To estimate the **Potential Peak Sales** for vimseltinib (Romvimza) in the indication of tenosynovial giant cell tumor (TGCT) 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 on patient populations, pricing, and penetration rates for vimseltinib are not publicly available in full detail, I will make reasonable assumptions based on available information about TGCT prevalence, treatment landscape, and typical pricing for rare disease drugs. I will also assume a 20% to 30% market share of treated patients as provided in the query.

Step 1: Background on TGCT and Market Context

- **Tenosynovial Giant Cell Tumor (TGCT)** is a rare, non-malignant tumor affecting the synovium, bursae, and tendon sheaths, often leading to pain, swelling, and joint dysfunction. It primarily affects adults, and surgical resection is the standard treatment. However, in cases where surgery is not feasible or would cause significant morbidity, systemic therapies like kinase inhibitors (e.g., vimseltinib) are used.

- **Vimseltinib (Romvimza)** is a kinase inhibitor targeting CSF1R, recently approved by the FDA for symptomatic TGCT in adults where surgery poses risks.

- **Prevalence of TGCT**: Estimated incidence is approximately 1.8 per million people annually, with prevalence higher due to its chronic nature. For estimation, we can assume a prevalence of around 10-15 per million in developed markets (US, EU5, Japan) and slightly lower in China due to underdiagnosis.

Step 2: Estimate Patient Population

Using prevalence data and population estimates for 2023:

- **US**: Population ~334 million; Prevalence ~3,340-5,010 patients (10-15 per million).

- **EU5**: Population ~262 million; Prevalence ~2,620-3,930 patients.

- **China**: Population ~1,412 million; Prevalence ~7,060-10,590 patients (assuming lower prevalence of 5-7.5 per million due to underdiagnosis).

- **Japan**: Population ~125 million; Prevalence ~1,250-1,875 patients.

Total Eligible Patients (Midpoint Estimate):

- US: ~4,175 patients

- EU5: ~3,275 patients

- China: ~8,825 patients

- Japan: ~1,563 patients

- **Total**: ~17,838 patients

However, not all patients are symptomatic or ineligible for surgery. Based on clinical data, approximately 30-50% of TGCT patients may be candidates for systemic therapy due to inoperability or risk of morbidity.

- **Treatable Population (40% of total)**:

- US: ~1,670 patients

- EU5: ~1,310 patients

- China: ~3,530 patients

- Japan: ~625 patients

- **Total Treatable**: ~7,135 patients

Step 3: Market Share and Treated Patients

Assuming vimseltinib captures **20% to 30% of treated patients**:

- **20% Share**:

- US: 334 patients

- EU5: 262 patients

- China: 706 patients

- Japan: 125 patients

- Total: 1,427 patients

- **30% Share**:

- US: 501 patients

- EU5: 393 patients

- China: 1,059 patients

- Japan: 188 patients

- Total: 2,141 patients

Step 4: Pricing Assumptions

Vimseltinib is a targeted therapy for a rare disease, so pricing will likely be high, similar to other kinase inhibitors or orphan drugs.

- **US**: Annual cost per patient ~$200,000 (typical for rare disease drugs).

- **EU5**: Annual cost per patient ~$150,000 (lower due to pricing negotiations).

- **Japan**: Annual cost per patient ~$150,000 (similar to EU5).

- **China**: Annual cost per patient ~$50,000 (lower due to market dynamics and affordability constraints).

Step 5: Potential Peak Sales Calculation

Peak Sales at 20% Market Share:

- US: 334 patients x $200,000 = **$66.8 million**

- EU5: 262 patients x $150,000 = **$39.3 million**

- China: 706 patients x $50,000 = **$35.3 million**

- Japan: 125 patients x $150,000 = **$18.8 million**

- **Total Peak Sales (20%)**: **$160.2 million**

Peak Sales at 30% Market Share:

- US: 501 patients x $200,000 = **$100.2 million**

- EU5: 393 patients x $150,000 = **$59.0 million**

- China: 1,059 patients x $50,000 = **$53.0 million**

- Japan: 188 patients x $150,000 = **$28.2 million**

- **Total Peak Sales (30%)**: **$240.4 million**

Range of Potential Peak Sales: **$160.2 million to $240.4 million annually** across US, EU5, China, and Japan.

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

A 1% share of treated patients corresponds to 1% of the treatable population (7,135 patients) = **71.35 patients**.

- US: 1,670 x 1% = 16.7 patients x $200,000 = **$3.34 million**

- EU5: 1,310 x 1% = 13.1 patients x $150,000 = **$1.97 million**

- China: 3,530 x 1% = 35.3 patients x $50,000 = **$1.77 million**

- Japan: 625 x 1% = 6.25 patients x $150,000 = **$0.94 million**

- **Total $ Value of 1% Share**: **$8.02 million**

Final Answer

- **Potential Peak Sales for Vimseltinib in TGCT** (20%-30% market share):

- US: $66.8M - $100.2M

- EU5: $39.3M - $59.0M

- China: $35.3M - $53.0M

- Japan: $18.8M - $28.2M

- **Total**: **$160.2M - $240.4M annually**

- **$ Value of 1% Share of Treated Patients**:

- US: $3.34M

- EU5: $1.97M

- China: $1.77M

- Japan: $0.94M

- **Total**: **$8.02M annually**

Caveats

- These estimates are based on assumptions about prevalence, treatable population, market share, and pricing, which may vary based on real-world data, reimbursement policies, competition (e.g., other therapies like pexidartinib), and market access challenges, especially in China.

- Peak sales may take several years to achieve post-launch as awareness and adoption grow.

- Adjustments may be needed if more precise data on patient numbers or pricing becomes available.