

To estimate the **Potential Peak Sales** for fam-trastuzumab deruxtecan-nxki (Enhertu) in the specified indication (unresectable or metastatic HER2-positive breast cancer) 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 epidemiology, market size, pricing, and penetration assumptions. Since exact data may not be publicly available, I will outline the methodology and provide reasonable estimates based on typical market dynamics for oncology drugs, particularly for HER2-positive breast cancer.

Step 1: Define the Target Population

The indication is for adult patients with **unresectable or metastatic HER2-positive breast cancer** who have received a prior anti-HER2-based regimen. HER2-positive breast cancer accounts for approximately **15-20% of all breast cancer cases**.

1. Epidemiology of Breast Cancer:

- **US:** ~290,000 new breast cancer cases annually (2023 estimate). ~15-20% are HER2-positive (~43,500–58,000 cases). Of these, ~30-50% are metastatic or unresectable at diagnosis or progress to this stage (~13,000–29,000 eligible patients).

- **EU5:** ~370,000 new breast cancer cases annually. HER2-positive: ~55,500–74,000. Metastatic/unresectable: ~16,500–37,000 eligible patients.

- **China:** ~420,000 new breast cancer cases annually. HER2-positive: ~63,000–84,000. Metastatic/unresectable: ~19,000–42,000 eligible patients.

- **Japan:** ~95,000 new breast cancer cases annually. HER2-positive: ~14,250–19,000. Metastatic/unresectable: ~4,300–9,500 eligible patients.

Total eligible patients across geographies (mid-range estimate):

- US: ~21,000

- EU5: ~26,750

- China: ~30,500

- Japan: ~6,900

- **Total: ~85,150 patients**

2. Treated Population:

Not all eligible patients receive treatment due to access, cost, or clinical decisions. Assuming a **treatment rate of 70-80%**:

- US: ~14,700–16,800

- EU5: ~18,700–21,400

- China: ~21,350–24,400

- Japan: ~4,800–5,500

- **Total Treated: ~59,550–68,100 (midpoint: ~63,825)**

3. Market Share Assumption:

The problem assumes a **20-30% share of treated patients** for Enhertu. Using the midpoint of 25%:

- Total patients treated with Enhertu: ~15,956 patients (25% of 63,825).

Step 2: Estimate Annual Cost of Treatment

Enhertu is a high-cost oncology drug. Pricing varies by geography due to healthcare systems and negotiations:

- **US:** Annual cost ~\$180,000–\$200,000 per patient (based on list price and typical treatment duration of ~12 months).
- **EU5:** Annual cost ~\$100,000–\$120,000 per patient (discounted due to payer negotiations).
- **Japan:** Annual cost ~\$120,000–\$140,000 per patient.
- **China:** Annual cost ~\$50,000–\$70,000 per patient (lower due to pricing controls and market access challenges).

Using midpoint estimates:

- US: \$190,000
- EU5: \$110,000
- China: \$60,000
- Japan: \$130,000

Step 3: Calculate Potential Peak Sales

Peak sales are calculated as: **Number of treated patients with Enhertu × Annual cost per patient.**

1. **US:**

- Treated patients (25% share): ~3,675–4,200 (midpoint: 3,938)
- Annual cost: \$190,000
- Peak Sales: **$3,938 \times \$190,000 = \sim\748 million**

2. **EU5:**

- Treated patients (25% share): ~4,675–5,350 (midpoint: 5,013)
- Annual cost: \$110,000
- Peak Sales: **$5,013 \times \$110,000 = \sim\551 million**

3. China:

- Treated patients (25% share): ~5,338–6,100 (midpoint: 5,719)
- Annual cost: \$60,000
- Peak Sales: **$5,719 \times \$60,000 = \sim\343 million**

4. Japan:

- Treated patients (25% share): ~1,200–1,375 (midpoint: 1,288)
- Annual cost: \$130,000
- Peak Sales: **$1,288 \times \$130,000 = \sim\167 million**

Total Potential Peak Sales (25% share):

- US: \$748M
- EU5: \$551M
- China: \$343M
- Japan: \$167M
- **Total: $\sim\$1,809 \text{ million (or } \sim\1.81 billion)**

For a range of 20-30% share:

- 20% share: $\sim\$1.45 \text{ billion}$
- 30% share: $\sim\$2.17 \text{ billion}$

Final Estimate for Potential Peak Sales: $\$1.45\text{--}\2.17 billion (midpoint: $\sim\$1.81 \text{ billion}$).

Step 4: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treated population (~63,825 patients), i.e., ~638 patients.

1. US:

- Treated patients (1% share): ~147–168 (midpoint: 158)
- Annual cost: \$190,000
- Value of 1% share: **$158 \times \$190,000 = \sim\30 million**

2. EU5:

- Treated patients (1% share): ~187–214 (midpoint: 201)
- Annual cost: \$110,000
- Value of 1% share: **$201 \times \$110,000 = \sim\22 million**

3. China:

- Treated patients (1% share): ~214–244 (midpoint: 229)
- Annual cost: \$60,000
- Value of 1% share: $229 \times \$60,000 = \sim\14 million

4. Japan:

- Treated patients (1% share): ~48–55 (midpoint: 52)
- Annual cost: \$130,000
- Value of 1% share: $52 \times \$130,000 = \sim\7 million

Total \$ Value of 1% Share of Treated Patients:

- US: \$30M
- EU5: \$22M
- China: \$14M
- Japan: \$7M
- **Total: ~\$73 million**

Final Answer:

1. **Potential Peak Sales for fam-trastuzumab deruxtecan-nxki (Enhertu)** in the specified indication (unresectable or metastatic HER2-positive breast cancer) with a 20-30% share of treated patients:

- **Range: \$1.45 billion to \$2.17 billion**
- **Midpoint: ~\$1.81 billion**

2. **\$ Value of 1% Share of Treated Patients** across the US, EU5, China, and Japan:

- **Total: ~\$73 million**

These estimates are based on assumptions about epidemiology, treatment rates, market share, and pricing. Actual figures may vary depending on real-world data, competition (e.g., other HER2-targeted therapies like trastuzumab, pertuzumab, or T-DM1), and market access dynamics. If specific data on patient numbers or pricing is available, the calculations can be refined further.