

To estimate the **Potential Peak Sales** for dostarlimab-gxly (Jemperli) in the indication of primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) 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. Since specific data such as exact patient numbers, pricing, and market penetration may not be publicly available, I will outline a methodology using reasonable assumptions based on available epidemiology data, market trends, and typical pricing for oncology drugs. The final numbers are illustrative and should be validated with real-world data.

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

Endometrial cancer (EC) is the most common gynecologic cancer in developed countries. The indication for dostarlimab-gxly is specifically for **primary advanced or recurrent EC** that is **dMMR or MSI-H**. These biomarkers are present in approximately 25-30% of EC cases.

### #### Epidemiology Assumptions:

- **US:** ~66,200 new EC cases/year (American Cancer Society, 2023). Advanced or recurrent cases are ~20-25% of total cases (~13,000-16,500 patients). Of these, ~25-30% are dMMR/MSI-H (~3,250-4,950 patients).
- **EU5:** ~100,000 new EC cases/year (combined). Advanced/recurrent cases (~20-25%) are ~20,000-25,000 patients. dMMR/MSI-H (~25-30%) results in ~5,000-7,500 patients.
- **China:** ~82,000 new EC cases/year (GLOBOCAN 2020). Advanced/recurrent cases (~20-25%) are ~16,400-20,500 patients. dMMR/MSI-H (~25-30%) results in ~4,100-6,150 patients.
- **Japan:** ~17,000 new EC cases/year (GLOBOCAN 2020). Advanced/recurrent cases (~20-25%) are ~3,400-4,250 patients. dMMR/MSI-H (~25-30%) results in ~850-1,275 patients.

### **Total Target Population (dMMR/MSI-H, Advanced/Recurrent EC):**

- US: ~4,100 patients (midpoint)
- EU5: ~6,250 patients (midpoint)
- China: ~5,125 patients (midpoint)
- Japan: ~1,060 patients (midpoint)
- **Total across geographies:** ~16,535 patients

### #### Treated Patient Share Assumption:

The query assumes a **20-30% share of treated patients**. This accounts for market competition (e.g., other immunotherapies like pembrolizumab), access, and physician adoption. We'll use the midpoint of **25%** for calculations.

- Treated patients (25% share):
- US:  $4,100 * 0.25 = \sim 1,025$  patients
- EU5:  $6,250 * 0.25 = \sim 1,563$  patients
- China:  $5,125 * 0.25 = \sim 1,281$  patients

- Japan:  $1,060 * 0.25 = \sim 265$  patients
- **Total treated patients:**  $\sim 4,134$  patients

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## **Step 2: Estimate Drug Pricing**

Dostarlimab-gxly is a PD-1 inhibitor, and pricing for such drugs in oncology is high, especially in the US and EU5. Pricing varies by region due to healthcare system differences and reimbursement policies.

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

- **US:**  $\sim \$150,000 - \$200,000/\text{year}$  (based on similar drugs like pembrolizumab or nivolumab). Midpoint:  $\$175,000$ .
- **EU5:**  $\sim \$100,000 - \$150,000/\text{year}$  (lower due to negotiations and health technology assessments). Midpoint:  $\$125,000$ .
- **Japan:**  $\sim \$100,000 - \$150,000/\text{year}$  (similar to EU5). Midpoint:  $\$125,000$ .
- **China:**  $\sim \$50,000 - \$80,000/\text{year}$  (lower due to pricing controls and local competition). Midpoint:  $\$65,000$ .

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## **Step 3: Calculate Potential Peak Sales (25% Market Share)**

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

- **US:**  $1,025 \text{ patients} * \$175,000 = \text{\$179.4 million}$
- **EU5:**  $1,563 \text{ patients} * \$125,000 = \text{\$195.4 million}$
- **China:**  $1,281 \text{ patients} * \$65,000 = \text{\$83.3 million}$
- **Japan:**  $265 \text{ patients} * \$125,000 = \text{\$33.1 million}$
- **Total Peak Sales (25% share):**  $\text{\$179.4M} + \text{\$195.4M} + \text{\$83.3M} + \text{\$33.1M} = \text{\$491.2 million}$

#### Range for Peak Sales (20-30% Share):

- **20% Share:**

- US:  $820 \text{ patients} * \$175,000 = \text{\$143.5M}$
- EU5:  $1,250 \text{ patients} * \$125,000 = \text{\$156.3M}$
- China:  $1,025 \text{ patients} * \$65,000 = \text{\$66.6M}$
- Japan:  $212 \text{ patients} * \$125,000 = \text{\$26.5M}$
- Total: **\\$393.0 million**

- **30% Share:**

- US: 1,230 patients \* \$175,000 = \$215.3M
- EU5: 1,875 patients \* \$125,000 = \$234.4M
- China: 1,538 patients \* \$65,000 = \$100.0M
- Japan: 318 patients \* \$125,000 = \$39.8M
- Total: **\$589.5 million**
- **Peak Sales Range: \$393M - \$589M** (midpoint: ~\$491M)

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### **Step 4: 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:** 4,100 patients \* 0.01 = 41 patients \* \$175,000 = **\$7.2 million**
- **EU5:** 6,250 patients \* 0.01 = 62.5 patients \* \$125,000 = **\$7.8 million**
- **China:** 5,125 patients \* 0.01 = 51.25 patients \* \$65,000 = **\$3.3 million**
- **Japan:** 1,060 patients \* 0.01 = 10.6 patients \* \$125,000 = **\$1.3 million**
- **Total Value of 1% Share:** \$7.2M + \$7.8M + \$3.3M + \$1.3M = **\$19.6 million**

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### **Final Answer**

#### **1. Potential Peak Sales for Dostarlimab-gxly (20-30% share of treated patients):**

- US: \$143.5M - \$215.3M
- EU5: \$156.3M - \$234.4M
- China: \$66.6M - \$100.0M
- Japan: \$26.5M - \$39.8M
- **Total Peak Sales: \$393M - \$589M** (midpoint: ~\$491M)

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

- US: \$7.2M
- EU5: \$7.8M
- China: \$3.3M
- Japan: \$1.3M
- **Total: \$19.6M**

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## **Caveats and Notes**

- These estimates are based on assumptions for epidemiology, pricing, and market share. Real-world data on patient numbers, adoption rates, and negotiated pricing could significantly alter these figures.
- Competition from other PD-1/PD-L1 inhibitors (e.g., pembrolizumab, which is also approved in dMMR/MSI-H solid tumors) could impact market share.
- Peak sales may take several years to achieve due to gradual market penetration and diagnostic testing uptake for dMMR/MSI-H status.
- Currency fluctuations, healthcare policy changes, and biosimilar/generic competition in the future could affect pricing and sales.

If you have access to more specific data (e.g., exact pricing, updated epidemiology, or market research), these calculations can be refined further.