

To estimate the **Potential Peak Sales** for osimertinib (Tagrisso) in the indication of locally advanced or metastatic non-small cell lung cancer (la/mNSCLC) 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 exact patient numbers, pricing, and market penetration data are not provided, I will outline the methodology and use reasonable assumptions based on publicly available data and market trends.

Please note that these are illustrative calculations and should be validated with up-to-date epidemiology data, pricing information, and market research.

****Step 1: Key Assumptions and Inputs****

1. Indication and Target Population:

- Osimertinib is approved for la/mNSCLC patients with EGFR exon 19 deletions or exon 21 L858R mutations.
- EGFR mutations account for approximately 10-15% of NSCLC cases in Western countries (US, EU5) and 30-40% in Asian countries (China, Japan).
- We will estimate the total NSCLC patient population and apply these mutation rates to identify the eligible patient pool.

2. Market Share:

- The problem states a 20% to 30% share of treated patients. We will calculate peak sales using both ends of this range.

3. Pricing:

- Osimertinib's annual cost per patient is approximately \$150,000-\$180,000 in the US (based on historical data for Tagrisso). For EU5, we assume a discount (~30-40% lower than US pricing), and for China and Japan, further discounts due to pricing controls (~50-60% lower than US pricing).
- Assumed annual costs:
 - US: \$150,000
 - EU5: \$100,000
 - China: \$75,000
 - Japan: \$90,000

4. Epidemiology (Estimated NSCLC Incidence and Eligible Patients):

- NSCLC accounts for ~85% of lung cancer cases.
- Incidence of lung cancer (per year, approximate):
 - US: ~230,000 cases → NSCLC: ~195,000 → EGFR mutated (15%): ~29,250
 - EU5: ~300,000 cases → NSCLC: ~255,000 → EGFR mutated (15%): ~38,250

- China: ~800,000 cases → NSCLC: ~680,000 → EGFR mutated (35%): ~238,000
- Japan: ~120,000 cases → NSCLC: ~102,000 → EGFR mutated (35%): ~35,700
- These are newly diagnosed cases. For Ia/mNSCLC, we assume ~60-70% of NSCLC cases are diagnosed at an advanced stage, so we adjust the eligible pool accordingly.

5. Treatment Rate:

- Not all eligible patients receive targeted therapy due to access, cost, or other factors. Assumed treatment rates:
- US: 80%
- EU5: 70%
- China: 50%
- Japan: 75%

6. Peak Sales Timeline:

- Peak sales typically occur 5-7 years post-launch after market penetration stabilizes. We assume the above patient numbers are treated annually at peak.

****Step 2: Estimate Eligible Treated Patient Pool****

Using the above data, calculate the number of treated patients per geography.

| Geography | NSCLC Cases | EGFR Mutated (Eligible) | Advanced Stage (70%) | Treated Patients (Adjusted by Treatment Rate) |

|-----|-----|-----|-----|-----|

| US | 195,000 | 29,250 (15%) | 20,475 | 16,380 (80%) |

| EU5 | 255,000 | 38,250 (15%) | 26,775 | 18,742 (70%) |

| China | 680,000 | 238,000 (35%) | 166,600 | 83,300 (50%) |

| Japan | 102,000 | 35,700 (35%) | 24,990 | 18,742 (75%) |

Total Treated Patients Across Geographies: 16,380 (US) + 18,742 (EU5) + 83,300 (China) + 18,742 (Japan) = **137,164**

****Step 3: Calculate Potential Peak Sales (20%-30% Market Share)****

Peak sales are calculated by multiplying the treated patient pool by the market share (20% and 30%) and the annual cost per patient.

At 20% Market Share

| Geography | Treated Patients | Market Share (20%) | Annual Cost/Patient | Peak Sales (20%) |

|-----|-----|-----|-----|-----|

| US | 16,380 | 3,276 | \$150,000 | \$491.4 million |

| EU5 | 18,742 | 3,748 | \$100,000 | \$374.8 million |

| China | 83,300 | 16,660 | \$75,000 | \$1,249.5 million |

| Japan | 18,742 | 3,748 | \$90,000 | \$337.3 million |

Total Peak Sales (20% Share): \$491.4M + \$374.8M + \$1,249.5M + \$337.3M = **\$2,453 million (~\$2.45 billion)**

At 30% Market Share

| Geography | Treated Patients | Market Share (30%) | Annual Cost/Patient | Peak Sales (30%) |

|-----|-----|-----|-----|-----|

| US | 16,380 | 4,914 | \$150,000 | \$737.1 million |

| EU5 | 18,742 | 5,623 | \$100,000 | \$562.3 million |

| China | 83,300 | 24,990 | \$75,000 | \$1,874.3 million |

| Japan | 18,742 | 5,623 | \$90,000 | \$506.1 million |

Total Peak Sales (30% Share): \$737.1M + \$562.3M + \$1,874.3M + \$506.1M = **\$3,679.8 million (~\$3.68 billion)**

Range of Potential Peak Sales: \$2.45 billion to \$3.68 billion

****Step 4: Calculate \$ Value of 1% Share of Treated Patients****

A 1% share of treated patients corresponds to 1% of the treated patient pool multiplied by the annual cost per patient.

| Geography | Treated Patients | 1% of Treated Patients | Annual Cost/Patient | \$ Value of 1% Share |

|-----|-----|-----|-----|-----|

| US | 16,380 | 163.8 | \$150,000 | \$24.57 million |

| EU5 | 18,742 | 187.4 | \$100,000 | \$18.74 million |

| China | 83,300 | 833.0 | \$75,000 | \$62.48 million |

| Japan | 18,742 | 187.4 | \$90,000 | \$16.87 million |

Total \$ Value of 1% Share Across Geographies: \$24.57M + \$18.74M + \$62.48M + \$16.87M = **\$122.66 million**

****Final Answer****

1. **Potential Peak Sales for Osimertinib** in the specified indication across the US, EU5, China, and Japan (assuming 20%-30% market share): **\$2.45 billion to \$3.68 billion**.

2. **\$ Value of 1% Share of Treated Patients** across these geographies: **\$122.66 million**.

Note: These estimates are based on assumptions and should be refined with actual epidemiology data, current pricing, reimbursement policies, and competitive landscape information. Additionally, peak sales may vary due to factors like generic competition, new therapies, or changes in treatment guidelines. If you have specific data or additional details, I can adjust the calculations accordingly.