LOCALLY ADVANCED

Clinical Trial Name: PurIST Classification-Guided Adaptive Neoadjuvant Chemotherapy by RNA Expression Profiling of EUS SAmples Study (PANCREAS)

Study Design: This is an open-label, single arm, phase II study in patients with resectable and borderline resectable pancreatic cancer. The study intervention involves molecular profiling Purity Independent Subtyping of Tumors (PurIST) subtyping of pretreatment Endoscopic Ultrasound Fine Needle Aspiration (EUS/FNA) samples to determine pancreatic cancer subtype. Neoadjuvant therapy is directed based on the molecular subtype (classical vs. basal). Patients with classical subtype will receive a standard chemotherapy (mFOLFIRINOX) and patients with basal subtype will receive an alternative standard therapy (gemcitabine/nab-paclitaxel).

NCT#: NCT04683315

Study PI:
Dr. Kathleen Christians

Clinical Research Coordinator:
Lauren Schmitz
Phone: 414-805-5175

Key Inclusion:

Eligibility for screening consent:

- Suspicion of PDAC and plan for endoscopic biopsy or enough archival tissue to be requested from previous screening endoscopic biopsy. Agrees to additional EUS biopsy at the first restaging and tissue collection from surgical specimen

Eligibility for Treatment consent:

- ECOG performance status < 2
- Histologically confirmed adenocarcinoma. Biopsy must have been completed prior to start of treatment
- Clinical stage consistent with resectable or borderline resectable or locally advanced type A adenocarcinoma of the pancreas, based on CT or MRI findings
- Adequate organ and bone marrow function, as defined by: total leukocytes >3 x103/μL; ANC >1.5x 103/μL; HgB >9 g/dL; platelets >100 x 10e3/μL; creatinine clearance >60 mL/min or creatinine <1.5 mg/dL; bilirubin < 2 mg/dL; AST/SGOT & ALT/SGPT <3 x ULN

Key Exclusion:

- Received chemotherapy and/or radiation within three years prior to study enrollment
- Previous history of another malignancy w/in 3 years of study (other than cured basal or squamous cell carcinoma and other in situ carcinomas that were completely treated or localized prostate cancer with normal prostate specific antigen)

Clinical Trial Name: Molecular Profile-related Individualized Targeted Therapy in Resected Pancreatic Cancer with High-Risk of Cancer Recurrence (PROTECT-PANC)

Study Design: This is a prospective, open-label therapeutic interventional investigation designed to interrogate the efficacy and safety of individualized matched therapies in patients with pancreatic cancer at high risk of disease recurrence post-surgery.

NCT#: NCT06228599

Study PI:
Dr. Mandana Kamgar

Clinical Research Coordinator:
Dawn Carini
Phone: 414-805-0789

Key Inclusion:

- Pathologically confirmed pancreatic cancer (excluding neuroendocrine histology).
- Pancreatic tumor is surgically removed and
  - Patient has received multimodal therapy (neoadjuvant, sandwich or adjuvant chemotherapy ± radiation) or
  - Patient is ineligible for or refuses multimodal therapy
- Patient has one of the following:
  - Post-surgical cancer antigen (CA) 19-9 elevation (> 35 U/mL at least 6 weeks post-surgical resection) in the setting of bilirubin < 2 mg/dL (unless bilirubin elevation is consistent with Gilbert's syndrome) OR
  - High-risk pathological features, defined as positive surgical margin or lymph node involvement in cancer.
- Patient has no definitive measurable disease recurrence or metastatic disease at the time of first post-surgical imaging (in those with high-risk pathological features) or within four weeks of elevated CA 19-9 value as evidenced by appropriate imaging
- Laboratory values:
  - Absolute neutrophil count (ANC) ≥ 1.0 × 109/L
  - Platelet count ≥ 75,000/mm^3 (125 × 109/L)
  - Hemoglobin (Hgb) ≥ 8 g/dL
  - aspartate aminotransferase (AST) serum glutamic-oxaloacetic transaminase (SGOT), alanine transaminase (ALT) serum glutamate-pyruvate transaminase (SGPT) ≤ 5 × upper limit of normal range (ULN)
  - ECOG Performance Status < 3
  - At the time of treatment, patient should be off other anti-tumor agents for at least five half-lives of the agent or three weeks from the last day of treatment, whichever is shorter
  - Patient must be presented at the Molecular Tumor Board (MTB) and agree to receive the MTB-recommended therapy

Key Exclusion:

- CA 19-9 non-producers, unless high-risk pathological features present.
- Receiving concomitant investigational agent(s) for pancreatic ductal adenocarcinoma (PDAC)
- Radiographic evidence of metastatic disease
- Inability to ingest study drugs by mouth
- Diarrheal bowel movements > 6 per day postoperatively on maximal medical therapy
- Patient has active, untreated, or uncontrolled bacterial, viral, or fungal infection(s) requiring systemic intravenous therapy
- Patient has undergone or planned major surgery other than diagnostic surgery (i.e., surgery done to obtain a biopsy for diagnosis without removal of an organ) within four weeks prior to Day 1 of study therapy
- Uncontrolled concurrent illness, including, but not limited to, unstable angina pectoris, uncontrolled and clinically significant cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements