Protocol Title: A Pilot Phase 2 Study of Albumin-bound Rapamycin Nanoparticles, ABI-009, in Patients with Metastatic, Unresectable, Low or Intermediate Grade Neuroendocrine Tumors of the Lung or Gastroenteropancreatic System

Target Population: Neuroendocrine Tumors

Summary: The purpose of this study is to determine whether ABI-009 will make advanced, malignant neuroendocrine tumor(s) of the lung, gastrointestinal tract and/or pancreas that cannot be removed by surgery smaller and slow the spread of your cancer in patients who have progressed or been intolerant to Everolimus. All eligible participants will receive ABI-009, the study drug.

Key Inclusion Criteria:
- Unresectable or metastatic patients with typical or atypical carcinoid tumors of the lung or low or intermediate grade gastroenteropancreatic neuroendocrine tumors (GEPNETs).
- Must have measurable disease per RECIST 1.1.
- Must have progressed on Everolimus or been intolerant to Everolimus.
- Patients ≥18 years old, must have ECOG Performance Status 0 or 1.
- Concurrent use of somatostatin analogs (SSAs) is allowed if currently used for symptom control.
- Adequate baseline organ function.
- Fasting serum triglyceride ≤300 mg/dL; fasting serum cholesterol ≤350 mg/dL.
- Life expectancy of >3 months, as determined by the investigator.

Key Exclusion Criteria:
- Patients currently undergoing anti-cancer therapy for neuroendocrine tumors (other than SSAs for symptoms).
- History of allergic reactions to compounds of similar chemical or biologic composition to ABI-009.
- Known active untreated or symptomatic central nervous system (CNS) metastases.
- Patients with a “currently active” second malignancy other than non-melanoma skin cancers, carcinoma in situ of the cervix, resected incidental prostate cancer (staged pathological tumor-2 (pT2) with Gleason Score ≤6 and postoperative PSA <0.5 ng/mL), or other adequately treated carcinoma-in-situ are ineligible.
- Recent infection requiring systemic anti-infective treatment that was completed ≤14 days prior to enrollment (with the exception of uncomplicated urinary tract infection or upper respiratory tract infection).
- Uncontrolled diabetes mellitus as defined by HbA1c >8% despite adequate therapy.
- Unstable coronary artery disease or myocardial infarction during preceding 6 months.
- Patients with history of interstitial lung disease and/or pneumonitis, or pulmonary hypertension.
- Use of strong inhibitors and inducers of CYP3A4 within 14 days prior to receiving the first dose of ABI-009.
- Known Human Immunodeficiency Virus (HIV) or active Hepatitis B or Hepatitis C.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03670030

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