To estimate the **Potential Peak Sales** for **asparaginase erwinia chrysanthemi (recombinant)-rywn (Rylaze)** in the indication of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **$ value of a 1% share of treated patients**, we need to follow a structured approach. Since specific data on patient populations, pricing, and market penetration may not be fully available, I will outline the methodology and provide reasonable assumptions based on publicly available information and typical market dynamics for rare disease drugs. Let's break this down step by step.

Step 1: Background and Indication

- **Drug**: Asparaginase erwinia chrysanthemi (recombinant)-rywn (Rylaze) is a treatment for acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in patients who have developed hypersensitivity to E. coli-derived asparaginase.

- **Indication**: Primarily used as a component of multi-agent chemotherapy regimens for ALL/LBL.

- **Target Population**: Patients with ALL/LBL who are hypersensitive to other asparaginase products (a subset of the total ALL/LBL population).

- **Approval**: Approved in the US (2021) by the FDA, with a dosing regimen of Monday-Wednesday-Friday or every 48 hours. Approval status in other regions (EU5, China, Japan) may vary and should be confirmed, but for this analysis, we assume it is approved or will be approved.

Step 2: Estimate the Target Patient Population

ALL is a rare cancer, primarily affecting children and adolescents, with a smaller proportion of adults. The target population for Rylaze is a subset of ALL/LBL patients who cannot tolerate E. coli-derived asparaginase due to hypersensitivity (estimated to be ~20-30% of ALL patients).

Incidence of ALL/LBL and Target Population (Hypersensitive Patients):

- **US**: ~6,000 new ALL cases per year (American Cancer Society). Assuming 20-30% develop hypersensitivity, the target population is ~1,200–1,800 patients/year.

- **EU5**: Incidence of ALL is ~5,000–6,000 new cases/year (combined for France, Germany, Italy, Spain, UK). Target population (20-30%) is ~1,000–1,800 patients/year.

- **China**: Incidence of ALL is higher due to population size, ~10,000–12,000 new cases/year (based on global cancer statistics). Target population (20-30%) is ~2,000–3,600 patients/year.

- **Japan**: Incidence of ALL is ~1,000–1,200 new cases/year. Target population (20-30%) is ~200–360 patients/year.

Total target population (hypersensitive patients):

- US: 1,500 (midpoint)

- EU5: 1,400 (midpoint)

- China: 2,800 (midpoint)

- Japan: 280 (midpoint)

- **Total**: ~6,000 patients/year across these geographies.

Treated Patients:

Assuming not all eligible patients receive treatment due to access, affordability, or other factors, let's assume a **treatment rate of 80%** of the target population:

- US: 1,200 treated patients

- EU5: 1,120 treated patients

- China: 2,240 treated patients

- Japan: 224 treated patients

- **Total Treated Patients**: ~4,800 patients/year.

Step 3: Market Share Assumption

The query assumes a **20-30% share of treated patients** for Rylaze. Using the midpoint of **25% market share**:

- US: 1,200 × 25% = 300 patients

- EU5: 1,120 × 25% = 280 patients

- China: 2,240 × 25% = 560 patients

- Japan: 224 × 25% = 56 patients

- **Total Patients Treated with Rylaze**: ~1,200 patients/year.

Step 4: Pricing Assumption

Rylaze is a specialty drug for a rare indication, and pricing reflects this. Based on available data:

- In the **US**, the cost of Rylaze is approximately $10,000–$15,000 per patient per course of treatment (assuming multiple doses per course). Let's use a midpoint of **$12,500 per patient per year**.

- In **EU5**, pricing is typically 60-70% of US prices due to healthcare system negotiations. Assume **$8,000 per patient per year**.

- In **China**, pricing is lower due to market access challenges and government pricing controls. Assume **$4,000 per patient per year**.

- In **Japan**, pricing is often similar to or slightly below EU levels. Assume **$7,500 per patient per year**.

Step 5: Calculate Potential Peak Sales

Peak sales are calculated as: **Number of patients treated with Rylaze × Price per patient per year**.

- **US**: 300 patients × $12,500 = **$3.75 million**

- **EU5**: 280 patients × $8,000 = **$2.24 million**

- **China**: 560 patients × $4,000 = **$2.24 million**

- **Japan**: 56 patients × $7,500 = **$0.42 million**

- **Total Peak Sales**: $3.75M + $2.24M + $2.24M + $0.42M = **$8.65 million per year**

Note: This estimate assumes peak sales at 25% market share. If we consider the range of 20-30% market share:

- At 20%: ~$6.92 million

- At 30%: ~$10.38 million

- **Range of Peak Sales**: **$6.9–$10.4 million per year**.

Step 6: $ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treated patients (~4,800 patients), which is **48 patients**.

Using the same pricing per region:

- **US**: 1% of 1,200 = 12 patients × $12,500 = **$150,000**

- **EU5**: 1% of 1,120 = 11.2 patients × $8,000 = **$89,600**

- **China**: 1% of 2,240 = 22.4 patients × $4,000 = **$89,600**

- **Japan**: 1% of 224 = 2.24 patients × $7,500 = **$16,800**

- **Total $ Value of 1% Share**: $150,000 + $89,600 + $89,600 + $16,800 = **$346,000**

Final Answer

1. **Potential Peak Sales for Rylaze** (at 20-30% market share of treated patients):

- **Range**: **$6.9 million to $10.4 million per year** across the US, EU5, China, and Japan.

- **Midpoint (25% share)**: **$8.65 million per year**.

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

- **Total**: **$346,000 per year** across the US, EU5, China, and Japan.

Caveats and Assumptions

- **Patient Population**: Incidence data is approximated based on public cancer statistics (e.g., American Cancer Society, GLOBOCAN). Exact numbers for hypersensitive patients may vary.

- **Pricing**: Pricing is estimated based on typical costs for rare disease drugs and regional pricing differences. Actual costs may differ based on negotiations, reimbursement, and access.

- **Market Share**: Assumes 20-30% penetration, but competition (e.g., other asparaginase products) and market access barriers could impact this.

- **Approval Status**: Assumes Rylaze is approved or will be approved in all regions. If not yet approved in certain markets (e.g., China), sales potential would be lower.

For more precise estimates, detailed market research, epidemiology data, and pricing information specific to each region would be required. If you have additional data or specific inputs, I can refine the calculations accordingly.