To estimate the **Potential Peak Sales** for encorafenib (BRAFTOVI) in the indication of metastatic colorectal cancer (CRC) with BRAF V600E mutation 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 based on available data and reasonable assumptions. Since exact figures may not be publicly available, I will outline the methodology and use realistic estimates for key parameters such as patient population, treatment penetration, pricing, and market share.

Key Assumptions and Methodology

1. **Indication**: Metastatic colorectal cancer (mCRC) with BRAF V600E mutation.

- BRAF V600E mutations occur in approximately 8-15% of CRC patients, with a higher prevalence in metastatic cases.

2. **Patient Population**:

- Estimate the total number of mCRC patients in each geography.

- Apply the BRAF V600E mutation prevalence (assumed ~10% for simplicity).

- Consider the proportion of patients eligible for second-line or later therapy (as encorafenib is approved for use after prior therapy).

3. **Market Share**:

- Assume 20-30% of treated patients with BRAF V600E mutation mCRC will receive encorafenib + cetuximab, as per the query.

4. **Pricing**:

- Use publicly available or estimated pricing for encorafenib + cetuximab combination therapy. In the US, the cost of encorafenib is approximately $10,000-$12,000 per month, and cetuximab is around $5,000-$7,000 per month, leading to a combined cost of ~$15,000-$19,000 per month or ~$180,000-$228,000 per year. Similar pricing (adjusted for local markets) will be assumed for other geographies.

5. **Treatment Duration**:

- Assume an average treatment duration of 6-12 months based on progression-free survival (PFS) data from clinical trials (e.g., BEACON CRC trial showed median PFS of ~4-5 months, but some patients may continue longer).

6. **Peak Sales**:

- Peak sales are typically achieved 3-5 years post-launch when market penetration stabilizes.

7. **Geographies**:

- US, EU5 (aggregate), China, and Japan.

Step 1: Estimate Eligible Patient Population

US

- Total CRC incidence: ~150,000 new cases/year (American Cancer Society).

- Metastatic CRC (mCRC): ~50% of cases (~75,000 patients/year).

- BRAF V600E mutation: ~10% of mCRC (~7,500 patients/year).

- Eligible for second-line or later therapy: ~70% of mCRC patients progress to second-line (~5,250 patients/year).

EU5 (Germany, France, Italy, Spain, UK)

- Total CRC incidence: ~300,000 new cases/year (EU data).

- mCRC: ~50% (~150,000 patients/year).

- BRAF V600E mutation: ~10% (~15,000 patients/year).

- Eligible for second-line or later: ~70% (~10,500 patients/year).

China

- Total CRC incidence: ~400,000 new cases/year (due to large population and rising incidence).

- mCRC: ~50% (~200,000 patients/year).

- BRAF V600E mutation: ~10% (~20,000 patients/year).

- Eligible for second-line or later: ~70% (~14,000 patients/year).

- Note: Access to targeted therapies may be lower due to pricing and reimbursement challenges; assume lower penetration.

Japan

- Total CRC incidence: ~150,000 new cases/year.

- mCRC: ~50% (~75,000 patients/year).

- BRAF V600E mutation: ~10% (~7,500 patients/year).

- Eligible for second-line or later: ~70% (~5,250 patients/year).

Step 2: Estimate Treated Patients (20-30% Market Share)

Assuming 20-30% of eligible patients receive encorafenib + cetuximab:

- **US**: 5,250 * 20-30% = 1,050-1,575 patients/year.

- **EU5**: 10,500 * 20-30% = 2,100-3,150 patients/year.

- **China**: 14,000 * 20-30% = 2,800-4,200 patients/year (assuming lower penetration due to access, ~15-20% may be more realistic, but using query range).

- **Japan**: 5,250 * 20-30% = 1,050-1,575 patients/year.

Step 3: Estimate Annual Cost per Patient

- **US**: ~$180,000-$228,000/year (based on monthly cost of $15,000-$19,000).

- **EU5**: ~$120,000-$150,000/year (lower due to pricing negotiations and reimbursement).

- **China**: ~$60,000-$90,000/year (significantly lower due to pricing and generics competition).

- **Japan**: ~$150,000-$180,000/year (similar to US but slightly discounted).

Step 4: Calculate Potential Peak Sales

Using the midpoint of the market share range (25%) and midpoint of cost range for simplicity:

- **US**: 1,312 patients * $204,000 = **$267 million/year**.

- **EU5**: 2,625 patients * $135,000 = **$354 million/year**.

- **China**: 3,500 patients * $75,000 = **$262 million/year**.

- **Japan**: 1,312 patients * $165,000 = **$216 million/year**.

Total Potential Peak Sales: $267M + $354M + $262M + $216M = **~$1.1 billion/year**.

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

1% of treated patients corresponds to 1% of the eligible population being treated with encorafenib + cetuximab.

- **US**: 5,250 * 1% = 52.5 patients * $204,000 = **$10.7 million/year**.

- **EU5**: 10,500 * 1% = 105 patients * $135,000 = **$14.2 million/year**.

- **China**: 14,000 * 1% = 140 patients * $75,000 = **$10.5 million/year**.

- **Japan**: 5,250 * 1% = 52.5 patients * $165,000 = **$8.7 million/year**.

Final Answer

- **Potential Peak Sales for Encorafenib (BRAFTOVI) in mCRC with BRAF V600E mutation** (assuming 20-30% market share, midpoint 25%):

- **US**: ~$267 million/year

- **EU5**: ~$354 million/year

- **China**: ~$262 million/year

- **Japan**: ~$216 million/year

- **Total**: ~**$1.1 billion/year**

- **$ Value of 1% Share of Treated Patients**:

- **US**: ~$10.7 million/year

- **EU5**: ~$14.2 million/year

- **China**: ~$10.5 million/year

- **Japan**: ~$8.7 million/year

Notes

- These figures are estimates based on publicly available data and assumptions. Actual sales may vary due to competition (e.g., other targeted therapies), reimbursement policies, and real-world treatment duration.

- Peak sales could be higher or lower depending on market penetration, pricing adjustments, and patient access in regions like China.

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