Cancer Research Consortium of West Michigan
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FAST FACTS

S1922, Randomized Phase II Selection Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel Adenocarcinoma

1. Eligibility Criteria

1.1 Disease Related Criteria

a. Patients must have histologically or cytologically confirmed small bowel adenocarcinoma. Ampullary adenocarcinomas are not eligible. Patients must have metastatic disease or locally advanced unresectable disease.

b. Brain metastases are allowed if they have been adequately treated with radiotherapy or surgery and stable for at least 30 days prior to registration. Patients must be neurologically asymptomatic and without corticosteroid treatment for at least 7 days prior to registration.

c. Patients must have measurable or non-measurable disease. A diagnostic quality CT scan or MRI used to assess all disease must be performed within 28 days prior to registration. Scans must include imaging of the chest, abdomen, and pelvis, except for patients with head/neck cancer, who must have imaging of the chest, abdomen, pelvis, and neck. If there is clinical suspicion for bone metastases at the time of enrollment (in the judgement of the treating investigator) bone scan should be performed. Bone scans done within 42 days prior to registration may be used to establish baseline condition at registration. All disease must be assessed and documented on the Baseline Tumor Assessment Form.

1.2 Prior/Concurrent Therapy Criteria

a. Patients must have progressed on prior therapy with a fluoropyrimidine and/or oxaliplatin, given either for metastatic / locally advanced disease or as adjuvant therapy completed within the previous 12 months.

b. Patients must not have received prior treatment with irinotecan, taxane, or ramucirumab for small bowel adenocarcinoma**.**

c. Patients must have completed prior chemotherapy, immunotherapy, or radiation therapy at least 14 days prior to registration and all toxicity must be resolved to Grade 1 (with the exception of Grade 2 neuropathy) prior to registration. In CTCAE version 5.0 Grade 2 sensory neuropathy is defined as "moderate symptoms: limiting instrumental activities of daily living (ADLs)"

d. Patients must not have had major surgery within 28 days prior to registration, or minor surgery within 7 days prior to registration, and must not be planned for elective major surgery to be performed during protocol treatment.

e. Patients must not be currently enrolled in or have discontinued within the last 28 days a clinical trial involving an investigational product or non-approved use of a drug, or concurrently enrolled in any other type of medical research judged not to be scientifically or medically compatible with this study. Patients participating in surveys or observational studies are eligible to participate in this study.

f. Patients must not be receiving chronic antiplatelet therapy, including dipyridamole or clopidogrel, or similar agents.