

To estimate the **Potential Peak Sales** for **enfortumab vedotin-ejfv (Padcev)** in the indication of locally advanced or metastatic urothelial cancer in the US, EU5 (France, Germany, Italy, Spain, and the 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, assumptions, and market analysis. Since exact figures may not be publicly available, I will provide a step-by-step methodology with reasonable assumptions. Note that this analysis is hypothetical and based on general market trends for oncology drugs.

Step 1: Define the Target Patient Population

Indication: Locally advanced or metastatic urothelial cancer (LA/mUC) in adult patients.

Epidemiology of Urothelial Cancer (Bladder Cancer as the primary type):

- Urothelial cancer primarily affects the bladder, and a subset of patients progress to locally advanced or metastatic stages.
- Incidence and prevalence vary by region due to differences in risk factors (e.g., smoking, industrial exposure) and healthcare access.
- Roughly 20-25% of bladder cancer patients progress to advanced or metastatic stages.

Estimated Annual Incidence of Bladder Cancer (2023 projections based on historical data):

- **US:** ~82,000 new cases (SEER data, American Cancer Society).
- **EU5:** ~150,000 new cases (combined estimate based on GLOBOCAN and EU cancer statistics).
- **China:** ~80,000 new cases (GLOBOCAN data, adjusted for population).
- **Japan:** ~22,000 new cases (GLOBOCAN and local data).

Proportion of LA/mUC Patients (assuming 20-25% of total bladder cancer cases):

- **US:** ~16,400-20,500 patients.
- **EU5:** ~30,000-37,500 patients.
- **China:** ~16,000-20,000 patients.
- **Japan:** ~4,400-5,500 patients.

Total Target Population (midpoint estimate):

- **US:** ~18,500 patients.
- **EU5:** ~33,750 patients.
- **China:** ~18,000 patients.
- **Japan:** ~5,000 patients.
- **Total across geographies:** ~75,250 patients.

Step 2: Estimate the Share of Treated Patients

- The problem assumes a **20% to 30% share of treated patients** for enfortumab vedotin-ejfv in this indication.
- This share accounts for factors such as:
 - Competition from other therapies (e.g., immune checkpoint inhibitors like pembrolizumab, nivolumab, or chemotherapy regimens).
 - Market access, pricing, and reimbursement policies.
 - Physician adoption and patient eligibility (e.g., prior treatment history, as Padcev is often used in later lines of therapy after platinum-based chemotherapy and PD-1/PD-L1 inhibitors).

Midpoint Assumption: 25% share of treated patients.

- **US:** $18,500 * 25\% = \sim 4,625$ treated patients.
- **EU5:** $33,750 * 25\% = \sim 8,438$ treated patients.
- **China:** $18,000 * 25\% = \sim 4,500$ treated patients.
- **Japan:** $5,000 * 25\% = \sim 1,250$ treated patients.
- **Total treated patients:** $\sim 18,813$ patients.

Step 3: Estimate Annual Cost of Therapy per Patient

- Enfortumab vedotin-ejfv (Padcev) is an antibody-drug conjugate (ADC) used in oncology, and such drugs typically have high annual costs.
- Based on public data and analyst reports, the annual cost of Padcev in the US is approximately **\$120,000–\$150,000 per patient** (depending on dosing schedule, duration of therapy, and payer discounts).
- Costs in other regions are typically lower due to pricing regulations and healthcare systems:
 - **EU5:** $\sim 60\text{--}80\%$ of US cost, i.e., \$72,000–\$120,000 (midpoint: \$96,000).
 - **Japan:** $\sim 70\text{--}90\%$ of US cost, i.e., \$84,000–\$135,000 (midpoint: \$109,500).
 - **China:** Significantly lower due to pricing controls and local competition, $\sim 30\text{--}50\%$ of US cost, i.e., \$36,000–\$75,000 (midpoint: \$55,500).

Midpoint Annual Cost per Patient:

- **US:** \$135,000.
- **EU5:** \$96,000.
- **China:** \$55,500.
- **Japan:** \$109,500.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as:

Peak Sales = Number of Treated Patients * Annual Cost per Patient

- **US:** 4,625 patients * \$135,000 = **\$624.4 million.**
- **EU5:** 8,438 patients * \$96,000 = **\$810.0 million.**
- **China:** 4,500 patients * \$55,500 = **\$249.8 million.**
- **Japan:** 1,250 patients * \$109,500 = **\$136.9 million.**
- **Total Peak Sales: \$1,821.1 million (~\$1.82 billion).**

Range of Peak Sales (based on 20% to 30% share):

- At 20% share: ~\$1.46 billion.
- At 30% share: ~\$2.19 billion.
- **Midpoint (25% share): \$1.82 billion.**

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

A 1% share of treated patients corresponds to 1% of the total target population being treated with enfortumab vedotin-ejfv.

- **US:** 18,500 * 1% = 185 patients * \$135,000 = **\$25.0 million.**
- **EU5:** 33,750 * 1% = 338 patients * \$96,000 = **\$32.4 million.**
- **China:** 18,000 * 1% = 180 patients * \$55,500 = **\$10.0 million.**
- **Japan:** 5,000 * 1% = 50 patients * \$109,500 = **\$5.5 million.**
- **Total Value of 1% Share: \$72.9 million.**

Final Answer

1. Potential Peak Sales for Enfortumab Vedotin-ejfv (at 20%-30% share of treated patients):

- **US:** \$499.5M (20%) to \$749.3M (30%), midpoint ~\$624.4M.
- **EU5:** \$648.0M (20%) to \$972.0M (30%), midpoint ~\$810.0M.
- **China:** \$199.8 **Japan:** \$109.4M (20%) to \$164.1M (30%), midpoint ~\$136.9M.
- **Total:** \$1.46B (20%) to \$2.19B (30%), midpoint ~**\$1.82 billion.**

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

- **US:** \$25.0M.
- **EU5:** \$32.4M.
- **China:** \$10.0M.
- **Japan:** \$5.5M.
- **Total:** **\$72.9 million.**

Note: These estimates are based on assumptions and publicly available data as of 2023. Actual figures may vary due to changes in pricing, market dynamics, competition, and real-world patient access. For precise figures, consult primary market research or financial reports from Astellas Pharma or Seagen (co-developer of Padcev).