To estimate the **Potential Peak Sales** for venetoclax (VENCLEXTA®) in the indication of newly-diagnosed acute myeloid leukemia (AML) in adults 75 years or older or with comorbidities 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. Since specific data such as exact patient numbers, pricing, and market penetration may not be fully available, I will make reasonable assumptions based on publicly available information, epidemiology data, and typical market dynamics for oncology drugs. If you have specific data points, they can be integrated for more precision.

Step 1: Define the Target Patient Population

Venetoclax is approved for newly-diagnosed AML patients who are either ≥75 years old or have comorbidities that preclude intensive chemotherapy. AML incidence and the proportion of patients in this subgroup need to be estimated for each geography.

AML Incidence and Eligible Population

- **US**: AML incidence is approximately 20,000 new cases per year. About 60-70% of AML patients are ≥60 years, and a significant portion (estimated 50-60%) are ≥75 or have comorbidities that prevent intensive therapy. Thus, the eligible population is ~10,000-12,000 patients annually.

- **EU5**: AML incidence in Europe is roughly 15,000-18,000 new cases per year across the EU5. Applying similar demographics, the eligible population is ~7,500-9,000 patients annually.

- **China**: AML incidence is less well-documented but estimated at 30,000-40,000 new cases per year due to the large population. Assuming a similar proportion of elderly/comorbid patients, the eligible population is ~15,000-20,000 patients annually.

- **Japan**: AML incidence is around 5,000-6,000 new cases per year. With a high aging population, the eligible population is ~3,000-3,600 patients annually.

Total eligible population across these regions: ~35,500-44,600 patients annually.

Treated Patients

Not all eligible patients receive treatment due to access, cost, or clinical decisions. Assuming a treatment rate of 70-80% in developed markets (US, EU5, Japan) and 50-60% in China:

- **US**: ~7,000-9,600 treated patients.

- **EU5**: ~5,250-7,200 treated patients.

- **China**: ~7,500-12,000 treated patients.

- **Japan**: ~2,100-2,880 treated patients.

Total treated patients: ~21,850-31,680 annually.

Step 2: Market Share Assumption

The query assumes a 20-30% share of treated patients for venetoclax in this indication. Applying this to the treated population:

- **US**: 20-30% of 7,000-9,600 = 1,400-2,880 patients.

- **EU5**: 20-30% of 5,250-7,200 = 1,050-2,160 patients.

- **China**: 20-30% of 7,500-12,000 = 1,500-3,600 patients.

- **Japan**: 20-30% of 2,100-2,880 = 420-864 patients.

Total venetoclax-treated patients: 4,370-9,504 annually.

Step 3: Pricing and Annual Cost per Patient

Venetoclax pricing varies by region due to healthcare systems, negotiations, and market access. The annual cost of venetoclax (often used in combination with azacitidine, decitabine, or LDAC) is estimated based on US list prices and discounts in other markets:

- **US**: Annual cost ~$100,000-120,000 per patient (based on list price and typical treatment duration of 6-12 months).

- **EU5**: Annual cost ~$60,000-80,000 per patient (due to negotiated discounts).

- **Japan**: Annual cost ~$70,000-90,000 per patient (similar to EU5 with slight variations).

- **China**: Annual cost ~$30,000-50,000 per patient (lower pricing due to market dynamics and government negotiations).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each region.

Low-End Estimate (20% share, lower patient numbers, lower pricing)

- **US**: 1,400 patients * $100,000 = $140 million.

- **EU5**: 1,050 patients * $60,000 = $63 million.

- **China**: 1,500 patients * $30,000 = $45 million.

- **Japan**: 420 patients * $70,000 = $29.4 million.

Total Low-End Peak Sales: $277.4 million.

High-End Estimate (30% share, higher patient numbers, higher pricing)

- **US**: 2,880 patients * $120,000 = $345.6 million.

- **EU5**: 2,160 patients * $80,000 = $172.8 million.

- **China**: 3,600 patients * $50,000 = $180 million.

- **Japan**: 864 patients * $90,000 = $77.8 million.

Total High-End Peak Sales: $776.2 million.

Potential Peak Sales Range: **$277 million to $776 million** annually across the US, EU5, China, and Japan for this indication.

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

A 1% share of treated patients corresponds to 1% of the total treated population (21,850-31,680 patients), which is 218.5-316.8 patients annually. Using the same pricing per region:

Low-End Estimate (lower patient numbers, lower pricing)

- **US**: 1% of 7,000 = 70 patients * $100,000 = $7 million.

- **EU5**: 1% of 5,250 = 52.5 patients * $60,000 = $3.15 million.

- **China**: 1% of 7,500 = 75 patients * $30,000 = $2.25 million.

- **Japan**: 1% of 2,100 = 21 patients * $70,000 = $1.47 million.

Total Low-End Value of 1% Share: $13.87 million.

High-End Estimate (higher patient numbers, higher pricing)

- **US**: 1% of 9,600 = 96 patients * $120,000 = $11.52 million.

- **EU5**: 1% of 7,200 = 72 patients * $80,000 = $5.76 million.

- **China**: 1% of 12,000 = 120 patients * $50,000 = $6 million.

- **Japan**: 1% of 2,880 = 28.8 patients * $90,000 = $2.59 million.

Total High-End Value of 1% Share: $25.87 million.

$ Value of 1% Share of Treated Patients: **$13.9 million to $25.9 million** annually across these geographies.

Final Answer

- **Potential Peak Sales for Venetoclax in this Indication**: **$277 million to $776 million** annually in the US, EU5, China, and Japan, assuming a 20-30% market share.

- **$ Value of 1% Share of Treated Patients**: **$13.9 million to $25.9 million** annually across these geographies.

Notes

- These estimates are based on assumptions regarding patient populations, treatment rates, market share, and pricing. Actual figures may vary due to real-world data on AML epidemiology, market access, competition (e.g., other AML therapies), and regional pricing negotiations.

- Venetoclax is used in combination with other drugs, so costs may include combination therapy pricing, though I've focused on venetoclax's contribution.

- Peak sales may take years to achieve due to market penetration dynamics and are specific to this AML indication (venetoclax has other indications like CLL/SLL that contribute to total sales). If you have additional data or need refinement (e.g., specific pricing or patient numbers), I can adjust the calculations.