

To estimate the **Potential Peak Sales** for sacituzumab govitecan-hziy (Trodelyv) in the indication of metastatic triple-negative breast cancer (mTNBC) 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 make several assumptions and follow a structured approach. Since exact data on patient populations, pricing, and market penetration may not be publicly available, I will use reasonable estimates based on available information, epidemiology data, and standard industry practices. Let's break this down step by step.

Step 1: Define the Target Patient Population

Sacituzumab govitecan-hziy (Trodelyv) is approved for adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. This is a specific subset of breast cancer patients.

Epidemiology of mTNBC:

- **Triple-negative breast cancer (TNBC)** accounts for approximately 10-15% of all breast cancer cases.
- Of these, a smaller subset progresses to metastatic TNBC (mTNBC).
- Only a fraction of mTNBC patients will have received at least two prior therapies, making the eligible population even smaller.

Estimated Eligible Patient Population (per geography):

Using breast cancer incidence data and adjusting for TNBC (12.5% of cases), metastatic progression (30-40% of TNBC cases), and patients failing two prior therapies (assumed 50% of mTNBC), we can estimate the eligible population. Below are approximate figures for annual new cases (incidence) of eligible patients for treatment with Trodelyv:

- **US:** ~280,000 new breast cancer cases/year. TNBC (~12.5%) = ~35,000. mTNBC (~35%) = ~12,250. Eligible after 2 prior therapies (~50%) = ~6,125 patients/year.
- **EU5:** ~370,000 new breast cancer cases/year. TNBC (~12.5%) = ~46,250. mTNBC (~35%) = ~16,200. Eligible (~50%) = ~8,100 patients/year.
- **China:** ~420,000 new breast cancer cases/year. TNBC (~12.5%) = ~52,500. mTNBC (~35%) = ~18,375. Eligible (~50%) = ~9,200 patients/year.
- **Japan:** ~90,000 new breast cancer cases/year. TNBC (~12.5%) = ~11,250. mTNBC (~35%) = ~3,940. Eligible (~50%) = ~1,970 patients/year.

Total Eligible Patients Across Geographies: ~6,125 (US) + ~8,100 (EU5) + ~9,200 (China) + ~1,970 (Japan) = **~25,395 patients/year**.

Note: These are rough estimates and may vary based on actual data, differences in diagnosis rates, treatment access, and disease progression.

Step 2: Estimate Market Share

The question assumes a **20% to 30% share of treated patients** for Trodelvy in this indication. This market share accounts for competition from other therapies (e.g., chemotherapy, other antibody-drug conjugates, or immunotherapies) and barriers to adoption (e.g., cost, access, physician preference).

- **Low-end share (20%):** 20% of 25,395 = ~5,079 treated patients/year.

- **High-end share (30%):** 30% of 25,395 = ~7,619 treated patients/year.

Step 3: Estimate Pricing and Treatment Cost per Patient

Trodelvy's pricing varies by geography due to differences in healthcare systems, negotiations, and purchasing power. The drug is administered intravenously, with a treatment regimen typically involving multiple cycles (e.g., 10-12 cycles per year depending on patient response and tolerability).

- **US:** List price for Trodelvy is approximately \$2,000 per vial, with an average annual cost per patient of ~\$100,000–\$120,000 (based on reported data and treatment duration).

- **EU5:** Pricing is typically 30-50% lower than in the US due to negotiations with health authorities. Assume ~\$60,000–\$80,000 per patient/year.

- **China:** Pricing is often significantly lower due to government negotiations and local manufacturing partnerships. Assume ~\$30,000–\$50,000 per patient/year.

- **Japan:** Pricing is generally closer to EU levels. Assume ~\$60,000–\$80,000 per patient/year.

For simplicity, let's use average annual costs per patient:

- US: \$110,000

- EU5: \$70,000

- China: \$40,000

- Japan: \$70,000

Step 4: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients (based on market share) by the average annual cost per patient in each geography.

Low-end Market Share (20%):

- **US:** 6,125 patients × 20% = 1,225 patients × \$110,000 = **\$134.8 million**

- **EU5:** 8,100 patients × 20% = 1,620 patients × \$70,000 = **\$113.4 million**

- **China:** 9,200 patients × 20% = 1,840 patients × \$40,000 = **\$73.6 million**

- **Japan:** 1,970 patients × 20% = 394 patients × \$70,000 = **\$27.6 million**
- **Total Peak Sales (20% share):** \$134.8M + \$113.4M + \$73.6M + \$27.6M = **\$349.4 million/year**

High-end Market Share (30%):

- **US:** 6,125 patients × 30% = 1,838 patients × \$110,000 = **\$202.2 million**
- **EU5:** 8,100 patients × 30% = 2,430 patients × \$70,000 = **\$170.1 million**
- **China:** 9,200 patients × 30% = 2,760 patients × \$40,000 = **\$110.4 million**
- **Japan:** 1,970 patients × 30% = 591 patients × \$70,000 = **\$41.4 million**
- **Total Peak Sales (30% share):** \$202.2M + \$170.1M + \$110.4M + \$41.4M = **\$524.1 million/year**

Potential Peak Sales Range: \$349.4 million to \$524.1 million per year across the US, EU5, China, and Japan for this indication.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population (25,395 patients) = **254 patients/year**.

Using the same per-patient cost assumptions:

- **US:** 6,125 patients × 1% = 61 patients × \$110,000 = **\$6.7 million**
- **EU5:** 8,100 patients × 1% = 81 patients × \$70,000 = **\$5.7 million**
- **China:** 9,200 patients × 1% = 92 patients × \$40,000 = **\$3.7 million**
- **Japan:** 1,970 patients × 1% = 20 patients × \$70,000 = **\$1.4 million**
- **Total Value of 1% Share:** \$6.7M + \$5.7M + \$3.7M + \$1.4M = **\$17.5 million/year**

\$ Value of 1% Share of Treated Patients: \$17.5 million per year across the US, EU5, China, and Japan.

Final Answer:

1. **Potential Peak Sales for Sacituzumab Govitecan-hziy (Trodelyv)** in the indication of metastatic triple-negative breast cancer (mTNBC) with a 20% to 30% share of treated patients:

- **Range: \$349.4 million to \$524.1 million per year** across the US, EU5, China, and Japan.

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

- **Total: \$17.5 million per year** across the US, EU5, China, and Japan.

Caveats: These estimates are based on assumptions regarding patient populations, market share, pricing, and treatment duration. Real-world figures may differ due to factors such as competition, reimbursement policies, market access, and evolving treatment landscapes. For more precise data, consult specific market research reports (e.g., from EvaluatePharma, GlobalData) or company disclosures from Gilead Sciences (which acquired Immunomedics, the developer of Trodelvy).