To estimate the **Potential Peak Sales** for larotrectinib (Vitrakvi) in the indication of solid tumors with NTRK gene fusions across the US, EU5 (France, Germany, 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. Since specific data on patient populations, pricing, and market penetration may not be fully available, I will make reasonable assumptions based on publicly available information, market research trends, and oncology drug pricing norms. Here's the step-by-step analysis:

Key Assumptions and Background Information

1. **Indication and Target Population**:

- Larotrectinib is approved for the treatment of adult and pediatric patients with solid tumors that have NTRK gene fusions, a rare genetic alteration.

- NTRK fusions are found in approximately 0.5%–1% of all solid tumors. Given the rarity, the eligible patient population is small but spans across various cancer types.

- Estimated incidence of solid tumors with NTRK fusions is approximately 1,500–5,000 new cases per year globally, with a significant portion in the US, EU5, China, and Japan.

2. **Treated Patient Share**:

- The query assumes a 20%–30% share of treated patients for larotrectinib. This accounts for competition (e.g., entrectinib by Roche), diagnostic challenges, and market access barriers.

- We will use the midpoint of 25% for calculations.

3. **Pricing**:

- Larotrectinib's annual cost in the US is approximately $400,000 per patient (based on reported figures for rare cancer drugs and oral therapies).

- Pricing in EU5 and Japan is typically 60%–80% of US pricing due to healthcare system negotiations (assume ~$300,000/year).

- Pricing in China may be lower due to market access and affordability constraints (assume ~$200,000/year).

4. **Patient Population Estimates**:

- Total solid tumor incidence (new cases per year) in these geographies is estimated as follows (based on cancer epidemiology data):

- US: ~1.7 million new cancer cases/year; NTRK fusion (~0.5%–1%) = ~8,500–17,000 patients.

- EU5: ~1.5 million new cases/year; NTRK fusion = ~7,500–15,000 patients.

- China: ~4.3 million new cases/year; NTRK fusion = ~21,500–43,000 patients.

- Japan: ~1 million new cases/year; NTRK fusion = ~5,000–10,000 patients.

- For simplicity, we'll use the midpoint of these ranges for eligible patients:

- US: 12,750 patients

- EU5: 11,250 patients

- China: 32,250 patients

- Japan: 7,500 patients

- Total eligible patients across geographies: ~63,750 patients.

5. **Treatment Duration**:

- Assume an average treatment duration of 1 year per patient (though some patients may be on therapy longer due to durable responses in NTRK fusion-driven cancers).

Step 1: Estimate Treated Patients with Larotrectinib

Using the assumed 25% share of treated patients:

- US: 12,750 * 25% = 3,188 patients

- EU5: 11,250 * 25% = 2,813 patients

- China: 32,250 * 25% = 8,063 patients

- Japan: 7,500 * 25% = 1,875 patients

- **Total treated patients**: 15,939 patients

Step 2: Estimate Potential Peak Sales

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

- **US**: 3,188 patients * $400,000/year = **$1,275 million** (~$1.28 billion)

- **EU5**: 2,813 patients * $300,000/year = **$844 million** (~$0.84 billion)

- **China**: 8,063 patients * $200,000/year = **$1,613 million** (~$1.61 billion)

- **Japan**: 1,875 patients * $300,000/year = **$563 million** (~$0.56 billion)

- **Total Peak Sales**: $1.28B + $0.84B + $1.61B + $0.56B = **$4.29 billion**

Thus, the **Potential Peak Sales** for larotrectinib in this indication across the specified geographies, assuming a 25% share of treated patients, is approximately **$4.3 billion annually**.

Step 3: Estimate $ Value of 1% Share of Treated Patients

To calculate the value of a 1% share, we divide the total peak sales by 25 (since 25% share corresponds to $4.3 billion).

- **1% share value** = $4.29 billion / 25 = **$171.6 million**

Alternatively, calculate per geography by applying 1% of the eligible patient population and multiplying by the annual treatment cost:

- US: 12,750 * 1% = 128 patients * $400,000 = **$51.2 million**

- EU5: 11,250 * 1% = 113 patients * $300,000 = **$33.9 million**

- China: 32,250 * 1% = 323 patients * $200,000 = **$64.6 million**

- Japan: 7,500 * 1% = 75 patients * $300,000 = **$22.5 million**

- **Total value of 1% share**: $51.2M + $33.9M + $64.6M + $22.5M = **$172.2 million**

This aligns closely with the earlier estimate of $171.6 million, confirming the calculation.

Final Answer

1. **Potential Peak Sales for Larotrectinib** (assuming 20%–30% share, calculated at 25%):

- US: ~$1.28 billion

- EU5: ~$0.84 billion

- China: ~$1.61 billion

- Japan: ~$0.56 billion

- **Total**: ~**$4.3 billion annually**

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

- US: ~$51.2 million

- EU5: ~$33.9 million

- China: ~$64.6 million

- Japan: ~$22.5 million

- **Total**: ~**$172 million annually**

Caveats and Sensitivities

- **Patient Population**: NTRK fusion prevalence and diagnosis rates may vary, and not all patients may be identified or treated due to limited access to NGS testing.

- **Pricing**: Actual pricing may differ based on negotiations, reimbursement policies, and patient assistance programs.

- **Competition**: Market share could be impacted by competitors like entrectinib or emerging therapies.

- **Market Access**: Penetration in China may be lower due to affordability and regulatory delays.

These estimates are based on high-level assumptions and should be refined with more precise epidemiology data, real-world pricing, and market access insights if available.