For Older Patients with Metastatic Pancreatic Cancer

**Patient Population**
See Section 3.0 for Complete Eligibility Details
- Age ≥ 70 years, ECOG PS 0-2, and adequate lab values
- Must have newly diagnosed untreated biopsy proven metastatic adenocarcinoma of the pancreas
  - If a patient had a biopsy and the clinical picture is consistent with metastatic pancreatic cancer, another biopsy of a metastatic site is not required
  - Acinar cell/adenosquamous carcinoma/neuroendocrine histologies are excluded
- Previous surgery, adjuvant/neoadjuvant chemotherapy and/or radiation therapy is allowed provided therapy was completed at least 6 months prior to randomization
  - Palliative radiation to a metastatic site prior to study enrollment is allowed
- Must be English speaking with the ability to understand and complete the IC and questionnaires
- HIV/HBV/HCV patients are permitted per protocol
- Patients with known history/current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the NYHA Functional Classification; to be eligible for this protocol, patients should be class 2 or better
- Must have measurable disease defined per protocol, and scans must be done within 4 weeks of randomization
- Patients classified to have mild-moderate abnormalities in any of the domains evaluated in the screening geriatric assessment (see protocol Section 10.1) and are classified as “vulnerable” are eligible; patients classified without any abnormalities (“fit”) or with severe cognitive/functional impairment/high co-morbidity score (“frail”) are ineligible
- Patient should avoid taking any medications/substances that are strong inhibitors/inducers of CYP3A4; those randomized to the liposomal irinotecan arm should avoid drugs that are UGT1A1 inhibitors

**Treatment Plan**
See Section 5.0 for Complete Treatment Details
1 cycle = 14 days
Patients will be randomized following completion of the geriatric assessment

**Arm A:**
- Gemcitabine 1000 mg/m² IV over 30 mins on day 1 of each cycle
- Nab-paclitaxel 125 mg/m² IV over 30 minutes on day 1 of each cycle
- Repeat cycles until disease progression or unacceptable toxicity

**Arm B:**
- 5-FU 2400 mg/m² IV over 46 hours starting day 1 of each cycle
- Leucovorin 400 mg/m² IV over 30 minutes on day 1 of each cycle
- Liposomal irinotecan 50 mg/m² IV over 90 minutes on day 1 of each cycle
- Repeat cycles until disease progression or unacceptable toxicity

All patients will be followed for response until progression, and for survival every 3-4 months for 3 years from the date of randomization

**Notes:**
- Doses are based on actual body weight
- Dose reductions/delays will occur based on treating physician discretion and will be managed according to standard medical practice
  - Dose re-escalations are permitted
  - The maximum dose delay is 21 days

**Patient Enrollment**
All Sites: Oncology Patient Enrollment Network (OPEN), [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**
ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!