To calculate the **Potential Peak Sales** for ponatinib (Iclusig) in the indication of newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) 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 on patient numbers, pricing, and market penetration may not be fully available, I will outline the methodology, make reasonable assumptions based on publicly available information, and provide a framework for the calculation. You can refine these numbers with more precise data if available.

Step 1: Define Key Parameters

To estimate potential peak sales and the value of a 1% share of treated patients, we need:

1. **Total addressable patient population** for Ph+ ALL in each geography (US, EU5, China, Japan).

2. **Percentage of patients treated** (assuming 20% to 30% share of treated patients as per the query).

3. **Annual cost of treatment** per patient for ponatinib in each geography (varies by region due to pricing differences).

4. **Peak sales** calculated as: (Number of treated patients) × (Annual cost per patient).

5. **Value of 1% share of treated patients** calculated as: (Total treated patients) × (1%) × (Annual cost per patient).

Indication Context:

- Ponatinib (Iclusig) is approved for newly diagnosed Ph+ ALL in combination with chemotherapy.

- Ph+ ALL is a subtype of acute lymphoblastic leukemia (ALL) characterized by the Philadelphia chromosome. It accounts for approximately **25-30% of adult ALL cases**.

Step 2: Estimate Addressable Patient Population

We need the number of newly diagnosed Ph+ ALL patients annually in each geography. Since exact numbers may not be available, we can estimate based on cancer incidence data and the proportion of Ph+ ALL.

Assumptions for Patient Population:

- **US**: Approximately 6,000 new ALL cases per year (American Cancer Society). Assuming 25-30% are Ph+ ALL, this is ~1,500-1,800 patients.

- **EU5**: ALL incidence is roughly similar per capita to the US. EU5 population is ~330 million (vs. US ~330 million), so estimate ~6,000 ALL cases, of which 25-30% are Ph+ ALL, i.e., ~1,500-1,800 patients.

- **China**: China has a population of ~1.4 billion. ALL incidence may be lower per capita due to demographic and healthcare access differences, but estimate ~10,000-12,000 ALL cases, of which 25-30% are Ph+ ALL, i.e., ~2,500-3,600 patients.

- **Japan**: Population ~125 million. ALL incidence ~2,000-2,500 cases, of which 25-30% are Ph+ ALL, i.e., ~500-750 patients.

Total Addressable Patients (Midpoint Estimate):

- US: 1,650

- EU5: 1,650

- China: 3,050

- Japan: 625

- **Total**: 6,975 patients annually

Step 3: Estimate Treated Patients (20%-30% Market Share)

Assuming ponatinib captures **20% to 30% of treated patients**, the number of patients treated with ponatinib would be:

- **20% Share**:

- US: 1,650 × 20% = 330

- EU5: 1,650 × 20% = 330

- China: 3,050 × 20% = 610

- Japan: 625 × 20% = 125

- **Total**: 1,395 patients

- **30% Share**:

- US: 1,650 × 30% = 495

- EU5: 1,650 × 30% = 495

- China: 3,050 × 30% = 915

- Japan: 625 × 30% = 188

- **Total**: 2,093 patients

Step 4: Estimate Annual Cost of Treatment per Patient

The cost of ponatinib varies by geography due to differences in healthcare systems, pricing regulations, and market dynamics. Based on available data for ponatinib (used in chronic myeloid leukemia and ALL):

- **US**: Annual cost ~$150,000–$180,000 per patient (based on list prices for specialty oncology drugs).

- **EU5**: Annual cost ~$80,000–$100,000 per patient (lower due to negotiated pricing and health system discounts).

- **China**: Annual cost ~$30,000–$50,000 per patient (lower pricing due to market access programs and generics competition).

- **Japan**: Annual cost ~$80,000–$100,000 per patient (similar to EU5 due to regulated pricing).

Midpoint Annual Cost Assumptions:

- US: $165,000

- EU5: $90,000

- China: $40,000

- Japan: $90,000

Step 5: Calculate Potential Peak Sales

Peak sales are calculated as (Number of treated patients) × (Annual cost per patient) for each geography at 20% and 30% market share.

At 20% Market Share:

- **US**: 330 patients × $165,000 = **$54.5 million**

- **EU5**: 330 patients × $90,000 = **$29.7 million**

- **China**: 610 patients × $40,000 = **$24.4 million**

- **Japan**: 125 patients × $90,000 = **$11.3 million**

- **Total Peak Sales (20% Share)**: $54.5M + $29.7M + $24.4M + $11.3M = **$120.0 million**

At 30% Market Share:

- **US**: 495 patients × $165,000 = **$81.7 million**

- **EU5**: 495 patients × $90,000 = **$44.6 million**

- **China**: 915 patients × $40,000 = **$36.6 million**

- **Japan**: 188 patients × $90,000 = **$16.9 million**

- **Total Peak Sales (30% Share)**: $81.7M + $44.6M + $36.6M + $16.9M = **$179.8 million**

Potential Peak Sales Range: **$120.0 million to $179.8 million annually** across the specified geographies for Ph+ ALL.

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

A 1% share of treated patients corresponds to 1% of the total addressable patient population in each geography. The value is calculated as (1% of total patients) × (Annual cost per patient).

- **US**: 1% of 1,650 = 16.5 patients × $165,000 = **$2.72 million**

- **EU5**: 1% of 1,650 = 16.5 patients × $90,000 = **$1.49 million**

- **China**: 1% of 3,050 = 30.5 patients × $40,000 = **$1.22 million**

- **Japan**: 1% of 625 = 6.25 patients × $90,000 = **$0.56 million**

- **Total Value of 1% Share**: $2.72M + $1.49M + $1.22M + $0.56M = **$5.99 million**

$ Value of 1% Share of Treated Patients: Approximately **$6.0 million annually** across all geographies.

Final Answer:

1. **Potential Peak Sales for Ponatinib in Ph+ ALL** (assuming 20%-30% market share):

- **US, EU5, China, Japan Combined**: **$120.0 million to $179.8 million annually**

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

- US: $54.5M / $81.7M

- EU5: $29.7M / $44.6M

- China: $24.4M / $36.6M

- Japan: $11.3M / $16.9M

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

- **US, EU5, China, Japan Combined**: **$6.0 million annually**

- Breakdown by geography:

- US: $2.72M

- EU5: $1.49M

- China: $1.22M

- Japan: $0.56M

Notes and Caveats:

- These estimates are based on assumptions for patient population, market share, and pricing. Actual numbers may vary based on real-world data, competition (e.g., other TKIs like imatinib or dasatinib), market access, and reimbursement policies.

- The calculations assume all diagnosed patients are eligible for treatment, which may not be true due to comorbidities, access issues, or physician preferences.

- Pricing may change over time due to generics, biosimilars, or pricing negotiations.

- Peak sales may take several years to achieve post-launch and depend on clinical adoption rates and trial outcomes.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market share projections), these estimates can be refined further.