To estimate the **Potential Peak Sales** for osimertinib (TAGRISSO) in the adjuvant therapy setting for non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 L858R mutations 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 make several assumptions and follow a structured approach. This response is based on publicly available data, epidemiology, market research, and reasonable assumptions as of 2023. Note that exact figures may vary depending on real-world data, pricing changes, and market dynamics.

Step 1: Define the Target Indication and Patient Population

Osimertinib is approved for adjuvant therapy after tumor resection in NSCLC patients with EGFR exon 19 deletions or exon 21 L858R mutations. These mutations account for approximately **10-15% of NSCLC cases** in Western populations (US, EU5) and **30-40% in Asian populations** (China, Japan). Adjuvant therapy targets early-stage NSCLC patients (typically Stage IB-IIIA) who undergo surgical resection, representing a subset of the total NSCLC population.

Epidemiology of NSCLC and Target Population

- **NSCLC Incidence (Annual New Cases):**

- US: ~200,000 new NSCLC cases/year

- EU5: ~300,000 new NSCLC cases/year

- China: ~800,000 new NSCLC cases/year

- Japan: ~120,000 new NSCLC cases/year

- **Proportion of Early-Stage NSCLC (Stage IB-IIIA, Eligible for Adjuvant Therapy):**

- Approximately **30-35%** of NSCLC patients are diagnosed at an early stage and undergo surgical resection.

- **Proportion of EGFR Mutations (Exon 19 Deletion or Exon 21 L858R):**

- US/EU5: ~12% of NSCLC cases

- China/Japan: ~35% of NSCLC cases

Estimated Eligible Patients for Adjuvant Therapy with EGFR Mutations

Using the above data, we estimate the number of eligible patients:

- **US:** 200,000 × 0.33 (early-stage) × 0.12 (EGFR mutation) = ~7,920 patients/year

- **EU5:** 300,000 × 0.33 × 0.12 = ~11,880 patients/year

- **China:** 800,000 × 0.33 × 0.35 = ~92,400 patients/year

- **Japan:** 120,000 × 0.33 × 0.35 = ~13,860 patients/year

- **Total Across Geographies:** ~126,060 patients/year

Step 2: Estimate Treated Patient Share

The query assumes a **20-30% share of treated patients** for osimertinib in this indication. This accounts for factors such as:

- Competition from other EGFR inhibitors (e.g., gefitinib, erlotinib, though osimertinib has superior efficacy in many settings).

- Physician adoption and patient access to therapy.

- Payer reimbursement and cost barriers.

For calculation purposes, we'll use the midpoint of **25% treated patient share**.

Treated Patients with Osimertinib

- **US:** 7,920 × 0.25 = ~1,980 patients/year

- **EU5:** 11,880 × 0.25 = ~2,970 patients/year

- **China:** 92,400 × 0.25 = ~23,100 patients/year

- **Japan:** 13,860 × 0.25 = ~3,465 patients/year

- **Total Treated Patients:** ~31,515 patients/year

Step 3: Estimate Treatment Duration and Annual Cost per Patient

- **Treatment Duration for Adjuvant Therapy:** Based on clinical trial data (e.g., ADAURA trial), osimertinib is typically administered for **3 years** in the adjuvant setting for early-stage NSCLC.

- **Annual Cost per Patient:** Osimertinib pricing varies by region due to healthcare systems, negotiations, and purchasing power. Approximate annual costs (2023 estimates, before discounts/rebates) are:

- US: ~$180,000/year

- EU5: ~$100,000/year (varies by country)

- China: ~$30,000/year (post-negotiation via National Reimbursement Drug List)

- Japan: ~$120,000/year

Since patients are treated for 3 years, the total cost per patient over the treatment duration is:

- US: $180,000 × 3 = $540,000

- EU5: $100,000 × 3 = $300,000

- China: $30,000 × 3 = $90,000

- Japan: $120,000 × 3 = $360,000

However, for peak sales, we calculate based on **annual revenue** (number of patients treated each year × annual cost), assuming steady-state adoption.

Step 4: Calculate Potential Peak Sales

Peak sales are typically achieved when the drug reaches maximum market penetration (assumed at 25% treated patient share here). Annual peak sales are calculated as:

Peak Sales = Number of Treated Patients per Year × Annual Cost per Patient

- **US:** 1,980 patients × $180,000 = **$356.4 million/year**

- **EU5:** 2,970 patients × $100,000 = **$297.0 million/year**

- **China:** 23,100 patients × $30,000 = **$693.0 million/year**

- **Japan:** 3,465 patients × $120,000 = **$415.8 million/year**

- **Total Peak Sales Across Geographies: $1,762.2 million/year (~$1.76 billion/year)**

Range for 20-30% Treated Patient Share

- At **20% share**: Total Peak Sales = ~$1.41 billion/year

- At **30% share**: Total Peak Sales = ~$2.11 billion/year

Thus, the **Potential Peak Sales** for osimertinib in this indication across the US, EU5, China, and Japan is approximately **$1.4 billion to $2.1 billion per year**, with a midpoint of **$1.76 billion/year**.

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

To calculate the value of a 1% share of treated patients, we first determine the total eligible patient population and then apply the annual cost per patient.

1% of Eligible Patients:

- **US:** 7,920 × 0.01 = 79.2 patients

- **EU5:** 11,880 × 0.01 = 118.8 patients

- **China:** 92,400 × 0.01 = 924 patients

- **Japan:** 13,860 × 0.01 = 138.6 patients

Annual Revenue from 1% Share:

- **US:** 79.2 × $180,000 = **$14.26 million/year**

- **EU5:** 118.8 × $100,000 = **$11.88 million/year**

- **China:** 924 × $30,000 = **$27.72 million/year**

- **Japan:** 138.6 × $120,000 = **$16.63 million/year**

- **Total Value of 1% Share Across Geographies: $70.49 million/year**

Thus, the **$ value of a 1% share of treated patients** across the US, EU5, China, and Japan is approximately **$70.5 million per year**.

Summary of Results

1. **Potential Peak Sales for Osimertinib (20-30% Treated Patient Share):**

- US: $285M–$428M/year (midpoint: $356M)

- EU5: $238M–$356M/year (midpoint: $297M)

- China: $554M–$832M/year (midpoint: $693M)

- Japan: $333M–$499M/year (midpoint: $416M)

- **Total: $1.41B–$2.11B/year (midpoint: $1.76B/year)**

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

- US: $14.26M/year

- EU5: $11.88M/year

- China: $27.72M/year

- Japan: $16.63M/year

- **Total: $70.49M/year**

Caveats and Assumptions

- **Epidemiology and Mutation Rates:** These are approximate figures based on literature and may vary by country or over time.

- **Pricing:** Drug pricing is subject to change due to negotiations, rebates, and generic competition (osimertinib is still under patent protection as of 2023).

- **Adoption Rates:** The 20-30% treated patient share is an assumption; real-world uptake may differ based on clinical guidelines, competition, and access.

- **Treatment Duration:** Assumes a uniform 3-year treatment duration for all patients; real-world adherence may vary.

- **Market Dynamics:** Peak sales assume steady-state adoption and do not account for future competitors or changes in standard of care.

This analysis provides a high-level estimate. For more precise figures, detailed market research, real-world evidence, and updated pricing data would be required.