Protocol Title: A Phase I/II Multicenter Investigation of ABI-009 (Nab-rapamycin) in Combination with FOLFOX and Bevacizumab as First-line Therapy in Patients with Advanced or Metastatic Colorectal Cancer

Target Population: Metastatic Colorectal Cancer

Summary: A phase I/II multicenter investigation of ABI-009 (nab-rapamycin) in combination with mFOLFOX6 and Bevacizumab as first-line therapy in patients with advanced or metastatic colorectal cancer.

Key Inclusion Criteria:
- Histologically confirmed advanced or metastatic colorectal cancers for whom chemotherapy is indicated
- No prior chemotherapy for advanced or metastatic disease
  - Could have received adjuvant chemotherapy or adjuvant chemo-radiotherapy
- Must have at least 1 measurable site of disease according to RECIST v1.1 that has not been previously irradiated
  - If the patient has had previous radiation to the marker lesion(s), there must be radiological evidence of progression since the radiation
- Eligible patients, 18 years or older, with ECOG performance status 0, 1, or 2
- Must not have been previously treated with an mTOR inhibitor
- Adequate liver, renal, and bone marrow function
- Minimum of 4 weeks since any major surgery, completion of radiation, or completion of all prior systemic anticancer therapy, and ≥ 6 months since adjuvant FOLFOX therapy (adequately recovered from the acute toxicities of any prior therapy, including neuropathy should be grade ≤ 1)
- Life expectancy of > 3 months, as determined by the investigator

Key Exclusion Criteria:
- History of severe and uncontrolled allergic reactions to Bevacizumab
- Prior treatment with FOLFOX or Bevacizumab within the preceding 4 weeks
- Patients currently receiving or have received anticancer therapies within 4 weeks of the start of study treatment (including chemotherapy, radiation therapy, antibody based therapy, etc.)
- Patients who have had a major surgery or significant traumatic injury within 4 weeks of start of study drug, patients who have not recovered from the side effects of any major surgery or patients that may require major surgery during the course of the study
- Chronic treatment with systemic steroids or another immunosuppressive agent
- Recent infection requiring systemic anti-infective treatment that was completed ≤ 14 days prior to enrollment
- Any severe and/or uncontrolled medical or psychiatric conditions or other conditions that could affect their participation
- History of interstitial lung disease and/or pneumonitis, or pulmonary hypertension
- Known history of HIV seropositivity
- Active Hepatitis B or Hepatitis C
- Active bleeding diathesis or on oral anti-vitamin K medication (except low dose Coumadin)
- Use of strong inhibitors and inducers of CYP3A4 within the 14 days prior to receiving the first dose of ABI-009; Additionally, use of any known CYP3A4 substrates with narrow therapeutic window within the 14 days prior to receiving the first dose of ABI-009

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03439462