To estimate the **Potential Peak Sales** for brigatinib (ALUNBRIG) in the indication of ALK-positive metastatic non-small cell lung cancer (NSCLC) in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **$ value of a 1% share of treated patients** in these geographies, we need to make several assumptions and follow a structured approach. Since specific data on patient populations, pricing, and market penetration may not be publicly available in real-time, this analysis will use reasonable estimates based on industry trends, epidemiology data, and market research norms. Here's the step-by-step process:

Key Assumptions and Inputs

1. **Indication**: ALK-positive metastatic NSCLC.

- Approximately 3-5% of NSCLC patients are ALK-positive, representing a small but significant subset of the NSCLC population.

2. **Market Share**: Assuming brigatinib captures 20% to 30% of treated ALK-positive NSCLC patients in the specified geographies.

3. **Patient Population**: Estimated number of ALK-positive NSCLC patients in each geography.

4. **Pricing**: Annual treatment cost of brigatinib is estimated based on publicly available data or analogs (e.g., other ALK inhibitors like crizotinib or alectinib).

5. **Treatment Duration**: Assumed to be 1 year for peak sales calculation (simplified assumption; in reality, it depends on progression-free survival and patient adherence).

6. **Geographies**: US, EU5 (combined), China, and Japan.

Step 1: Estimate the Total Addressable Patient Population

- **NSCLC Incidence**: Using epidemiology data, we estimate the total NSCLC incidence and apply the 3-5% ALK-positive rate.

- **US**: ~230,000 new NSCLC cases/year $\rightarrow$ ~6,900-11,500 ALK-positive patients.

- **EU5**: ~300,000 new NSCLC cases/year $\rightarrow$ ~9,000-15,000 ALK-positive patients.

- **China**: ~735,000 new NSCLC cases/year $\rightarrow$ ~22,000-36,750 ALK-positive patients.

- **Japan**: ~125,000 new NSCLC cases/year $\rightarrow$ ~3,750-6,250 ALK-positive patients.

- For simplicity, we'll use the midpoint of the range:

- US: ~9,200 patients

- EU5: ~12,000 patients

- China: ~29,375 patients

- Japan: ~5,000 patients

- **Total Addressable Population**: ~55,575 ALK-positive NSCLC patients across these geographies.

Step 2: Estimate Treated Patients

- Not all diagnosed patients receive treatment due to factors like late-stage diagnosis, comorbidities, or lack of access. Assume ~70% of diagnosed ALK-positive patients are treated with targeted therapies:

- US: 9,200 × 70% = ~6,440 treated patients

- EU5: 12,000 × 70% = ~8,400 treated patients

- China: 29,375 × 70% = ~20,563 treated patients

- Japan: 5,000 × 70% = ~3,500 treated patients

- **Total Treated Patients**: ~38,903 patients.

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

- Assuming brigatinib captures 20%-30% of treated patients:

- At 20% share:

- US: 6,440 × 20% = 1,288 patients

- EU5: 8,400 × 20% = 1,680 patients

- China: 20,563 × 20% = 4,113 patients

- Japan: 3,500 × 20% = 700 patients

- **Total**: 7,781 patients

- At 30% share:

- US: 6,440 × 30% = 1,932 patients

- EU5: 8,400 × 30% = 2,520 patients

- China: 20,563 × 30% = 6,169 patients

- Japan: 3,500 × 30% = 1,050 patients

- **Total**: 11,671 patients

Step 4: Estimate Annual Treatment Cost

- Brigatinib's annual cost varies by region due to pricing differences, reimbursement policies, and healthcare systems. Based on available data for ALK inhibitors:

- US: ~$200,000 per patient per year (list price before discounts/rebates).

- EU5: ~$120,000 per patient per year (lower due to negotiated pricing).

- China: ~$50,000 per patient per year (lower pricing due to market access challenges and generics competition).

- Japan: ~$150,000 per patient per year (similar to EU/US but with some variation).

Step 5: Calculate Potential Peak Sales

- **Peak Sales at 20% Market Share**:

- US: 1,288 patients × $200,000 = $257.6 million

- EU5: 1,680 patients × $120,000 = $201.6 million

- China: 4,113 patients × $50,000 = $205.7 million

- Japan: 700 patients × $150,000 = $105.0 million

- **Total Peak Sales (20% share)**: ~$770 million

- **Peak Sales at 30% Market Share**:

- US: 1,932 patients × $200,000 = $386.4 million

- EU5: 2,520 patients × $120,000 = $302.4 million

- China: 6,169 patients × $50,000 = $308.5 million

- Japan: 1,050 patients × $150,000 = $157.5 million

- **Total Peak Sales (30% share)**: ~$1,155 million

- **Range of Potential Peak Sales**: **$770 million to $1,155 million annually**.

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

- 1% of treated patients corresponds to:

- US: 6,440 × 1% = 64.4 patients

- EU5: 8,400 × 1% = 84 patients

- China: 20,563 × 1% = 205.6 patients

- Japan: 3,500 × 1% = 35 patients

- Revenue for 1% share:

- US: 64.4 patients × $200,000 = $12.9 million

- EU5: 84 patients × $120,000 = $10.1 million

- China: 205.6 patients × $50,000 = $10.3 million

- Japan: 35 patients × $150,000 = $5.3 million

- **Total $ Value of 1% Share**: ~$38.6 million annually.

Final Answer

1. **Potential Peak Sales for Brigatinib** in ALK-positive metastatic NSCLC (20%-30% market share):

- **US, EU5, China, Japan Combined**: **$770 million to $1,155 million annually**.

- Breakdown by region:

- US: $257.6M - $386.4M

- EU5: $201.6M - $302.4M

- China: $205.7M - $308.5M

- Japan: $105.0M - $157.5M

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

- **US, EU5, China, Japan Combined**: **$38.6 million annually**.

- Breakdown by region:

- US: $12.9M

- EU5: $10.1M

- China: $10.3M

- Japan: $5.3M

Caveats and Notes

- These estimates are based on assumptions for patient numbers, treatment rates, pricing, and market share. Real-world data may vary due to competition (e.g., other ALK inhibitors like alectinib, lorlatinib), reimbursement policies, and patient access.

- Peak sales typically occur several years after launch, depending on market penetration and patent exclusivity (brigatinib was approved in the US in 2017).

- Pricing in China may be lower due to recent healthcare reforms and inclusion in national reimbursement lists, which could reduce per-patient revenue.

- Adjustments may be needed for real-world treatment duration, discounts, and patient compliance.

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