

To estimate the **Potential Peak Sales** for durvalumab (Imfinzi) in the indication of locally advanced or metastatic biliary tract cancer (BTC) in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since specific data on patient populations, pricing, and market dynamics may not be fully available, I will outline the methodology and make reasonable assumptions based on publicly available information and industry standards. You can refine these numbers with more precise data if available.

Step 1: Key Assumptions and Methodology

1. **Indication and Approval:** Durvalumab is approved in combination with gemcitabine and cisplatin for locally advanced or metastatic BTC, a rare cancer with limited treatment options. This approval is based on the TOPAZ-1 trial results, which demonstrated improved survival outcomes.
2. **Market Share Assumption:** As per your query, we assume durvalumab captures **20% to 30% of treated patients** in this indication.
3. **Patient Population:** BTC includes cholangiocarcinoma and gallbladder cancer. Incidence rates and eligible patient populations will vary by geography.
4. **Pricing:** Durvalumab is a premium-priced immunotherapy. Pricing will vary by region due to healthcare systems and reimbursement policies. For simplicity, we will assume an approximate annual cost per patient based on typical pricing for immune checkpoint inhibitors (ICIs).
5. **Peak Sales Timing:** Peak sales are typically achieved 5-7 years after launch in a given indication, assuming market penetration and adoption.

Step 2: Estimate Patient Population for BTC

BTC is a rare cancer, and the number of patients with locally advanced or metastatic disease (eligible for systemic therapy like durvalumab) is a subset of the total incidence. Below are approximate annual incidence numbers for BTC in the specified geographies, with a focus on advanced/metastatic cases (typically 60-70% of diagnosed cases):

- **US:** ~12,000 new BTC cases annually; ~8,000-9,000 advanced/metastatic.
- **EU5:** ~15,000 new BTC cases annually (combined); ~10,000-11,000 advanced/metastatic.
- **China:** ~50,000 new BTC cases annually (higher incidence due to risk factors like liver fluke infections); ~35,000-40,000 advanced/metastatic.
- **Japan:** ~20,000 new BTC cases annually; ~14,000-15,000 advanced/metastatic.

Total Eligible Patients (Advanced/Metastatic BTC):

- US: ~8,500
- EU5: ~10,500
- China: ~37,500
- Japan: ~14,500

- **Total across geographies:** ~71,000 patients annually.

Step 3: Estimate Treated Patient Share

Not all eligible patients receive treatment due to factors like comorbidities, access to care, or late diagnosis. We assume **70-80% of advanced/metastatic patients receive systemic therapy** in developed markets (US, EU5, Japan) and **50-60% in China** due to access and affordability constraints.

- **US:** ~6,800 treated patients (80% of 8,500).
- **EU5:** ~8,400 treated patients (80% of 10,500).
- **China:** ~20,625 treated patients (55% of 37,500).
- **Japan:** ~11,600 treated patients (80% of 14,500).
- **Total Treated Patients:** ~47,425 annually.

Durvalumab Market Share (20%-30%):

- **Low End (20%):** ~9,485 patients treated with durvalumab.
- **High End (30%):** ~14,228 patients treated with durvalumab.

Step 4: Estimate Pricing per Patient

Durvalumab pricing varies by region due to healthcare systems, negotiations, and discounts. As an ICI, annual treatment costs are high. Below are approximate annual costs per patient (based on typical pricing for drugs like pembrolizumab or nivolumab):

- **US:** \$150,000 per patient per year.
- **EU5:** \$100,000 per patient per year (lower due to reimbursement and negotiations).
- **China:** \$50,000 per patient per year (significant discounts or local pricing strategies).
- **Japan:** \$120,000 per patient per year (slightly lower than the US but higher than EU5).

Step 5: Calculate Potential Peak Sales

Using the number of treated patients with durvalumab (20%-30% share) and regional pricing, we calculate peak sales.

Low End (20% Market Share: 9,485 patients)

- **US:** $6,800 * 20\% = 1,360$ patients * \$150,000 = **\$204 million**.

- **EU5:** $8,400 * 20\% = 1,680$ patients * \$100,000 = **\$168 million.**
- **China:** $20,625 * 20\% = 4,125$ patients * \$50,000 = **\$206 million.**
- **Japan:** $11,600 * 20\% = 2,320$ patients * \$120,000 = **\$278 million.**
- **Total Peak Sales (20% share): \$856 million annually.**

High End (30% Market Share: 14,228 patients)

- **US:** $6,800 * 30\% = 2,040$ patients * \$150,000 = **\$306 million.**
- **EU5:** $8,400 * 30\% = 2,520$ patients * \$100,000 = **\$252 million.**
- **China:** $20,625 * 30\% = 6,188$ patients * \$50,000 = **\$309 million.**
- **Japan:** $11,600 * 30\% = 3,480$ patients * \$120,000 = **\$418 million.**
- **Total Peak Sales (30% share): \$1,285 million annually.**

Potential Peak Sales Range for Durvalumab in BTC: \$856 million to \$1.285 billion annually across the US, EU5, China, and Japan.

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

A 1% share of treated patients corresponds to 1% of the total treated patient population (~47,425 patients), which is **474 patients**. Using regional distribution and pricing:

- **US:** $6,800 * 1\% = 68$ patients * \$150,000 = **\$10.2 million.**
- **EU5:** $8,400 * 1\% = 84$ patients * \$100,000 = **\$8.4 million.**
- **China:** $20,625 * 1\% = 206$ patients * \$50,000 = **\$10.3 million.**
- **Japan:** $11,600 * 1\% = 116$ patients * \$120,000 = **\$13.9 million.**
- **Total \$ Value of 1% Share: \$42.8 million annually.**

Final Answer

1. Potential Peak Sales for Durvalumab in BTC (20%-30% market share) in the US, EU5, China, and Japan: \$856 million to \$1.285 billion annually.

2. \$ Value of 1% Share of Treated Patients: \$42.8 million annually.

Note: These estimates are based on assumptions about patient populations, treatment rates, market share, and pricing. Real-world figures may differ due to factors like competition, reimbursement, access to care, and duration of therapy. If you have access to more specific data (e.g., exact patient numbers or pricing), I can refine these calculations further.