

To estimate the **Potential Peak Sales** for the drug "a new fixed-dose combination of pertuzumab, trastuzumab, and hyaluronidase-zzxf" (PHESGO) in the specified indication across the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data such as the exact indication, patient population, pricing, and penetration rates are not fully provided in your query, I will outline a general methodology with assumptions based on publicly available information about PHESGO and the oncology market (specifically for HER2-positive breast cancer, as PHESGO is approved for this indication). You can refine these numbers with more specific data if available.

PHESGO is a subcutaneous fixed-dose combination of pertuzumab and trastuzumab with hyaluronidase, approved for the treatment of HER2-positive breast cancer (early and metastatic). It offers a more convenient administration compared to intravenous formulations, which could drive market uptake.

Step 1: Define the Indication and Target Population

PHESGO is approved for:

- **Early HER2-positive breast cancer** (adjuvant and neoadjuvant settings).
- **Metastatic HER2-positive breast cancer** (first-line treatment in combination with chemotherapy).

For this analysis, we will focus on HER2-positive breast cancer (both early and metastatic) as the primary indication.

Incidence and Prevalence of HER2-Positive Breast Cancer

- HER2-positive breast cancer accounts for ~15-20% of all breast cancer cases.
- Annual incidence of breast cancer (all types) in the geographies:
 - **US**: ~280,000 new cases/year (American Cancer Society).
 - **EU5**: ~250,000 new cases/year (combined estimate based on ECIS data).
 - **China**: ~420,000 new cases/year (GLOBOCAN).
 - **Japan**: ~90,000 new cases/year (GLOBOCAN).
- Proportion of HER2-positive cases: Assume 20% of total breast cancer cases.
- Total new HER2-positive breast cancer cases per year:
 - **US**: ~56,000 ($280,000 * 0.2$).
 - **EU5**: ~50,000 ($250,000 * 0.2$).
 - **China**: ~84,000 ($420,000 * 0.2$).
 - **Japan**: ~18,000 ($90,000 * 0.2$).
- Prevalent cases (including metastatic patients eligible for ongoing treatment) are typically 2-3x the incidence for breast cancer due to longer survival. For simplicity, assume prevalent HER2-positive cases are 2.5x the incidence:

- **US:** ~140,000.
- **EU5:** ~125,000.
- **China:** ~210,000.
- **Japan:** ~45,000.
- Total treated population depends on diagnosis rates, access to therapy, and treatment guidelines. Assume 70% of prevalent cases are treated annually (accounting for undiagnosed or untreated patients):
- **US:** ~98,000.
- **EU5:** ~87,500.
- **China:** ~147,000 (lower access in some regions may reduce this; assume 50% treated = ~73,500).
- **Japan:** ~31,500.

Total treated HER2-positive breast cancer patients across geographies: ~290,500 (US: 98,000; EU5: 87,500; China: 73,500; Japan: 31,500).

Step 2: Market Share Assumption

The query assumes a **20-30% share of treated patients** for PHESGO. Factors influencing market share include:

- PHESGO's subcutaneous administration offers convenience over IV trastuzumab/pertuzumab (e.g., Herceptin and Perjeta).
- Competition from biosimilars of trastuzumab (Herceptin biosimilars are already in the market).
- Pricing and reimbursement dynamics in each region.

For peak sales estimation, assume a **25% market share** (midpoint of 20-30%) of treated patients:

- **US:** $98,000 * 0.25 = 24,500$ patients.
- **EU5:** $87,500 * 0.25 = 21,875$ patients.
- **China:** $73,500 * 0.25 = 18,375$ patients.
- **Japan:** $31,500 * 0.25 = 7,875$ patients.
- **Total patients on PHESGO:** ~72,625 patients.

Step 3: Pricing per Patient per Year

Pricing for PHESGO varies by region due to healthcare systems, reimbursement policies, and purchasing power. PHESGO combines pertuzumab and trastuzumab, so its pricing is comparable to the combined cost of Perjeta and Herceptin (IV formulations), with a potential premium for convenience.

- **US:** Annual cost of Perjeta + Herceptin (IV) is ~\$150,000-\$180,000 per patient. Assume PHESGO is priced at ~\$160,000/year.

- **EU5:** Pricing is lower due to negotiations and cost controls. Assume ~\$80,000-\$100,000/year (average ~\$90,000).

- **Japan:** Pricing is similar to EU5, assume ~\$90,000/year.

- **China:** Pricing is significantly lower due to market access challenges and local competition. Assume ~\$30,000/year (reflecting discounts and local production).

Annual cost per patient:

- **US:** \$160,000.

- **EU5:** \$90,000.

- **China:** \$30,000.

- **Japan:** \$90,000.

Step 4: Calculate Potential Peak Sales

Peak sales = (Number of patients on PHESGO) * (Annual cost per patient) for each region.

- **US:** 24,500 patients * \$160,000 = **\$3.92 billion**.

- **EU5:** 21,875 patients * \$90,000 = **\$1.97 billion**.

- **China:** 18,375 patients * \$30,000 = **\$0.55 billion**.

- **Japan:** 7,875 patients * \$90,000 = **\$0.71 billion**.

Total Potential Peak Sales: \$3.92B (US) + \$1.97B (EU5) + \$0.55B (China) + \$0.71B (Japan) = **~\$7.15 billion**.

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

1% share of treated patients = 1% of the total treated population (~290,500 patients) = 2,905 patients.

Annual revenue for 1% share:

- **US:** 1% of 98,000 = 980 patients * \$160,000 = **\$156.8 million**.

- **EU5:** 1% of 87,500 = 875 patients * \$90,000 = **\$78.75 million**.

- **China:** 1% of 73,500 = 735 patients * \$30,000 = **\$22.05 million**.

- **Japan:** 1% of 31,500 = 315 patients * \$90,000 = **\$28.35 million**.

Total \$ Value of 1% Share: \$156.8M (US) + \$78.75M (EU5) + \$22.05M (China) + \$28.35M (Japan) = ~\$286 million.

Final Answers

1. **Potential Peak Sales for PHESGO** (assuming 25% share of treated patients) in the US, EU5, China, and Japan: ~\$7.15 billion.

- US: \$3.92 billion.
- EU5: \$1.97 billion.
- China: \$0.55 billion.
- Japan: \$0.71 billion.

2. **\$ Value of 1% Share of Treated Patients** in these geographies: ~\$286 million.

- US: \$156.8 million.
- EU5: \$78.75 million.
- China: \$22.05 million.
- Japan: \$28.35 million.

Key Assumptions and Caveats

- **Patient population:** Based on rough estimates of HER2-positive breast cancer incidence and prevalence. Actual treated population may vary due to access, diagnosis rates, and treatment duration.
- **Market share:** Assumed 25% penetration (midpoint of 20-30%). Actual uptake depends on competition (biosimilars), payer policies, and physician/patient preference for subcutaneous vs. IV.
- **Pricing:** Estimated based on current costs of Perjeta/Herceptin and regional pricing trends. Actual pricing for PHESGO may differ.
- **Treatment duration:** Assumed annual cost covers full-year treatment; actual duration may vary (especially in early breast cancer settings).

If you have specific data on patient numbers, pricing, or market share forecasts, these estimates can be refined further. Additionally, if the indication includes other cancers or specific sub-populations, the analysis can be adjusted accordingly.