

To estimate the **Potential Peak Sales** for encorafenib (Braftovi) in the indication of metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation 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 based on available data and reasonable assumptions. Since exact figures (e.g., total addressable patient population, pricing, or market penetration) are not provided, I will outline the methodology and use illustrative numbers based on industry trends and publicly available data. You can refine these numbers with specific data if available.

Key Indication and Context

- **Drug:** Encorafenib (Braftovi) in combination with binimetinib (Mektovi).
- **Indication:** Metastatic NSCLC with BRAF V600E mutation.
- **Approval:** US FDA approval (as of October 2023, per the provided context).
- **Geographies:** US, EU5, China, Japan.
- **Assumption:** 20% to 30% market share of treated patients.

Step 1: Estimate the Addressable Patient Population

- **NSCLC Incidence:** NSCLC accounts for ~85% of all lung cancer cases. BRAF V600E mutations are rare, occurring in approximately 1-2% of NSCLC cases.
- **Annual Incidence of NSCLC** (approximate figures for 2023, based on cancer statistics):
 - **US:** ~200,000 new NSCLC cases → ~2,000-4,000 BRAF V600E patients.
 - **EU5:** ~250,000 new NSCLC cases → ~2,500-5,000 BRAF V600E patients.
 - **China:** ~700,000 new NSCLC cases → ~7,000-14,000 BRAF V600E patients.
 - **Japan:** ~100,000 new NSCLC cases → ~1,000-2,000 BRAF V600E patients.
- **Total Addressable Population (new cases per year):**
 - US: ~3,000 (midpoint).
 - EU5: ~3,750 (midpoint).
 - China: ~10,500 (midpoint).
 - Japan: ~1,500 (midpoint).
- **Total:** ~18,750 patients annually.
- **Prevalent Population:** Since metastatic NSCLC patients may survive 1-2 years or more with treatment, the prevalent population (total treatable patients at any given time) could be 1.5-2x the annual incidence. For simplicity, let's assume a multiplier of 1.5:
 - Total prevalent BRAF V600E NSCLC patients: ~28,125 across these geographies.

Step 2: Estimate Treatment Rate

- Not all patients will be treated due to factors like late diagnosis, comorbidities, or lack of access to targeted therapies. Assume:

- **US/EU5/Japan:** ~70% of eligible patients receive targeted therapy.
- **China:** ~50% due to access and cost barriers.
- **Treated Patients** (prevalent population x treatment rate):
- US: $3,000 \times 1.5 \times 0.7 = \sim 3,150$.
- EU5: $3,750 \times 1.5 \times 0.7 = \sim 3,940$.
- China: $10,500 \times 1.5 \times 0.5 = \sim 7,875$.
- Japan: $1,500 \times 1.5 \times 0.7 = \sim 1,575$.
- **Total Treated Patients:** ~16,540.

Step 3: Estimate Market Share

- As per the query, assume encorafenib captures **20% to 30% of treated patients**:
- **Low End (20%):** $16,540 \times 0.2 = \sim 3,308$ patients.
- **High End (30%):** $16,540 \times 0.3 = \sim 4,962$ patients.

Step 4: Estimate Annual Cost of Therapy

- Encorafenib + binimetinib is a targeted therapy, and pricing for such drugs in oncology is high, especially in the US. Based on pricing for similar drugs (e.g., other BRAF/MEK inhibitors like dabrafenib + trametinib):
- **US:** ~\$150,000–\$200,000 per patient per year.
- **EU5/Japan:** ~\$100,000–\$150,000 per patient per year (lower due to price controls/negotiations).
- **China:** ~\$50,000–\$80,000 per patient per year (lower due to market access programs or generics competition).
- For simplicity, assume midpoint annual costs:
- US: \$175,000.
- EU5: \$125,000.
- Japan: \$125,000.
- China: \$65,000.

Step 5: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients (at 20% and 30% market share) multiplied by the annual cost per patient in each geography.

At 20% Market Share (~3,308 patients):

- **US:** $(3,150 \text{ total treated} \times 0.2) = 630 \text{ patients} \times \$175,000 = \mathbf{\$110.25M}$.
- **EU5:** $(3,940 \times 0.2) = 788 \text{ patients} \times \$125,000 = \mathbf{\$98.5M}$.

- **China:** $(7,875 \times 0.2) = 1,575 \text{ patients} \times \$65,000 = \text{\$102.38M}$.
- **Japan:** $(1,575 \times 0.2) = 315 \text{ patients} \times \$125,000 = \text{\$39.38M}$.
- **Total Peak Sales (20%):** $\text{\$110.25M} + \text{\$98.5M} + \text{\$102.38M} + \text{\$39.38M} = \text{\$350.5M}$.

At 30% Market Share (~4,962 patients):

- **US:** $(3,150 \times 0.3) = 945 \text{ patients} \times \$175,000 = \text{\$165.38M}$.
- **EU5:** $(3,940 \times 0.3) = 1,182 \text{ patients} \times \$125,000 = \text{\$147.75M}$.
- **China:** $(7,875 \times 0.3) = 2,363 \text{ patients} \times \$65,000 = \text{\$153.6M}$.
- **Japan:** $(1,575 \times 0.3) = 473 \text{ patients} \times \$125,000 = \text{\$59.13M}$.
- **Total Peak Sales (30%):** $\text{\$165.38M} + \text{\$147.75M} + \text{\$153.6M} + \text{\$59.13M} = \text{\$525.86M}$.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

- **Total Treated Patients:** ~16,540.
- **1% of Treated Patients:** $16,540 \times 0.01 = \sim 165 \text{ patients}$.
- Break down by geography and apply per-patient cost:
- **US:** $(3,150 \times 0.01) = 31.5 \text{ patients} \times \$175,000 = \text{\$5.51M}$.
- **EU5:** $(3,940 \times 0.01) = 39.4 \text{ patients} \times \$125,000 = \text{\$4.93M}$.
- **China:** $(7,875 \times 0.01) = 78.75 \text{ patients} \times \$65,000 = \text{\$5.12M}$.
- **Japan:** $(1,575 \times 0.01) = 15.75 \text{ patients} \times \$125,000 = \text{\$1.97M}$.
- **Total \$ Value of 1% Share:** $\text{\$5.51M} + \text{\$4.93M} + \text{\$5.12M} + \text{\$1.97M} = \text{\$17.53M}$.

Final Answer

- **Potential Peak Sales for Encorafenib** in metastatic NSCLC with BRAF V600E mutation (assuming 20% to 30% market share):

- **20% Market Share:** ~\$350.5 million annually.

- **30% Market Share:** ~\$525.9 million annually.

- **\$ Value of 1% Share of Treated Patients:** ~\$17.5 million annually across the US, EU5, China, and Japan.

Caveats and Notes

1. These estimates are based on assumptions about patient population, treatment rates, market share, and pricing. Actual figures may vary due to competition (e.g., other BRAF/MEK inhibitors like dabrafenib + trametinib), reimbursement policies, or real-world treatment durations.
2. Peak sales typically occur several years after launch, factoring in market penetration and uptake.
3. If you have access to specific data (e.g., exact patient numbers, pricing, or market share forecasts), these estimates can be refined further.

