Protocol Title: Targeted Intra-arterial Gemcitabine vs. Continuation of IV Gemcitabine Plus Nab-Paclitaxel Following Induction with Sequential IV Gemcitabine Plus Nab-Paclitaxel and Radiotherapy for Locally Advanced Pancreatic Cancer

Target Population: Locally Advanced Pancreatic Cancer

Summary: All subjects will receive induction therapy of IV Gemcitabine + nab-Paclitaxel, as well as RT for approximately 4 Months. Subjects who remain eligible will then be randomized to receive either intra-arterial chemotherapy with Gemcitabine or continue Gemcitabine + nab-Paclitaxel. Subjects will receive the randomized treatments for up to 16 Weeks or until progression. Both groups will receive IV Gemcitabine + nab-Paclitaxel or oral Capecitabine following 16 Week treatment course until disease progression at the discretion of the Investigator.

Key Inclusion Criteria:
- Histologically confirmed Pancreatic Adenocarcinoma with initial diagnosis within 6 Weeks of consent
- Locally advanced, unresectable disease, as defined by NCCN criteria
- ECOG Performance Status 0-1
- Adequate bone marrow, renal, and liver function
- Life expectancy > 12 Weeks
- Women of childbearing potential must have a negative serum or urine pregnancy test within 1 Day prior to administration of the first dose of chemotherapy
- Willing to participate in the study for at least 8 Months

Key Exclusion Criteria:
- Any prior treatment for Pancreatic Cancer
- Any evidence of metastatic disease or another active malignancy within the past 2 Years except for cervical cancer in situ, in situ carcinoma of the bladder or non-melanoma carcinoma of the skin
- Prior biliary bypass surgery
- Unable or unwilling to have their first randomized treatment within 3 Weeks of the post induction imaging and within 5 Weeks of their last induction treatment
- Stenosis or occlusion in intended artery for treatment that precludes IA therapy as determined by CT or MRI
- Tortuosity preventing the delivery of guide sheath and or RenovoCath™ catheter to intended site by CT or MRI
- Inability to exclude major side branches in the area of the intended RenovoCath™ occlusion by CT or MRI
- No suitable artery with a diameter > 4mm in proximity of at least 1 side of tumor as determined by CT or MRI
- Severe infections within 4 Weeks prior to the first study treatment
- Received oral or IV antibiotics for an infection within 2 Weeks prior to the first study treatment
  - Subjects receiving prophylactic antibiotics are eligible
- History of severe allergic, anaphylactic, or other hypersensitivity reactions to Gemcitabine or nab-Paclitaxel
- Anti-cancer therapy including chemotherapy, hormonal therapy, or radiotherapy within 2 Weeks prior to initiation of study treatment
- Uncontrolled seizures
- Life-threatening visceral disease or other severe concurrent disease
- Concurrently receiving any other investigational agents within 2 Weeks prior to first study treatment
- Any psychiatric illness or social situations that would limit compliance with study requirements

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03257033

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