

To estimate the **Potential Peak Sales** for rituximab (Rituxan) in the specified indication (pediatric patients with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL)) 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 based on available data and reasonable assumptions. Since exact data for this specific pediatric indication may not be publicly available, I will outline the methodology and provide an estimate based on general epidemiology, market dynamics, and pricing assumptions.

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## **Step 1: Define Key Parameters and Assumptions**

### **1. Target Population (Pediatric Patients with Specified Indications):**

- These are rare cancers in pediatric patients (aged  $\geq 6$  months to  $< 18$  years). Incidence rates for DLBCL, BL, BLL, and B-AL in children are low compared to adults.
- Estimated annual incidence in pediatric patients (based on literature and cancer statistics):
  - DLBCL: ~1-2 cases per million children.
  - Burkitt Lymphoma (BL/BLL): ~2-3 cases per million children (higher in some regions due to endemic forms).
  - Mature B-cell acute leukemia (B-AL): Rare, ~0.5-1 case per million children.
- Total pediatric population (aged 0-17 years) in each geography (approximate, based on 2023 data):
  - US: ~73 million
  - EU5: ~60 million
  - China: ~240 million
  - Japan: ~15 million
- Incidence rate for combined indications: ~5-7 cases per million children annually (conservative estimate based on literature for rare pediatric lymphomas/leukemias).
- Percentage of advanced stage at diagnosis: Assume ~70-80% of cases are advanced stage (common in aggressive lymphomas like BL and DLBCL).
- CD20-positive cases: Assume ~90-95% of DLBCL and BL/BLL are CD20-positive (based on biology of these cancers).

### **2. Treatable Population:**

- Assume 100% of diagnosed, advanced stage, CD20-positive patients are eligible for rituximab + chemotherapy (as per FDA approval).
- Assume diagnosis rate: ~80-90% in developed markets (US, EU5, Japan) and ~50-60% in China due to disparities in healthcare access.

### **3. Market Share of Rituximab:**

- Given the query specifies a 20-30% share of treated patients, we will calculate potential peak sales for this range.

- Rituximab faces competition from biosimilars in many markets (since patent expiry), which may limit market share. However, in pediatric indications, brand loyalty and clinical trial data may support a 20-30% share.

#### **4. Pricing of Rituximab:**

- Rituximab pricing varies by region and is influenced by biosimilar competition.
- Average cost per treatment course (assuming multiple cycles for pediatric lymphoma/leukemia, ~6-8 doses per patient):
  - US: ~\$40,000-\$50,000 per patient (based on historical pricing and discounts).
  - EU5: ~\$20,000-\$30,000 per patient (lower due to healthcare systems and biosimilars).
  - Japan: ~\$25,000-\$35,000 per patient.
  - China: ~\$10,000-\$15,000 per patient (lower pricing due to market access programs and biosimilars).
- Assume annual peak sales are based on incident (newly diagnosed) patients each year.

#### **5. Peak Sales Timeline:**

- Peak sales are typically reached 3-5 years after approval in a new indication, assuming market penetration and physician adoption.

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### **Step 2: Estimate Incident Cases (Newly Diagnosed Patients per Year)**

Using the incidence rate of ~5-7 cases per million children:

- **US:**
  - Pediatric population: 73 million
  - Incident cases:  $73 \text{ million} * 6/1,000,000 = \sim 438 \text{ cases/year}$
  - Advanced stage (75%):  $\sim 329 \text{ cases}$
  - CD20-positive (92%):  $\sim 303 \text{ cases}$
  - Diagnosed (85%):  $\sim 257 \text{ cases}$
- **EU5:**
  - Pediatric population: 60 million
  - Incident cases:  $60 \text{ million} * 6/1,000,000 = \sim 360 \text{ cases/year}$
  - Advanced stage (75%):  $\sim 270 \text{ cases}$
  - CD20-positive (92%):  $\sim 248 \text{ cases}$
  - Diagnosed (85%):  $\sim 211 \text{ cases}$
- **China:**

- Pediatric population: 240 million
- Incident cases:  $240 \text{ million} * 6/1,000,000 = \sim 1,440 \text{ cases/year}$
- Advanced stage (75%):  $\sim 1,080 \text{ cases}$
- CD20-positive (92%):  $\sim 994 \text{ cases}$
- Diagnosed (55%):  $\sim 547 \text{ cases}$
- **Japan:**
- Pediatric population: 15 million
- Incident cases:  $15 \text{ million} * 6/1,000,000 = \sim 90 \text{ cases/year}$
- Advanced stage (75%):  $\sim 68 \text{ cases}$
- CD20-positive (92%):  $\sim 62 \text{ cases}$
- Diagnosed (85%):  $\sim 53 \text{ cases}$
- **Total Diagnosed Patients Across Geographies:**  $\sim 257 \text{ (US)} + 211 \text{ (EU5)} + 547 \text{ (China)} + 53 \text{ (Japan)}$   
 $= \sim 1,068 \text{ patients/year}$

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### **Step 3: Estimate Treated Patients with Rituximab (20-30% Share)**

- **20% Share of Treated Patients:**
- US:  $257 * 0.2 = \sim 51 \text{ patients}$
- EU5:  $211 * 0.2 = \sim 42 \text{ patients}$
- China:  $547 * 0.2 = \sim 109 \text{ patients}$
- Japan:  $53 * 0.2 = \sim 11 \text{ patients}$
- Total:  $\sim 213 \text{ patients}$
- **30% Share of Treated Patients:**
- US:  $257 * 0.3 = \sim 77 \text{ patients}$
- EU5:  $211 * 0.3 = \sim 63 \text{ patients}$
- China:  $547 * 0.3 = \sim 164 \text{ patients}$
- Japan:  $53 * 0.3 = \sim 16 \text{ patients}$
- Total:  $\sim 320 \text{ patients}$

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### **Step 4: Calculate Potential Peak Sales (20-30% Share)**

Using average cost per treatment course:

- **US:** \$45,000/patient

- **EU5:** \$25,000/patient
- **China:** \$12,500/patient
- **Japan:** \$30,000/patient

#### At 20% Share:

- US: 51 patients \* \$45,000 = ~\$2.3 million
- EU5: 42 patients \* \$25,000 = ~\$1.1 million
- China: 109 patients \* \$12,500 = ~\$1.4 million
- Japan: 11 patients \* \$30,000 = ~\$0.3 million
- **Total Peak Sales (20% Share):** ~\$5.1 million/year

#### At 30% Share:

- US: 77 patients \* \$45,000 = ~\$3.5 million
- EU5: 63 patients \* \$25,000 = ~\$1.6 million
- China: 164 patients \* \$12,500 = ~\$2.1 million
- Japan: 16 patients \* \$30,000 = ~\$0.5 million
- **Total Peak Sales (30% Share):** ~\$7.7 million/year

**Potential Peak Sales Range for Rituximab in this Indication:** ~\$5.1 million to \$7.7 million annually across the specified geographies.

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

- **Total Diagnosed Patients:** ~1,068 patients/year
- **1% of Treated Patients:**  $1,068 * 0.01 = \sim 11$  patients

#### Revenue per 1% Share:

- US:  $(257 * 0.01) * \$45,000 = 2.57 * \$45,000 = \sim \$0.12$  million
- EU5:  $(211 * 0.01) * \$25,000 = 2.11 * \$25,000 = \sim \$0.05$  million
- China:  $(547 * 0.01) * \$12,500 = 5.47 * \$12,500 = \sim \$0.07$  million
- Japan:  $(53 * 0.01) * \$30,000 = 0.53 * \$30,000 = \sim \$0.02$  million
- **Total \$ Value of 1% Share:** ~\$0.26 million (or \$260,000) per year

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**Final Answer:**

**1. Potential Peak Sales for Rituximab in this Indication (20-30% Share):**

- Across US, EU5, China, and Japan: **\$5.1 million to \$7.7 million annually.**

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

- Across US, EU5, China, and Japan: **\$260,000 annually.**

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**Notes and Caveats:**

- These estimates are based on approximate epidemiology data for rare pediatric cancers and may vary depending on actual incidence, diagnosis rates, and market access.

- Pricing assumptions account for biosimilar competition and regional differences but may not reflect exact current pricing or reimbursement policies.

- The pediatric indication is a niche market, and peak sales are modest compared to adult indications for rituximab (e.g., NHL, CLL, RA).

- If more specific data on patient numbers or pricing becomes available, these estimates can be refined.