LOCALLY ADVANCED

Clinical Trial Name: Stereotactic Body Radiation Therapy or Conventionally Fractionated Concurrent Chemotherapy and Radiation Therapy Preoperatively for Resectable or Borderline Resectable Pancreatic Adenocarcinoma (SOFT Trial)

Study Design: This study is a prospective, open-label, randomized, parallel, two-arm, phase II clinical trial. Patients meeting the eligibility criteria will be randomized after a minimum of two months of induction chemotherapy. These patients will be required to have no biopsy-proven distant disease on repeat staging studies before randomization. Patients who have radiologically equivocal evidence of distant metastatic disease (small lung nodules, or liver lesions that cannot be definitively characterized, etc.) are also eligible for enrollment. Patients with biopsy-proven metastatic disease are not eligible.

NCT#: NCT03704662

Study PI: Dr. William Hall

Research Coordinator: Kathryn Hallada

Phone: 414-805-0124

Key Inclusion

- Confirmed, resectable/borderline resectable, locally advanced Type A pancreatic adenocarcinoma
- Patients with and without regional adenopathy are eligible
- No evidence of distant metastatic disease
- ≥ 1 cycle of systemic chemotherapy without evidence of distant progression

Key Exclusion:

- Distant metastatic disease
- Prior invasive malignancy within the last 3 years
- Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields
- Major surgery within 28 days prior to study entry

Clinical Trial Name: A Phase I Dose-Escalation Study of CPI-613 (Devimistat) in Combination with Chemoradiation in Patients with Pancreatic Adenocarcinoma (CPI-613 with Gem-RT in PDAC)

Study Design: This study is a single site, open-label, phase I trial to investigate whether patients with pancreatic cancer (medically inoperable, locally advanced, or oligometastatic) that, by the consensus of the institutional pancreatic tumor board or multidisciplinary review, would benefit from chemoradiation for local control of the primary tumor. Therefore, this study aims to determine the maximum tolerated dose (MTD), recommended phase II dose (RP2D), and safety of CPI-613® in combination with chemoradiation.

NCT#: **NCT05325281**

Study PI: Dr. Mandana Kamgar

Research Coordinator: Dawn Carini

Phone: 414-805- 0789

Key Inclusion

- Eligible patients should have an inoperable disease (locally advanced, oligometastatic for which all sites of metastases can be treated curatively, or medically inoperable) and, based on institutional pancreatic tumor board or multidisciplinary review, should otherwise benefit from chemoradiation for definitive local control of the primary tumor. Oligometastatic is defined as less than three total metastases planned to be treated with definitive therapy.
- ECOG 0-2
- Pathologically confirmed (histologic or cytologic) adenocarcinoma of the pancreas

Key Exclusion:

	• Prior invasive malignancy (except nonmelanomatous skin cancer, noninvasive breast cancer [ductal carcinoma in situ, or DCIS], or prostate cancer under active surveillance). Other malignancies are allowed if the patient has been disease free for a minimum of two years. • Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields. • Concurrent therapy with approved or investigational anticancer therapeutics other that what is stipulated by the protocol.