

To estimate the **Potential Peak Sales** for avelumab (BAVENCIO) in the indication of maintenance treatment for locally advanced or metastatic urothelial carcinoma (UC) 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 figures for patient populations, pricing, and penetration rates are not provided, I will outline the methodology and use illustrative numbers based on industry standards and publicly available data as of my last update (October 2023). Please note that these are hypothetical calculations and should be validated with current market research or proprietary data for accuracy.

Step 1: Define Key Parameters for Peak Sales Calculation

1. **Target Patient Population:** Estimate the number of patients eligible for avelumab in the indication of maintenance treatment for locally advanced or metastatic UC who have not progressed on first-line platinum-containing chemotherapy.
2. **Market Share:** Given as 20% to 30% share of treated patients.
3. **Pricing:** Annual cost of treatment per patient for avelumab.
4. **Treatment Duration:** Average duration of maintenance therapy.
5. **Geographies:** US, EU5, China, and Japan.

Step 2: Estimate Eligible Patient Population

Urothelial carcinoma is a subset of bladder cancer and other urinary tract cancers. Maintenance therapy applies to patients who have not progressed after first-line platinum-based chemotherapy (approximately 40-50% of patients respond or have stable disease). Below are rough estimates of the annual incident cases of advanced/metastatic UC eligible for maintenance therapy in each geography, based on epidemiology data and cancer statistics:

- **US:** ~80,000 new bladder cancer cases/year; ~20% are advanced/metastatic at diagnosis or progress to this stage (~16,000). Of these, ~40-50% do not progress on first-line therapy (~6,400–8,000 eligible patients).
- **EU5:** ~120,000 new bladder cancer cases/year; ~20% advanced/metastatic (~24,000). Of these, ~40-50% eligible (~9,600–12,000 patients).
- **China:** ~80,000 new bladder cancer cases/year; ~20% advanced/metastatic (~16,000). Of these, ~40-50% eligible (~6,400–8,000 patients).
- **Japan:** ~20,000 new bladder cancer cases/year; ~20% advanced/metastatic (~4,000). Of these, ~40-50% eligible (~1,600–2,000 patients).

Total Eligible Patients (Midpoint Estimate):

- US: 7,200
- EU5: 10,800
- China: 7,200
- Japan: 1,800

- **Total:** 27,000 patients/year

Step 3: Estimate Pricing for Avelumab

Avelumab is a PD-L1 inhibitor, and its pricing is aligned with other immune checkpoint inhibitors. The annual cost of treatment varies by region due to differences in healthcare systems and pricing negotiations:

- **US:** ~\$150,000–\$180,000 per patient/year (based on similar drugs like pembrolizumab or nivolumab).
- **EU5:** ~\$80,000–\$100,000 per patient/year (lower due to price controls and negotiations).
- **China:** ~\$50,000–\$70,000 per patient/year (lower pricing due to market access programs and generics competition).
- **Japan:** ~\$100,000–\$120,000 per patient/year (similar to EU5 but with specific pricing structures).

Assumed Annual Cost (Midpoint):

- US: \$165,000
- EU5: \$90,000
- China: \$60,000
- Japan: \$110,000

Step 4: Calculate Potential Peak Sales at 20% and 30% Market Share

Peak sales are calculated as:

Peak Sales = Eligible Patients × Market Share × Annual Cost per Patient

At 20% Market Share:

- **US:** $7,200 \times 0.20 \times \$165,000 = \$237.6 \text{ million}$
- **EU5:** $10,800 \times 0.20 \times \$90,000 = \$194.4 \text{ million}$
- **China:** $7,200 \times 0.20 \times \$60,000 = \$86.4 \text{ million}$
- **Japan:** $1,800 \times 0.20 \times \$110,000 = \$39.6 \text{ million}$
- **Total Peak Sales at 20% Share:** $\$237.6\text{M} + \$194.4\text{M} + \$86.4\text{M} + \$39.6\text{M} = \$558 \text{ million}$

At 30% Market Share:

- **US:** $7,200 \times 0.30 \times \$165,000 = \$356.4 \text{ million}$
- **EU5:** $10,800 \times 0.30 \times \$90,000 = \$291.6 \text{ million}$
- **China:** $7,200 \times 0.30 \times \$60,000 = \$129.6 \text{ million}$
- **Japan:** $1,800 \times 0.30 \times \$110,000 = \$59.4 \text{ million}$
- **Total Peak Sales at 30% Share:** $\$356.4\text{M} + \$291.6\text{M} + \$129.6\text{M} + \$59.4\text{M} = \$837 \text{ million}$

Potential Peak Sales Range: \$558 million to \$837 million annually across the specified geographies.

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

The value of a 1% share is calculated as:

Value of 1% Share = Eligible Patients × 0.01 × Annual Cost per Patient

- **US:** $7,200 \times 0.01 \times \$165,000 = \$11.88 \text{ million}$
- **EU5:** $10,800 \times 0.01 \times \$90,000 = \$9.72 \text{ million}$
- **China:** $7,200 \times 0.01 \times \$60,000 = \$4.32 \text{ million}$
- **Japan:** $1,800 \times 0.01 \times \$110,000 = \$1.98 \text{ million}$
- **Total Value of 1% Share:** $\$11.88\text{M} + \$9.72\text{M} + \$4.32\text{M} + \$1.98\text{M} = \$27.9 \text{ million}$

Final Answers:

1. **Potential Peak Sales for Avelumab** in the indication of maintenance treatment for locally advanced or metastatic UC (assuming 20% to 30% market share):

- **Range: \$558 million to \$837 million annually** across the US, EU5, China, and Japan.
- Breakdown by region (at 20% and 30% share):
 - US: \$237.6M to \$356.4M
 - EU5: \$194.4M to \$291.6M
 - China: \$86.4M to \$129.6M
 - Japan: \$39.6M to \$59.4M

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

- **Total: \$27.9 million**
- Breakdown by region:
 - US: \$11.88M
 - EU5: \$9.72M
 - China: \$4.32M
 - Japan: \$1.98M

Caveats and Assumptions:

- Patient population estimates are based on general bladder cancer incidence and assumptions about the proportion eligible for maintenance therapy.
- Pricing is approximated based on typical costs for PD-L1 inhibitors and may vary due to discounts, rebates, or local pricing agreements.

- Market share assumptions (20%-30%) are as provided, but actual penetration may depend on competition (e.g., other checkpoint inhibitors like pembrolizumab), physician adoption, and payer coverage.
- Treatment duration is assumed to be one year for simplicity; actual duration may vary based on clinical guidelines and patient response.
- These figures do not account for market dynamics, patent expiry, or biosimilar competition.

For precise figures, consult recent market research reports (e.g., from EvaluatePharma, GlobalData) or internal data on patient populations and pricing. If you have specific data points or need adjustments (e.g., different market share or pricing), I can refine the calculations accordingly.