To estimate the **Potential Peak Sales** for erdafitinib (Balversa) in the indication of locally advanced or metastatic urothelial carcinoma (mUC) with FGFR3 genetic alterations in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, and to calculate the **$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach. Given that specific data (e.g., exact patient numbers, pricing, or penetration rates) may not be publicly available, I will outline the methodology and use reasonable assumptions based on available information and industry standards. If you have specific data points, they can be incorporated for more precise calculations.

Step 1: Key Assumptions and Methodology

1. **Target Patient Population**: Erdafitinib targets patients with locally advanced or metastatic urothelial carcinoma (mUC) with FGFR3 genetic alterations who have progressed after at least one prior systemic therapy.

- FGFR3 alterations are present in approximately 15-20% of mUC patients (based on published literature).

- We need to estimate the total number of mUC patients in each geography and apply the FGFR3 alteration prevalence.

2. **Treated Patient Share**: The problem assumes a 20-30% share of treated patients for erdafitinib. This accounts for market penetration, competition, and patient eligibility.

3. **Pricing**: Drug pricing varies by region. We will use approximate annual treatment costs for targeted therapies in oncology:

- US: ~$150,000–$200,000 per patient per year (based on pricing for similar targeted therapies).

- EU5: ~$80,000–$120,000 per patient per year (lower due to price negotiations and healthcare systems).

- Japan: ~$100,000–$150,000 per patient per year.

- China: ~$30,000–$50,000 per patient per year (lower due to pricing controls and generics competition).

4. **Peak Sales Timing**: Peak sales are typically achieved 5-7 years after launch, assuming no major competition or patent expiry during this period.

5. **Epidemiology Data**: We will estimate the number of mUC patients based on incidence and prevalence data for urothelial carcinoma, focusing on advanced/metastatic cases.

Step 2: Estimating Target Patient Population

Urothelial carcinoma incidence and prevalence data are derived from cancer registries and published studies. Below are rough estimates for advanced/metastatic cases (mUC) in each geography (based on public data and scaling for metastatic cases, which are ~20-30% of total UC cases):

- **US**:

- Annual incidence of urothelial carcinoma: ~80,000 cases.

- Advanced/metastatic (mUC): ~20,000–24,000 patients.

- FGFR3 alterations (15-20%): ~3,000–4,800 patients.

- **EU5**:

- Annual incidence of urothelial carcinoma: ~120,000 cases.

- Advanced/metastatic (mUC): ~30,000–36,000 patients.

- FGFR3 alterations (15-20%): ~4,500–7,200 patients.

- **Japan**:

- Annual incidence of urothelial carcinoma: ~25,000 cases.

- Advanced/metastatic (mUC): ~6,000–7,500 patients.

- FGFR3 alterations (15-20%): ~900–1,500 patients.

- **China**:

- Annual incidence of urothelial carcinoma: ~80,000 cases (adjusted for population size and lower incidence rates compared to Western countries).

- Advanced/metastatic (mUC): ~20,000–24,000 patients.

- FGFR3 alterations (15-20%): ~3,000–4,800 patients.

Total Target Population (FGFR3+ mUC):

- US: ~3,900 (midpoint of 3,000–4,800).

- EU5: ~5,850 (midpoint of 4,500–7,200).

- Japan: ~1,200 (midpoint of 900–1,500).

- China: ~3,900 (midpoint of 3,000–4,800).

- **Total across geographies**: ~14,850 patients.

Step 3: Estimating Treated Patients with 20-30% Market Share

Using the assumed 20-30% share of treated patients:

- **20% Share**:

- US: 3,900 × 0.2 = 780 patients.

- EU5: 5,850 × 0.2 = 1,170 patients.

- Japan: 1,200 × 0.2 = 240 patients.

- China: 3,900 × 0.2 = 780 patients.

- **Total**: 2,970 patients.

- **30% Share**:

- US: 3,900 × 0.3 = 1,170 patients.

- EU5: 5,850 × 0.3 = 1,755 patients.

- Japan: 1,200 × 0.3 = 360 patients.

- China: 3,900 × 0.3 = 1,170 patients.

- **Total**: 4,455 patients.

Step 4: Estimating Peak Sales

Using midpoint pricing per patient per year:

- US: $175,000.

- EU5: $100,000.

- Japan: $125,000.

- China: $40,000.

Peak Sales at 20% Share:

- US: 780 × $175,000 = **$136.5 million**.

- EU5: 1,170 × $100,000 = **$117 million**.

- Japan: 240 × $125,000 = **$30 million**.

- China: 780 × $40,000 = **$31.2 million**.

- **Total Peak Sales (20%)**: **$314.7 million**.

Peak Sales at 30% Share:

- US: 1,170 × $175,000 = **$204.8 million**.

- EU5: 1,755 × $100,000 = **$175.5 million**.

- Japan: 360 × $125,000 = **$45 million**.

- China: 1,170 × $40,000 = **$46.8 million**.

- **Total Peak Sales (30%)**: **$472.1 million**.

Potential Peak Sales Range: **$314.7 million to $472.1 million annually** across the US, EU5, Japan, and China.

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

A 1% share corresponds to 1% of the target population being treated with erdafitinib.

- US: 3,900 × 0.01 = 39 patients × $175,000 = **$6.8 million**.

- EU5: 5,850 × 0.01 = 58.5 patients × $100,000 = **$5.9 million**.

- Japan: 1,200 × 0.01 = 12 patients × $125,000 = **$1.5 million**.

- China: 3,900 × 0.01 = 39 patients × $40,000 = **$1.6 million**.

- **Total $ Value of 1% Share**: **$15.8 million**.

Final Answer:

- **Potential Peak Sales for Erdafitinib** in the US, EU5, China, and Japan for the mUC indication with FGFR3 alterations (assuming 20-30% share of treated patients): **$314.7 million to $472.1 million**

annually.

- **$ Value of 1% Share of Treated Patients** across these geographies: **$15.8 million annually**.

Notes:

- These estimates are based on assumptions and may vary depending on actual pricing, market access, competition (e.g., other FGFR inhibitors or immunotherapies), and real-world patient numbers.

- Erdafitinib's uptake could be influenced by diagnostic testing rates for FGFR3 alterations and physician adoption.

- If you have access to more specific data (e.g., exact patient numbers or pricing), the calculations can be refined accordingly.