To estimate the **Potential Peak Sales** for mobocertinib (Exkivity) in the specified indication (locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations, post-platinum-based chemotherapy) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **$ value of a 1% share of treated patients**, we need to follow a structured approach based on available data and reasonable assumptions. Since exact patient numbers, pricing, and penetration rates are not fully public, I will outline the methodology and provide estimates based on industry-standard assumptions and data from NSCLC epidemiology, EGFR mutation prevalence, and drug pricing trends.

Step 1: Define the Target Patient Population

- **Indication**: Locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, post-platinum-based chemotherapy (second-line or later treatment).

- **Geographies**: US, EU5 (Germany, France, Italy, Spain, UK), China, Japan.

- **Key Data Points**:

- NSCLC accounts for ~85% of all lung cancer cases.

- EGFR mutations are present in ~10-15% of NSCLC cases in Western populations (US, EU5) and ~30-40% in Asian populations (China, Japan).

- EGFR exon 20 insertion mutations specifically account for ~4-10% of all EGFR mutations (i.e., ~0.4-1.5% of all NSCLC cases in Western populations and ~1.2-4% in Asian populations).

- Approximately 60-70% of NSCLC patients are diagnosed at a locally advanced or metastatic stage (Stage IIIB/IV).

- Of these, a significant portion progress after first-line platinum-based chemotherapy, making them eligible for second-line therapies like mobocertinib.

Estimated Annual Incident Cases of NSCLC (2023 Estimates)

- **US**: ~200,000 new lung cancer cases, ~85% NSCLC = ~170,000 cases.

- **EU5**: ~300,000 new lung cancer cases, ~85% NSCLC = ~255,000 cases.

- **China**: ~800,000 new lung cancer cases, ~85% NSCLC = ~680,000 cases.

- **Japan**: ~120,000 new lung cancer cases, ~85% NSCLC = ~102,000 cases.

Proportion with EGFR Exon 20 Insertion Mutations

- **US/EU5**: ~1% of NSCLC cases (midpoint of 0.4-1.5%) = ~1,700 (US), ~2,550 (EU5).

- **China/Japan**: ~2.5% of NSCLC cases (midpoint of 1.2-4%) = ~17,000 (China), ~2,550 (Japan).

Proportion Eligible for Second-Line Treatment

- Assume ~60% of NSCLC cases are diagnosed at advanced stages, and of those, ~70% progress after first-line therapy and are eligible for second-line treatment.

- Eligibility factor: 60% * 70% = 42% of incident cases.

- **US**: 1,700 * 0.42 = ~700 patients.

- **EU5**: 2,550 * 0.42 = ~1,070 patients.

- **China**: 17,000 * 0.42 = ~7,140 patients.

- **Japan**: 2,550 * 0.42 = ~1,070 patients.

Total Eligible Patients Across Geographies

- **Total**: 700 (US) + 1,070 (EU5) + 7,140 (China) + 1,070 (Japan) = ~9,980 patients annually.

Step 2: Estimate Market Share of Treated Patients

- The problem assumes a **20-30% share of treated patients** for mobocertinib.

- Assume a midpoint of **25% market share** for peak sales estimation.

- **Treated Patients**:

- US: 700 * 0.25 = 175 patients.

- EU5: 1,070 * 0.25 = 268 patients.

- China: 7,140 * 0.25 = 1,785 patients.

- Japan: 1,070 * 0.25 = 268 patients.

- **Total Treated Patients**: 175 + 268 + 1,785 + 268 = ~2,496 patients annually.

Step 3: Estimate Drug Pricing

- Mobocertinib is a targeted oncology therapy for a rare mutation, so pricing will be high, similar to other EGFR inhibitors (e.g., osimertinib, which costs ~$15,000-$17,000 per month in the US).

- Assume annual cost per patient (based on monthly cost and ~12 months of treatment, though real-world duration may be shorter due to progression or toxicity):

- **US**: $180,000 per year.

- **EU5**: $120,000 per year (lower due to pricing negotiations and healthcare systems).

- **Japan**: $120,000 per year (similar to EU5).

- **China**: $60,000 per year (significantly lower due to market access programs and pricing controls, though uptake may vary).

Step 4: Calculate Potential Peak Sales

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

- **US**: 175 patients * $180,000 = **$31.5 million**.

- **EU5**: 268 patients * $120,000 = **$32.2 million**.

- **China**: 1,785 patients * $60,000 = **$107.1 million**.

- **Japan**: 268 patients * $120,000 = **$32.2 million**.

- **Total Peak Sales**: $31.5M + $32.2M + $107.1M + $32.2M = **~$203 million annually**.

Sensitivity Analysis (20-30% Market Share)

- At 20% share: Total treated patients = ~1,996; Total Peak Sales = ~$162 million.

- At 30% share: Total treated patients = ~2,994; Total Peak Sales = ~$244 million.

- **Range**: **$162M - $244M annually**, with a midpoint of ~$203M.

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

- **1% of eligible patients**:

- US: 700 * 0.01 = 7 patients.

- EU5: 1,070 * 0.01 = 10.7 patients (~11).

- China: 7,140 * 0.01 = 71.4 patients (~71).

- Japan: 1,070 * 0.01 = 10.7 patients (~11).

- **Total**: ~100 patients.

- **Revenue for 1% share**:

- US: 7 * $180,000 = **$1.26 million**.

- EU5: 11 * $120,000 = **$1.32 million**.

- China: 71 * $60,000 = **$4.26 million**.

- Japan: 11 * $120,000 = **$1.32 million**.

- **Total $ Value of 1% Share**: $1.26M + $1.32M + $4.26M + $1.32M = **~$8.16 million annually**.

Final Answers

1. **Potential Peak Sales for Mobocertinib (20-30% Market Share)**:

- Range: **$162 million to $244 million annually**.

- Midpoint Estimate: **~$203 million annually**.

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

- **~$8.16 million annually**.

Notes and Assumptions

- **Epidemiology**: Patient numbers are based on estimated incidence and prevalence of EGFR exon 20 insertion mutations, which are rare and vary by region. Real-world data may differ.

- **Pricing**: Pricing assumptions are based on benchmarks for targeted NSCLC therapies. Actual pricing may vary due to negotiations, reimbursement, and market access.

- **Market Share**: The 20-30% range is as provided, though competition (e.g., amivantamab by Janssen) and clinical adoption rates could impact this.

- **Treatment Duration**: Assumed 12 months of therapy; real-world duration may be shorter, reducing revenue per patient.

- **China Market**: Uptake in China may be limited by pricing and access, despite the large patient pool.

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