To estimate the **Potential Peak Sales** for azacitidine tablets (ONUREG®) in the indication of continued treatment of acute myeloid leukemia (AML) in the US, EU5 (Germany, France, 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. This involves estimating the target patient population, treatment penetration, pricing, and market share assumptions. Since specific data (e.g., exact patient numbers or pricing in all regions) may not be publicly available, I will use reasonable assumptions based on general market trends, epidemiology data for AML, and typical pricing for oncology drugs. You can adjust these assumptions based on more precise data if available.

Step 1: Key Assumptions

1. **Indication and Patient Population**: Azacitidine tablets (ONUREG®) are approved for AML patients in first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) who cannot complete intensive curative therapy (e.g., stem cell transplant). This is a subset of AML patients.

2. **Market Share**: As per the query, assuming 20% to 30% of treated patients in this indication will use azacitidine tablets.

3. **Pricing**: Pricing for oncology drugs like azacitidine tablets varies by region. ONUREG® is an oral formulation, and pricing is often based on a monthly or annual treatment cost. For estimation:

- US: ~$20,000 per month (based on typical oral oncology drug pricing).

- EU5: ~$15,000 per month (adjusted for lower pricing in Europe).

- China: ~$5,000 per month (significant price reductions due to market access and negotiations).

- Japan: ~$15,000 per month (similar to EU5, adjusted for local pricing).

4. **Treatment Duration**: Assume an average treatment duration of 12 months for maintenance therapy in AML.

5. **Epidemiology**: AML incidence and prevalence vary by region. A proportion of AML patients achieve CR/CRi, and a subset of these are ineligible for intensive therapy. We will estimate the eligible population based on general AML data.

Step 2: Estimate Eligible Patient Population

AML incidence and the proportion of patients achieving CR/CRi and ineligible for intensive therapy are critical. Based on literature:

- AML incidence is approximately 4-5 per 100,000 people annually in developed countries.

- About 50-60% of AML patients achieve CR/CRi after induction chemotherapy.

- Of these, around 50-60% may be ineligible for intensive curative therapy (e.g., due to age or comorbidities), making them eligible for maintenance therapy like ONUREG®.

Population Estimates (2023, Approximate)

- **US**: Population ~330 million; AML incidence ~20,000 new cases/year; ~10,000-12,000 achieve CR/CRi; ~5,000-7,000 ineligible for intensive therapy.

- **EU5**: Population ~320 million; AML incidence ~18,000-20,000 new cases/year; ~9,000-12,000 achieve CR/CRi; ~4,500-7,000 ineligible.

- **China**: Population ~1.4 billion; AML incidence ~40,000-50,000 new cases/year (lower incidence rate but larger population); ~20,000-30,000 achieve CR/CRi; ~10,000-18,000 ineligible.

- **Japan**: Population ~125 million; AML incidence ~7,000-8,000 new cases/year; ~3,500-4,800 achieve CR/CRi; ~1,750-2,900 ineligible.

Total Eligible Patients (Midpoint Estimates):

- US: 6,000 patients

- EU5: 5,750 patients

- China: 14,000 patients

- Japan: 2,325 patients

- **Total**: ~28,075 patients

Step 3: Estimate Treated Patients with Azacitidine Tablets

Assuming a market share of 20% to 30% among eligible patients:

- **20% Share**:

- US: 1,200 patients

- EU5: 1,150 patients

- China: 2,800 patients

- Japan: 465 patients

- Total: 5,615 patients

- **30% Share**:

- US: 1,800 patients

- EU5: 1,725 patients

- China: 4,200 patients

- Japan: 698 patients

- Total: 8,423 patients

Step 4: Estimate Annual Revenue (Peak Sales)

Using the pricing assumptions and 12-month treatment duration:

- **Annual Cost per Patient**:
- US: $20,000/month x 12 = $240,000
- EU5: $15,000/month x 12 = $180,000
- China: $5,000/month x 12 = $60,000
- Japan: $15,000/month x 12 = $180,000

Peak Sales at 20% Market Share
- US: 1,200 patients x $240,000 = **$288 million**
- EU5: 1,150 patients x $180,000 = **$207 million**
- China: 2,800 patients x $60,000 = **$168 million**
- Japan: 465 patients x $180,000 = **$83.7 million**
- **Total Peak Sales (20%)**: **$746.7 million**

Peak Sales at 30% Market Share
- US: 1,800 patients x $240,000 = **$432 million**
- EU5: 1,725 patients x $180,000 = **$310.5 million**
- China: 4,200 patients x $60,000 = **$252 million**
- Japan: 698 patients x $180,000 = **$125.6 million**
- **Total Peak Sales (30%)**: **$1,120.1 million**

Potential Peak Sales Range: **$747 million to $1,120 million annually**

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

Using the total eligible patient population and the same pricing:
- **1% of Eligible Patients**:
- US: 6,000 x 0.01 = 60 patients; 60 x $240,000 = **$14.4 million**
- EU5: 5,750 x 0.01 = 57.5 patients; 57.5 x $180,000 = **$10.35 million**
- China: 14,000 x 0.01 = 140 patients; 140 x $60,000 = **$8.4 million**
- Japan: 2,325 x 0.01 = 23.25 patients; 23.25 x $180,000 = **$4.185 million**
- **Total $ Value of 1% Share**: **$37.335 million**

Final Answer

1. **Potential Peak Sales for Azacitidine Tablets (ONUREG®)** in the US, EU5, China, and Japan for the specified AML indication:

- At 20% market share: **$747 million annually**

- At 30% market share: **$1,120 million annually**

- **Range: $747 million to $1,120 million annually**

2. **$ Value of 1% Share of Treated Patients** in these geographies: **$37.3 million annually**

Note: These estimates are based on assumptions and should be refined with more precise data on patient numbers, local pricing, market access, and competitor dynamics. Factors like reimbursement, generic competition, and treatment duration could also impact these figures. If you have access to specific data (e.g., from market research reports or company filings), I can help adjust the calculations accordingly.