

Surufatinib and Sintilimab in Combination With Capecitabine for Metastatic Adenocarcinoma of Small Intestine or Appendix Carcinoma

NCT05472948

Status	RECRUITING
Phase	Phase 2
Sponsor	Sun Yat-sen University
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (8)

- Histological or cytological documentation of adenocarcinoma of Small Intestine or Appendix Carcinoma. All other histological types are excluded.
 - Subjects with metastatic adenocarcinoma of Small Intestine or Appendix Carcinoma.
 - Subjects must have failed at least one line of prior treatment.
 - Progression during or within 3 months following the last administration of approved standard therapies . 4.1 Subjects an adjuvant setting should have progressed during or within 6 months of completion of adjuvant therapy. 4.2 Subjects who have withdrawn from standard treatment due to unacceptable toxicity warranting discontinuation of treatment and precluding retreatment with the same agent prior to progression of disease will also be allowed into the study. 4.3 Subjects may have received prior treatment with Avastin (bevacizumab)
 - Subjects must have measurable or non measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) criteria, version 1.1.
- ... and 3 more (see full listing online)

Exclusion (9)

- Prior treatment with Surufatinib
 - Previously received anti-programmed death-1 (PD-1) or its ligand (PD-L1) antibody, anti-cytotoxic T lymphocyte-associated antigen 4 (cytotoxic T-lymphocyte-associated Protein 4, CTLA-4) antibody or other drug/antibody that acts on T cell costimulation or checkpoint pathways.
 - Previous or concurrent cancer that is distinct in primary site or histology from colorectal cancer within 5 years prior to randomization EXCEPT for curatively treated cervical cancer in situ, non-melanoma skin cancer and superficial bladder tumors \[Ta (non-invasive tumor), Tis (carcinoma in situ) and T1 (tumor invades lamina propria)\].
 - Cardiological disease including Congestive heart failure, Unstable angina, Myocardial infarction, Cardiac arrhythmias requiring anti-arrhythmic therapy.
 - Uncontrolled hypertension. (Systolic blood pressure 150 mmHg or diastolic pressure 90 mmHg despite optimal medical management).
- ... and 4 more (see full listing online)

Locations (1 total)

The Sixth Affiliated Hospital of Sun Yat-sen University, Guangzhou, Guangdong, China

<https://clinicaltrials.gov/study/NCT05472948>

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