CHOA Clinical Trial Master List

PANCREATIC

CANSTEM111P: A Phase III Study of BB1-608 plus nab-Paclitaxel (Abraxane) with Gemcitabine (Gemzar) in Adult Patients with Metastatic Pancreatic Adenocarcinoma	
Sponsor: Boston Biomedical ****ECOG must be verified and documented by 2 observers at 2 separate visits**** ***Patient must have 1 or more metastatic tumors evaluable by CT scan.***	Therapy Line**: 1st Line NO PRIOR TREATMENT in Metastatic setting** Drug Classification: **Cancer Stem Cell (CSC) inhibitor (targets CSCs by inhibiting STAT3)**
Principal Investigator: James M. Orcutt, MD	**CRC:** Ashley Morrill ext. 291
Basic Enrollment Criteria: Must have histologically or cytologically confirmed advanced PDAC that is metastatic. Must not have previously received chemotherapy or any investigational agent for the treatment of metastatic PDAC. A fluoropyrimidine or gemcitabine administered as a radiation sensitizer in the adjuvant setting is allowed for as long as last dose was administered > 6 months prior to randomization and no lingering toxicities are present. ECOG 0 or 1. Must have life-expectancy of > 12 weeks. Baseline laboratory evaluations must be done within 14 days prior to randomization and some must be repeated < 72 hours prior to randomization, as listed in Section 6.0. Patients requiring biliary stent placement must have biliary stent placed > 7 days prior to screening. Pain symptoms should be stable and should not require modifications in analgesic management. Patient must consent to provision of, and Investigator(s) must confirm access to and agree to submit a representative formalin fixed paraffin block of tumor tissue in order that the specific correlative marker assays proscribed in Section 14.6. Where local center regulations prohibit submission of blocks of tumor tissue, two 2 mm cores of tumor from the block and 5-20 unstained slides of whole sections of representative tumor tissue are preferred. Where it is not possible to obtain two 2 mm cores of tumor from the block, 5-20 unstained slides of representative tumor tissue are also acceptable. Where no previously resected or biopsied tumor tissue exists or is available, on the approval of the Sponsor/designated CRO, the patient may still be considered eligible for the study. Patient must consent to provision of a sample of blood in order that the specific correlative marker assays proscribed in Section 14.6. **Exclusion Criteria:** Patient has experienced a decline in ECOG performance status between Baseline visit and within 72 hours prior to randomization. Patient has a > 20% decrease in serum albumin level between Baseline visit and within 72 hours prior to randomization. Major surgery within 4 weeks prior to randomization. Any known brain or leptomeningeal metastases are excluded, even if treated. Patients with clinically significant ascites. Uncontrolled inter-current illness including, but not limited to, ongoing or active infection, clinically significant non-healing or healing wounds, symptomatic congestive heart failure, unstable angina pectoris, clinically significant cardiac arrhythmia, significant pulmonary disease (shortness of breath at rest or mild exertion), uncontrolled infection or psychiatric illness/social situations that would limit compliance with study requirements. Neurosensory neuropathy > grade 2 at baseline. Patients being treated with Warfarin. Patients with a history of other malignancies except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, or other solid tumors curatively treated by surgery alone or surgery plus radiotherapy with no evidence of disease continuously for > 5 years.	