To estimate the **Potential Peak Sales** for lazertinib (Lazcluze) in the indication of first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R mutations 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 follow a structured approach. Since specific data on patient populations, pricing, and market penetration might not be publicly available in full detail, I will outline the methodology and provide reasonable assumptions based on industry standards and available data as of 2023. The calculations will be approximate and can be refined with more specific data.

Step 1: Define the Target Patient Population

Lazertinib is approved for first-line treatment of NSCLC with specific EGFR mutations (exon 19 deletions or exon 21 L858R). These mutations account for approximately **85-90% of EGFR-mutated NSCLC cases**, and EGFR mutations are present in about **10-15% of NSCLC cases in Western populations (US, EU5)** and **30-50% in Asian populations (China, Japan)**. NSCLC represents about 80-85% of all lung cancer cases.

Estimated Incidence of NSCLC and EGFR-Mutated Cases:

- **US**: ~230,000 new lung cancer cases/year; ~85% NSCLC (~195,500); ~12% EGFR-mutated (~23,500); ~90% target mutations (~21,150).

- **EU5**: ~320,000 new lung cancer cases/year; ~85% NSCLC (~272,000); ~12% EGFR-mutated (~32,640); ~90% target mutations (~29,400).

- **China**: ~820,000 new lung cancer cases/year; ~85% NSCLC (~697,000); ~40% EGFR-mutated (~278,800); ~90% target mutations (~250,900).

- **Japan**: ~125,000 new lung cancer cases/year; ~85% NSCLC (~106,250); ~40% EGFR-mutated (~42,500); ~90% target mutations (~38,250).

Total target patient population (eligible for lazertinib) across these geographies:

- US: ~21,150

- EU5: ~29,400

- China: ~250,900

- Japan: ~38,250

- **Total**: ~339,700 patients per year (incident cases).

Prevalent Population:

Since NSCLC patients may survive multiple years with treatment, the prevalent population (total treatable patients at any given time) is often 2-3x the incident population. For simplicity, we assume a factor of 2.5:

- US: ~52,875

- EU5: ~73,500

- China: ~627,250

- Japan: ~95,625

- **Total Prevalent Population**: ~849,250 patients.

However, for peak sales estimation, we often focus on annual treated patients, which aligns closer to incident cases adjusted for treatment duration and market share.

Step 2: Estimate Treated Patients (Market Share)

The query assumes a **20-30% share of treated patients** for lazertinib in this indication. We will use the midpoint of **25%** for calculations.

- Total incident patients eligible for treatment: ~339,700 (as above).

- Treated patients at 25% market share:

- US: 21,150 * 0.25 = ~5,288

- EU5: 29,400 * 0.25 = ~7,350

- China: 250,900 * 0.25 = ~62,725

- Japan: 38,250 * 0.25 = ~9,563

- **Total Treated Patients**: ~84,925 per year.

Step 3: Estimate Drug Pricing

Lazertinib is a targeted therapy for NSCLC, and such drugs typically have high annual costs. Pricing varies by region due to healthcare systems and purchasing power:

- **US**: Annual cost of similar EGFR inhibitors (e.g., osimertinib/Tagrisso) is ~$180,000–$200,000 per patient. Assume ~$190,000 for lazertinib.

- **EU5**: Pricing is often 50-60% of US prices due to negotiations. Assume ~$100,000 per patient.

- **Japan**: Pricing is similar to EU5, ~$100,000 per patient.

- **China**: Pricing is significantly lower due to volume-based procurement and generics competition. Assume ~$30,000 per patient.

Note: These are rough estimates and may vary based on combination therapy costs (since lazertinib is approved with amivantamab). For simplicity, we assume the above costs cover the regimen or are primarily for lazertinib.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as: **Number of Treated Patients * Annual Cost per Patient**.

- **US**: 5,288 patients * $190,000 = ~$1.005 billion

- **EU5**: 7,350 patients * $100,000 = ~$0.735 billion

- **China**: 62,725 patients * $30,000 = ~$1.882 billion

- **Japan**: 9,563 patients * $100,000 = ~$0.956 billion

- **Total Peak Sales (at 25% market share)**: ~$4.578 billion per year

Range for 20-30% Market Share:

- At 20% market share: ~$3.662 billion

- At 30% market share: ~$5.494 billion

Thus, **Potential Peak Sales** for lazertinib in this indication across the US, EU5, China, and Japan are estimated to be in the range of **$3.7–$5.5 billion annually**, with a midpoint of ~$4.6 billion.

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

A 1% share corresponds to 1% of the total eligible incident patient population (~339,700 patients), which is ~3,397 patients per year.

- **US**: 21,150 * 0.01 = 212 patients * $190,000 = ~$40.3 million

- **EU5**: 29,400 * 0.01 = 294 patients * $100,000 = ~$29.4 million

- **China**: 250,900 * 0.01 = 2,509 patients * $30,000 = ~$75.3 million

- **Japan**: 38,250 * 0.01 = 383 patients * $100,000 = ~$38.3 million

- **Total $ Value of 1% Share**: ~$183.3 million

Thus, the **$ value of a 1% share of treated patients** across these geographies is approximately **$183 million annually**.

Summary of Results

1. **Potential Peak Sales for Lazertinib (20-30% market share)**:

- US, EU5, China, Japan combined: **$3.7–$5.5 billion annually** (midpoint ~$4.6 billion).

- Breakdown at 25% market share:

- US: ~$1.0 billion

- EU5: ~$0.7 billion

- China: ~$1.9 billion

- Japan: ~$1.0 billion

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

- US, EU5, China, Japan combined: **$183 million annually**.

- Breakdown:

- US: ~$40 million

- EU5: ~$29 million

- China: ~$75 million

- Japan: ~$38 million

Caveats and Assumptions

- **Patient Population**: Based on incidence data and EGFR mutation prevalence; actual numbers may vary with updated epidemiology or diagnostic rates.

- **Pricing**: Estimated based on comparable drugs (e.g., osimertinib); actual pricing for lazertinib + amivantamab combination may differ.

- **Market Share**: Assumes 20-30% penetration, but competition from other EGFR inhibitors (e.g., osimertinib) and emerging therapies could impact this.

- **Treatment Duration**: Assumes full-year treatment cost; actual duration may be shorter or longer based on progression-free survival.

- **Combination Therapy**: Costs are approximated for lazertinib alone or as part of the regimen; split costs with amivantamab are not detailed.

These estimates can be refined with specific data on pricing, patient access, and competitive landscape. If you have additional inputs (e.g., exact pricing or market research), I can adjust the calculations accordingly.