11-C-0100: A pilot study to test the feasibility of the combination of Gemcitabine and anti-PD1 monoclonal antibody (mAb) CT-011 in the treatment of Resected Pancreatic Cancer. Pro00000667 IND#110294

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CT-011 is a humanized IgG1 kappa recombinant monoclonal antibody against PD-1 receptor that blocks the interaction of PD-L1 with PD-1.

Objectives:
• Primary endpoint – To determine the feasibility and safety of the combination of CT-011 and Gemcitabine in patients after primary macroscopic resection of pancreatic adenocarcinoma.
• Secondary endpoint – To determine if the addition of CT-011 to Gemcitabine can improve the median disease-free survival in resected pancreatic cancer.

Eligibility:
• Adult patients with histologic verification of adenocarcinoma of the pancreas (T1-3, N0-1) who have undergone surgical resection within the past 4-12 weeks.
• Must meet all laboratory safety criteria and not have active or history of autoimmune disease or conditions, not have been treated with immunosuppressive drugs, or require the use of systemic steroids.
• Pregnant or nursing women will be excluded. Subjects with active infection, HIV, Hepatitis B or C will be excluded.

Design:
• Eligible subjects will receive adjuvant combination CT-011 and Gemcitabine. Gemcitabine will be given at a dose of 1000mg/m² by IV infusion over 30 minutes on Days 8, 15 and 22 of each cycle. NOTE: Gemzar may be given at local oncologist’s office if desired
• CT-011 will be given at a dose of 3mg/kg by IV infusion over 2 hours on day 1, one week prior to the first Gemcitabine infusion of each cycle.
• Treatment will be continued for a total of 6 cycles or until disease recurrence or grade IV non-hematological toxicity if occurred before the completion of 6 cycles.
• The study will be conducted as an optimal two-stage phase II trial, in order to rule out an unacceptably low 50% of patients who do not received the full dose of CT-011 in favor or a modestly high 80% fraction who receive the full dose of CT-011. It is anticipated that up to 32 patients may be enrolled onto this trial.

Continued on page 2
**Screening Process:** Screening may begin at knowledge of diagnosis. Study Coordinator will work with referring physician for required proof of diagnosis and assurance that disease has not progressed. Some procedures can be completed prior to protocol enrollment, as they may be part of standard of care treatment required for post-surgical treatments. Once consent is signed, baseline procedures will be completed within 2 weeks prior to the protocol entry.

**Central labs:** Pharmacokinetics and Immunogenicity testing

**Inclusion Criteria (partial listing)**
- Histological diagnosis of adenocarcinoma of the pancreas after primary macroscopic resection staged as T1-3, N0-1 by AJCC staging criteria.
- Patients must be 4-12 weeks removed from primary resection and adequately recovered from surgery.
- Patients cannot have had any previous systemic therapy including radiation or chemotherapy, **except for the primary resection. Primary intraoperative chemotherapy will be allowed.**
- Patients who have no contraindications for Gemcitabine treatment
- ECOG status of 0-1
- No active coronary disease; ECG with no evidence of arrhythmia, conduction abnormality or ischemia; no arrhythmia requiring treatment
- Willing to travel to GHSU for treatment and follow up visits up to two years during the follow up period

**Exclusion Criteria (partial listing)**
- Patients with R1 resections
- Concurrent treatment with other cancer therapies including radiation, chemotherapy or other investigational agent(s)
- History of second active malignancy in the last 2 years other than non-melanoma skin cancers or carcinoma in situ of the cervix
- Patients who have active or history of autoimmune disease/symptom/conditions including: type I diabetes, rheumatoid arthritis, systemic lupus erythematosus (SLE), ulcerative colitis, Crohn’s Disease, multiple sclerosis (MS), ankylosing spondylitis. Chronic diabetes mellitus, vitiligo or stable hypothyroidism are not considered exclusion criteria.
- Patients who have acquired, hereditary, or congenital immunodeficiencies including cellular immunodeficiencies, hypogammaglobulinemia and dysgammaglobulinemia.
- Positive HIV or Hepatitis c antibodies or Hepatitis B anti-core antibodies.