

To estimate the **Potential Peak Sales** for sacituzumab govitecan (Trodely) in the indication of locally advanced or metastatic urothelial cancer (mUC) 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 based on available data and reasonable assumptions. Since exact patient numbers, pricing, and market penetration can vary, I will outline the methodology and use approximate figures based on industry trends, epidemiology data, and market research. Please note that these are illustrative calculations and should be validated with up-to-date data.

Step 1: Key Assumptions and Data Points

1. **Indication:** Locally advanced or metastatic urothelial cancer (mUC) in patients who have received prior platinum-containing chemotherapy and PD-1/PD-L1 inhibitors (second-line or later therapy).
2. **Market Share:** Assuming a 20% to 30% share of treated patients in this indication.
3. **Patient Population:** Estimate the eligible patient population in each geography based on incidence, prevalence, and treatment rates for mUC.
4. **Pricing:** Estimate the annual cost of therapy for sacituzumab govitecan. In the US, the cost of Trodely is approximately \$100,000–\$120,000 per year per patient (based on oncology drug pricing trends and reported costs for Trodely in other indications like breast cancer). Pricing in other regions will be lower due to healthcare system differences (e.g., ~50–70% of US price in EU5, ~30–50% in China and Japan).
5. **Treatment Duration:** Assume an average treatment duration of 6–12 months per patient, but for simplicity, we'll calculate based on annual cost.

Step 2: Estimate Eligible Patient Population

The incidence of urothelial cancer (bladder cancer being the most common form) and the proportion of patients reaching advanced/metastatic stages with prior treatment failure can be estimated as follows (based on epidemiology data and cancer statistics):

- **US:** ~80,000 new bladder cancer cases annually; ~20–25% are metastatic or locally advanced at diagnosis or progression. Of these, ~50% may fail first-line therapy (platinum-based) and progress to second-line (PD-1/PD-L1 inhibitors). Of those, ~50% fail and become eligible for later-line therapies. Estimated eligible patients: ~5,000–7,000.
- **EU5:** Combined bladder cancer incidence is ~120,000 annually; similar progression rates as the US. Estimated eligible patients: ~8,000–10,000.
- **China:** Bladder cancer incidence is ~80,000 annually; lower access to advanced therapies may reduce eligible patients. Estimated eligible patients: ~3,000–5,000.
- **Japan:** Bladder cancer incidence is ~20,000 annually; high access to therapies. Estimated eligible patients: ~1,500–2,000.

Total Eligible Patients (Approximate):

- US: 6,000
- EU5: 9,000
- China: 4,000

- Japan: 1,750
- **Total Across Geographies:** ~20,750 patients

Step 3: Estimate Treated Patients with Sacituzumab Govitecan

Assuming a market share of 20% to 30% of eligible patients:

- **20% Share:** 20% of 20,750 = ~4,150 patients
- **30% Share:** 30% of 20,750 = ~6,225 patients

Breakdown by geography (using 20% and 30% share):

- **US:** 1,200 (20%) to 1,800 (30%) patients
- **EU5:** 1,800 (20%) to 2,700 (30%) patients
- **China:** 800 (20%) to 1,200 (30%) patients
- **Japan:** 350 (20%) to 525 (30%) patients

Step 4: Estimate Annual Cost per Patient by Geography

- **US:** \$110,000 per patient per year
- **EU5:** \$70,000 per patient per year (lower due to pricing negotiations)
- **China:** \$40,000 per patient per year (significant price reductions)
- **Japan:** \$60,000 per patient per year (moderate price reductions)

Step 5: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each geography.

At 20% Market Share:

- **US:** 1,200 patients * \$110,000 = \$132 million
- **EU5:** 1,800 patients * \$70,000 = \$126 million
- **China:** 800 patients * \$40,000 = \$32 million
- **Japan:** 350 patients * \$60,000 = \$21 million
- **Total Peak Sales (20% share):** \$132M + \$126M + \$32M + \$21M = **\$311 million**

At 30% Market Share:

- **US:** 1,800 patients * \$110,000 = \$198 million
- **EU5:** 2,700 patients * \$70,000 = \$189 million
- **China:** 1,200 patients * \$40,000 = \$48 million
- **Japan:** 525 patients * \$60,000 = \$31.5 million

- **Total Peak Sales (30% share):** $\$198\text{M} + \$189\text{M} + \$48\text{M} + \$31.5\text{M} = \$466.5 \text{ million}$

Potential Peak Sales Range: Approximately **\$311 million to \$466.5 million** annually across the US, EU5, China, and Japan for this indication.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total eligible patient population (20,750 patients) = ~207.5 patients.

Breakdown by geography:

- **US:** 1% of 6,000 = 60 patients
- **EU5:** 1% of 9,000 = 90 patients
- **China:** 1% of 4,000 = 40 patients
- **Japan:** 1% of 1,750 = 17.5 patients

Value of 1% share (patients * annual cost per patient):

- **US:** 60 patients * \$110,000 = \$6.6 million
- **EU5:** 90 patients * \$70,000 = \$6.3 million
- **China:** 40 patients * \$40,000 = \$1.6 million
- **Japan:** 17.5 patients * \$60,000 = \$1.05 million
- **Total Value of 1% Share:** $\$6.6\text{M} + \$6.3\text{M} + \$1.6\text{M} + \$1.05\text{M} = \$15.55 \text{ million}$

Final Answer

- **Potential Peak Sales for Sacituzumab Govitecan in mUC (20% to 30% market share):**
- Range: **\$311 million to \$466.5 million annually** across the US, EU5, China, and Japan.
- **\$ Value of 1% Share of Treated Patients:**
- Approximately **\$15.55 million annually** across the US, EU5, China, and Japan.

Caveats

1. These estimates are based on assumptions about patient numbers, pricing, and market penetration. Actual figures may vary due to competition, reimbursement policies, and real-world treatment patterns.
2. Peak sales may take several years to achieve post-launch and depend on clinical trial outcomes, label expansions, and market access.
3. For more accurate data, consult sources like company reports (Gilead Sciences, which acquired Immunomedics), oncology market research (e.g., EvaluatePharma, GlobalData), or epidemiology databases (e.g., SEER, GLOBOCAN).

If you have specific data (e.g., exact patient numbers or pricing), I can refine the calculations further.

