To estimate the **Potential Peak Sales** for futibatinib (Lytgobi) in the indication of previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (ICC) with FGFR2 gene fusions or rearrangements 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 on patient populations, pricing, and market penetration may not be publicly available in full detail, I will outline the methodology and make reasonable assumptions based on available information and industry standards.

Step 1: Define the Target Patient Population

Intrahepatic cholangiocarcinoma (ICC) is a rare cancer, and FGFR2 fusions or rearrangements are present in approximately **10-15% of ICC cases**. The total incidence of ICC varies by region, with higher rates in Asia (e.g., China) compared to Western countries. Below are rough estimates of ICC incidence and the target population with FGFR2 alterations:

- **US**: Incidence of ICC is ~1-2 per 100,000, with a population of ~330 million, leading to ~3,300-6,600 new cases annually. Of these, 10-15% have FGFR2 alterations, so ~330-990 patients.

- **EU5**: Combined population of ~320 million, with a similar incidence of ~1-2 per 100,000, leading to ~3,200-6,400 new cases annually. FGFR2 alterations in 10-15% = ~320-960 patients.

- **China**: Incidence is higher, ~2-6 per 100,000, with a population of ~1.4 billion, leading to ~28,000-84,000 new cases annually. FGFR2 alterations = ~2,800-12,600 patients.

- **Japan**: Incidence of ~2-3 per 100,000, with a population of ~125 million, leading to ~2,500-3,750 new cases annually. FGFR2 alterations = ~250-560 patients.

Since futibatinib is indicated for **previously treated** patients, we assume a subset of these incident cases will progress to second-line treatment. Let's assume **50% of diagnosed patients reach second-line therapy** (a common assumption for advanced cancers). Thus, the eligible population is:

- **US**: ~165-495 patients

- **EU5**: ~160-480 patients

- **China**: ~1,400-6,300 patients

- **Japan**: ~125-280 patients

Total eligible patients across all regions: ~1,850-7,555 patients annually.

Step 2: Estimate Market Share

The query assumes a **20-30% share of treated patients** for futibatinib. This accounts for competition from other therapies (e.g., pemigatinib, another FGFR inhibitor for the same indication in some markets) and other treatment options. Applying this range to the eligible population:

- **US**: 20-30% of 165-495 = ~33-149 patients

- **EU5**: 20-30% of 160-480 = ~32-144 patients

- **China**: 20-30% of 1,400-6,300 = ~280-1,890 patients

- **Japan**: 20-30% of 125-280 = ~25-84 patients

Total treated patients at 20-30% share: ~370-2,267 patients annually.

Step 3: Estimate Drug Pricing

Pricing for rare cancer drugs like futibatinib varies by region due to differences in healthcare systems and purchasing power. Futibatinib's US price is not publicly detailed in this context, but similar drugs (e.g., pemigatinib) are priced at ~**$17,000-$20,000 per month** in the US for rare indications. Assuming a treatment duration of ~6-12 months (based on progression-free survival data for FGFR inhibitors), the annual cost per patient is:

- **US**: $17,000 x 12 = ~$204,000 (assuming full-year treatment for simplicity)

- **EU5**: Pricing is typically 50-70% of US price due to negotiations; assume ~$100,000-$140,000 per year.

- **China**: Pricing is often lower due to market access programs; assume ~$50,000-$70,000 per year.

- **Japan**: Pricing is closer to EU levels; assume ~$100,000-$140,000 per year.

Step 4: Calculate Potential Peak Sales

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

At 20% Market Share (Low End):

- **US**: 33 patients x $204,000 = **$6.7 million**

- **EU5**: 32 patients x $120,000 (midpoint) = **$3.8 million**

- **China**: 280 patients x $60,000 (midpoint) = **$16.8 million**

- **Japan**: 25 patients x $120,000 = **$3.0 million**

- **Total Peak Sales (20%)**: **~$30.3 million**

At 30% Market Share (High End):

- **US**: 149 patients x $204,000 = **$30.4 million**

- **EU5**: 144 patients x $120,000 = **$17.3 million**

- **China**: 1,890 patients x $60,000 = **$113.4 million**

- **Japan**: 84 patients x $120,000 = **$10.1 million**

- **Total Peak Sales (30%)**: **~$171.2 million**

Thus, the **Potential Peak Sales** for futibatinib in this indication across the US, EU5, China, and Japan, assuming a 20-30% market share, is approximately **$30 million to $171 million annually**.

Step 5: Calculate $ Value of 1% Share of Treated Patients

To calculate the value of a 1% share, we divide the number of eligible patients by 100 and multiply by the annual cost per patient in each region.

- **US**: 1% of 165-495 patients = 1.65-4.95 patients x $204,000 = **$0.34-$1.01 million**

- **EU5**: 1% of 160-480 patients = 1.6-4.8 patients x $120,000 = **$0.19-$0.58 million**

- **China**: 1% of 1,400-6,300 patients = 14-63 patients x $60,000 = **$0.84-$3.78 million**

- **Japan**: 1% of 125-280 patients = 1.25-2.8 patients x $120,000 = **$0.15-$0.34 million**

Total $ Value of 1% Share Across All Regions: **~$1.52-$5.71 million**

Final Answer:

- **Potential Peak Sales for futibatinib** (20-30% market share) in the US, EU5, China, and Japan for the given indication: **$30 million to $171 million annually**.

- **$ Value of 1% Share of Treated Patients** across these geographies: **$1.5 million to $5.7 million annually**.

Notes:

1. These estimates are based on rough incidence rates, assumptions about second-line treatment eligibility, and pricing benchmarks for rare disease drugs. Actual numbers may vary based on real-world data, market access, and competition.

2. Peak sales could be influenced by factors like duration of therapy, reimbursement policies, and uptake in each region.

3. If more precise data on patient numbers, pricing, or market dynamics is available, these calculations can be refined.