To estimate the **Potential Peak Sales** for capecitabine tablets (Xeloda) in the specified indication across 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 based on available data and reasonable assumptions. Since specific indication details are not provided in the query, I will assume the indication aligns with capecitabine's primary uses (e.g., colorectal cancer, breast cancer, or gastric cancer) and base calculations on general oncology market data, prevalence, and treatment rates. Note that capecitabine is a generic drug in many markets, which impacts pricing and market share.

Step 1: Key Assumptions

1. **Indication**: Capecitabine is primarily used for colorectal cancer, metastatic breast cancer, and gastric cancer. For this analysis, I'll assume the indication is colorectal cancer (one of the largest markets for capecitabine).

2. **Market Share**: The query assumes a 20% to 30% share of treated patients for capecitabine in this indication.

3. **Patient Population**: Based on cancer incidence and prevalence data for colorectal cancer in the specified geographies.

4. **Treatment Rate**: Not all diagnosed patients receive treatment with capecitabine; I'll assume a treatment-eligible population based on stage and standard of care.

5. **Pricing**: Capecitabine is generic in most markets, so pricing will be lower than branded drugs. I'll use approximate annual treatment costs per patient.

6. **Peak Sales Timeline**: Peak sales are typically reached 3–5 years after label updates or expanded indications, assuming steady market penetration.

Step 2: Estimate Treated Patient Population

Below are approximate figures for colorectal cancer incidence (as a proxy for the indication) and treated patients in each geography. Data is derived from public sources like WHO, GLOBOCAN, and market research reports (2023 estimates).

- **US**:

- Incidence: ~150,000 new cases/year.

- Prevalence (eligible for treatment over 5 years): ~500,000 patients.

- Treatment-eligible (Stage III/IV or adjuvant): ~50% (~250,000 patients).

- **EU5 (Germany, France, Italy, Spain, UK)**:

- Incidence: ~300,000 new cases/year.

- Prevalence: ~1,000,000 patients.

- Treatment-eligible: ~50% (~500,000 patients).

- **China**:

- Incidence: ~550,000 new cases/year.

- Prevalence: ~1,500,000 patients.

- Treatment-eligible: ~40% (~600,000 patients, lower due to access issues).

- **Japan**:

- Incidence: ~150,000 new cases/year.

- Prevalence: ~500,000 patients.

- Treatment-eligible: ~50% (~250,000 patients).

Total Treated Patients (Eligible for Capecitabine):

- US: 250,000

- EU5: 500,000

- China: 600,000

- Japan: 250,000

- **Total**: 1,600,000 patients

Step 3: Estimate Capecitabine's Share of Treated Patients

- Assuming a 20% to 30% market share:

- **20% Share**: 1,600,000 × 0.20 = 320,000 patients.

- **30% Share**: 1,600,000 × 0.30 = 480,000 patients.

Step 4: Estimate Annual Treatment Cost per Patient

Capecitabine is generic, so costs vary by region due to healthcare systems and pricing structures:

- **US**: ~$5,000–$10,000/year (generic pricing, depending on dosage and duration).

- **EU5**: ~$3,000–$6,000/year (lower due to price controls).

- **China**: ~$1,500–$3,000/year (lower pricing and access issues).

- **Japan**: ~$4,000–$7,000/year (similar to EU5 but with higher reimbursement rates).

For simplicity, I'll use an average cost per patient per year:

- US: $7,500

- EU5: $4,500

- China: $2,000

- Japan: $5,500

Step 5: Calculate Potential Peak Sales

Using the treated patient numbers and average cost per patient, we calculate peak sales for 20% and 30% market shares.

At 20% Market Share (320,000 patients):

- **US**: 250,000 × 0.20 = 50,000 patients × $7,500 = **$375M**

- **EU5**: 500,000 × 0.20 = 100,000 patients × $4,500 = **$450M**

- **China**: 600,000 × 0.20 = 120,000 patients × $2,000 = **$240M**

- **Japan**: 250,000 × 0.20 = 50,000 patients × $5,500 = **$275M**

- **Total Peak Sales (20%)**: $375M + $450M + $240M + $275M = **$1,340M (or ~$1.34B)**

At 30% Market Share (480,000 patients):

- **US**: 250,000 × 0.30 = 75,000 patients × $7,500 = **$562.5M**

- **EU5**: 500,000 × 0.30 = 150,000 patients × $4,500 = **$675M**

- **China**: 600,000 × 0.30 = 180,000 patients × $2,000 = **$360M**

- **Japan**: 250,000 × 0.30 = 75,000 patients × $5,500 = **$412.5M**

- **Total Peak Sales (30%)**: $562.5M + $675M + $360M + $412.5M = **$2,010M (or ~$2.01B)**

Potential Peak Sales Range: **$1.34B to $2.01B** annually across US, EU5, China, and Japan for a 20% to 30% share of treated patients.

Step 6: Calculate $ Value of 1% Share of Treated Patients

A 1% share of treated patients = 1,600,000 × 0.01 = 16,000 patients.

- **US**: 250,000 × 0.01 = 2,500 patients × $7,500 = **$18.75M**

- **EU5**: 500,000 × 0.01 = 5,000 patients × $4,500 = **$22.5M**

- **China**: 600,000 × 0.01 = 6,000 patients × $2,000 = **$12M**

- **Japan**: 250,000 × 0.01 = 2,500 patients × $5,500 = **$13.75M**

- **Total $ Value of 1% Share**: $18.75M + $22.5M + $12M + $13.75M = **$67M**

$ Value of 1% Share of Treated Patients: **$67M** annually across US, EU5, China, and Japan.

Final Answer:

- **Potential Peak Sales for Capecitabine Tablets** (20% to 30% share of treated patients):

- **$1.34 Billion to $2.01 Billion** annually across US, EU5, China, and Japan.

- **$ Value of 1% Share of Treated Patients**:

- **$67 Million** annually across US, EU5, China, and Japan.

Caveats:

1. These estimates are based on colorectal cancer as the indication. If the specific indication differs (e.g., breast or gastric cancer), the patient population and market share may vary.

2. Pricing for generic capecitabine can fluctuate based on local competition and healthcare policies.

3. Market access, reimbursement, and competition from other therapies (e.g., biologics, other chemotherapies) could impact the assumed market share.

4. The Project Renewal labeling update may not significantly expand the eligible patient pool unless new indications or combinations are approved.

For more precise figures, detailed epidemiology data, specific indication details, and current market dynamics would be required. If you have additional information on the specific indication or market, I can refine the analysis further.