

To estimate the **Potential Peak Sales** for quizartinib (Vandflyta) 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.

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## **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**.

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## **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**.

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## **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.

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## **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  $\times$  20% = 1,000 patients  $\times$  \$150,000 = **\$150 million**.
- **EU5:** 4,500 patients  $\times$  20% = 900 patients  $\times$  \$100,000 = **\$90 million**.
- **China:** 6,250 patients  $\times$  20% = 1,250 patients  $\times$  \$50,000 = **\$62.5 million**.
- **Japan:** 1,500 patients  $\times$  20% = 300 patients  $\times$  \$120,000 = **\$36 million**.
- **Total Peak Sales (20%):** \$150M + \$90M + \$62.5M + \$36M = **\$338.5 million**.

### **#### High-End Penetration (30%)**

- **US:** 5,000 patients  $\times$  30% = 1,500 patients  $\times$  \$150,000 = **\$225 million**.
- **EU5:** 4,500 patients  $\times$  30% = 1,350 patients  $\times$  \$100,000 = **\$135 million**.
- **China:** 6,250 patients  $\times$  30% = 1,875 patients  $\times$  \$50,000 = **\$93.75 million**.
- **Japan:** 1,500 patients  $\times$  30% = 450 patients  $\times$  \$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.

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## **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:**  $5,000 \times 1\% = 50 \text{ patients} \times \$150,000 = \text{\$7.5 million}.$
- **EU5:**  $4,500 \times 1\% = 45 \text{ patients} \times \$100,000 = \text{\$4.5 million}.$
- **China:**  $6,250 \times 1\% = 62.5 \text{ patients} \times \$50,000 = \text{\$3.125 million}.$
- **Japan:**  $1,500 \times 1\% = 15 \text{ patients} \times \$120,000 = \text{\$1.8 million}.$
- **Total \$ Value of 1% Share:**  $\$7.5\text{M} + \$4.5\text{M} + \$3.125\text{M} + \$1.8\text{M} = \text{\$16.925 million}.$

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## **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.**

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## **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.