

To estimate the **Potential Peak Sales** for sacituzumab govitecan (Trodelyv) in the indication of unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) 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 exact data on patient populations, pricing, and penetration rates may not be publicly available, I will outline the methodology and use reasonable assumptions based on available data and market trends.

## **Step 1: Key Assumptions and Methodology**

1. **Patient Population:** Estimate the number of eligible mTNBC patients in each geography who have received two or more prior systemic therapies, at least one for metastatic disease.
2. **Market Penetration:** Assume a 20% to 30% share of treated patients as provided in the query.
3. **Pricing:** Estimate the annual cost of treatment per patient for sacituzumab govitecan based on publicly available data or benchmarks.
4. **Peak Sales:** Calculate potential peak sales by multiplying the number of treated patients by the annual cost of treatment.
5. **1% Share Value:** Calculate the dollar value of a 1% share of treated patients by dividing the peak sales (at 20%-30% penetration) by the respective penetration rate and then taking 1% of that total addressable market.

#### Assumptions:

- **Patient Population:** Based on epidemiology data, triple-negative breast cancer (TNBC) accounts for ~10-15% of all breast cancer cases, and a subset progresses to metastatic TNBC (mTNBC). Of these, a further subset meets the criteria of having received  $\geq 2$  prior therapies.
- **Annual Treatment Cost:** In the US, sacituzumab govitecan's list price is approximately \$2,000 per vial, with a typical annual cost per patient estimated at ~\$100,000-\$150,000 (based on dosing schedules and treatment duration). For EU5, costs are typically 30-50% lower due to pricing regulations. In China and Japan, costs may vary further based on local pricing and reimbursement policies.
- **Market Penetration:** 20%-30% of eligible patients as per the query.
- **Treatment Duration:** Assume an average treatment duration of 6-12 months, consistent with clinical trial data (e.g., ASCENT trial).

## **Step 2: Estimate Eligible Patient Population**

Using epidemiology data and breast cancer incidence rates:

- **US:** ~280,000 new breast cancer cases annually; ~10-15% are TNBC (~28,000-42,000). Of these, ~30-40% progress to mTNBC (~8,400-16,800). Assuming ~50% have received  $\geq 2$  prior therapies, eligible patients are ~4,200-8,400.
- **EU5:** Combined breast cancer incidence is ~400,000 annually; ~10-15% TNBC (~40,000-60,000). ~30-40% progress to mTNBC (~12,000-24,000). Assuming ~50% have  $\geq 2$  prior therapies, eligible patients are ~6,000-12,000.
- **China:** Breast cancer incidence is ~300,000 annually; ~10-15% TNBC (~30,000-45,000). ~30-40% progress to mTNBC (~9,000-18,000). Assuming ~50% have  $\geq 2$  prior therapies, eligible patients are ~4,500-9,000.

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- **Japan:** Breast cancer incidence is ~90,000 annually; ~10-15% TNBC (~9,000-13,500). ~30-40% progress to mTNBC (~2,700-5,400). Assuming ~50% have  $\geq 2$  prior therapies, eligible patients are ~1,350-2,700.

#### **Midpoint Estimates for Eligible Patients:**

- US: ~6,300
- EU5: ~9,000
- China: ~6,750
- Japan: ~2,025

### **Step 3: Annual Treatment Cost per Patient**

- **US:** ~\$125,000 (midpoint of \$100,000-\$150,000).
- **EU5:** ~\$75,000 (lower due to pricing controls).
- **China:** ~\$50,000 (lower due to local pricing and access programs).
- **Japan:** ~\$80,000 (slightly higher than EU5 due to advanced healthcare system).

### **Step 4: Potential Peak Sales Calculation (20%-30% Penetration)**

#### At 20% Penetration:

- **US:** 6,300 patients \* 20% = 1,260 treated patients \* \$125,000 = **\$157.5M**
- **EU5:** 9,000 patients \* 20% = 1,800 treated patients \* \$75,000 = **\$135M**
- **China:** 6,750 patients \* 20% = 1,350 treated patients \* \$50,000 = **\$67.5M**
- **Japan:** 2,025 patients \* 20% = 405 treated patients \* \$80,000 = **\$32.4M**
- **Total (20% Penetration):** \$157.5M + \$135M + \$67.5M + \$32.4M = **\$392.4M**

#### At 30% Penetration:

- **US:** 6,300 patients \* 30% = 1,890 treated patients \* \$125,000 = **\$236.25M**
- **EU5:** 9,000 patients \* 30% = 2,700 treated patients \* \$75,000 = **\$202.5M**
- **China:** 6,750 patients \* 30% = 2,025 treated patients \* \$50,000 = **\$101.25M**
- **Japan:** 2,025 patients \* 30% = 607.5 treated patients \* \$80,000 = **\$48.6M**
- **Total (30% Penetration):** \$236.25M + \$202.5M + \$101.25M + \$48.6M = **\$588.6M**

**Potential Peak Sales Range: \$392.4M to \$588.6M annually** across US, EU5, China, and Japan for this indication.

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

To calculate the value of a 1% share, we use the total addressable market (100% penetration) and take 1% of that value.

- **US:** 6,300 patients \* \$125,000 = \$787.5M total market; 1% = **\$7.875M**
- **EU5:** 9,000 patients \* \$75,000 = \$675M total market; 1% = **\$6.75M**
- **China:** 6,750 patients \* \$50,000 = \$337.5M total market; 1% = **\$3.375M**
- **Japan:** 2,025 patients \* \$80,000 = \$162M total market; 1% = **\$1.62M**
- **Total (1% Share Across Geographies):** \$7.875M + \$6.75M + \$3.375M + \$1.62M = **\$19.62M**

## **Final Answer**

1. **Potential Peak Sales for Sacituzumab Govitecan in mTNBC** (20%-30% share of treated patients):

- **US:** \$157.5M to \$236.25M
- **EU5:** \$135M to \$202.5M
- **China:** \$67.5M to \$101.25M
- **Japan:** \$32.4M to \$48.6M
- **Total: \$392.4M to \$588.6M annually**

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

- **US:** \$7.875M
- **EU5:** \$6.75M
- **China:** \$3.375M
- **Japan:** \$1.62M
- **Total: \$19.62M**

## **Caveats**

- These estimates are based on assumptions and publicly available data. Actual patient numbers, pricing, and penetration rates may differ based on real-world access, reimbursement, competition, and clinical adoption.

- Peak sales may vary depending on additional indications, label expansions, or changes in treatment guidelines.

- Local pricing and healthcare policies (especially in China) may significantly impact costs and sales potential.