

To calculate the **Potential Peak Sales** for the drug "fludarabine phosphate" with updated labeling in the specified indication across 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 on the indication, patient population, pricing, and market penetration isn't provided, I will outline a general methodology with assumptions. You can adjust the numbers based on specific data for the indication (e.g., chronic lymphocytic leukemia or other hematologic malignancies for which fludarabine is typically used).

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## **Step 1: Key Assumptions and Methodology**

1. **Indication and Patient Population:** Fludarabine phosphate is primarily used for chronic lymphocytic leukemia (CLL) and other hematologic malignancies. For this analysis, we assume the updated labeling targets a specific indication (e.g., CLL) and expands or clarifies its use, potentially increasing market share or treated patient population.

2. **Treated Patient Share:** The problem assumes a 20% to 30% share of treated patients. We will use the midpoint (25%) for peak sales calculations.

3. **Pricing:** Drug pricing varies by region due to differences in healthcare systems and reimbursement. We will estimate an average annual treatment cost per patient for fludarabine phosphate based on publicly available data or typical costs for oncology drugs.

4. **Market Size:** We will estimate the total number of treatable patients in the target indication across the US, EU5, China, and Japan using epidemiology data for CLL or other relevant indications.

5. **Peak Sales:** Peak sales are calculated as (Number of treated patients) x (Annual treatment cost per patient) at the assumed market share.

6. **1% Share Value:** The value of a 1% share of treated patients is calculated as (Total treated patients) x (Annual treatment cost per patient) x 1%.

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## **Step 2: Estimated Patient Population for CLL (as an Example Indication)**

Using chronic lymphocytic leukemia (CLL) as a representative indication for fludarabine phosphate, we estimate the number of treatable patients. These numbers are illustrative and based on general epidemiology data (e.g., from sources like the American Cancer Society, WHO, or market research reports). Adjust these based on the specific indication or updated labeling.

- **US:** ~20,000 new CLL cases per year; assuming a treatable population (prevalent cases eligible for treatment) of ~60,000 patients.

- **EU5:** ~25,000 new cases per year; treatable population of ~75,000 patients.

- **China:** ~10,000 new cases per year (lower incidence due to population differences); treatable population of ~30,000 patients.

- **Japan:** ~5,000 new cases per year; treatable population of ~15,000 patients.

- **Total Treatable Population:** ~180,000 patients across these geographies.

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### **Step 3: Estimated Annual Treatment Cost per Patient**

Fludarabine phosphate is a generic drug in many markets, so pricing is lower compared to novel oncology therapies. However, updated labeling under Project Renewal may allow for premium pricing or increased adoption. Approximate costs (per patient per year) are based on typical treatment regimens (e.g., IV administration over multiple cycles):

- **US:** ~\$10,000 per year (higher due to healthcare costs).
- **EU5:** ~\$7,000 per year (lower due to price controls and generics).
- **China:** ~\$4,000 per year (lower due to pricing and access constraints).
- **Japan:** ~\$8,000 per year (similar to EU but with higher reimbursement rates).

Weighted average annual cost per patient (based on patient distribution): ~\$7,500.

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### **Step 4: Potential Peak Sales Calculation (25% Market Share)**

Using a 25% share of treated patients:

- **Total Treated Patients at 25% Share:**  $180,000 \times 25\% = 45,000$  patients.
- **Peak Sales:**  $45,000 \text{ patients} \times \$7,500 \text{ per patient} = \text{\$337.5 million annually}$ .

**Breakdown by Geography (using region-specific pricing and patient distribution):**

- **US:**  $60,000 \times 25\% \times \$10,000 = \$150$  million.
- **EU5:**  $75,000 \times 25\% \times \$7,000 = \$131.25$  million.
- **China:**  $30,000 \times 25\% \times \$4,000 = \$30$  million.
- **Japan:**  $15,000 \times 25\% \times \$8,000 = \$30$  million.
- **Total Peak Sales:** **\\$341.25 million** (slightly adjusted for regional pricing).

For the range of 20% to 30% share:

- **20% Share:**  $180,000 \times 20\% \times \$7,500 = \text{\$270 million}$ .
- **30% Share:**  $180,000 \times 30\% \times \$7,500 = \text{\$405 million}$ .
- **Range of Peak Sales:** **\\$270 million to \\$405 million annually**.

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

- **Total Treated Patients for 1% Share:**  $180,000 \times 1\% = 1,800$  patients.
- **Value of 1% Share (using weighted average cost):**  $1,800 \times \$7,500 = \text{\$13.5 million annually}$ .

**Breakdown by Geography (using region-specific pricing):**

- **US:**  $60,000 \times 1\% \times \$10,000 = \$6$  million.
- **EU5:**  $75,000 \times 1\% \times \$7,000 = \$5.25$  million.
- **China:**  $30,000 \times 1\% \times \$4,000 = \$1.2$  million.
- **Japan:**  $15,000 \times 1\% \times \$8,000 = \$1.2$  million.
- **Total Value of 1% Share:** **\\$13.65 million annually.**

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## **Final Answer**

1. **Potential Peak Sales for Fludarabine Phosphate (Updated Labeling)** in the US, EU5, China, and Japan at 20% to 30% share of treated patients:

- Range: **\\$270 million to \\$405 million annually.**
- Midpoint (25% share): **~\\$340 million annually.**

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

- Total: **~\\$13.5 million to \\$13.65 million annually.**

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## **Notes and Caveats**

- These estimates are based on assumptions for patient population, pricing, and market share. The actual indication targeted by the updated labeling (e.g., expanded use or specific subgroup) could significantly alter the numbers.

- Fludarabine phosphate is a generic drug in many markets, so competition and pricing pressures may reduce peak sales potential unless the updated labeling provides a significant clinical or regulatory advantage.

- Market access, reimbursement policies, and adoption rates vary widely across geographies, especially in China, where oncology drug access is growing but still limited compared to the US and EU.

- If you have specific data on the indication, patient numbers, or pricing, I can refine these calculations further.