

# New drug for metastatic colorectal cancer enters phase 3 trial

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A new therapy for metastatic colorectal cancer that has been granted fast-track designation by the U.S. Food and Drug Administration is being tested in a phase 3 clinical trial at Vanderbilt-Ingram Cancer Center.

Cathy Eng, MD, David H. Johnson Chair in Surgical and Medical Oncology at Vanderbilt University and co-leader of the Gastrointestinal Cancer Research Program at Vanderbilt-Ingram Cancer Center, is the U.S. senior national principal investigator for the FRESCO 2 study, an international clinical trial for [metastatic colorectal cancer](#) for patients that have received (or are intolerant to) three prior lines of chemotherapy; patients must have been exposed to either regorafenib and/or lonsurf. The drug being tested in the trial is fruquintinib, which is designed to stop [new blood vessels](#) forming from pre-existing vessels that feed cancer tumors. It is an oral small-molecule inhibitor of vascular endothelial growth factor.

In the randomized, [double-blind trial](#), patients will be randomized in a 2:1 fashion to fruquintinib plus supportive care. In the other arm (control arm), participants will receive placebo plus supportive care.

"This is the only phase 3 trial that I am aware of for metastatic colorectal cancer in the United States at this time," Eng said.

There are no approved effective treatments in the U.S. for metastatic colorectal patients who have progressed on standard treatments.

Fruquintinib was approved by the China Food and Drug Administration in 2018 for patients with metastatic colorectal cancer who had undergone at least two prior standard anticancer treatments. In a prior phase 3 clinical trial conducted in China involving 416 patients, overall survival was 9.3 months for patients who received fruquintinib versus 6.6 months for patients who received placebo. The FDA granted fruquintinib fast track designation in June 2020.

**More information:** A Study of Efficacy and Safety of Fruquintinib (HMPL-013) in Patients With Metastatic Colorectal Cancer: [www.vicc.org/clinical-trials/protocol-viccg2045](http://www.vicc.org/clinical-trials/protocol-viccg2045)

Provided by Vanderbilt University

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