PANCREATIC ADENOCARCINOMA – LOCALLY ADVANCED

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

Testing the Safety of the Anti-Cancer Drugs Durvalumab and Olaparib During Radiation Therapy for Locally Advanced Unresectable Pancreatic Cancer

Clinical Trial Website: NCT05411094	**Current Status:** Recruiting

Description: This phase I trial tests the safety and tolerability of olaparib in combination with durvalumab and radiation therapy in patients with pancreatic cancer that has spread to nearby tissue or lymph nodes (locally advanced) and cannot be removed by surgery (unresectable).

Key Inclusion:

- Patients at least 18 years old
- Patients must have unresectable locally advanced pancreatic cancer
- Must have received prior first-line chemotherapy for at least 16 weeks without progression

Key Exclusion:

- Prior upper abdominal radiotherapy
- Major surgical procedure within the last 28 days
- Current or prior use of immunosuppressive medication within 14 days of first dose of durvalumab
- 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

Description: 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

Tumor Subtypes in Subjects on FOLFIRINOX with Non-Metastatic Pancreatic Cancer

Clinical Trial Website: NCT03977233	**Current Status:** Recruiting

Description: This is a research study to evaluate how the genetic makeup of Pancreatic Ductal Adenocarcinoma (PDAC) can affect the response to FDA-approved chemotherapy treatment, FOLFIRINOX, given before surgery to remove the tumor. Certain types of PDAC tumors can be surgically resected (removed). However, not all types of PDACs are resectable, especially if they are close to important structures like blood vessels or intestines. These types of PDACs are treated with chemotherapy such as FOLFIRINOX. Research studies showed that chemotherapy after surgical resection of PDAC tumors reduced the risk of the cancer returning.

Key Inclusion:

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

Key Exclusion:

- Evidence of metastatic pancreatic cancer
- Prior chemotherapy, chemoradiotherapy, or surgery for pancreatic cancer
- Any other malignancies in the past 5 years

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

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

Description: 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

Description: 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