

To estimate the **Potential Peak Sales** for inotuzumab ozogamicin (Besponsa) in the indication of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) in pediatric patients (1 year and older) in the US, EU5 (France, Germany, 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 exact data on patient populations, pricing, and market penetration may not be publicly available, I will make reasonable assumptions based on available information, epidemiology data, and standard industry practices. Let's break this down step by step.

****Key Assumptions and Methodology****

1. Indication and Patient Population:

- The drug is approved for pediatric patients (1 year and older) with relapsed or refractory CD22-positive B-cell precursor ALL.
- B-cell precursor ALL is the most common type of ALL, and approximately 85-90% of cases are CD22-positive.
- Relapsed or refractory ALL accounts for a subset of ALL cases (approximately 15-20% of pediatric ALL patients relapse or are refractory to initial treatment).
- We will estimate the total number of eligible patients in each geography using incidence rates of pediatric ALL and relapse/refractory rates.

2. Market Share:

- As per the query, we assume a 20-30% market share of treated patients for inotuzumab ozogamicin.

3. Pricing:

- Pricing for inotuzumab ozogamicin varies by region. In the US, the cost of treatment per patient is approximately \$100,000–\$150,000 per course (based on historical data for Besponsa in adult ALL and adjusted for pediatric dosing). In EU5, pricing is typically 60-70% of US pricing due to healthcare system negotiations. In China and Japan, pricing is assumed to be 50-60% of US pricing due to market access and reimbursement constraints.
- For simplicity, we assume a full course of treatment per patient annually (or as needed for relapse/refractory cases).

4. Geographies:

- US, EU5 (combined), China, and Japan are considered. Population and incidence data will be used to estimate patient numbers.

5. Peak Sales:

- Peak sales are typically achieved 5-7 years post-launch after market penetration stabilizes. We will estimate based on treated patients and pricing.

****Step 1: Estimate Eligible Patient Population****

We start by estimating the incidence of pediatric ALL, the proportion of relapsed/refractory cases, and the proportion of CD22-positive B-cell precursor ALL.

- Pediatric ALL Incidence:

- US: ~3,000 new cases per year (based on American Cancer Society data).
- EU5: ~3,500 new cases per year (combined, based on population and incidence rates similar to the US).
- China: ~6,000 new cases per year (higher population, adjusted for lower diagnosis rates).
- Japan: ~600 new cases per year (based on population and incidence rates).

- Relapsed/Refractory Rate: ~15-20% of pediatric ALL cases relapse or are refractory. We use 18% for calculations.

- CD22-Positive B-Cell Precursor ALL: ~85-90% of cases. We use 88% for calculations.

Eligible Patients Calculation:

- Eligible patients = Total new cases × Relapsed/Refractory rate × CD22-positive rate

| Geography | New Cases/Year | Relapsed/Refractory (18%) | CD22-Positive (88%) | Eligible Patients/Year |

|-----|-----|-----|-----|-----|

| US | 3,000 | 540 | 475 | 475 |

| EU5 | 3,500 | 630 | 554 | 554 |

| China | 6,000 | 1,080 | 950 | 950 |

| Japan | 600 | 108 | 95 | 95 |

| **Total** | **13,100** | **2,358** | **2,074** | **2,074** |

****Step 2: Estimate Treated Patients with 20-30% Market Share****

Assuming 20-30% of eligible patients are treated with inotuzumab ozogamicin:

| Geography | Eligible Patients/Year | Treated Patients (20%) | Treated Patients (30%) |

|-----|-----|-----|-----|

| US | 475 | 95 | 143 |

| EU5 | 554 | 111 | 166 |

| China | 950 | 190 | 285 |

| Japan | 95 | 19 | 29 |

| **Total** | **2,074** | **415** | **623** |

****Step 3: Estimate Pricing per Patient****

Assumed pricing per treatment course (adjusted for regional differences):

| Geography | Price per Patient (USD) |

|-----|-----|

| US | 125,000 |

| EU5 | 87,500 (70% of US) |

| China | 62,500 (50% of US) |

| Japan | 75,000 (60% of US) |

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

Peak sales = Treated Patients × Price per Patient

At 20% Market Share:

| Geography | Treated Patients | Price per Patient (USD) | Peak Sales (USD Million) |

|-----|-----|-----|-----|

| US | 95 | 125,000 | 11.88 |

| EU5 | 111 | 87,500 | 9.71 |

| China | 190 | 62,500 | 11.88 |

| Japan | 19 | 75,000 | 1.43 |

| **Total** | **415** | - | **34.90** |

At 30% Market Share:

| Geography | Treated Patients | Price per Patient (USD) | Peak Sales (USD Million) |

|-----|-----|-----|-----|

| US | 143 | 125,000 | 17.88 |

| EU5 | 166 | 87,500 | 14.53 |

| China | 285 | 62,500 | 17.81 |

| Japan | 29 | 75,000 | 2.18 |

| **Total** | **623** | - | **52.40** |

Potential Peak Sales Range: \$34.9 million to \$52.4 million annually across all geographies.

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

1% share of treated patients corresponds to 1% of the eligible patients being treated with inotuzumab ozogamicin.

| Geography | Eligible Patients/Year | 1% of Eligible Patients | Price per Patient (USD) | Value of 1% Share (USD Million) |

|-----|-----|-----|-----|-----|

| US | 475 | 4.75 | 125,000 | 0.59 |

| EU5 | 554 | 5.54 | 87,500 | 0.48 |

| China | 950 | 9.50 | 62,500 | 0.59 |

| Japan | 95 | 0.95 | 75,000 | 0.07 |

| **Total** | **2,074** | **20.74** | - | **1.73** |

\$ Value of 1% Share of Treated Patients: \$1.73 million annually across all geographies.

****Final Answer****

1. **Potential Peak Sales for inotuzumab ozogamicin** in the specified indication (relapsed or refractory CD22-positive B-cell precursor ALL in pediatric patients) with a 20-30% market share:

- **US, EU5, China, and Japan combined: \$34.9 million to \$52.4 million annually.**

- Breakdown by geography (at 20-30% share):

- US: \$11.9M to \$17.9M

- EU5: \$9.7M to \$14.5M

- China: \$11.9M to \$17.8M

- Japan: \$1.4M to \$2.2M

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

- **US, EU5, China, and Japan combined: \$1.73 million annually.**

- Breakdown by geography:

- US: \$0.59M

- EU5: \$0.48M

- China: \$0.59M

- Japan: \$0.07M

Note: These estimates are based on assumptions regarding patient numbers, relapse rates, CD22 positivity, pricing, and market penetration. Actual figures may vary depending on real-world data, competition, reimbursement policies, and market dynamics. If specific data (e.g., exact patient numbers or pricing) is available, the calculations can be refined further.