To estimate the **Potential Peak Sales** for dostarlimab-gxly (Jemperli) in the indication of primary advanced or recurrent endometrial cancer (EC) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. This will involve making assumptions based on available data, epidemiology, pricing, and market penetration. Since specific sales data or exact patient numbers are not publicly available in this hypothetical query, I will outline the methodology and provide a reasonable estimate based on industry standards and publicly available information as of October 2023.

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## **Step 1: Key Assumptions and Methodology**

1. **Indication and Target Population**: Dostarlimab-gxly is approved for primary advanced or recurrent endometrial cancer (EC), including the subset with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) status. We will focus on the broader indication (all advanced or recurrent EC) as the recent approval expands beyond just dMMR/MSI-H.

#### 2. Epidemiology:

- Endometrial cancer incidence varies by region. We will estimate the number of advanced or recurrent EC patients eligible for treatment.
- Approximately 20-30% of EC patients are diagnosed at an advanced stage or experience recurrence.
- dMMR/MSI-H accounts for ~25-30% of EC cases, but since the approval now covers all advanced/recurrent EC, we will estimate based on the total population.
- 3. **Market Penetration**: As per the query, assuming a 20-30% share of treated patients for dostarlimab-gxly.
- 4. **Pricing**: Dostarlimab-gxly is a PD-1 inhibitor, and its pricing is comparable to other immunotherapies like pembrolizumab or nivolumab. We will assume an annual treatment cost of ~\$150,000-\$200,000 per patient in the US and slightly lower in other regions due to pricing differences (e.g., ~\$100,000-\$150,000 in EU5, ~\$80,000-\$120,000 in Japan, and ~\$50,000-\$80,000 in China due to
- $\sim$ \$100,000-\$150,000 in EO5,  $\sim$ \$80,000-\$120,000 in Japan, and  $\sim$ \$50,000-\$80,000 in China due to market access and pricing constraints).
- 5. **Treatment Duration**: Assume an average treatment duration of 1 year per patient (based on clinical trial data and real-world usage of PD-1 inhibitors).
- 6. Geographies: US, EU5 (combined), China, and Japan.

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# **Step 2: Estimate Target Patient Population**

We will estimate the number of advanced or recurrent EC patients in each geography using incidence data and prevalence of advanced/recurrent cases.

- US:
- Annual EC incidence: ~66,000 (American Cancer Society, 2023).
- Advanced/recurrent cases: ~20-30%  $\rightarrow$  ~13,200-19,800 patients.
- EU5 (Germany, France, Italy, Spain, UK):

- Annual EC incidence: ~100,000 (combined, based on GLOBOCAN 2020).
- Advanced/recurrent cases:  $\sim$ 20-30%  $\rightarrow$   $\sim$ 20,000-30,000 patients.
- China:
- Annual EC incidence: ~80,000 (GLOBOCAN 2020, adjusted for population size).
- Advanced/recurrent cases:  $\sim$ 20-30%  $\rightarrow$   $\sim$ 16,000-24,000 patients.
- Japan:
- Annual EC incidence: ~15,000 (GLOBOCAN 2020).
- Advanced/recurrent cases: ~20-30%  $\rightarrow$  ~3,000-4,500 patients.

### Total Target Population (Advanced/Recurrent EC):

- US: ~16,500 (midpoint of range).
- EU5: ~25,000.
- China: ~20,000.
- Japan: ~3,750.
- Total across geographies: ~65,250 patients.

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# <u>Step 3: Estimate Treated Patients with Dostarlimab-gxly (20-30% Market Share)</u>

- **US**:  $16,500 \times 20-30\% = -3,300-4,950$  patients.
- **EU5**:  $25,000 \times 20-30\% = -5,000-7,500$  patients.
- **China**:  $20,000 \times 20-30\% = \sim 4,000-6,000$  patients.
- **Japan**:  $3,750 \times 20-30\% = ~750-1,125$  patients.
- Total treated patients: ~13,050-19,575.

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# Step 4: Estimate Annual Treatment Cost per Patient

- US: \$175,000 (midpoint of \$150,000-\$200,000).
- **EU5**: \$125,000 (midpoint of \$100,000-\$150,000).
- China: \$65,000 (midpoint of \$50,000-\$80,000).
- Japan: \$100,000 (midpoint of \$80,000-\$120,000).

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## **Step 5: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients by the annual treatment cost per patient in each geography.

#### At 20% Market Share:

- **US**: 3,300 patients  $\times$  \$175,000 = \$577.5 million.
- **EU5**: 5,000 patients  $\times$  \$125,000 = **\$625** million.
- China: 4,000 patients  $\times$  \$65,000 = \$260 million.
- Japan: 750 patients × \$100,000 = **\$75 million**.
- Total Peak Sales (20% share): \$1,537.5 million (~\$1.54 billion).

#### At 30% Market Share:

- **US**: 4,950 patients × \$175,000 = **\$866.25 million**.
- **EU5**: 7,500 patients  $\times$  \$125,000 = **\$937.5 million**.
- China: 6,000 patients  $\times$  \$65,000 = \$390 million.
- Japan: 1,125 patients  $\times $100,000 = $112.5$  million.
- Total Peak Sales (30% share): \$2,306.25 million (~\$2.31 billion).

Potential Peak Sales Range: \$1.54 billion to \$2.31 billion annually across the specified geographies for this indication.

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

A 1% share of treated patients corresponds to 1% of the total target population in each geography.

- **US**: 16,500 patients  $\times 1\% = 165$  patients  $\times \$175,000 = \$28.875$  million.
- **EU5**: 25,000 patients  $\times$  1% = 250 patients  $\times$  \$125,000 = **\$31.25 million**.
- **China**: 20,000 patients  $\times$  1% = 200 patients  $\times$  \$65,000 = **\$13 million**.
- **Japan**: 3,750 patients  $\times$  1% = 37.5 patients  $\times$  \$100,000 = **\$3.75** million.
- Total \$ Value of 1% Share: \$76.875 million.

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# **Final Answer**

- 1. **Potential Peak Sales for Dostarlimab-gxly** in the indication of primary advanced or recurrent endometrial cancer (assuming 20-30% market share):
- Range: \$1.54 billion to \$2.31 billion annually across the US, EU5, China, and Japan.

- Breakdown by geography (midpoint of range for simplicity, at 25% share):
- US: ~\$721.875 million.
- EU5: ~\$781.25 million.
- China: ~\$325 million.
- Japan: ~\$93.75 million.

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

- US: \$28.875 million.

- EU5: \$31.25 million.

- China: \$13 million.

- Japan: \$3.75 million.

- Total: **\$76.875 million**.

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## **Caveats and Notes**

- These estimates are based on assumptions about patient numbers, pricing, and market penetration. Real-world figures may differ due to competition (e.g., other PD-1 inhibitors like pembrolizumab), reimbursement policies, and adoption rates.
- Pricing in China and Japan may be lower due to government negotiations or local manufacturing partnerships.
- The analysis assumes peak sales are achieved at a steady state of market penetration, which may take several years post-launch.
- If more specific data (e.g., exact patient numbers, pricing, or trial outcomes) becomes available, these estimates can be refined.