To estimate the **Potential Peak Sales** for sacituzumab govitecan-hziy (Trodelvy) in the indication of unresectable locally advanced or metastatic HR-positive, HER2-negative breast cancer 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 such as exact patient numbers, pricing, or market penetration may not be fully available, I will outline the methodology and make reasonable assumptions based on publicly available information and industry standards. The final numbers are illustrative and should be validated with up-to-date market research and financial data.

Step 1: Define the Target Patient Population

The indication is for patients with unresectable locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting. This is a specific subset of breast cancer patients, often referred to as "triple-negative-like" or heavily pre-treated HR+/HER2- patients.

Incidence and Prevalence Data:

- **Breast Cancer Incidence**: According to the World Health Organization (WHO) and cancer registries, breast cancer is the most common cancer globally, with HR+/HER2- being the most common subtype (approximately 60-70% of all breast cancer cases).

- **Metastatic Breast Cancer (mBC)**: About 20-30% of early-stage breast cancer patients progress to metastatic disease, and a smaller percentage are diagnosed at the metastatic stage.

- **HR+/HER2- mBC in Later Lines**: The target population is patients who have progressed after endocrine therapy and at least two systemic therapies. This is typically a third-line or later setting, which represents a smaller subset (estimated 10-20% of mBC patients).

Estimated Eligible Patients (Annual Incidence):

Using rough estimates based on epidemiology data (e.g., SEER, Globocan, and local cancer registries), we can approximate the number of eligible patients per geography. These are new cases or prevalent cases eligible for treatment annually:

- **US**: ~40,000-50,000 eligible patients (based on ~250,000 new breast cancer cases/year, with ~60% HR+/HER2-, and ~15-20% in later lines).

- **EU5**: ~40,000-50,000 eligible patients (based on ~350,000 new cases/year across EU5, adjusted similarly).

- **China**: ~60,000-80,000 eligible patients (based on ~400,000 new cases/year, with a higher proportion of late-stage diagnoses).

- **Japan**: ~10,000-15,000 eligible patients (based on ~90,000 new cases/year, adjusted for later lines).

Total Eligible Patients Across Geographies: ~150,000-195,000 annually (midpoint ~172,500).

Step 2: Market Share Assumption

The problem states a **20% to 30% share of treated patients**. This refers to the proportion of eligible patients who will receive sacituzumab govitecan-hziy. We will use the midpoint of **25%** for calculations.

- **Treated Patients**: 25% of 172,500 = ~43,125 patients treated annually across all geographies.

Breakdown by Geography (based on patient distribution):

- **US**: ~25% of eligible (45,000 midpoint) = ~11,250 patients.

- **EU5**: ~25% of eligible (45,000 midpoint) = ~11,250 patients.

- **China**: ~25% of eligible (70,000 midpoint) = ~17,500 patients.

- **Japan**: ~25% of eligible (12,500 midpoint) = ~3,125 patients.

Step 3: Pricing and Annual Cost per Patient

Pricing for sacituzumab govitecan-hziy (Trodelvy) varies by region due to differences in healthcare systems, reimbursement, and purchasing power. Trodelvy is a high-cost oncology drug, and pricing is often based on a per-cycle or annual treatment cost.

Estimated Annual Cost per Patient:

- **US**: ~$100,000–$150,000 per patient per year (based on list prices for similar antibody-drug conjugates like Trodelvy, which is administered every 3 weeks).

- **EU5**: ~$60,000–$100,000 per patient per year (discounted due to negotiations with payers and health technology assessments).

- **China**: ~$30,000–$50,000 per patient per year (lower pricing due to market access challenges and government negotiations).

- **Japan**: ~$80,000–$120,000 per patient per year (similar to US but with some discounts).

Using midpoint values for simplicity:

- **US**: $125,000

- **EU5**: $80,000

- **China**: $40,000

- **Japan**: $100,000

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as: **Number of Treated Patients × Annual Cost per Patient** in each geography.

Peak Sales by Geography:

- **US**: 11,250 patients × $125,000 = **$1.406 billion**

- **EU5**: 11,250 patients × $80,000 = **$0.900 billion** ($900 million)

- **China**: 17,500 patients × $40,000 = **$0.700 billion** ($700 million)

- **Japan**: 3,125 patients × $100,000 = **$0.313 billion** ($313 million)

Total Potential Peak Sales:

$1.406B (US) + $0.900B (EU5) + $0.700B (China) + $0.313B (Japan) = **$3.319 billion annually**

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

A 1% share of treated patients corresponds to 1% of the eligible patients treated with the drug, i.e., 1% of 172,500 = **1,725 patients**.

Breakdown by Geography:

- **US**: 1% of 45,000 = 450 patients

- **EU5**: 1% of 45,000 = 450 patients

- **China**: 1% of 70,000 = 700 patients

- **Japan**: 1% of 12,500 = 125 patients

$ Value of 1% Share:

- **US**: 450 patients × $125,000 = **$56.25 million**

- **EU5**: 450 patients × $80,000 = **$36.00 million**

- **China**: 700 patients × $40,000 = **$28.00 million**

- **Japan**: 125 patients × $100,000 = **$12.50 million**

Total $ Value of 1% Share:

$56.25M (US) + $36.00M (EU5) + $28.00M (China) + $12.50M (Japan) = **$132.75 million**

Final Answers

1. **Potential Peak Sales for Sacituzumab Govitecan-hziy** (at 25% market share):

- **US**: $1.406 billion

- **EU5**: $0.900 billion ($900 million)

- **China**: $0.700 billion ($700 million)

- **Japan**: $0.313 billion ($313 million)

- **Total**: **$3.319 billion annually**

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

- **US**: $56.25 million

- **EU5**: $36.00 million

- **China**: $28.00 million

- **Japan**: $12.50 million

- **Total**: **$132.75 million**

Notes and Caveats

- These estimates are based on assumptions for patient populations, market share, and pricing. Real-world numbers may vary due to factors like competition (e.g., other therapies in HR+/HER2- mBC), reimbursement challenges, and market access delays.

- Peak sales typically occur several years after launch as the drug gains market penetration and regulatory approvals in different regions.

- Pricing in China and other emerging markets may be significantly lower due to government policies and generics/biosimilars.

- Patient numbers should be validated with more granular data from sources like IQVIA, EvaluatePharma, or clinical trial enrollment figures.

- Duration of treatment (e.g., progression-free survival on Trodelvy) impacts annual cost; if patients are on therapy for less than a year, costs may be lower.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market forecasts), I can refine these calculations further.