

To estimate the **Potential Peak Sales** for tremelimumab (Imjudo) in the indication of unresectable hepatocellular carcinoma (uHCC) 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 market penetration may not be publicly available, I will outline the methodology and provide illustrative calculations based on typical industry benchmarks and assumptions.

Tremelimumab is approved in combination with durvalumab for uHCC, a form of liver cancer with significant unmet need. The drug's market potential depends on the number of eligible patients, treatment cost, market share, and regional pricing differences.

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## **Step 1: Estimate the Target Patient Population**

uHCC represents the majority of hepatocellular carcinoma (HCC) cases, as many patients are diagnosed at an advanced stage where surgery or other curative treatments are not viable. The incidence of HCC varies by region due to differences in risk factors like hepatitis B/C prevalence, alcohol use, and non-alcoholic fatty liver disease (NAFLD).

#### Incidence and Treatable Population Estimates (Annual New Cases of uHCC):

- **US:** HCC incidence is ~40,000 cases/year. Approximately 70-80% are unresectable at diagnosis, so ~28,000–32,000 uHCC patients/year.
- **EU5:** HCC incidence is ~60,000 cases/year across EU5. Assuming 70-80% are unresectable, ~42,000–48,000 uHCC patients/year.
- **China:** HCC incidence is very high due to hepatitis B prevalence, ~400,000 cases/year. Assuming 70-80% are unresectable, ~280,000–320,000 uHCC patients/year.
- **Japan:** HCC incidence is ~40,000 cases/year. Assuming 70-80% are unresectable, ~28,000–32,000 uHCC patients/year.

#### Total Treatable Population (Annual):

- US: ~30,000 patients
- EU5: ~45,000 patients
- China: ~300,000 patients
- Japan: ~30,000 patients
- **Total across geographies:** ~405,000 uHCC patients/year

**Assumption on Treated Patients:** Not all uHCC patients receive systemic therapy (e.g., due to poor performance status, lack of access, or cost). Let's assume 50% of uHCC patients are eligible for systemic therapies like tremelimumab + durvalumab.

- US: 15,000 treated patients
- EU5: 22,500 treated patients
- China: 150,000 treated patients

- Japan: 15,000 treated patients
- **Total treated patients:** ~202,500 patients/year

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## **Step 2: Estimate Market Share**

The question assumes a 20-30% share of treated patients for tremelimumab + durvalumab in this indication. This is reasonable given competition from other therapies like atezolizumab + bevacizumab (approved for uHCC), sorafenib, lenvatinib, and emerging therapies. For calculations, we will use the midpoint of **25% market share**.

### **- Treated patients receiving tremelimumab + durvalumab:**

- US:  $15,000 \times 25\% = 3,750$  patients
- EU5:  $22,500 \times 25\% = 5,625$  patients
- China:  $150,000 \times 25\% = 37,500$  patients
- Japan:  $15,000 \times 25\% = 3,750$  patients
- **Total:** 50,625 patients/year

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## **Step 3: Estimate Annual Treatment Cost per Patient**

Tremelimumab is an anti-CTLA-4 monoclonal antibody used in combination with durvalumab (anti-PD-L1). Pricing for such immunotherapies varies by region due to healthcare system differences, reimbursement policies, and purchasing power.

- **US:** Annual cost for combination immunotherapies (e.g., durvalumab + tremelimumab) can be ~\$150,000–\$200,000 per patient. Assume \$180,000/year.
- **EU5:** Pricing is typically 40-60% of US prices due to negotiations and cost controls. Assume \$100,000/year.
- **Japan:** Pricing is often similar to EU5 levels. Assume \$100,000/year.
- **China:** Pricing is significantly lower due to local policies and generics/biosimilars. Assume \$30,000/year (reflecting discounts or tiered pricing).

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## **Step 4: Calculate Potential Peak Sales**

Peak sales are calculated as: (Number of treated patients with tremelimumab)  $\times$  (Annual cost per patient).

- **US:**  $3,750 \text{ patients} \times \$180,000 = \$675 \text{ million}$

- **EU5:** 5,625 patients × \$100,000 = **\$562.5 million**
- **China:** 37,500 patients × \$30,000 = **\$1,125 million**
- **Japan:** 3,750 patients × \$100,000 = **\$375 million**
- **Total Peak Sales:** \$675M + \$562.5M + \$1,125M + \$375M = **~\$2,737.5 million (or ~\$2.74 billion)**

**Note:** This assumes steady-state peak sales at 25% market share, which may take a few years post-launch to achieve due to uptake curves and competition.

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

A 1% share of treated patients corresponds to 1% of the total treated patient population in each region (from Step 1: ~202,500 total treated patients).

- **Treated patients per 1% share:**
  - US: 15,000 × 1% = 150 patients
  - EU5: 22,500 × 1% = 225 patients
  - China: 150,000 × 1% = 1,500 patients
  - Japan: 15,000 × 1% = 150 patients
  - **Total per 1% share:** 2,025 patients
- **\$ Value of 1% share** (using per-patient costs from Step 3):
  - US: 150 patients × \$180,000 = **\$27 million**
  - EU5: 225 patients × \$100,000 = **\$22.5 million**
  - China: 1,500 patients × \$30,000 = **\$45 million**
  - Japan: 150 patients × \$100,000 = **\$15 million**
  - **Total \$ Value of 1% share:** \$27M + \$22.5M + \$45M + \$15M = **\$109.5 million**

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## **Summary of Results**

### **1. Potential Peak Sales for Tremelimumab in uHCC (at 25% market share):**

- US: \$675 million
- EU5: \$562.5 million
- China: \$1,125 million
- Japan: \$375 million
- **Total:** ~\$2.74 billion

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

- US: \$27 million
- EU5: \$22.5 million
- China: \$45 million
- Japan: \$15 million
- **Total:** \$109.5 million

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## Key Assumptions and Caveats

- **Epidemiology:** Patient numbers are estimates based on general HCC incidence data and assumptions on the proportion of unresectable cases and treated patients. Real-world data may differ.
- **Market Share:** 25% is a midpoint assumption. Actual share depends on clinical differentiation, competition (e.g., atezolizumab + bevacizumab), and payer acceptance.
- **Pricing:** Costs are illustrative and may vary based on negotiations, discounts, or biosimilar entry (especially in China). Tremelimumab's dosing schedule (often a single dose or limited cycles compared to durvalumab) may also affect total cost.
- **Access:** Penetration in China may be lower due to affordability and reimbursement challenges, potentially reducing peak sales.

These figures provide a high-level estimate and should be refined with more granular data on patient segmentation, real-world pricing, and competitive dynamics if available. If you have specific data or additional inputs (e.g., trial results, pricing announcements), I can adjust the calculations accordingly.