

To estimate the **Potential Peak Sales** for olutasidenib (Rezlidhia) in the indication of relapsed or refractory acute myeloid leukemia (AML) with IDH1 mutation 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 such as exact patient numbers, pricing, or market penetration may not be publicly available, I will outline the methodology and provide illustrative calculations based on reasonable assumptions. These assumptions will be grounded in general market data for AML, IDH1 mutation prevalence, and typical pricing for oncology drugs.

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## **Step 1: Define the Target Population**

Olutasidenib is indicated for adult patients with **relapsed or refractory AML with IDH1 mutation**. Let's break this down:

### **1. Total AML Incidence and Prevalence:**

- AML is a rare cancer with varying incidence rates across geographies.
- Approximate annual incidence of AML (new cases per year) in the specified regions (based on historical data and cancer statistics):
  - **US:** ~20,000 new cases/year
  - **EU5:** ~18,000 new cases/year (combined for Germany, France, Italy, Spain, UK)
  - **China:** ~30,000 new cases/year
  - **Japan:** ~5,000 new cases/year
- Of these, approximately 30-40% of AML patients are relapsed or refractory (R/R AML). For simplicity, assume 35% are R/R AML.

### **2. IDH1 Mutation Prevalence:**

- IDH1 mutations are present in ~6-10% of AML patients. For this analysis, assume 8%.

### **3. Relapsed/Refractory AML with IDH1 Mutation:**

- US:  $20,000 * 0.35 \text{ (R/R)} * 0.08 \text{ (IDH1)} = \sim 560 \text{ patients/year}$
- EU5:  $18,000 * 0.35 * 0.08 = \sim 504 \text{ patients/year}$
- China:  $30,000 * 0.35 * 0.08 = \sim 840 \text{ patients/year}$
- Japan:  $5,000 * 0.35 * 0.08 = \sim 140 \text{ patients/year}$
- **Total Target Population:**  $560 + 504 + 840 + 140 = \sim 2,044 \text{ patients/year}$

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## **Step 2: Market Share of Treated Patients**

The problem states a **20% to 30% share of treated patients**. Assuming olutasidenib captures this share of the target population:

- At 20% share:  $2,044 * 0.20 = \sim 409$  patients treated/year
- At 30% share:  $2,044 * 0.30 = \sim 613$  patients treated/year

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### **Step 3: Pricing Assumptions**

Olutasidenib is a targeted oncology drug, and pricing for such therapies in AML typically ranges from \$100,000 to \$300,000 per patient per year in the US, with lower prices in other regions due to healthcare system differences. For simplicity, assume:

- **US:** \$200,000 per patient/year
- **EU5:** \$150,000 per patient/year (lower due to pricing negotiations)
- **China:** \$50,000 per patient/year (significantly lower due to market access and affordability)
- **Japan:** \$150,000 per patient/year (similar to EU5)

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### **Step 4: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients in each region by the annual cost per patient. Let's calculate for both 20% and 30% market shares.

##### At 20% Market Share (409 treated patients):

- **US:**  $(560 * 0.20) = 112$  patients \* \$200,000 = \$22.4 million
- **EU5:**  $(504 * 0.20) = 101$  patients \* \$150,000 = \$15.2 million
- **China:**  $(840 * 0.20) = 168$  patients \* \$50,000 = \$8.4 million
- **Japan:**  $(140 * 0.20) = 28$  patients \* \$150,000 = \$4.2 million
- **Total Peak Sales at 20% Share:** \$22.4M + \$15.2M + \$8.4M + \$4.2M = **\$50.2 million**

##### At 30% Market Share (613 treated patients):

- **US:**  $(560 * 0.30) = 168$  patients \* \$200,000 = \$33.6 million
- **EU5:**  $(504 * 0.30) = 151$  patients \* \$150,000 = \$22.7 million
- **China:**  $(840 * 0.30) = 252$  patients \* \$50,000 = \$12.6 million
- **Japan:**  $(140 * 0.30) = 42$  patients \* \$150,000 = \$6.3 million
- **Total Peak Sales at 30% Share:** \$33.6M + \$22.7M + \$12.6M + \$6.3M = **\$75.2 million**

Thus, the **Potential Peak Sales** for olutasidenib in this indication across the US, EU5, China, and Japan range from **\$50.2 million (20% share)** to **\$75.2 million (30% share)** per year.

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

A 1% share of the treated population corresponds to 1% of the total target population (2,044 patients), which is ~20.44 patients.

- **US:**  $(560 * 0.01) = 5.6 \text{ patients} * \$200,000 = \$1.12 \text{ million}$
- **EU5:**  $(504 * 0.01) = 5.04 \text{ patients} * \$150,000 = \$0.76 \text{ million}$
- **China:**  $(840 * 0.01) = 8.4 \text{ patients} * \$50,000 = \$0.42 \text{ million}$
- **Japan:**  $(140 * 0.01) = 1.4 \text{ patients} * \$150,000 = \$0.21 \text{ million}$
- **Total \$ Value of 1% Share:**  $\$1.12\text{M} + \$0.76\text{M} + \$0.42\text{M} + \$0.21\text{M} = \text{\$2.51 million}$

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$2.51 million**.

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## **Summary of Results**

1. **Potential Peak Sales for Olutasidenib** (relapsed/refractory AML with IDH1 mutation):

- At 20% market share: **\$50.2 million**
- At 30% market share: **\$75.2 million**

2. **\$ Value of 1% Share of Treated Patients: \$2.51 million**

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## **Caveats and Assumptions**

- **Patient Population:** The incidence numbers and mutation rates are approximations based on general AML epidemiology. Actual numbers may vary based on updated data or specific studies.

- **Pricing:** Drug pricing is assumed based on typical costs for targeted AML therapies. Actual pricing for olutasidenib may differ by region and over time due to negotiations, rebates, or generic competition.

- **Market Share:** The 20-30% market share is as provided, but actual penetration depends on competition (e.g., other IDH1 inhibitors like ivosidenib), physician adoption, and payer coverage.

- **Treatment Duration:** Assumed to be one year for simplicity, but actual treatment duration may vary based on patient response and disease progression.

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