

To estimate the **Potential Peak Sales** for trifluridine and tipiracil (LONSURF) in the indication of metastatic colorectal cancer (mCRC) 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 follow a structured approach. Since exact data (e.g., patient population, pricing, or market penetration) is not provided, I will outline the methodology and use reasonable assumptions based on publicly available data and industry standards.

## **Step 1: Define Key Parameters and Assumptions**

1. **Indication and Patient Population:** LONSURF is approved for mCRC patients previously treated with specific therapies (third-line or later). This is a niche population within the broader colorectal cancer patient pool.
2. **Treated Patient Share:** Assuming 20% to 30% of eligible patients are treated with LONSURF.
3. **Geographies:** US, EU5, China, Japan.
4. **Pricing:** Drug pricing varies by region due to differences in healthcare systems and purchasing power. LONSURF's price is based on reported costs (e.g., ~\$10,000–\$15,000 per month in the US; lower in other regions due to discounts or negotiations).
5. **Treatment Duration:** Average treatment duration for mCRC in third-line settings is ~3–6 months.
6. **Peak Sales Timing:** Peak sales are typically reached 5–7 years post-launch or approval of a new combination (e.g., with bevacizumab, approved in 2023).

## **Step 2: Estimate Eligible Patient Population**

Using colorectal cancer incidence and prevalence data, we can estimate the mCRC patient population and further narrow it to third-line or later patients:

- **US:** ~150,000 new colorectal cancer cases annually; ~30% are metastatic at diagnosis, and ~50% progress to mCRC. Of these, ~20–30% reach third-line treatment (~15,000–20,000 patients).
- **EU5:** ~250,000 new cases annually; similar progression rates (~25,000–35,000 third-line patients).
- **China:** ~550,000 new cases annually; lower access to advanced treatments but a large population (~30,000–50,000 third-line patients with access).
- **Japan:** ~130,000 new cases annually; high access to treatments (~10,000–15,000 third-line patients).

Total eligible patients (third-line mCRC) across geographies: ~80,000–120,000.

## **Step 3: Estimate Treated Patients (20%–30% Share)**

- At 20% share: ~16,000–24,000 treated patients.
- At 30% share: ~24,000–36,000 treated patients.

## **Step 4: Estimate Annual Cost per Patient**

- **US:** ~\$12,000/month x 4 months (average duration) = \$48,000/year.
- **EU5:** ~\$6,000–\$8,000/month x 4 months = \$24,000–\$32,000/year (lower due to negotiated prices).

- **China:** ~\$3,000–\$5,000/month x 4 months = \$12,000–\$20,000/year (lower pricing and access barriers).
- **Japan:** ~\$8,000–\$10,000/month x 4 months = \$32,000–\$40,000/year (similar to EU5 but slightly higher).

## **Step 5: Calculate Potential Peak Sales**

Using the treated patient numbers and cost per patient, we calculate peak sales at 20% and 30% market share. For simplicity, I'll use midpoint patient numbers and costs, weighted by geography (US and EU5 contribute more to revenue due to higher pricing).

- **US:** 5,000–7,000 treated patients (20–30%) x \$48,000 = \$240M–\$336M.
- **EU5:** 6,000–9,000 treated patients x \$28,000 (midpoint) = \$168M–\$252M.
- **China:** 3,000–5,000 treated patients x \$16,000 (midpoint) = \$48M–\$80M.
- **Japan:** 2,000–3,000 treated patients x \$36,000 (midpoint) = \$72M–\$108M.

**Total Peak Sales (20% share):** \$240M (US) + \$168M (EU5) + \$48M (China) + \$72M (Japan) = **~\$528M.**

**Total Peak Sales (30% share):** \$336M (US) + \$252M (EU5) + \$80M (China) + \$108M (Japan) = **~\$776M.**

Thus, **Potential Peak Sales** for LONSURF in this indication across the specified geographies is approximately **\$528M–\$776M annually**, depending on the 20%–30% treated patient share.

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

A 1% share corresponds to 1% of the eligible patient population being treated with LONSURF (~800–1,200 patients total across geographies).

Using the same weighted average cost per patient:

- **US:** ~200 patients x \$48,000 = \$9.6M.
- **EU5:** ~300 patients x \$28,000 = \$8.4M.
- **China:** ~400 patients x \$16,000 = \$6.4M.
- **Japan:** ~100 patients x \$36,000 = \$3.6M.

**Total \$ Value of 1% Share:** \$9.6M (US) + \$8.4M (EU5) + \$6.4M (China) + \$3.6M (Japan) = **~\$28M.**

## **Final Answer**

- **Potential Peak Sales for LONSURF** in mCRC (third-line or later) in the US, EU5, China, and Japan, assuming 20%–30% share of treated patients: **\$528M–\$776M annually.**
- **\$ Value of 1% Share of Treated Patients** in these geographies: **~\$28M annually.**

## **Notes and Caveats**

1. These estimates are based on assumptions for patient numbers, pricing, and treatment duration. Actual figures may vary due to market access, competition (e.g., other therapies for mCRC), reimbursement policies, and real-world treatment patterns.
2. The combination approval with bevacizumab (2023) may increase market share or treatment duration, potentially pushing peak sales higher.
3. China's contribution is highly uncertain due to pricing and access barriers; actual revenue may be lower.
4. These figures represent annual peak sales at steady-state market penetration; actual sales will ramp up over time post-launch or post-combination approval.

If you have specific data (e.g., exact patient numbers or pricing), I can refine the calculations further.