

To estimate the **Potential Peak Sales** for mitomycin (JELMYTO) in the indication of low-grade upper tract urothelial cancer (LG-UTUC) in 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 based on epidemiology, market size, treatment rates, pricing, and market share assumptions. Since specific data might not be publicly available for all variables, I will outline the methodology and use reasonable assumptions based on available information and typical market dynamics for oncology drugs.

Step 1: Define Key Parameters

1. **Indication:** Low-grade upper tract urothelial cancer (LG-UTUC).
2. **Target Geographies:** US, EU5, China, Japan.
3. **Market Share Assumption:** 20% to 30% of treated patients.
4. **Pricing:** Drug pricing for rare or niche indications like LG-UTUC can vary widely. JELMYTO is a novel treatment, and pricing in the US is reported to be high (around \$20,000–\$25,000 per treatment cycle, with multiple cycles often required).
5. **Epidemiology:** Upper tract urothelial cancer (UTUC) is rare, accounting for 5–10% of urothelial cancers. Low-grade UTUC is a subset of this population. Incidence rates vary by region.

Step 2: Estimate Patient Population

Incidence of LG-UTUC

- **US:** UTUC incidence is approximately 1–2 cases per 100,000 people annually. With a population of ~330 million, this translates to ~3,300–6,600 new cases per year. Low-grade UTUC is estimated to be ~60–70% of cases, so ~2,000–4,600 patients annually.
- **EU5:** Combined population of ~320 million. Assuming similar incidence (1–2 per 100,000), ~3,200–6,400 new cases, with ~1,900–4,500 LG-UTUC cases.
- **China:** Population of ~1.4 billion. Incidence of UTUC may be slightly lower due to differences in risk factors (e.g., smoking, industrial exposure), estimated at ~0.5–1 per 100,000, or ~7,000–14,000 new cases, with ~4,200–9,800 LG-UTUC cases.
- **Japan:** Population of ~125 million. Incidence similar to the US/EU (1–2 per 100,000), or ~1,250–2,500 new cases, with ~750–1,750 LG-UTUC cases.

Treated Patient Population

Not all diagnosed patients receive active treatment (some may undergo surveillance or surgery alone). Assuming ~70–80% of LG-UTUC patients are eligible for treatment like JELMYTO (a non-surgical option), the treated population is:

- **US:** ~1,400–3,700 patients.
- **EU5:** ~1,300–3,600 patients.
- **China:** ~2,900–7,800 patients.
- **Japan:** ~500–1,400 patients.
- **Total Treated Patients:** ~6,100–16,500 annually.

Step 3: Pricing Assumptions

JELMYTO is a high-cost therapy for a rare disease. Based on available data:

- **US:** ~\$20,000–\$25,000 per treatment cycle. Assuming 4–6 cycles per patient, annual cost per patient is ~\$80,000–\$150,000.
- **EU5:** Pricing is typically 30–50% lower than the US due to healthcare system negotiations. Assume ~\$50,000–\$100,000 per patient annually.
- **China:** Pricing is significantly lower due to market access challenges and local pricing controls. Assume ~\$20,000–\$40,000 per patient annually.
- **Japan:** Pricing is closer to EU levels, ~\$50,000–\$100,000 per patient annually.

Step 4: Estimate Market Size for Treated Patients (Total Addressable Market)

Using the mid-point of treated patients and cost per patient:

- **US:** 2,550 patients × \$115,000 = ~\$293 million.
- **EU5:** 2,450 patients × \$75,000 = ~\$184 million.
- **China:** 5,350 patients × \$30,000 = ~\$161 million.
- **Japan:** 950 patients × \$75,000 = ~\$71 million.
- **Total Market Size:** ~\$709 million annually.

Step 5: Calculate Potential Peak Sales (20%–30% Market Share)

Assuming mitomycin (JELMYTO) captures 20%–30% of treated patients:

- **20% Share:** \$709 million × 0.2 = ~\$142 million.
- **30% Share:** \$709 million × 0.3 = ~\$213 million.
- **Potential Peak Sales Range:** **\$142–\$213 million annually** across all geographies.

Breakdown by Geography (Peak Sales at 20%–30% Share):

- **US:** \$293 million × 20%–30% = **\$59–\$88 million**.
- **EU5:** \$184 million × 20%–30% = **\$37–\$55 million**.
- **China:** \$161 million × 20%–30% = **\$32–\$48 million**.
- **Japan:** \$71 million × 20%–30% = **\$14–\$21 million**.

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

Using the total market size:

- **Total Market Size:** \$709 million.
- **1% Share:** \$709 million × 0.01 = **\$7.09 million**.

Breakdown by Geography (1% Share):

- **US:** \$293 million \times 0.01 = **\$2.93 million.**
- **EU5:** \$184 million \times 0.01 = **\$1.84 million.**
- **China:** \$161 million \times 0.01 = **\$1.61 million.**
- **Japan:** \$71 million \times 0.01 = **\$0.71 million.**

Final Answer

- **Potential Peak Sales for Mitomycin (JELMYTO) in LG-UTUC (20%–30% Share):**

- Total: **\$142–\$213 million annually.**
- US: **\$59–\$88 million.**
- EU5: **\$37–\$55 million.**
- China: **\$32–\$48 million.**
- Japan: **\$14–\$21 million.**
- **\$ Value of 1% Share of Treated Patients:**
- Total: **\$7.09 million.**
- US: **\$2.93 million.**
- EU5: **\$1.84 million.**
- China: **\$1.61 million.**
- Japan: **\$0.71 million.**

Notes and Caveats

1. These estimates are based on assumptions about epidemiology, treatment rates, pricing, and market penetration. Actual figures may differ based on real-world data, competition, reimbursement policies, and market access.
2. Peak sales may take several years to achieve, depending on adoption rates and regulatory approvals in each region.
3. China's market potential may be limited by pricing controls and access to innovative therapies.
4. If more precise data (e.g., exact patient numbers, pricing, or market share forecasts) are available, these estimates can be refined.

Would you like me to adjust any assumptions or dive deeper into a specific geography or parameter?