

To calculate the **Potential Peak Sales** for toripalimab-tpzi (LOQTORZI) in the specified indication (nasopharyngeal carcinoma, NPC) across the US, EU5 (Germany, France, 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. Since specific data such as exact patient numbers, pricing, or market penetration may not be publicly available, I will outline the methodology using reasonable assumptions based on epidemiology, market dynamics, and typical pricing for oncology drugs. I will also highlight where assumptions are made and suggest refining these with real-world data if available.

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## **Step 1: Define the Indication and Target Population**

Toripalimab-tpzi is approved for:

1. **First-line treatment** of adults with metastatic or recurrent, locally advanced NPC in combination with cisplatin and gemcitabine.
2. **Second-line treatment** as a single agent for adults with recurrent unresectable or metastatic NPC after progression on platinum-containing chemotherapy.

NPC is a rare cancer in most regions except in parts of Asia, particularly Southern China, where it is more prevalent. We will estimate the target patient population in each geography based on incidence and prevalence data for NPC.

#### Epidemiology Assumptions:

- **US:** NPC incidence is low (~0.5-1 per 100,000). Estimated new cases ~3,000-3,500 per year. Assuming 50% are metastatic/recurrent/locally advanced, target population for first-line ~1,500-1,750. Second-line population is smaller (~30-40% of first-line) due to mortality and ineligibility, so ~500-700.
- **EU5:** Similar incidence to the US (~0.5-1 per 100,000). Population of EU5 ~260 million, so ~1,300-2,600 new cases annually. Target first-line ~650-1,300; second-line ~200-500.
- **China:** NPC is endemic in Southern China (incidence ~20-30 per 100,000 in high-risk areas). Estimated new cases ~60,000-70,000 annually. First-line target ~30,000-35,000; second-line ~10,000-15,000.
- **Japan:** Lower incidence than China but higher than US/EU (~1-2 per 100,000). Population ~125 million, so ~1,250-2,500 new cases. First-line target ~600-1,250; second-line ~200-500.

**Total Annual Treatable Population (First + Second Line):**

- US: ~2,000-2,450
- EU5: ~850-1,800
- China: ~40,000-50,000
- Japan: ~800-1,750

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## **Step 2: Estimate Treated Patients (Assuming 20%-30% Market Share)**

The problem states a 20%-30% share of treated patients. This implies toripalimab-tpzi captures 20%-30% of the eligible patient population in this indication.

**Treated Patients with Toripalimab-tpzi (20%-30% of Treatable Population):**

- **US:**  $2,000-2,450 * 0.2 \text{ to } 0.3 = \mathbf{400-735 \text{ patients}}$
- **EU5:**  $850-1,800 * 0.2 \text{ to } 0.3 = \mathbf{170-540 \text{ patients}}$
- **China:**  $40,000-50,000 * 0.2 \text{ to } 0.3 = \mathbf{8,000-15,000 \text{ patients}}$
- **Japan:**  $800-1,750 * 0.2 \text{ to } 0.3 = \mathbf{160-525 \text{ patients}}$

**Total Treated Patients Across Geographies (20%-30% Share):**

- Low end (20%):  $400 + 170 + 8,000 + 160 = \mathbf{8,730 \text{ patients}}$
- High end (30%):  $735 + 540 + 15,000 + 525 = \mathbf{16,800 \text{ patients}}$

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### **Step 3: Estimate Pricing per Patient per Year**

Toripalimab-tpzi is a PD-1 inhibitor, and pricing for such drugs varies by region. We assume annual treatment costs based on typical oncology drug pricing (e.g., pembrolizumab or nivolumab, which are in the range of \$100,000-\$150,000 per year in the US).

**Pricing Assumptions (Annual Cost per Patient):**

- **US:** \$120,000 (high due to lack of price controls)
- **EU5:** \$80,000 (lower due to negotiated pricing and health systems)
- **China:** \$30,000 (significantly lower due to local pricing and volume-based procurement)
- **Japan:** \$90,000 (high but slightly below US due to regulatory pricing)

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

Peak sales are calculated as (Number of Treated Patients) \* (Annual Cost per Patient) for each geography.

#### At 20% Market Share (Low End):

- **US:**  $400 \text{ patients} * \$120,000 = \mathbf{\$48 \text{ million}}$
- **EU5:**  $170 \text{ patients} * \$80,000 = \mathbf{\$13.6 \text{ million}}$
- **China:**  $8,000 \text{ patients} * \$30,000 = \mathbf{\$240 \text{ million}}$
- **Japan:**  $160 \text{ patients} * \$90,000 = \mathbf{\$14.4 \text{ million}}$
- **Total Peak Sales (20% Share):**  $\$48\text{M} + \$13.6\text{M} + \$240\text{M} + \$14.4\text{M} = \mathbf{\$316 \text{ million}}$

#### At 30% Market Share (High End):

- **US:** 735 patients \* \$120,000 = **\$88.2 million**
- **EU5:** 540 patients \* \$80,000 = **\$43.2 million**
- **China:** 15,000 patients \* \$30,000 = **\$450 million**
- **Japan:** 525 patients \* \$90,000 = **\$47.25 million**
- **Total Peak Sales (30% Share):** \$88.2M + \$43.2M + \$450M + \$47.25M = **\$628.65 million**

**Potential Peak Sales Range: \$316 million to \$628.65 million annually**

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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 treatable population in each geography.

**1% of Treatable Population:**

- **US:** 2,000-2,450 \* 0.01 = **20-24.5 patients**
- **EU5:** 850-1,800 \* 0.01 = **8.5-18 patients**
- **China:** 40,000-50,000 \* 0.01 = **400-500 patients**
- **Japan:** 800-1,750 \* 0.01 = **8-17.5 patients**

**Revenue from 1% Share (Using Annual Cost per Patient):**

#### Low End of Patient Range:

- **US:** 20 patients \* \$120,000 = **\$2.4 million**
- **EU5:** 8.5 patients \* \$80,000 = **\$0.68 million**
- **China:** 400 patients \* \$30,000 = **\$12 million**
- **Japan:** 8 patients \* \$90,000 = **\$0.72 million**
- **Total for 1% Share (Low End):** \$2.4M + \$0.68M + \$12M + \$0.72M = **\$15.8 million**

#### High End of Patient Range:

- **US:** 24.5 patients \* \$120,000 = **\$2.94 million**
- **EU5:** 18 patients \* \$80,000 = **\$1.44 million**
- **China:** 500 patients \* \$30,000 = **\$15 million**
- **Japan:** 17.5 patients \* \$90,000 = **\$1.575 million**
- **Total for 1% Share (High End):** \$2.94M + \$1.44M + \$15M + \$1.575M = **\$20.955 million**

**\$ Value of 1% Share of Treated Patients: \$15.8 million to \$20.955 million annually**

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### **Final Answer:**

1. **Potential Peak Sales for Toripalimab-tpzi (20%-30% Market Share)** in the US, EU5, China, and Japan for NPC:

- **\$316 million to \$628.65 million annually**

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

- **\$15.8 million to \$20.955 million annually**

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### **Notes and Caveats:**

- **Epidemiology Data:** NPC incidence and prevalence vary widely, especially in China. These numbers are approximations and should be validated with specific data from sources like WHO, SEER, or local health authorities.

- **Pricing:** Drug pricing can vary significantly based on negotiations, reimbursement policies, and competition. Toripalimab-tpzi may be priced lower in some markets (e.g., China) due to local production by Shanghai Junshi Biosciences.

- **Market Share:** The 20%-30% assumption may be optimistic or pessimistic depending on competition (e.g., other PD-1 inhibitors like pembrolizumab or nivolumab) and adoption rates.

- **Treatment Duration:** Annual cost assumes a full year of treatment, but actual duration may be shorter due to disease progression or adverse events.

If you have access to specific data (e.g., exact patient numbers, pricing, or market forecasts), these estimates can be refined further.