PANCREATIC ADENOCARCINOMA – METASTATIC

PROmoting CLinicAl TrIal EngageMent for Pancreatic Cancer App Study (PROCLAIM Study)

Clinical Trial Website: NCT06252545	**Current Status:** Recruiting

Description: This two-part, randomized trial seeks to identify and address barriers to enrollment of Black patients in pancreatic cancer clinical trials by conducting interviews and creating a culturally-informed mobile health application to promote participation.

Key Inclusion:

- Patients at least 18 years old
- Patients must identify as Black
- Have newly diagnosed or progressive pancreatic cancer
- Have access to a mobile device

Key Exclusion:

- Inability to read and speak English
- Dementia altered mental status or a psychiatric condition prohibiting informed consent
- Active participation in a therapeutic clinical trial

Principal Investigator: Jen Jen Yeh, MD	**Coordinator:** Brent Henderson **Phone:** 919-966-7706

CA-4948 Added to Standard Chemotherapy to Treat Metastatic or Unresectable Pancreatic Cancer

Clinical Trial Website: NCT05685602	**Current Status:** Recruiting

Design: This phase I trial tests the safety, side effects, and best dose of emavusertib (CA-4948) in combination with gemcitabine and nab-paclitaxel in treating patients with pancreatic ductal adenocarcinoma that has spread from primary site to other places in the body or cannot be removed by surgery.

Key Inclusion:

- Patients at least 18 years old
- Patients must have histologically or cytologically confirmed metastatic or unresectable pancreatic cancer for which standard curative or palliative measures do not exist or are no longer effective
- Must have had disease progression on or after fluorouracil (5-FU)-based therapy

Key Exclusion:

- Chemo or radiotherapy within 4 weeks (6 weeks for nitrosoureas or mitomycin C) of study
- Have not recovered from significant adverse events due to prior anti-cancer therapy (except alopecia)
- History of allergic reactions from compounds similar to CA-4948 or others used in study

Principal Investigator: Ashwin Somasundaram, MD	**Coordinator:** Catherine Griffin **Phone:** (984) 974-8771

A Study of ERK Inhibition Alone or in Combination with HCQ in Patients with Pancreatic Cancer

Clinical Trial Website: NCT04386057	**Current Status:** Active, not recruiting

Design: This randomized phase II trial studies ERK inhibition to see how well it works when combined with the autophagy inhibitor, hydroxychloroquine, compared with ERK inhibition alone in patients with pancreatic cancer that has spread to other places in the body.

Key Inclusion:

- Patients at least 18 years old
- Patients must have biopsy proven and measurable pancreatic cancer
- Able to tolerate therapy

Key Exclusion:

- More than two lines of prior therapy
- History of allergic reactions to ERK inhibitors or hydroxychloroquine
- Concurrent uncontrolled illnesses

Principal Investigator: Ashwin Somasundaram, MD	**Coordinator:** Catherine Griffin **Phone:** (984) 974-8771

Ulixertinib/Palbociclib in Patients with Advanced Pancreatic and Other Solid Tumors

Clinical Trial Website: NCT03454035	**Current Status:** Recruiting

Design: This phase I study is designed to establish the safety, maximally tolerated dose, and recommended phase II dose of the ERK inhibitor ulixertinib when combined with the CDK4/6 inhibitor palbociclib.

Key Inclusion:

- Patients at least 18 years old
- Patients must have biopsy proven and measurable pancreatic cancer
- Able to tolerate therapy

Key Exclusion:

- Cancer-directed treatment within the last 28 days
- Certain conflicting medicines
- Concurrent uncontrolled illnesses

Principal Investigator: Hanna Sanoff, MD	**Coordinator:** Brian Burgess **Phone:** (984) 974-8772

(more below)

A Study of RGX-202-01 as a Single Agent and as Combination Therapy in Patients with Advanced Gastrointestinal Malignancies

Clinical Trial Website: NCT03597581	**Current Status:** Recruiting

Design: This is a Phase 1, first-in-human, dose escalation and expansion study of RGX-202-01, which inhibits certain mechanisms of gastrointestinal cancer progression. RGX-202-01 will be studied as a single agent or in combination with FOLFIRI +/- bevacizumab. This study will fous on patients with advanced gastrointestinal tumors (i.e., locally advanced and unresectable, or metastatic) who have had PD on available standard systemic therapies or for which there are no standard systemic therapies of relevant clinical impact.

Key Inclusion:

- Patients at least 18 years old
- Patients must have proven and measurable pancreatic cancer
- Able to tolerate therapy

Key Exclusion:

- Additional malignancies that may confound results
- Ongoing adverse events from previous cancer treatments

Principal Investigator: Hanna Sanoff, MD	**Coordinator:** Brian Burgess **Phone:** (984) 974-8772

Efficacy and Safety Study of Tisotumab Vedotin for Patients with Solid Tumors

Clinical Trial Website: NCT03485209	**Current Status:** Recruiting

Design: This trial will study tisotumab vedotin to find out whether it is an effective treatment for certain solid tumors and what side effects (unwanted effects) may occur. There are three parts to this study. In Part A, the treatment will be given to participants every 3 weeks (3-week cycles). In Part B, participants will receive tisotumab vedotin on Days 1, 8, and 15 every 4-week cycle. In Part C, participants may receive tisotumab vedotin on Days 1 and 15 or Days 1, 8, and 15 on a 4- week cycle.

Key Inclusion:

- Relapsed, locally-advanced, or metastatic colorectal or pancreatic cancer patients who are not candidates for standard therapy
- Must have prior treatment and experienced disease progression

Key Exclusion:

- History of another malignancy within the last 3 years
- Certain uncontrolled medical conditions

Principal Investigator: Shetal Patel, MD	**Coordinator:** Brian Burgess **Phone:** (984) 974-8772