

To estimate the **Potential Peak Sales** for tisotumab vedotin-tftv (Tivdak) in the indication of recurrent or metastatic cervical cancer with disease progression on or after chemotherapy, as well as the **\$ value of a 1% share of treated patients** in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, we need to follow a structured approach based on available data, assumptions, and market analysis. Since exact figures for patient populations, pricing, and market penetration are not provided, I will outline the methodology and use reasonable assumptions based on publicly available data and industry standards.

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

1. **Indication and Patient Population:** The drug is approved for recurrent or metastatic cervical cancer patients who progressed on or after chemotherapy. This is a niche indication with a relatively small patient population.
2. **Market Share:** Assuming a 20% to 30% share of treated patients as per the query.
3. **Pricing:** Pricing for oncology drugs like antibody-drug conjugates (ADCs) can vary widely by region. In the US, such drugs often cost \$100,000–\$200,000 per patient per year. In the EU5, pricing is typically lower due to healthcare system negotiations (e.g., 50–70% of US prices). In China and Japan, pricing may be further discounted or adjusted based on local policies.
4. **Peak Sales:** Peak sales are typically achieved 5–10 years post-launch after maximum market penetration.
5. **Epidemiology:** Cervical cancer incidence and prevalence data will be used to estimate the eligible patient population.
6. **Treatment Duration:** Assuming an average treatment duration of 6–12 months for recurrent/metastatic patients.

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

Using approximate figures for cervical cancer incidence and prevalence (sourced from WHO, GLOBOCAN, and other public data as of 2020/2021):

- **US:** ~14,000 new cervical cancer cases annually; ~4,000 deaths. Recurrent/metastatic cases post-chemotherapy are estimated at 2,000–3,000 patients annually.
- **EU5:** ~30,000 new cases annually; recurrent/metastatic post-chemotherapy estimated at 5,000–7,000 patients.
- **China:** ~110,000 new cases annually; recurrent/metastatic post-chemotherapy estimated at 15,000–20,000 patients (higher incidence due to population size and limited early screening in some regions).
- **Japan:** ~10,000 new cases annually; recurrent/metastatic post-chemotherapy estimated at 1,500–2,000 patients.

**Total eligible patients across geographies:** ~23,500–32,000 patients annually.

## **Step 3: Estimating Market Share and Treated Patients**

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

- **20% share:** ~4,700–6,400 treated patients.
- **30% share:** ~7,050–9,600 treated patients.

Breakdown by region (approximate distribution based on population size and healthcare access):

- **US:** 10–15% of total patients (20% share: ~470–960; 30% share: ~705–1,440).
- **EU5:** 20–25% of total patients (20% share: ~940–1,600; 30% share: ~1,410–2,400).
- **China:** 50–60% of total patients (20% share: ~2,350–3,840; 30% share: ~3,525–5,760).
- **Japan:** 5–10% of total patients (20% share: ~235–640; 30% share: ~352–960).

## **Step 4: Pricing Assumptions**

Annual cost per patient (hypothetical, based on ADC pricing trends):

- **US:** \$150,000 per patient per year.
- **EU5:** \$90,000 per patient per year (60% of US price).
- **China:** \$50,000 per patient per year (lower due to pricing controls and generics competition).
- **Japan:** \$100,000 per patient per year (closer to US but with some discounts).

## **Step 5: Potential Peak Sales Calculation**

Peak sales are calculated as: (Number of treated patients) × (Annual cost per patient).

#### At 20% Market Share:

- **US:** 470–960 patients × \$150,000 = **\$70.5M–\$144M.**
- **EU5:** 940–1,600 patients × \$90,000 = **\$84.6M–\$144M.**
- **China:** 2,350–3,840 patients × \$50,000 = **\$117.5M–\$192M.**
- **Japan:** 235–640 patients × \$100,000 = **\$23.5M–\$64M.**
- **Total Peak Sales (20% share):** **\$296M–\$544M.**

#### At 30% Market Share:

- **US:** 705–1,440 patients × \$150,000 = **\$105.8M–\$216M.**
- **EU5:** 1,410–2,400 patients × \$90,000 = **\$126.9M–\$216M.**
- **China:** 3,525–5,760 patients × \$50,000 = **\$176.3M–\$288M.**
- **Japan:** 352–960 patients × \$100,000 = **\$35.2M–\$96M.**
- **Total Peak Sales (30% share):** **\$444M–\$816M.**

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

A 1% share corresponds to 1% of the total eligible patient population (23,500–32,000), i.e., 235–320 patients.

- **US:** 10–15% of patients (23–48 patients) × \$150,000 = **\$3.5M–\$7.2M.**
- **EU5:** 20–25% of patients (47–80 patients) × \$90,000 = **\$4.2M–\$7.2M.**
- **China:** 50–60% of patients (118–192 patients) × \$50,000 = **\$5.9M–\$9.6M.**
- **Japan:** 5–10% of patients (12–32 patients) × \$100,000 = **\$1.2M–\$3.2M.**
- **Total \$ Value of 1% Share: \$14.8M–\$27.2M.**

### **Final Answer:**

1. **Potential Peak Sales for tisotumab vedotin-tftv** in recurrent or metastatic cervical cancer (post-chemotherapy) across the US, EU5, China, and Japan:

- At 20% market share: **\$296M–\$544M.**
- At 30% market share: **\$444M–\$816M.**

2. **\$ Value of 1% Share of Treated Patients** across the same geographies: **\$14.8M–\$27.2M.**

**Note:** These figures are based on assumptions and should be refined with actual patient data, real-world pricing, market access barriers, competition, and uptake rates. Factors like reimbursement policies, competitor drugs (e.g., pembrolizumab in cervical cancer), and regional healthcare disparities could impact these estimates. If you have specific data on pricing or patient numbers, I can adjust the calculations accordingly.