

To estimate the **Potential Peak Sales** for **fam-trastuzumab deruxtecan-nxki (Enhertu)** in the indication of unresectable or metastatic HER2-positive (IHC3+) solid tumors 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. Since specific data (e.g., exact patient population, pricing, or market penetration rates) isn't provided, I'll outline the methodology and make reasonable assumptions based on publicly available information and typical market dynamics for oncology drugs. The final numbers are illustrative and should be validated with precise data.

Step 1: Define the Target Patient Population

The indication is for adult patients with **unresectable or metastatic HER2-positive (IHC3+) solid tumors** who have received prior systemic treatment and have no satisfactory alternative treatment options. HER2-positive solid tumors include breast cancer, gastric cancer, colorectal cancer, non-small cell lung cancer (NSCLC), and others, but the prevalence of HER2 overexpression (IHC3+) varies by tumor type. For simplicity, we focus on key cancers with significant HER2 positivity rates.

- Prevalence of HER2-positive solid tumors (IHC3+):

- Breast cancer: ~15-20% are HER2-positive.
- Gastric cancer: ~10-15% are HER2-positive.
- Other solid tumors (NSCLC, colorectal, etc.): ~2-5% are HER2-positive.

- **Eligible patients:** These are late-stage (unresectable/metastatic) patients who have failed prior therapies, representing a smaller subset of the total HER2-positive population.

We estimate the **addressable patient population** for this indication using cancer incidence data and adjusting for HER2 positivity and late-stage disease.

Estimated Incidence of Solid Tumors (Annual New Cases, Approx.)

- **US:** ~1.9 million new cancer cases (2023, American Cancer Society); ~15-20% are HER2-eligible tumors (breast, gastric, etc.), and ~30-40% of these are metastatic/unresectable at diagnosis or progression. Assume ~10-15% of total cancer cases are eligible after prior treatment failure: ~190,000-285,000 patients.
- **EU5:** ~2.7 million new cancer cases (2022, ECIS); similar HER2 and metastatic proportions: ~270,000-405,000 patients.
- **China:** ~4.8 million new cancer cases (2022, GLOBOCAN); similar proportions: ~480,000-720,000 patients.
- **Japan:** ~1 million new cancer cases (2022, GLOBOCAN); similar proportions: ~100,000-150,000 patients.

Total addressable patients (pre-treated, metastatic, HER2+):

- US: ~25,000-40,000 (conservative estimate after prior treatment failure).
- EU5: ~35,000-50,000.
- China: ~60,000-90,000.

- Japan: ~10,000-15,000.

Total across geographies: ~130,000-195,000 patients annually.

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

The problem assumes a **20%-30% share of treated patients**. This accounts for competition (e.g., trastuzumab, pertuzumab, T-DM1 for HER2+ cancers), physician adoption, reimbursement, and patient access.

- **Treated patients with Enhertu** (20%-30% of addressable population):

- US: 5,000-12,000 patients.

- EU5: 7,000-15,000 patients.

- China: 12,000-27,000 patients.

- Japan: 2,000-4,500 patients.

- **Total treated patients:** ~26,000-58,500 annually across geographies.

Step 3: Estimate Drug Pricing and Annual Cost per Patient

Enhertu is a high-cost oncology drug, typically priced based on a course of treatment or annual cost per patient. Pricing varies by region due to healthcare systems, reimbursement policies, and purchasing power.

- **US:** ~\$180,000-\$200,000 per patient per year (based on pricing for HER2+ breast cancer, ~\$13,000 per 3-week cycle, ~14 cycles/year).

- **EU5:** ~\$120,000-\$150,000 per patient per year (discounted due to payer negotiations).

- **Japan:** ~\$130,000-\$160,000 per patient per year (similar to EU pricing with some variation).

- **China:** ~\$60,000-\$80,000 per patient per year (lower due to price controls and generics competition, though access to innovative drugs is expanding).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as:

Peak Sales = Number of Treated Patients × Annual Cost per Patient

Peak Sales at 20%-30% Market Share (in \$ Millions)

- **US:**

- 5,000-12,000 patients × \$180,000-\$200,000 = **\$900M - \$2,400M.**

- **EU5:**

- 7,000-15,000 patients × \$120,000-\$150,000 = **\$840M - \$2,250M.**

- **China:**

- 12,000-27,000 patients × \$60,000-\$80,000 = **\$720M - \$2,160M.**

- **Japan:**

- 2,000-4,500 patients × \$130,000-\$160,000 = **\$260M - \$720M.**

Total Peak Sales Across Geographies: \$2,720M - \$7,530M (~\$2.7B to \$7.5B).

This range reflects the uncertainty in patient numbers, market share, and pricing. A midpoint estimate of ~\$5B in peak sales is reasonable for a blockbuster oncology drug like Enhertu in this broad indication, considering its success in breast cancer and potential expansion to other HER2+ tumors.

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

A 1% share of treated patients corresponds to 1% of the total addressable patient population being treated with Enhertu.

- **Addressable patients per 1% share:**

- US: 250-400 patients (1% of 25,000-40,000).

- EU5: 350-500 patients (1% of 35,000-50,000).

- China: 600-900 patients (1% of 60,000-90,000).

- Japan: 100-150 patients (1% of 10,000-15,000).

- **Revenue per 1% share** (using average pricing per region):

- US: 250-400 patients × \$190,000 (avg.) = **\$47.5M - \$76M.**

- EU5: 350-500 patients × \$135,000 (avg.) = **\$47.3M - \$67.5M.**

- China: 600-900 patients × \$70,000 (avg.) = **\$42M - \$63M.**

- Japan: 100-150 patients × \$145,000 (avg.) = **\$14.5M - \$21.8M.**

Total \$ Value of 1% Share Across Geographies: \$151.3M - \$228.3M.

Final Answer

1. **Potential Peak Sales for fam-trastuzumab deruxtecan-nxki (Enhertu)** in the indication of unresectable or metastatic HER2-positive (IHC3+) solid tumors, assuming 20%-30% market share:

- **US:** \$900M - \$2,400M.
- **EU5:** \$840M - \$2,250M.
- **China:** \$720M - \$2,160M.
- **Japan:** \$260M - \$720M.
- **Total: \$2.7B - \$7.5B** (midpoint ~\$5B).

2. \$ Value of 1% Share of Treated Patients:

- **US:** \$47.5M - \$76M.
- **EU5:** \$47.3M - \$67.5M.
- **China:** \$42M - \$63M.
- **Japan:** \$14.5M - \$21.8M.
- **Total: \$151.3M - \$228.3M** (midpoint ~\$190M).

Notes and Assumptions

- The patient population estimates are approximate and based on cancer incidence data and HER2 positivity rates. Real-world data on pre-treated, metastatic HER2+ patients may differ.
- Pricing is based on Enhertu's known costs in breast cancer and adjusted for regional variations. Actual pricing in China and other markets may vary due to negotiations or access programs.
- Peak sales assume steady-state market penetration (20%-30%) without accounting for patent expiry, biosimilars, or additional competition.
- These figures are for illustrative purposes. For precise estimates, detailed epidemiology data, competitive landscape analysis, and payer insights are required.