

To estimate the **Potential Peak Sales** for encorafenib (Braftovi) in the indication of metastatic colorectal cancer (mCRC) 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, assumptions, and market analysis. Since exact figures (e.g., patient population, pricing, or penetration rates) are not provided, I will outline the methodology and use reasonable estimates based on industry trends and publicly available data as of my last update in October 2023. You may need to refine these numbers with specific data or consult market research reports for precision.

Step 1: Define Key Parameters

1. **Target Patient Population:** mCRC patients with BRAF V600E mutation.
 - BRAF V600E mutation occurs in approximately 8-15% of mCRC patients.
 - Total mCRC patient population in each geography must be estimated based on colorectal cancer incidence, metastatic rates, and mutation prevalence.
2. **Treated Patient Share:** Assuming 20-30% of eligible patients are treated with encorafenib.
3. **Annual Treatment Cost:** Pricing of encorafenib varies by region. For simplicity, we will use approximate costs based on US pricing and adjust for other regions.
4. **Peak Sales:** Calculated as (Eligible Patients) x (Treated Share) x (Annual Cost per Patient).
5. **1% Share Value:** Calculated as (Eligible Patients) x (1%) x (Annual Cost per Patient).

Step 2: Estimate mCRC BRAF V600E Patient Population

- **US:**
 - Annual colorectal cancer (CRC) incidence: ~150,000 cases.
 - ~40-50% progress to mCRC: ~60,000-75,000 mCRC cases.
 - BRAF V600E mutation: ~10% (midpoint of 8-15%): ~6,000-7,500 patients.
- **EU5:**
 - Annual CRC incidence: ~300,000 cases (combined for EU5).
 - mCRC: ~40-50%: ~120,000-150,000 cases.
 - BRAF V600E: ~10%: ~12,000-15,000 patients.
- **China:**
 - Annual CRC incidence: ~550,000 cases (due to large population and rising incidence).
 - mCRC: ~40-50%: ~220,000-275,000 cases.
 - BRAF V600E: ~10%: ~22,000-27,500 patients.
- **Japan:**
 - Annual CRC incidence: ~150,000 cases.
 - mCRC: ~40-50%: ~60,000-75,000 cases.
 - BRAF V600E: ~10%: ~6,000-7,500 patients.

Total Eligible Patients (midpoint estimates):

- US: 6,750
- EU5: 13,500
- China: 24,750
- Japan: 6,750
- **Total across geographies: 51,750 patients.**

Step 3: Estimate Annual Treatment Cost

- **US:** Encorafenib + cetuximab combination therapy is expensive. Encorafenib alone is ~\$10,000-\$12,000/month, or ~\$120,000-\$144,000/year. With cetuximab, total cost may approach ~\$150,000-\$200,000/year. Assume midpoint: \$175,000/year.
- **EU5:** Pricing is typically 60-80% of US due to healthcare negotiations. Assume ~\$105,000-\$140,000/year. Midpoint: \$122,500/year.
- **China:** Pricing is lower due to market access and affordability. Assume 30-50% of US price: ~\$52,500-\$87,500/year. Midpoint: \$70,000/year.
- **Japan:** Pricing is often similar to EU, ~60-80% of US. Assume midpoint: \$122,500/year.

Step 4: Calculate Potential Peak Sales (20-30% Treated Share)

Peak sales = (Eligible Patients) x (Treated Share) x (Annual Cost per Patient)

At 20% Treated Share:

- **US:** $6,750 \times 0.2 \times \$175,000 = \$236.25 \text{ million}$
- **EU5:** $13,500 \times 0.2 \times \$122,500 = \$330.75 \text{ million}$
- **China:** $24,750 \times 0.2 \times \$70,000 = \$346.5 \text{ million}$
- **Japan:** $6,750 \times 0.2 \times \$122,500 = \$165.375 \text{ million}$
- **Total: \$1,079 million (~\$1.08 billion)**

At 30% Treated Share:

- **US:** $6,750 \times 0.3 \times \$175,000 = \$354.375 \text{ million}$
- **EU5:** $13,500 \times 0.3 \times \$122,500 = \$496.125 \text{ million}$
- **China:** $24,750 \times 0.3 \times \$70,000 = \$519.75 \text{ million}$
- **Japan:** $6,750 \times 0.3 \times \$122,500 = \$248.0625 \text{ million}$
- **Total: \$1,618.3125 million (~\$1.62 billion)**

Potential Peak Sales Range: \$1.08 billion to \$1.62 billion across US, EU5, China, and Japan.

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

1% share value = (Eligible Patients) x (0.01) x (Annual Cost per Patient)

- **US:** $6,750 \times 0.01 \times \$175,000 = \$11.8125 \text{ million}$
- **EU5:** $13,500 \times 0.01 \times \$122,500 = \$16.5375 \text{ million}$
- **China:** $24,750 \times 0.01 \times \$70,000 = \$17.325 \text{ million}$
- **Japan:** $6,750 \times 0.01 \times \$122,500 = \$8.26875 \text{ million}$
- **Total:** $\$53.94375 \text{ million}$ (~\$53.94 million)

\$ Value of 1% Share of Treated Patients: \$53.94 million across all geographies.

Final Answer:

- **Potential Peak Sales for Encorafenib in mCRC (BRAF V600E):**
- At 20% treated share: **\$1.08 billion**
- At 30% treated share: **\$1.62 billion**
- **\$ Value of 1% Share of Treated Patients: \$53.94 million**

Notes and Caveats:

1. These estimates are based on assumptions for patient numbers, mutation prevalence, treatment costs, and market penetration. Real-world data may differ due to competition, reimbursement policies, or access barriers.
2. Pricing in China and other emerging markets may be significantly lower or higher based on government negotiations or generics/biosimilars.
3. Peak sales may take years to achieve and depend on clinical adoption, competitor therapies (e.g., other BRAF/MEK inhibitors), and duration of therapy.
4. For more accurate figures, consult market research reports (e.g., EvaluatePharma, GlobalData) or company filings from Pfizer/Array BioPharma.

If you have specific data (e.g., exact patient numbers or pricing), I can refine these calculations further.