

Patients with refractory metastatic colorectal cancer experience survival benefits with fruquintinib

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Researchers from The University of Texas MD Anderson Cancer Center reported study results showing that the targeted therapy fruquintinib significantly improved overall survival (OS) and progression-free survival (PFS) in patients with refractory metastatic colorectal cancer. Findings from the global FRESCO-2 trial, published today in [The Lancet](#), were first presented at the European Society for Medical Oncology (ESMO) Congress 2022.

The OS was 7.4 months with fruquintinib versus 4.8 months in the placebo arm, while the median PFS was 3.7 months with fruquintinib compared to 1.8 months in the placebo arm. These results represent a statistically significant improvement relative to controls.

"Patients with refractory metastatic colorectal cancer have very limited treatment possibilities and poor outcomes," said principal investigator Arvind Dasari, M.D., associate professor of Gastrointestinal Medical Oncology. "These results are very encouraging and confirm that fruquintinib may be a novel treatment opportunity for patients who previously had no other options."

The randomized Phase III [FRESCO-2 clinical trial](#) was conducted at 153 sites in the United States, Europe, Japan and Australia. The double-blind study evaluated treatment with the novel oral therapy fruquintinib—a small-molecule tyrosine kinase inhibitor of vascular endothelial growth factor receptors (VEGFR)—plus best supportive care compared to placebo plus best supportive care in heavily pre-treated patients with treatment-resistant metastatic colorectal cancer. The primary endpoint was OS.

According to the American Cancer Society, colorectal cancer is the third leading cause of cancer-related death in men and in women, and the second most common cause of cancer death for men and women combined. Despite treatment advances, patients with metastatic

colorectal cancer still have poor long-term survival rates. After patients progress through several lines of therapy, they typically live only four to five months. Therefore, there is a large need for treatment alternatives after current therapies are exhausted.

In the original Phase III FRESCO study, which led to the drug's approval in China in September 2018, fruquintinib given as third-line therapy or later improved median OS in patients with metastatic colorectal cancer compared with placebo (6.6 months versus 9.3 months). At that time, standard of care for patients with metastatic colorectal cancer in China differed from the U.S., the European Union and Japan.

In June 2020, the Food and Drug Administration granted fast track designation to fruquintinib for the treatment of some patients with previously treated colorectal cancer.

The FRESCO-2 trial randomized 691 patients with advanced refractory metastatic colorectal cancer. Patients were eligible for treatment if they had documented metastatic colorectal cancer and were previously treated either with chemotherapy, anti-VEGF therapy or immune checkpoint inhibitors (if their disease was microsatellite instability-high or mismatch-repair deficient). Patients had an ECOG performance status scale score of 0 or 1, measurable disease and expected survival of 12 weeks or more.

Patients received either fruquintinib or placebo daily for three weeks, followed by one week off, in 28-day cycles. Subsequent anti-cancer therapies were given to 29.4% in the fruquintinib arm and 34.3% in the placebo arm. The disease control rate was 55.5% for fruquintinib versus 16.1% for placebo.

Grade 3 or 4 treatment-related adverse events occurred in 62.7% of patients in the fruquintinib group and 50.4% in the placebo group. The

most frequent events seen in those receiving fruquintinib were hypertension (13.6%), asthenia (7.7%) and hand-foot syndrome (6.4%).

"This study supports the meaningful survival improvement and manageable safety profile of fruquintinib," Dasari said. "I am excited that this treatment could extend the lives of advanced colorectal cancer patients and preserve their quality of life."

The investigators will continue to review quality of life data from trial participants, as these patients have high tumor burden and residual side effects from multiple therapies that are known to reduce quality of life measures. Ongoing and future studies will explore additional fruquintinib treatment combinations for patients with colorectal cancer.

More information: Fruquintinib versus placebo in patients with refractory metastatic colorectal cancer (FRESCO-2): an international, multicentre, randomised, double-blind, phase 3 study, *The Lancet* (2023). DOI: 10.1016/S0140-6736(23)00772-9
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