Protocol Title: Preoperative Extended Chemotherapy vs. Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas

Target Population: Pancreatic Adenocarcinoma or Borderline Resectable Adenocarcinoma of the Head of the Pancreas

Summary: Randomized Phase II study to evaluate 18-Month overall survival rate in patients with Borderline Resectable Cancer of the Head of the Pancreas using one of the treatment regimens.

Key Inclusion Criteria:
- Pathology: Cytologic or Histologic proof of Adenocarcinoma of Pancreatic Head or Uncinate Process.
- TNM Stage: TX, T1-4N0-1 or NxM0*
  - M1 disease includes spread to distant lymph nodes, organs, and ascites.
- Criteria for Borderline Resectable Disease: Local radiographic reading must be consistent with Borderline Resectable Cancer of the Pancreatic Head as defined by intergroup radiographic criteria and must meet any one or more of the following on CT/MRI:
  - An interface is present between the Primary Tumor and the Superior Mesenteric Vein or Portal Vein and measures ≥ 180° of the circumference of the vessel wall.
  - Short-segment occlusion of the SMV-PV is present with normal vein above and below the level of obstruction that is amenable to resection and venous reconstruction.
  - Short segment interface (of any degree) is present between tumor and Hepatic Artery with normal artery proximal and distal to interface that is amenable to resection and reconstruction.
  - An interface is present between the tumor and Superior Mesenteric Artery or Celiac Axis measuring < 180° of the circumference of the vessel wall.
- Patients with less extensive disease/more extensive disease than the above four (4) criteria are considered potentially resectable/locally advanced and are NOT eligible.
- In addition patients with the following are considered locally advanced and are NOT eligible: Any interface between the tumor and the Aorta.
- Registration Eligibility Criteria: Confirmation of radiographic stage as Borderline Resectable by real-time Alliance Central Radiographic Review.

Key Exclusion Criteria:
- No prior chemotherapy or radiation for Pancreatic Cancer.
- No definitive resection of Pancreatic Cancer.
- Chronic concomitant treatment with strong inhibitors of CYP3A4 is not allowed on this study.
  - Patients on strong CYP3A4 inhibitors must discontinue use for 14 Days prior to registration.
- Chronic concomitant treatment with strong CYP3A4 inducers is not allowed.
  - Patients must discontinue use 14 Days prior to the start of study treatment.
- No grade ≥ 2 neuropathy
- No known Gilbert's Syndrome or known homozygosity for UGAT1A1*28 polymorphism.
- No uncontrolled gastric ulcer disease (Grade 3 Gastric Ulcer Disease) within 28 Days of registration.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02839343