To estimate the **Potential Peak Sales** for pirtobrutinib (Jaypirca) in the indication of relapsed or refractory mantle cell lymphoma (MCL) 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 may not be fully available, I will make reasonable assumptions based on publicly available information, market trends for oncology drugs, and the rarity of MCL. I will also assume a 20% to 30% market share of treated patients as provided in the query.

Step 1: Key Assumptions and Background

1. **Indication**: Pirtobrutinib is approved for relapsed or refractory MCL after at least two lines of systemic therapy, including a BTK inhibitor. MCL is a rare form of non-Hodgkin lymphoma (NHL), accounting for ~6% of NHL cases.

2. **Patient Population**:

- MCL incidence is approximately 0.5-1 per 100,000 people annually in Western countries.

- Relapsed/refractory patients after two lines of therapy represent a smaller subset of the total MCL population.

- Based on literature, ~30-50% of MCL patients may reach relapsed/refractory status after multiple lines of therapy.

3. **Geographies**: US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan.

4. **Market Share**: Assuming 20% to 30% of treated patients in this indication.

5. **Drug Pricing**: Pricing for targeted oncology drugs like BTK inhibitors can range from $150,000 to $200,000 per patient per year in the US, with lower prices in other regions due to healthcare system differences (e.g., ~50-70% of US price in EU5, lower in China and Japan due to pricing controls).

6. **Treatment Duration**: Assuming an average treatment duration of 1 year for simplicity (actual duration may vary based on progression-free survival data).

Step 2: Estimate Treated Patient Population

Using approximate incidence rates and population sizes, we can estimate the number of MCL patients and the subset eligible for pirtobrutinib (relapsed/refractory after 2+ lines of therapy).

- **US**:

- Population: ~330 million

- MCL incidence: ~0.8 per 100,000 $\rightarrow$ ~2,640 new cases/year

- Relapsed/refractory after 2+ lines: ~40% $\rightarrow$ ~1,056 patients/year

- **EU5**:

- Population: ~340 million (combined)

- MCL incidence: ~0.8 per 100,000 $\rightarrow$ ~2,720 new cases/year

- Relapsed/refractory after 2+ lines: ~40% $\rightarrow$ ~1,088 patients/year

- **China**:

- Population: ~1,400 million

- MCL incidence: ~0.5 per 100,000 (lower due to differences in epidemiology) → ~7,000 new cases/year

- Relapsed/refractory after 2+ lines: ~40% → ~2,800 patients/year

- **Japan**:

- Population: ~125 million

- MCL incidence: ~0.6 per 100,000 → ~750 new cases/year

- Relapsed/refractory after 2+ lines: ~40% → ~300 patients/year

Total Eligible Patients Across Geographies: ~1,056 (US) + 1,088 (EU5) + 2,800 (China) + 300 (Japan) = **5,244 patients/year**

Step 3: Estimate Annual Cost per Patient

- **US**: ~$180,000 per patient/year (based on pricing of similar BTK inhibitors like ibrutinib or acalabrutinib)

- **EU5**: ~$100,000 per patient/year (lower due to negotiated pricing and reimbursement)

- **China**: ~$50,000 per patient/year (significant pricing pressure and generics competition)

- **Japan**: ~$80,000 per patient/year (moderate pricing controls)

Step 4: Estimate Potential Peak Sales (20%-30% Market Share)

Peak sales are calculated by multiplying the number of eligible patients by the market share (20%-30%) and the annual cost per patient.

At 20% Market Share:

- **US**: 1,056 patients × 20% × $180,000 = **$38.0 million**

- **EU5**: 1,088 patients × 20% × $100,000 = **$21.8 million**

- **China**: 2,800 patients × 20% × $50,000 = **$28.0 million**

- **Japan**: 300 patients × 20% × $80,000 = **$4.8 million**

- **Total Peak Sales (20%)**: $38.0M + $21.8M + $28.0M + $4.8M = **$92.6 million**

At 30% Market Share:

- **US**: 1,056 patients × 30% × $180,000 = **$57.0 million**

- **EU5**: 1,088 patients × 30% × $100,000 = **$32.6 million**

- **China**: 2,800 patients × 30% × $50,000 = **$42.0 million**

- **Japan**: 300 patients × 30% × $80,000 = **$7.2 million**

- **Total Peak Sales (30%)**: $57.0M + $32.6M + $42.0M + $7.2M = **$138.8 million**

Potential Peak Sales Range: **$92.6 million to $138.8 million annually** across the specified geographies for this indication.

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

The value of a 1% share is calculated by dividing the total peak sales at 100% market share by 100.

- **US**: 1,056 patients × $180,000 = $190.1 million → **1% = $1.90 million**

- **EU5**: 1,088 patients × $100,000 = $108.8 million → **1% = $1.09 million**

- **China**: 2,800 patients × $50,000 = $140.0 million → **1% = $1.40 million**

- **Japan**: 300 patients × $80,000 = $24.0 million → **1% = $0.24 million**

- **Total Across Geographies**: $190.1M + $108.8M + $140.0M + $24.0M = $462.9 million → **1% = $4.63 million**

Final Answer:

1. **Potential Peak Sales for Pirtobrutinib** in relapsed/refractory MCL (20%-30% market share):

- **US, EU5, China, Japan Combined**: **$92.6 million to $138.8 million annually**

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

- **US**: $1.90 million

- **EU5**: $1.09 million

- **China**: $1.40 million

- **Japan**: $0.24 million

- **Total Across Geographies**: **$4.63 million**

Notes:

- These estimates are based on assumptions about patient numbers, pricing, and market penetration. Actual figures could vary based on real-world data, competition (e.g., other BTK inhibitors), reimbursement policies, and clinical trial outcomes.

- Peak sales could be higher if pirtobrutinib gains approval in additional indications (e.g., other B-cell malignancies) or if pricing or treatment duration exceeds assumptions.

- China’s larger patient pool is offset by lower pricing, while the US contributes significantly due to higher pricing despite a smaller population.