To estimate the **Potential Peak Sales** for dostarlimab-gxly (Jemperli) in the indication of mismatch repair deficient (dMMR) recurrent or advanced solid tumors 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. Since specific data such as exact patient numbers, pricing, and market penetration may not be fully available, I will outline a methodology with assumptions based on typical oncology market dynamics, epidemiology, and drug pricing trends. You can refine these numbers with more specific data if available.

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

- **Indication**: dMMR recurrent or advanced solid tumors in patients with no satisfactory alternative treatment options.
- **Epidemiology**: dMMR mutations are found in a subset of solid tumors, most commonly in colorectal cancer (CRC), endometrial cancer, and gastric cancer. Approximately 5-15% of colorectal cancers, 20-30% of endometrial cancers, and a smaller percentage of other solid tumors are dMMR.
- **Patient Population**: We need to estimate the number of patients with recurrent or advanced dMMR solid tumors eligible for treatment in the specified geographies. This involves:
- Total incidence/prevalence of solid tumors.
- Proportion of dMMR tumors.
- Proportion of recurrent/advanced stage patients with no other treatment options.

For simplicity, let's assume the following approximate eligible patient populations (based on published cancer statistics and dMMR prevalence):

- **US**: ~15,000-20,000 patients annually (based on high incidence of CRC and endometrial cancer, with dMMR prevalence).
- **EU5**: ~12,000-18,000 patients annually (slightly lower incidence rates than the US, adjusted for population).
- **China**: ~20,000-30,000 patients annually (higher overall cancer incidence due to large population, but lower diagnosis rates for dMMR).
- **Japan**: ~5,000-8,000 patients annually (smaller population, high diagnosis rates).

Total Eligible Patients (Annual): ~52,000-76,000 across all geographies.

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

- The query assumes a **20-30% share of treated patients**. This accounts for competition (e.g., pembrolizumab and nivolumab, which are also approved in dMMR tumors), physician preference, pricing, and access.
- Let's use the midpoint of 25% market share for peak sales calculation.

#### Treated Patients at Peak (25% share):

- US: 3,750-5,000 patients.
- EU5: 3,000-4,500 patients.
- China: 5,000-7,500 patients.
- Japan: 1,250-2,000 patients.
- **Total**: ~13,000-19,000 patients annually.

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### \*\*Step 3: Estimate Drug Pricing\*\*

- Dostarlimab-gxly is an immune checkpoint inhibitor (anti-PD-1), and pricing for such drugs typically ranges from \$100,000 to \$150,000 per patient per year in the US for a full treatment course (often 1-2 years of therapy). Pricing in other regions is typically lower due to healthcare system negotiations and cost controls:
- US: \$120,000 per patient/year (midpoint estimate).
- EU5: \$80,000 per patient/year (lower due to price negotiations).
- Japan: \$90,000 per patient/year (similar to EU5 but slightly higher due to market dynamics).
- China: \$40,000 per patient/year (significantly lower due to pricing controls and local competition).

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

Peak sales are calculated as: Number of treated patients × Annual cost per patient.

- **US**: 4,375 patients (midpoint) × \$120,000 = **\$525** million.
- **EU5**: 3,750 patients (midpoint)  $\times$  \$80,000 = **\$300 million**.
- China: 6,250 patients (midpoint)  $\times$  \$40,000 = \$250 million.
- Japan: 1,625 patients (midpoint)  $\times$  \$90,000 = \$146 million.
- Total Peak Sales: \$525M + \$300M + \$250M + \$146M = \$1.221 billion annually.

#### Range of Peak Sales (based on 20-30% share):

- Low end (20% share): ~\$975 million.
- High end (30% share): ~\$1.465 billion.
- Midpoint Estimate: ~\$1.22 billion.

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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 eligible patient population being treated with dostarlimab-gxly.

- Total Eligible Patients: 64,000 (midpoint of 52,000-76,000).
- 1% of Patients: 640 patients.
- Value Calculation (using the same pricing per region):
- US:  $(15,000-20,000 \text{ patients}) \rightarrow 175 \text{ patients (midpoint)} \times $120,000 = $21 \text{ million}.$
- EU5: (12,000-18,000 patients)  $\to$  150 patients (midpoint) **x** \$80,000 = **\$12 million**.
- China:  $(20,000-30,000 \text{ patients}) \rightarrow 250 \text{ patients (midpoint)} \times $40,000 = $10 \text{ million}.$
- Japan:  $(5,000-8,000 \text{ patients}) \rightarrow 65 \text{ patients (midpoint)} \times \$90,000 = \$5.85 \text{ million}.$
- Total Value of 1% Share: \$21M + \$12M + \$10M + \$5.85M = \$48.85 million.

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#### \*\*Final Answer\*\*

- 1. Potential Peak Sales for Dostarlimab-gxly (20-30% share of treated patients):
- **US**: \$420M \$600M (midpoint: \$525M).
- EU5: \$240M \$360M (midpoint: \$300M).
- China: \$200M \$300M (midpoint: \$250M).
- Japan: \$117M \$175M (midpoint: \$146M).
- Total: \$975M \$1.465B (midpoint: \$1.22 billion annually).
- 2. \$ Value of 1% Share of Treated Patients:
- US: \$21 million.
- EU5: \$12 million.
- China: \$10 million.
- Japan: \$5.85 million.
- Total: \$48.85 million.

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# \*\*Caveats and Assumptions\*\*

- Patient population estimates are approximate and based on general cancer incidence and dMMR prevalence. Real-world data may differ.
- Pricing assumptions are based on typical checkpoint inhibitor costs and may vary by country or over time due to negotiations, biosimilars, or generics.

- Market share assumptions (20-30%) account for competition from other PD-1 inhibitors like pembrolizumab (Keytruda) and nivolumab (Opdivo), which are already established in dMMR indications.
- Peak sales assume steady-state market penetration, which may take several years post-launch to achieve.
- Access and reimbursement policies in China and other regions may impact actual sales.

If you have access to more precise epidemiology data, pricing information, or market research, these estimates can be refined further. Let me know if you'd like to adjust any assumptions or dive deeper into a specific region or aspect!