To estimate the **Potential Peak Sales** for gemtuzumab ozogamicin (Mylotarg) in the indication of newly-diagnosed CD33-positive acute myeloid leukemia (AML) 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 based on available data and reasonable assumptions. Since exact figures for patient populations, treatment rates, and pricing may not be publicly available or up-to-date, I will outline the methodology and provide an estimate based on general market trends and data from similar analyses in the pharmaceutical industry. Note that these are illustrative calculations and should be refined with precise, current data for accuracy.

Step 1: Define the Target Patient Population

Gemtuzumab ozogamicin is approved for newly-diagnosed CD33-positive AML, including pediatric patients (1 month and older). AML is a rare cancer, and CD33-positive AML accounts for approximately 85-90% of AML cases.

Incidence of AML in Target Geographies

- **US**: ~20,000 new AML cases per year (American Cancer Society).

- **EU5**: ~18,000 new AML cases per year (based on population and incidence rates of ~3-5 per 100,000).

- **China**: ~40,000 new AML cases per year (higher population, incidence rate ~3 per 100,000).

- **Japan**: ~5,000 new AML cases per year (aging population, incidence rate ~4 per 100,000).

Total newly-diagnosed AML cases across geographies: ~83,000 per year.

CD33-Positive AML

Assuming 85% of AML cases are CD33-positive:

- **US**: 17,000 patients

- **EU5**: 15,300 patients

- **China**: 34,000 patients

- **Japan**: 4,250 patients

Total CD33-positive AML patients: ~70,550 per year.

Pediatric and Adult Breakdown

Pediatric AML accounts for ~15-20% of AML cases. For simplicity, we assume the indication covers all newly-diagnosed CD33-positive AML patients (as the approval includes pediatrics but was initially for adults).

Treated Patient Population

Not all diagnosed patients receive treatment due to age, comorbidities, or access to healthcare. Assuming a treatment rate of 60-70% in developed markets (US, EU5, Japan) and 40-50% in China:

- **US**: 11,900 patients (70% of 17,000)

- **EU5**: 10,710 patients (70% of 15,300)

- **China**: 15,300 patients (45% of 34,000)

- **Japan**: 2,975 patients (70% of 4,250)

Total treated patients: ~40,885 per year.

Step 2: Market Share Assumption

The problem states a 20% to 30% share of treated patients for gemtuzumab ozogamicin. We will calculate peak sales for both ends of this range.

- At 20% share: ~8,177 patients treated with gemtuzumab ozogamicin.

- At 30% share: ~12,265 patients treated with gemtuzumab ozogamicin.

Distribution Across Geographies (Proportional to Treated Population)

- **US**: 29% of total treated patients (11,900/40,885)

- **EU5**: 26% (10,710/40,885)

- **China**: 37% (15,300/40,885)

- **Japan**: 7% (2,975/40,885)

At 20% share:

- US: 2,380 patients

- EU5: 2,142 patients

- China: 3,060 patients

- Japan: 595 patients

At 30% share:

- US: 3,570 patients

- EU5: 3,213 patients

- China: 4,590 patients

- Japan: 893 patients

Step 3: Pricing per Patient

Gemtuzumab ozogamicin is a high-cost biologic drug. Pricing varies by region due to healthcare systems and purchasing power.

- **US**: ~$20,000 per treatment course (based on historical pricing for Mylotarg and similar drugs).

- **EU5**: ~$15,000 per treatment course (discounts due to public health systems).

- **China**: ~$8,000 per treatment course (lower pricing due to market dynamics and generics competition).

- **Japan**: ~$18,000 per treatment course (similar to US but slightly lower due to price controls).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as (number of treated patients) × (price per treatment course) for each geography, summed across regions.

At 20% Market Share

- **US**: 2,380 patients × $20,000 = $47.6 million

- **EU5**: 2,142 patients × $15,000 = $32.1 million

- **China**: 3,060 patients × $8,000 = $24.5 million

- **Japan**: 595 patients × $18,000 = $10.7 million

Total Peak Sales at 20% share: $47.6M + $32.1M + $24.5M + $10.7M = **$114.9 million**

At 30% Market Share

- **US**: 3,570 patients × $20,000 = $71.4 million

- **EU5**: 3,213 patients × $15,000 = $48.2 million

- **China**: 4,590 patients × $8,000 = $36.7 million

- **Japan**: 893 patients × $18,000 = $16.1 million

Total Peak Sales at 30% share: $71.4M + $48.2M + $36.7M + $16.1M = **$172.4 million**

Range of Potential Peak Sales: **$114.9 million to $172.4 million per year.**

Step 5: $ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treated patient population (~40,885 patients), which is ~409 patients.

Distribution Across Geographies

- **US**: 119 patients (29% of 409)

- **EU5**: 107 patients (26% of 409)

- **China**: 153 patients (37% of 409)

- **Japan**: 30 patients (7% of 409)

Revenue for 1% Share

- **US**: 119 patients × $20,000 = $2.38 million

- **EU5**: 107 patients × $15,000 = $1.61 million

- **China**: 153 patients × $8,000 = $1.22 million

- **Japan**: 30 patients × $18,000 = $0.54 million

Total $ Value of 1% Share: $2.38M + $1.61M + $1.22M + $0.54M = **$5.75 million**

Final Answer

- **Potential Peak Sales** for gemtuzumab ozogamicin in newly-diagnosed CD33-positive AML (20% to 30% market share) in the US, EU5, China, and Japan: **$114.9 million to $172.4 million per year**.

- **$ Value of 1% Share of Treated Patients** in these geographies: **$5.75 million per year**.

Caveats and Assumptions

1. **Patient Population**: Incidence rates and treatment rates are estimates based on general data. Actual numbers may vary.

2. **Pricing**: Drug pricing is assumed based on historical data for Mylotarg and similar oncology drugs. Real-world pricing may differ due to negotiations, rebates, or generic competition.

3. **Market Share**: The 20-30% share is as provided, but actual penetration depends on competition, clinical guidelines, and reimbursement.

4. **Treatment Duration**: Assumed one treatment course per patient; multiple cycles or combination therapies could alter costs.

For precise figures, primary market research, updated epidemiology data, and current pricing information would be necessary. If you have specific data or additional context, I can refine the calculations further.