To estimate the **Potential Peak Sales** for entrectinib (Rozlytrek) in the specified indication (solid tumors with NTRK gene fusion) 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 make several assumptions and calculations based on available data. Since exact patient numbers, pricing, and market penetration data may not be fully public, I will outline a structured approach with reasonable estimates. Note that this is a high-level analysis and should be refined with more specific data if available.

Step 1: Define the Indication and Target Population

Entrectinib is approved for pediatric patients with solid tumors harboring an NTRK gene fusion, a rare genetic alteration. NTRK fusions occur in approximately **0.5% to 1% of solid tumors**, and the condition is even rarer in pediatric populations. The indication includes:

- Pediatric patients >1 month (US) or ≥12 years (earlier approval) with metastatic solid tumors or tumors where surgical resection would cause severe morbidity.

- Patients who have progressed following treatment or have no satisfactory alternative therapy.

Given the rarity of NTRK fusions, the eligible patient population is very small, often referred to as an "ultra-rare" indication.

Step 2: Estimate the Eligible Patient Population

To estimate the number of eligible patients, we need:

1. **Incidence of pediatric solid tumors** in each geography.

2. **Proportion of tumors with NTRK fusions** (assumed as 0.5% to 1%).

3. **Proportion of patients who are metastatic or unresectable and have no alternative therapy** (assumed as 50% for simplicity, though this may vary).

Pediatric Solid Tumor Incidence (Rough Estimates):

- **US**: ~15,000 new pediatric cancer cases/year; ~30% are solid tumors (~4,500 cases).

- **EU5**: ~10,000 new pediatric cancer cases/year; ~30% solid tumors (~3,000 cases).

- **China**: ~40,000 new pediatric cancer cases/year; ~30% solid tumors (~12,000 cases).

- **Japan**: ~2,500 new pediatric cancer cases/year; ~30% solid tumors (~750 cases).

NTRK Fusion Prevalence:

Assuming 0.5% to 1% of solid tumors have NTRK fusions:

- **US**: 4,500 * 0.005 to 0.01 = 23 to 45 patients/year.

- **EU5**: 3,000 * 0.005 to 0.01 = 15 to 30 patients/year.

- **China**: 12,000 * 0.005 to 0.01 = 60 to 120 patients/year.

- **Japan**: 750 * 0.005 to 0.01 = 4 to 8 patients/year.

Eligible Patients (Metastatic/Unresectable, No Alternative Therapy):

Assuming 50% of NTRK fusion patients are eligible:

- **US**: 12 to 23 patients/year.

- **EU5**: 8 to 15 patients/year.

- **China**: 30 to 60 patients/year.

- **Japan**: 2 to 4 patients/year.

Total Eligible Patients Across Geographies:

- Low estimate: 52 patients/year.

- High estimate: 102 patients/year.

Since entrectinib is a chronic therapy (patients may remain on treatment for multiple years), we can estimate **prevalent patients** over a 5-year period (assuming average treatment duration of 2-3 years, with some overlap due to mortality or progression). For simplicity, multiply annual incidence by 3 to account for prevalence:

- Low estimate: 52 * 3 = **156 prevalent patients**.

- High estimate: 102 * 3 = **306 prevalent patients**.

Step 3: Estimate Market Penetration

The problem states a **20% to 30% share of treated patients**. Since NTRK fusion tumors have limited treatment options, entrectinib (along with larotrectinib, a competitor) is likely to capture a significant share of eligible patients. We will use the provided range of 20% to 30%.

Treated Patients with Entrectinib:

- Low estimate (20% share of 156 patients): **31 patients**.

- High estimate (30% share of 306 patients): **92 patients**.

Step 4: Estimate Drug Pricing

Entrectinib is a high-cost targeted therapy for a rare disease. Pricing varies by geography due to differences in healthcare systems and reimbursement policies. Based on available data for similar drugs (e.g., larotrectinib):

- **US**: ~$17,000/month for pediatric dosing (based on weight; lower than adult dosing of ~$20,000/month). Annual cost: ~$204,000.

- **EU5**: ~60-70% of US price due to discounts/negotiations. Annual cost: ~$122,000 to $143,000 (average: $132,500).

- **China**: Lower pricing due to market access challenges and government negotiations. Annual cost: ~$50,000.

- **Japan**: Pricing closer to EU levels due to regulated pricing. Annual cost: ~$132,500.

Annual Revenue per Patient (Weighted by Geography):

Roughly weighting patient distribution (US: 20%, EU5: 15%, China: 60%, Japan: 5% based on earlier estimates):

- Weighted average cost per patient/year:

- US: $204,000 * 0.2 = $40,800

- EU5: $132,500 * 0.15 = $19,875

- China: $50,000 * 0.6 = $30,000

- Japan: $132,500 * 0.05 = $6,625

- **Total weighted average cost/patient/year**: ~$97,300.

Step 5: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients multiplied by the annual cost per patient.

- **Low estimate**: 31 patients * $97,300 = **$3.0 million**.

- **High estimate**: 92 patients * $97,300 = **$9.0 million**.

Thus, the **Potential Peak Sales** for entrectinib in this indication across the US, EU5, China, and Japan range from **$3 million to $9 million annually** (based on 20% to 30% market share).

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

A 1% share of treated patients corresponds to 1% of the total prevalent eligible patients:

- Low estimate: 1% of 156 patients = **1.56 patients**.

- High estimate: 1% of 306 patients = **3.06 patients**.

Using the weighted average cost per patient/year ($97,300):

- Low estimate: 1.56 * $97,300 = **$151,788**.

- High estimate: 3.06 * $97,300 = **$297,738**.

Thus, the **$ value of a 1% share of treated patients** across these geographies ranges from **$152,000 to $298,000 annually**.

Final Answer:

1. **Potential Peak Sales** for entrectinib in the specified indication (solid tumors with NTRK gene fusion) across the US, EU5, China, and Japan, assuming a 20% to 30% share of treated patients:

- **$3 million to $9 million annually**.

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

- **$152,000 to $298,000 annually**.

Caveats and Assumptions:

- Patient population estimates are rough due to the rarity of NTRK fusions and lack of precise epidemiology data for pediatric solid tumors in each geography.

- Pricing is estimated based on similar drugs (e.g., larotrectinib) and may vary due to local negotiations, access programs, or payer policies.

- Market share assumptions (20%-30%) are as provided, but competition (e.g., larotrectinib) and diagnostic testing rates for NTRK fusions could impact actual penetration.

- Treatment duration and prevalence estimates are simplified; real-world data on survival and therapy duration would refine these numbers.

- This analysis focuses solely on the pediatric indication for NTRK fusion-positive solid tumors and does not include adult populations or other indications (e.g., ROS1-positive NSCLC).

For more accurate figures, detailed market research, real-world evidence, and current pricing data would be required.