

To estimate the **Potential Peak Sales** for sotorasib (Lumakras) in the indication of KRAS G12C-mutated metastatic colorectal cancer (mCRC) 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 based on epidemiology, market assumptions, and pricing data. Since exact figures may vary depending on real-world data, I will outline the methodology and provide reasonable estimates based on publicly available information and typical market dynamics for oncology drugs.

Step 1: Define the Patient Population

- **Indication:** KRAS G12C-mutated metastatic colorectal cancer (mCRC) in patients who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

- **Mutation Prevalence:** KRAS G12C mutations occur in approximately 3-4% of colorectal cancer cases.

- **Epidemiology:**

- **US:** ~150,000 new colorectal cancer cases annually; ~50,000 are metastatic. Thus, ~1,500-2,000 patients with KRAS G12C-mutated mCRC.

- **EU5:** ~250,000 new colorectal cancer cases annually; ~80,000-100,000 are metastatic. Thus, ~2,400-4,000 patients with KRAS G12C mutations.

- **China:** ~550,000 new colorectal cancer cases annually; ~200,000 are metastatic. Thus, ~6,000-8,000 patients with KRAS G12C mutations.

- **Japan:** ~150,000 new colorectal cancer cases annually; ~50,000 are metastatic. Thus, ~1,500-2,000 patients with KRAS G12C mutations.

- **Total Eligible Patients (prior chemo failure):** Assuming ~50% of mCRC patients progress after first- and second-line therapies, the eligible population is roughly half of the above numbers:

- US: ~750-1,000 patients

- EU5: ~1,200-2,000 patients

- China: ~3,000-4,000 patients

- Japan: ~750-1,000 patients

- **Total:** ~5,700-8,000 patients annually across these geographies.

Step 2: Market Penetration (20%-30% Share of Treated Patients)

- Assuming sotorasib captures **20%-30%** of the eligible treated patients in this indication:

- US: 150-300 patients

- EU5: 240-600 patients

- China: 600-1,200 patients

- Japan: 150-300 patients
- **Total Treated Patients:** ~1,140-2,400 patients annually.

Step 3: Pricing and Treatment Duration

- **Pricing:** Sotorasib's annual cost in the US for non-small cell lung cancer (NSCLC) is approximately **\$215,000 per patient** (based on publicly reported figures for a 960 mg daily dose). For mCRC, pricing may be similar, though discounts or regional pricing variations apply:
- **US:** ~\$215,000/year
- **EU5:** ~\$100,000-\$150,000/year (due to pricing negotiations and healthcare systems)
- **China:** ~\$50,000-\$70,000/year (lower pricing due to market access programs and generics competition)
- **Japan:** ~\$150,000-\$180,000/year (aligned with developed market pricing but with potential discounts)
- **Treatment Duration:** Average duration for mCRC patients in later lines of therapy is ~6-12 months. For simplicity, assume an average of **9 months** of treatment per patient annually, so the cost per patient is ~75% of the annual cost.

Adjusted cost per patient:

- US: ~\$161,250
- EU5: ~\$75,000-\$112,500
- China: ~\$37,500-\$52,500
- Japan: ~\$112,500-\$135,000

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as (Number of Treated Patients) x (Adjusted Cost per Patient).

- **US:**
 - 150-300 patients x \$161,250 = **\$24.2M - \$48.4M**
- **EU5:**
 - 240-600 patients x \$75,000-\$112,500 = **\$18M - \$67.5M**
- **China:**
 - 600-1,200 patients x \$37,500-\$52,500 = **\$22.5M - \$63M**
- **Japan:**
 - 150-300 patients x \$112,500-\$135,000 = **\$16.9M - \$40.5M**

- **Total Potential Peak Sales** (20%-30% share):

- Low end (20% share): \$24.2M (US) + \$18M (EU5) + \$22.5M (China) + \$16.9M (Japan) = **\$81.6M**

- High end (30% share): \$48.4M (US) + \$67.5M (EU5) + \$63M (China) + \$40.5M (Japan) = **\$219.4M**

Thus, **Potential Peak Sales for sotorasib in this indication** across the US, EU5, China, and Japan are approximately **\$82M to \$219M annually**.

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

A 1% share corresponds to 1% of the eligible treated patient population (from Step 1, total eligible patients = 5,700-8,000).

- **Patients per 1% share:**

- US: 7.5-10 patients

- EU5: 12-20 patients

- China: 30-40 patients

- Japan: 7.5-10 patients

- Total: ~57-80 patients

- **Revenue per 1% share** (using adjusted cost per patient):

- US: 7.5-10 patients x \$161,250 = **\$1.21M - \$1.61M**

- EU5: 12-20 patients x \$75,000-\$112,500 = **\$0.9M - \$2.25M**

- China: 30-40 patients x \$37,500-\$52,500 = **\$1.13M - \$2.1M**

- Japan: 7.5-10 patients x \$112,500-\$135,000 = **\$0.84M - \$1.35M**

- **Total \$ Value of 1% Share:**

- Low end: \$1.21M (US) + \$0.9M (EU5) + \$1.13M (China) + \$0.84M (Japan) = **\$4.08M**

- High end: \$1.61M (US) + \$2.25M (EU5) + \$2.1M (China) + \$1.35M (Japan) = **\$7.31M**

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$4.1M to \$7.3M annually**.

Summary of Results

1. **Potential Peak Sales for Sotorasib (20%-30% share)** in KRAS G12C-mutated mCRC:

- US, EU5, China, Japan: **\$82M to \$219M annually**

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

- US, EU5, China, Japan: \$4.1M to \$7.3M annually

Caveats and Assumptions

- These estimates are based on approximate epidemiology data, mutation prevalence, and pricing for oncology drugs. Real-world numbers may differ due to diagnostic testing rates, market access, competition, and reimbursement policies.

- The mCRC indication is a smaller market compared to sotorasib's primary indication (NSCLC), and peak sales may be influenced by combination therapies (e.g., with panitumumab) and emerging competitors.

- Pricing in China and EU5 may be lower due to government negotiations and volume-based procurement.

If you have access to more specific data (e.g., exact patient numbers, pricing, or market share projections), I can refine these estimates further.