

To estimate the **Potential Peak Sales** for tazemetostat (TAZVERIK) in the indication of metastatic or locally advanced epithelioid sarcoma (not eligible for complete resection) 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 follow a structured approach. Since specific data on patient numbers, pricing, and market penetration may not be publicly available in real-time, I will make reasonable assumptions based on available information, epidemiology data, and typical market dynamics for rare cancer drugs. Let's break this down step by step.

Step 1: Indication and Target Population

Tazemetostat is approved for adults and pediatric patients aged 16 years and older with **metastatic or locally advanced epithelioid sarcoma (ES)** not eligible for complete resection. Epithelioid sarcoma is a rare soft tissue sarcoma with an incidence of approximately **0.1–0.4 per 100,000 people** annually. It primarily affects younger adults, and about 50–70% of cases may present as locally advanced or metastatic at diagnosis.

Estimated Incidence and Prevalence:

- **Annual Incidence:** ~0.1–0.4 per 100,000.
- **Prevalence:** Given the poor prognosis (5-year survival rate of ~50–60% for advanced cases), prevalence is often 2–3 times the annual incidence for rare cancers.
- For simplicity, we will focus on **incident cases** eligible for treatment annually, assuming a proportion are not eligible for resection.

Population in Target Geographies (2023 estimates):

- US: ~330 million
- EU5 (Germany, France, Italy, Spain, UK): ~320 million
- China: ~1,400 million
- Japan: ~125 million
- **Total Population:** ~2,175 million

Estimated Incident Cases of Epithelioid Sarcoma:

Using an incidence of 0.2 per 100,000 (midpoint of the range):

- US: $330M \times 0.2/100,000 = \sim 660$ cases/year
- EU5: $320M \times 0.2/100,000 = \sim 640$ cases/year
- China: $1,400M \times 0.2/100,000 = \sim 2,800$ cases/year
- Japan: $125M \times 0.2/100,000 = \sim 250$ cases/year
- **Total Incident Cases:** ~4,350 cases/year

Eligible Patients (Not Eligible for Resection):

Approximately 50–70% of epithelioid sarcoma cases are locally advanced or metastatic at diagnosis and may not be eligible for complete resection. Let's assume **60%** are eligible for systemic therapy like tazemetostat:

- US: $660 * 0.6 = \sim 400$ patients/year
- EU5: $640 * 0.6 = \sim 385$ patients/year
- China: $2,800 * 0.6 = \sim 1,680$ patients/year
- Japan: $250 * 0.6 = \sim 150$ patients/year
- **Total Eligible Patients:** $\sim 2,615$ patients/year

Step 2: Market Penetration (Share of Treated Patients)

The query assumes a **20% to 30% share of treated patients**. This accounts for factors like physician adoption, competition, access to therapy, and payer reimbursement. Let's calculate for both ends of the range:

- At 20% penetration:
 - US: $400 * 0.2 = 80$ patients/year
 - EU5: $385 * 0.2 = 77$ patients/year
 - China: $1,680 * 0.2 = 336$ patients/year
 - Japan: $150 * 0.2 = 30$ patients/year
 - **Total:** 523 patients/year
- At 30% penetration:
 - US: $400 * 0.3 = 120$ patients/year
 - EU5: $385 * 0.3 = 116$ patients/year
 - China: $1,680 * 0.3 = 504$ patients/year
 - Japan: $150 * 0.3 = 45$ patients/year
 - **Total:** 785 patients/year

Step 3: Pricing of Tazemetostat

Tazemetostat is a targeted therapy for a rare cancer, so pricing is typically high in developed markets. Based on publicly available data and typical pricing for orphan drugs:

- **US:** Annual cost of therapy is approximately **\$400,000–\$450,000** per patient (based on TAZVERIK's pricing for other indications like follicular lymphoma, adjusted for epithelioid sarcoma).
- **EU5:** Pricing is often 60–80% of US prices due to healthcare system negotiations. Assume **~\$300,000** per patient/year.

- **Japan:** Pricing is similar to EU5, ~\$300,000 per patient/year.
- **China:** Pricing is significantly lower due to market access challenges and local pricing policies. Assume ~\$100,000 per patient/year.

(Note: These are rough estimates. Actual pricing may vary based on reimbursement, patient assistance programs, and market-specific factors. Treatment duration may also be less than a full year for some patients due to disease progression or tolerability, but we assume full-year cost for peak sales estimation.)

Step 4: Potential Peak Sales Calculation

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

At 20% Penetration:

- **US:** 80 patients * \$425,000 = **\$34.0 million**
- **EU5:** 77 patients * \$300,000 = **\$23.1 million**
- **China:** 336 patients * \$100,000 = **\$33.6 million**
- **Japan:** 30 patients * \$300,000 = **\$9.0 million**
- **Total Peak Sales (20%):** **\$99.7 million**

At 30% Penetration:

- **US:** 120 patients * \$425,000 = **\$51.0 million**
- **EU5:** 116 patients * \$300,000 = **\$34.8 million**
- **China:** 504 patients * \$100,000 = **\$50.4 million**
- **Japan:** 45 patients * \$300,000 = **\$13.5 million**
- **Total Peak Sales (30%):** **\$149.7 million**

Potential Peak Sales Range: **\$99.7 million to \$149.7 million** annually for this indication across the specified geographies.

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

A 1% share of treated patients corresponds to 1% of the eligible patient pool in each geography. Using the eligible patient numbers calculated earlier:

- **US:** 400 * 0.01 = 4 patients
- **EU5:** 385 * 0.01 = 3.85 (~4) patients
- **China:** 1,680 * 0.01 = 16.8 (~17) patients

- Japan: $150 * 0.01 = 1.5$ (~2) patients

Now multiply by the annual cost per patient in each geography:

- **US:** 4 patients * \$425,000 = **\$1.7 million**

- **EU5:** 4 patients * \$300,000 = **\$1.2 million**

- **China:** 17 patients * \$100,000 = **\$1.7 million**

- **Japan:** 2 patients * \$300,000 = **\$0.6 million**

- **Total \$ Value of 1% Share: \$5.2 million**

Final Answers:

1. **Potential Peak Sales for Tazemetostat** in the indication of metastatic or locally advanced epithelioid sarcoma (not eligible for complete resection) across the US, EU5, China, and Japan, assuming a 20% to 30% share of treated patients:

- **Range: \$99.7 million to \$149.7 million annually**

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

- **Total: \$5.2 million**

Caveats and Assumptions:

- **Epidemiology Data:** Incidence and prevalence estimates for epithelioid sarcoma are based on general rare cancer data and may vary by region.

- **Pricing:** Costs are estimated based on typical orphan drug pricing and may differ due to local negotiations, reimbursement policies, or patient assistance programs.

- **Treatment Duration:** Assumes full-year treatment cost, though real-world duration may be shorter due to progression or tolerability.

- **Market Penetration:** Assumes 20–30% share as provided, but actual adoption depends on competition, clinical outcomes, and access.

- **Peak Sales Timing:** Peak sales may take several years post-launch to achieve, depending on market uptake.

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