To estimate the **Potential Peak Sales** for quizartinib (Vanflyta) in the indication of newly diagnosed acute myeloid leukemia (AML) with FLT3-ITD mutation 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 numbers, pricing, and market penetration may not be publicly available in full detail, I will base this analysis on reasonable assumptions, industry benchmarks, and available epidemiology data for AML with FLT3-ITD mutation. Let's break this down step by step.

Step 1: Define the Target Patient Population

- **Indication**: Newly diagnosed AML with FLT3-ITD mutation.

- **Epidemiology**: FLT3-ITD mutations occur in approximately 25-30% of AML cases. AML incidence varies by region.

- **Annual Incidence of AML** (approximate figures based on publicly available data and estimates):

- **US**: ~20,000 new cases per year.

- **EU5**: ~18,000 new cases per year (combined).

- **China**: ~25,000 new cases per year (based on population size and incidence rates).

- **Japan**: ~6,000 new cases per year.

- **FLT3-ITD Positive Cases (assuming 25% of AML cases)**:

- US: 5,000 patients/year.

- EU5: 4,500 patients/year.

- China: 6,250 patients/year.

- Japan: 1,500 patients/year.

- **Total Target Population (annual new cases)**: 5,000 (US) + 4,500 (EU5) + 6,250 (China) + 1,500 (Japan) = **17,250 patients/year**.

Step 2: Estimate the Share of Treated Patients

- The problem states a **20% to 30% share of treated patients**. This likely refers to quizartinib's market penetration among eligible FLT3-ITD positive AML patients.

- For peak sales estimation, we will assume:

- **Low-end penetration (20%)**: 20% of 17,250 = **3,450 patients treated annually**.

- **High-end penetration (30%)**: 30% of 17,250 = **5,175 patients treated annually**.

Step 3: Estimate Annual Treatment Cost per Patient

- Quizartinib is a targeted therapy for a rare mutation in a serious condition (AML), so pricing is expected to be high, similar to other oncology drugs.

- Based on pricing benchmarks for AML therapies (e.g., midostaurin, another FLT3 inhibitor), the annual cost per patient is estimated as follows (hypothetical, as exact pricing may vary):

- **US**: ~$150,000 per patient per year (higher due to pricing dynamics).

- **EU5**: ~$100,000 per patient per year (lower due to price negotiations and healthcare systems).

- **China**: ~$50,000 per patient per year (lower due to pricing controls and generics competition).

- **Japan**: ~$120,000 per patient per year (similar to US but slightly lower).

- For simplicity, we can calculate a **weighted average cost per patient** based on patient distribution across regions (or use region-specific costs for precision). For now, let's compute region-specific sales.

Step 4: Calculate Potential Peak Sales

Peak sales are typically calculated based on the maximum market penetration and annual revenue at steady state. We will calculate for both **20% and 30% penetration**.

Low-End Penetration (20%)

- **US**: 5,000 patients × 20% = 1,000 patients × $150,000 = **$150 million**.

- **EU5**: 4,500 patients × 20% = 900 patients × $100,000 = **$90 million**.

- **China**: 6,250 patients × 20% = 1,250 patients × $50,000 = **$62.5 million**.

- **Japan**: 1,500 patients × 20% = 300 patients × $120,000 = **$36 million**.

- **Total Peak Sales (20%)**: $150M + $90M + $62.5M + $36M = **$338.5 million**.

High-End Penetration (30%)

- **US**: 5,000 patients × 30% = 1,500 patients × $150,000 = **$225 million**.

- **EU5**: 4,500 patients × 30% = 1,350 patients × $100,000 = **$135 million**.

- **China**: 6,250 patients × 30% = 1,875 patients × $50,000 = **$93.75 million**.

- **Japan**: 1,500 patients × 30% = 450 patients × $120,000 = **$54 million**.

- **Total Peak Sales (30%)**: $225M + $135M + $93.75M + $54M = **$507.75 million**.

Range of Potential Peak Sales: $338.5 million to $507.75 million annually.

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

A 1% share of treated patients refers to 1% of the total target population (17,250 patients/year) = **172.5 patients treated annually**.

- **US**: 5,000 × 1% = 50 patients × $150,000 = **$7.5 million**.

- **EU5**: 4,500 × 1% = 45 patients × $100,000 = **$4.5 million**.

- **China**: 6,250 × 1% = 62.5 patients × $50,000 = **$3.125 million**.

- **Japan**: 1,500 × 1% = 15 patients × $120,000 = **$1.8 million**.

- **Total $ Value of 1% Share**: $7.5M + $4.5M + $3.125M + $1.8M = **$16.925 million**.

Final Answer

1. **Potential Peak Sales for Quizartinib** in the US, EU5, China, and Japan for newly diagnosed AML with FLT3-ITD mutation (assuming 20% to 30% market share of treated patients):

- **Range**: **$338.5 million to $507.75 million annually**.

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

- **Total**: **$16.925 million annually**.

Notes and Caveats

- These estimates are based on assumptions about patient numbers, market penetration, and pricing. Actual figures may vary depending on real-world data, competition (e.g., midostaurin, gilteritinib), reimbursement policies, and treatment duration.

- Peak sales may also be influenced by factors such as off-label use, combination therapies, or expanded indications.

- Pricing in China and EU5 may be lower than estimated due to government negotiations or access programs.

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