

To estimate the **Potential Peak Sales** for fruquintinib (Fruzaqla) 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. This will involve making assumptions about the patient population, treatment rates, market share, and pricing. Since exact data may not be publicly available, I will outline the methodology and use reasonable estimates based on available information and industry standards.

Step 1: Define the Target Patient Population for mCRC

Fruquintinib is approved for adult patients with mCRC who have progressed after prior therapies (third-line or later). This is a specific subset of the overall mCRC population.

Estimated mCRC Incidence and Treated Population in Target Geographies

Using epidemiology data and cancer statistics, we can estimate the number of mCRC patients eligible for third-line treatment. Below are approximate annual incidence rates for colorectal cancer (CRC), assuming ~40-50% of CRC cases progress to metastatic stage (mCRC), and ~20-30% of mCRC patients reach third-line treatment (based on disease progression and treatment paradigms).

1. US:

- CRC incidence: ~150,000 new cases/year (American Cancer Society).
- mCRC: ~60,000-75,000 cases (40-50% of CRC).
- Third-line eligible: ~12,000-22,500 patients (20-30% of mCRC).
- Assume ~70% are treated in third-line: **8,400-15,750 treated patients.**

2. EU5 (France, Germany, Italy, Spain, UK):

- CRC incidence: ~300,000 new cases/year (combined, based on GLOBOCAN).
- mCRC: ~120,000-150,000 cases (40-50% of CRC).
- Third-line eligible: ~24,000-45,000 patients (20-30% of mCRC).
- Assume ~70% treated: **16,800-31,500 treated patients.**

3. China:

- CRC incidence: ~550,000 new cases/year (highest globally, GLOBOCAN).
- mCRC: ~220,000-275,000 cases (40-50% of CRC).
- Third-line eligible: ~44,000-82,500 patients (20-30% of mCRC).
- Assume ~50% treated (lower access to advanced therapies): **22,000-41,250 treated patients.**

4. Japan:

- CRC incidence: ~150,000 new cases/year (GLOBOCAN).
- mCRC: ~60,000-75,000 cases (40-50% of CRC).

- Third-line eligible: ~12,000-22,500 patients (20-30% of mCRC).
- Assume ~70% treated: **8,400-15,750 treated patients.**

Total Treated Patients Across Geographies (Midpoint Estimate):

- US: ~12,075 patients.
- EU5: ~24,150 patients.
- China: ~31,625 patients.
- Japan: ~12,075 patients.
- **Total:** ~80,000 treated patients annually (midpoint estimate).

Step 2: Market Share Assumption

The query assumes a **20% to 30% share of treated patients** for fruquintinib. Using the midpoint of 25% for peak sales estimation:

- **Treated patients on fruquintinib:** 25% of 80,000 = **20,000 patients.**

Breakdown by Geography (25% share):

- US: $12,075 * 25\% = 3,019$ patients.
- EU5: $24,150 * 25\% = 6,038$ patients.
- China: $31,625 * 25\% = 7,906$ patients.
- Japan: $12,075 * 25\% = 3,019$ patients.

Step 3: Pricing Assumption for Fruquintinib

Pricing for oncology drugs varies significantly by region due to healthcare systems, reimbursement policies, and purchasing power. Fruquintinib's pricing is based on its status as a targeted therapy for a late-line mCRC indication. Below are rough annual cost estimates per patient (based on similar drugs like regorafenib or trifluridine/tipiracil):

- **US:** ~\$150,000/year per patient (high pricing due to private insurance and lack of price controls).
- **EU5:** ~\$80,000/year per patient (lower due to negotiated pricing and public health systems).
- **China:** ~\$30,000/year per patient (lower pricing due to affordability and government policies; fruquintinib is already marketed in China by Hutchmed at a lower cost).
- **Japan:** ~\$100,000/year per patient (high pricing but slightly below US due to government regulation).

Note: These are rough estimates and assume a full year of treatment, though actual duration may be shorter (e.g., 6-9 months) due to disease progression or tolerability.

Step 4: Calculate Potential Peak Sales (25% Market Share)

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

1. US:

- 3,019 patients * \$150,000 = **\$452.9 million.**

2. EU5:

- 6,038 patients * \$80,000 = **\$483.0 million.**

3. China:

- 7,906 patients * \$30,000 = **\$237.2 million.**

4. Japan:

- 3,019 patients * \$100,000 = **\$301.9 million.**

Total Potential Peak Sales (25% share):

- \$452.9M (US) + \$483.0M (EU5) + \$237.2M (China) + \$301.9M (Japan) = **~\$1.48 billion annually.**

Range for 20%-30% Market Share:

- At 20% share (16,000 patients): **~\$1.18 billion.**

- At 30% share (24,000 patients): **~\$1.77 billion.**

- **Potential Peak Sales Range: \$1.2 billion to \$1.8 billion annually.**

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

A 1% share of treated patients corresponds to 1% of the total treated patient population (~80,000 patients = 800 patients).

Breakdown by Geography (1% share = 800 patients total, proportional to population):

- US: $12,075 / 80,000 * 800 = \sim 121$ patients.

- EU5: $24,150 / 80,000 * 800 = \sim 242$ patients.

- China: $31,625 / 80,000 * 800 = \sim 316$ patients.

- Japan: $12,075 / 80,000 * 800 = \sim 121$ patients.

Revenue for 1% Share:

1. **US:** 121 patients * \$150,000 = **\$18.2 million.**
2. **EU5:** 242 patients * \$80,000 = **\$19.4 million.**
3. **China:** 316 patients * \$30,000 = **\$9.5 million.**
4. **Japan:** 121 patients * \$100,000 = **\$12.1 million.**

Total \$ Value of 1% Share:

- \$18.2M (US) + \$19.4M (EU5) + \$9.5M (China) + \$12.1M (Japan) = **~\$59.2 million annually.**

Final Answer

1. Potential Peak Sales for Fruquintinib in mCRC (20%-30% market share):

- Across US, EU5, China, and Japan: **\$1.2 billion to \$1.8 billion annually.**
- Midpoint (25% share): **~\$1.5 billion annually.**

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

- Across US, EU5, China, and Japan: **~\$59.2 million annually.**

Caveats and Assumptions

- **Patient Population:** Estimates are based on rough epidemiology data and assumptions about progression to third-line treatment. Real-world numbers may differ based on access to care and treatment patterns.

- **Pricing:** Pricing is assumed based on comparable therapies and regional differences. Actual pricing for fruquintinib may vary.

- **Market Share:** Achieving 20-30% share depends on competition (e.g., regorafenib, trifluridine/tipiracil), clinical differentiation, and payer reimbursement.

- **Treatment Duration:** Assumes full-year treatment cost, though actual duration may be shorter, reducing revenue estimates.

If more specific data on pricing, patient numbers, or market dynamics is available, these estimates can be refined further.