Combination Immunotherapy for the Treatment of Chemotherapy-refractory Metastatic MSS CRC

NCT07281716

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Dan Feng
Enrollment	24 participants

Plain Language Summary

This study is testing a combination of immunotherapy drugs for people with metastatic colorectal cancer (cancer that has spread) that does not respond to immunotherapy on its own — specifically cancer that lacks a marker called MSI-H, which normally makes it more responsive to these drugs.

You may be eligible if...
- Your colorectal cancer has been confirmed by biopsy and is classified as non-MSI-H (microsatellite stable)
- Your cancer has progressed or you could not tolerate standard chemotherapy regimens including fluoropyrimidines, oxaliplatin, and irinotecan
- You have at least one tumor that can be measured on imaging (at least 10 mm)
- You have at least one tumor site accessible for a biopsy
- You are willing to provide blood samples at scheduled study visits

You may NOT be eligible if...
- You have not yet tried standard chemotherapy options
- You are unable or unwilling to undergo biopsies or blood draws as required
- You do not meet organ function or performance status requirements

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (10)

- Patients must have a pathologically confirmed diagnosis of non-MSI-H/pMMR CRC.
- Patients must have progressed (clinically or radiographically) on or after standard chemotherapy, including fluoropyrimidines, oxaliplatin, and irinotecan, or are intolerant to standard chemotherapy. Patients may have received, if eligible, anti-VEGF or anti-EGFR antibodies in combination with chemotherapy.
- Patients must have at least 1 measurable target lesion at baseline e 10mm in the longest diameter.
- Patient must be willing and able to provide blood samples (6 heparinized, and two streck tubes, roughly 70 - 80 mL) at the time points indicated in the Study Calendar.
- Patients must have at least 1 lesion suitable for core needle biopsies.

... and 5 more (see full listing online)

Exclusion (19)

- Patients who have had chemotherapy within 14 days from start of therapy.
- Palliative radiotherapy is permitted at anytime, if deemed in the best interest of the patient.
- Patients may not be receiving any other investigational agents.
- Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection requiring antibiotics (exception is a brief (d10days) course of antibiotics to be completed before initiation of treatment), symptomatic congestive heart failure, unstable angina pectoris, or psychiatric illness/social situations that would limit compliance with study requirements.

• Patients who have undergone major surgery within 4 weeks prior to the first dose of treatment.

... and 14 more (see full listing online)

Locations (1 total)

Icahn School of Medicine at Mount Sinai, New York, New York, United States