Potential Peak Sales for Fyarro (at 25% market share)**:

- US: **$29 million**

- EU5: **$28 million**

- China: **$70 million**

- Japan: **$9.4 million**

- Total: **$136.4 million annually**

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

- US: **$1.16 million**

- EU5: **$1.12 million**

- China: **$2.8 million**

- Japan: **$0.38 million**

- Total: **$5.46 million annually**

Notes and Caveats

- These estimates are based on assumptions about prevalence, diagnosis rates, treatment costs, and market share. Real-world data may vary significantly due to differences in healthcare access, pricing negotiations, and reimbursement policies across regions.

- Pricing in China may be lower due to government negotiations and affordability constraints, which could reduce peak sales in that market.

- Peak sales may take several years to achieve post-launch, depending on market adoption and regulatory approvals in regions beyond the US (e.g., EU5, China, Japan). As of now, Fyarro is FDA-approved, but approval status in other regions should be confirmed.

- The rarity of PEComa makes patient population estimates uncertain; actual numbers could be lower or higher based on better epidemiological data.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market research), these calculations can be refined accordingly.