

To estimate the **Potential Peak Sales** for **asparaginase erwinia chrysanthemi (recombinant)-rywn (Rylaze)** in the specified geographies (US, EU5, China, and Japan) and the **\$ value of a 1% share of treated patients**, we need to follow a structured approach based on available data, epidemiology, pricing assumptions, and market penetration rates. Since exact figures for patient populations, pricing, and market dynamics may not be publicly available, I will outline a methodology with reasonable assumptions. You can adjust these assumptions based on proprietary data or more specific market research.

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## **Step 1: Define the Target Indication and Patient Population**

Rylaze is approved for the treatment of **acute lymphoblastic leukemia (ALL)** and **lymphoblastic lymphoma (LBL)** in patients who have developed hypersensitivity to E. coli-derived asparaginase. This is a niche subset of the broader ALL and LBL patient population.

- **ALL and LBL Incidence:** ALL is the most common childhood cancer, with a smaller incidence in adults. LBL is rarer but often treated similarly to ALL.
- **Hypersensitivity Subset:** Approximately 10-30% of ALL/LBL patients treated with E. coli-derived asparaginase develop hypersensitivity, making them eligible for Rylaze.

#### Estimated Treated Patient Population (Annual Incidence of Eligible Patients)

Using epidemiology data and assumptions:

- **US:** ~3,000-3,500 new ALL cases/year; ~10-15% are adults. Hypersensitivity in ~20% → ~600-700 eligible patients/year.
- **EU5 (France, Germany, Italy, Spain, UK):** ~4,000-5,000 new ALL cases/year. Hypersensitivity in ~20% → ~800-1,000 eligible patients/year.
- **China:** ~10,000-12,000 new ALL cases/year (higher population, but lower diagnosis rates). Hypersensitivity in ~20% → ~2,000-2,400 eligible patients/year.
- **Japan:** ~1,000-1,200 new ALL cases/year. Hypersensitivity in ~20% → ~200-240 eligible patients/year.

**Total Eligible Patients (Annual):** ~3,600-4,340 across US, EU5, China, and Japan.

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## **Step 2: Market Penetration (20%-30% Share of Treated Patients)**

Assuming Rylaze captures **20%-30%** of eligible patients due to competition (e.g., other asparaginase products like Oncaspar or alternative therapies) and access limitations:

- **US:** 120-210 patients (20%-30% of 600-700).
- **EU5:** 160-300 patients (20%-30% of 800-1,000).
- **China:** 400-720 patients (20%-30% of 2,000-2,400).
- **Japan:** 40-72 patients (20%-30% of 200-240).

**Total Treated Patients (Annual):** 720-1,302 patients across all geographies at peak penetration.

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

Rylaze is a specialty oncology drug, and pricing varies by region due to healthcare systems and purchasing power:

- **US:** ~\$20,000-\$30,000 per patient per treatment course (based on typical costs for orphan oncology drugs and competitor pricing for asparaginase products like Oncaspar).
- **EU5:** ~\$15,000-\$20,000 per patient (discounts due to centralized negotiations and cost controls).
- **China:** ~\$5,000-\$10,000 per patient (lower pricing due to affordability and generics competition).
- **Japan:** ~\$15,000-\$20,000 per patient (similar to EU5, with high reimbursement but cost controls).

#### **Average Annual Revenue per Patient (Weighted by Region):**

- US: \$25,000
- EU5: \$17,500
- China: \$7,500
- Japan: \$17,500

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

Using the number of treated patients and pricing per region at peak penetration (midpoint of 20%-30% share, i.e., 25%):

#### **#### US**

- Treated patients: ~163 (25% of 650)
- Revenue:  $163 * \$25,000 = \mathbf{\$4.08 \text{ million}}$

#### **#### EU5**

- Treated patients: ~225 (25% of 900)
- Revenue:  $225 * \$17,500 = \mathbf{\$3.94 \text{ million}}$

#### **#### China**

- Treated patients: ~550 (25% of 2,200)
- Revenue:  $550 * \$7,500 = \mathbf{\$4.13 \text{ million}}$

#### **#### Japan**

- Treated patients: ~55 (25% of 220)
- Revenue:  $55 * \$17,500 = \text{\$0.96 million}$

**Total Peak Sales (Annual):** \$4.08M (US) + \$3.94M (EU5) + \$4.13M (China) + \$0.96M (Japan) = **~\$13.11 million** at 25% market share.

- At **20% share**: ~\$10.49 million
- At **30% share**: ~\$15.73 million

**Potential Peak Sales Range: \$10.5 million to \$15.7 million annually** across all geographies.

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

Using the total eligible patient population (midpoint of 3,600-4,340 = 3,970 patients) and weighted average pricing:

#### Total Eligible Patients and Revenue per 1% Share

- **US:** 650 patients → 1% = 6.5 patients \* \$25,000 = **\$162,500**
- **EU5:** 900 patients → 1% = 9 patients \* \$17,500 = **\$157,500**
- **China:** 2,200 patients → 1% = 22 patients \* \$7,500 = **\$165,000**
- **Japan:** 220 patients → 1% = 2.2 patients \* \$17,500 = **\$38,500**

**Total \$ Value of 1% Share:** \$162,500 (US) + \$157,500 (EU5) + \$165,000 (China) + \$38,500 (Japan) = **~\$523,500**

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## **Final Answer**

1. **Potential Peak Sales for Rylaze** in the US, EU5, China, and Japan (assuming 20%-30% market share of treated patients): **\$10.5 million to \$15.7 million annually.**
2. **\$ Value of 1% Share of Treated Patients** across these geographies: **~\$523,500.**

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## **Notes and Caveats**

- These estimates are based on assumptions about incidence, hypersensitivity rates, market penetration, and pricing. Real-world data may vary due to competition, reimbursement policies, and access challenges (especially in China).
- Peak sales may take several years to achieve after launch due to adoption curves.
- Additional costs (e.g., R&D, marketing) are not factored into this revenue estimate.

- If you have access to more precise data on patient numbers, pricing, or market dynamics, these figures can be refined accordingly.