

To estimate the **Potential Peak Sales** for osimertinib (Tagrisso) in the specified indication (locally advanced, unresectable Stage III 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 follow a structured approach. Since specific data such as exact patient numbers or pricing may not be publicly available in real-time, I will outline the methodology using reasonable assumptions based on available epidemiology data, market trends, and drug pricing. This response will provide a framework and approximate figures, which can be refined with more precise data if available.

## **Step 1: Define the Target Patient Population**

Osimertinib is approved for Stage III NSCLC patients with specific EGFR mutations (exon 19 deletions or exon 21 L858R) who have not progressed after platinum-based chemoradiation. We need to estimate the number of eligible patients in each geography.

- **NSCLC Incidence:** NSCLC accounts for ~85% of all lung cancer cases. Stage III NSCLC represents ~30% of NSCLC cases.
- **EGFR Mutation Prevalence:** EGFR mutations are present in ~10-15% of NSCLC patients in Western populations (US, EU5) and ~30-40% in Asian populations (China, Japan).
- **Stage III Unresectable:** Of Stage III patients, ~50-60% are unresectable and eligible for chemoradiation.
- **Non-progression after Chemoradiation:** ~60-70% of patients do not progress during or following chemoradiation and could be eligible for osimertinib.

### #### Approximate Eligible Patient Numbers (Annual Incidence)

Using rough estimates based on cancer incidence data (e.g., from GLOBOCAN, SEER, or market research reports):

- **US:**
  - Total lung cancer incidence: ~230,000 cases/year.
  - NSCLC: ~195,500 cases (85%).
  - Stage III: ~58,650 cases (30%).
  - Unresectable: ~35,190 cases (60%).
  - EGFR mutation: ~3,519-5,279 cases (10-15%).
  - Non-progression: ~2,111-3,167 cases (60%).
- **EU5:**
  - Total lung cancer incidence: ~300,000 cases/year.
  - NSCLC: ~255,000 cases.
  - Stage III: ~76,500 cases.
  - Unresectable: ~45,900 cases.
  - EGFR mutation: ~4,590-6,885 cases (10-15%).
  - Non-progression: ~2,754-4,131 cases.

**- China:**

- Total lung cancer incidence: ~800,000 cases/year.
- NSCLC: ~680,000 cases.
- Stage III: ~204,000 cases.
- Unresectable: ~122,400 cases.
- EGFR mutation: ~36,720-48,960 cases (30-40%).
- Non-progression: ~22,032-29,376 cases.

**- Japan:**

- Total lung cancer incidence: ~130,000 cases/year.
- NSCLC: ~110,500 cases.
- Stage III: ~33,150 cases.
- Unresectable: ~19,890 cases.
- EGFR mutation: ~5,967-7,956 cases (30-40%).
- Non-progression: ~3,580-4,774 cases.

**Total Eligible Patients (Approximate Midpoint):**

- US: ~2,640 patients/year.
- EU5: ~3,440 patients/year.
- China: ~25,700 patients/year.
- Japan: ~4,180 patients/year.
- **Total across geographies:** ~36,000 patients/year.

**Step 2: Market Share Assumption (20% to 30%)**

Assuming osimertinib captures **20-30% of treated patients** in this indication:

**- Treated Patients:**

- US: 528-792 patients.
- EU5: 688-1,032 patients.
- China: 5,140-7,710 patients.
- Japan: 836-1,254 patients.
- **Total:** 7,192-10,788 patients.

**Step 3: Pricing of Osimertinib**

Osimertinib's pricing varies by region due to healthcare systems, negotiations, and market access. Approximate annual cost per patient (based on historical data and market reports for NSCLC)

indication):

- **US:** ~\$180,000/year (list price, though discounts/rebates may apply).
- **EU5:** ~\$100,000-\$120,000/year (varies by country due to pricing negotiations).
- **China:** ~\$50,000-\$70,000/year (lower due to price controls and inclusion in National Reimbursement Drug List).
- **Japan:** ~\$100,000-\$130,000/year (similar to EU5, adjusted for local pricing).

Using midpoint values for simplicity:

- US: \$180,000.
- EU5: \$110,000.
- China: \$60,000.
- Japan: \$115,000.

#### **Step 4: Calculate Potential Peak Sales (20-30% Market Share)**

Peak sales are calculated as (number of treated patients) × (annual cost per patient).

- **US:**

- 20% share (528 patients):  $528 \times \$180,000 = \text{\$95 million}$ .
- 30% share (792 patients):  $792 \times \$180,000 = \text{\$142 million}$ .

- **EU5:**

- 20% share (688 patients):  $688 \times \$110,000 = \text{\$76 million}$ .
- 30% share (1,032 patients):  $1,032 \times \$110,000 = \text{\$113 million}$ .

- **China:**

- 20% share (5,140 patients):  $5,140 \times \$60,000 = \text{\$308 million}$ .
- 30% share (7,710 patients):  $7,710 \times \$60,000 = \text{\$463 million}$ .

- **Japan:**

- 20% share (836 patients):  $836 \times \$115,000 = \text{\$96 million}$ .
- 30% share (1,254 patients):  $1,254 \times \$115,000 = \text{\$144 million}$ .

**Total Peak Sales Across Geographies:**

- 20% share: \$95M (US) + \$76M (EU5) + \$308M (China) + \$96M (Japan) = **\$575 million**.
- 30% share: \$142M (US) + \$113M (EU5) + \$463M (China) + \$144M (Japan) = **\$862 million**.

**Potential Peak Sales Range: \$575 million to \$862 million annually.**

#### **Step 5: \$ Value of 1% Share of Treated Patients**

A 1% share of treated patients corresponds to 1% of the total eligible patient pool in each geography.

- **US:** 2,640 patients  $\times$  1% = 26.4 patients  $\times$  \$180,000 = **\$4.75 million.**

- **EU5:** 3,440 patients  $\times$  1% = 34.4 patients  $\times$  \$110,000 = **\$3.78 million.**

- **China:** 25,700 patients  $\times$  1% = 257 patients  $\times$  \$60,000 = **\$15.42 million.**

- **Japan:** 4,180 patients  $\times$  1% = 41.8 patients  $\times$  \$115,000 = **\$4.81 million.**

**Total \$ Value of 1% Share Across Geographies:** \$4.75M (US) + \$3.78M (EU5) + \$15.42M (China) + \$4.81M (Japan) = **\$28.76 million.**

## **Final Answer**

- **Potential Peak Sales for Osimertinib (20-30% market share)** in the US, EU5, China, and Japan for the specified indication: **\$575 million to \$862 million annually.**

- **\$ Value of 1% Share of Treated Patients** across these geographies: **\$28.76 million.**

## **Caveats and Notes**

1. These figures are rough estimates based on assumed epidemiology, mutation rates, pricing, and market penetration. Real-world data may vary due to factors like competition (e.g., other EGFR inhibitors), reimbursement policies, and actual patient access.

2. Peak sales may take several years to achieve post-approval as market uptake ramps up.

3. Pricing assumptions may differ based on discounts, rebates, or local negotiations (e.g., China's volume-based procurement could lower costs further).

4. The analysis assumes annual treatment duration; if treatment duration is shorter or longer, sales estimates would adjust accordingly.

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