A Trial to Evaluate the Safety and Activity of Fruquintinib in Minority Populations With Advanced, Previously Treated Colorectal Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Provide written (or electronic) informed consent. 2. Male or female aged more than or equal to (≥)18 years. 3. Presence of histologically and/or cytologically documented metastatic colorectal adenocarcinoma. Rat sarcoma virus (RAS) status for each participant must be documented. 4. Have been previously treated with standard approved therapies: * Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, * An anti-vascular endothelial growth factor (VEGF) biological therapy (e.g., bevacizumab, aflibercept, ramucirumab \[regorafenib is NOT an anti-VEGF biologic\]), and * If RAS wild-type and medically appropriate, an anti-epidermal growth factor receptor (EGFR) therapy (e.g., cetuximab, panitumumab). * If known microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumor and medically appropriate, a programmed cell death protein 1 (PD1) inhibitor. 5. Self-identify as Black and/or African American or Hispanic and/or Latino or as both. 6. Body weight ≥40 kilograms (kg). 7. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 at screening. 8. Have assessable disease according to RECIST version 1.1, assessed locally. 9. In participants of childbearing potential, agreement to use highly effective form(s) of contraception, which results in a low failure rate (less than \[\<\]1 percent \[%\] per year) when used consistently and correctly, starting during the screening period, continuing throughout the entire trial period, and for 2 weeks after taking the last dose of the trial intervention. Such methods include oral (PO) hormonal contraception (combined estrogen/progestogen or progestogen-only) associated with inhibition of ovulation, intrauterine device, intrauterine hormone-releasing system (IUS), bilateral tubal ligation, vasectomized partner, or true sexual abstinence in line with the preferred and usual lifestyle of the participant. Those assigned male sex at birth must always use a condom.

Exclusion Criteria:

1. Absolute neutrophil count (ANC) \<1.5 times 10\^9 per liter (10\^9/L), platelet count \<100 times 10\^9/L, or hemoglobin \<9.0 grams per deciliter (g/dL). Blood transfusion within 1 week prior to enrollment for the purpose of increasing the likelihood of eligibility is not allowed. 2. Serum total bilirubin more than (\>)1.5 times the upper limit of normal range (ULN). Participants with previously documented Gilbert syndrome and bilirubin \<2 times ULN are eligible. 3. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) \>2.5 times ULN in participants without hepatic metastases; ALT or AST \>5 times ULN in participants with hepatic metastases. 4. Creatinine clearance \<30 milliliters per minute (mL/min). Creatinine clearance can either be measured in a 24-hour urine collection or estimated by the Cockcroft-Gault equation. Where available and appropriate, other formulae may be used to estimate clearance after consultation with the trial medical monitor. 5. Urine dipstick or urinalysis with protein ≥2 positive or 24-hour urine protein ≥1.0 gram per 24 hours (g/24 hours). Participants with 1+ positive proteinuria must undergo a 24-hour urine collection to assess urine protein level. 6. Uncontrolled hypertension, defined as systolic BP ≥140 millimeter of mercury (mmHg) and/or diastolic blood pressure (BP) ≥90 mmHg despite optimal medical management. The participant must have BP below both limits. Repeated assessments are permitted. 7. International normalized ratio (INR) \>1.5 times ULN or activated partial thromboplastin time (aPTT) \>1.5 times ULN, unless the participant is currently receiving or intended to receive anticoagulants for prophylactic purposes. 8. History of or active gastric/duodenal ulcer or ulcerative colitis, active hemorrhage of an unresected gastrointestinal tumor, history of perforation or fistulas, or any other condition that could, in the investigator's judgment, result in gastrointestinal hemorrhage or perforation within the 6 months prior to screening. 9. History or presence of hemorrhage from any other site (e.g, hemoptysis or hematemesis) within 2 months prior to screening. 10. History of a thromboembolic event, including deep vein thrombosis, pulmonary embolism, or arterial embolism within 6 months prior to screening. 11. Stroke and/or transient ischemic attack within 12 months prior to screening. 12. Clinically significant cardiovascular disease, including but not limited to, acute myocardial infarction or coronary artery bypass surgery within 6 months prior to enrollment, severe or unstable angina pectoris, New York Heart Association Class III/IV congestive heart failure, ventricular arrhythmias requiring treatment, or left ventricular ejection fraction \<50% by echocardiogram. 13. QT interval, corrected using the Fridericia method (QTcF) \>480 milliseconds or any factors that increase the risk of QT interval, corrected based on the patient's heart rate (QTc) prolongation or risk of arrhythmic events such as hypokalemia, congenital long QT syndrome, or family history of long QT syndrome. 14. Systemic antineoplastic therapies (except for that described in exclusion criterion no. 15) or any investigational therapy within 2 weeks prior to the first dose of the trial intervention, including chemotherapy, radical radiotherapy, hormonotherapy, biotherapy, and immunotherapy. 15. Systemic small molecule targeted therapies (e.g., tyrosine kinase inhibitors \[TKIs\]) within 5 half-lives or 4 weeks (whichever is shorter) prior to the first dose of the trial intervention. 16. Palliative radiotherapy for bone metastasis/lesion within 2 weeks prior to the initiation of the trial intervention. 17. Brachytherapy (i.e., implantation of radioactive seeds) within 60 days prior to the first dose of the trial intervention. 18. Surgery or invasive procedure (i.e., a procedure that includes a biopsy; central venous catheter placement is allowed) within 14 days prior to the first dose of the trial intervention or unhealed surgical incision. 19. Any unresolved toxicities from previous antitumor treatments greater than NCI CTCAE, version 5.0, Grade 1 (except for alopecia or neurotoxicity Grade less than or equal to \[≤\]2). 20. Known human immunodeficiency virus infection. 21. Known history of active viral hepatitis. For participants with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load had to be undetectable on suppressive therapy, if indicated. Participants with hepatitis C virus (HCV) infection who are currently on treatment are eligible if they have an undetectable HCV viral load. 22. Clinically uncontrolled active infection requiring intravenous (IV) antibiotics. 23. Tumor invasion of a large vascular structure (e.g., pulmonary artery or superior or inferior vena cava). 24. Those who are currently pregnant or lactating. 25. Brain metastases and/or spinal cord compression untreated with surgery and/or radiotherapy, and without clinical imaging evidence of SD for 14 days or longer; participants requiring steroids within 4 weeks prior to the start of the trial intervention are to be excluded. 26. Other malignancy, except for non-melanoma skin cancer, in situ cervical carcinoma, or bladder carcinoma (tumor in situ and T1) that had been adequately treated during the 5 years prior to screening. Participants with another primary malignancy that has been adequately treated may be included after consultation with the trial medical monitor. 27. Inability to take medication PO, dysphagia, or an active gastric ulcer resulting from previous surgery (e.g., gastric bypass) or a severe gastrointestinal disease, or any other condition that investigators believe might affect absorption of the investigational medicinal product (IMP). 28. Other disease, metabolic disorder, physical examination anomaly, abnormal laboratory result, or any other condition (e.g., current alcohol or drug abuse) that investigators suspect might prohibit use of the IMP, affect interpretation of trial results, or put the participant at undue risk of harm based on the investigator's assessment. 29. Known hypersensitivity to fruquintinib or any of its inactive ingredients, including the azo dyes Tartrazine- Federal Food, Drug, and Cosmetic Act (FD\&C) Yellow 5 and Sunset yellow For Coloring Food (FCF)-FD\&C Yellow 6. 30. Received prior fruquintinib. 31. Live vaccine ≤28 days before the first dose of the trial intervention. Seasonal vaccines for influenza are generally inactivated vaccines and are allowed. Intranasal vaccines are live vaccines and are not allowed. 32. Use of strong inducers of cytochrome P450 3A4 (CYP3A4) within 2 weeks before the first dose of the trial intervention.

Conditions & Interventions

Interventions:
DRUG: Fruquintinib
Conditions:
Colorectal Cancer
Keywords:

Keywords:
colorectal cancer, fruquintinib

More Information

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