Pancratic mucinous cystic lesions have significant potential for malignant transformation; delivery of SPP as a direct intratumoral injection confirmed SPP persistence within the deliver for at least 100 days in a prior study; intratumoral injection with SPP may prevent progression to cancer without corresponding systemic injection.

**Aim**
To determine safety and preliminary efficacy of SPP for treatment of pancreatic mucinous cystic lesions using endoscopic ultrasound fine needle injection (EUS-FN-Injection).

**Materials and Methods**
Subjects with confirmed mucinous cystic lesions, based on elevated intraductal CEA and cystic fluid concentrations of SPP at equivalent to the aspirated cyst fluid volume in sequential cohorts at 6, 10, and 15 mg/mL in a standard 3+1 dose-escalation protocol. The highest dose with acceptable safety and tolerability profile, as determined by a DSMB, proceeded into the double-injection phase of the study. 9 additional subjects were injected with SPP at the same concentration, 12 weeks apart. Subjects were followed for 6 months for clinical endpoints including safety and tolerability evaluation, physical examinations, and vital signs. Pharmacokinetic analysis of systemic paclitaxel drug levels, and cyst volume response were reported by imaging at 3 and 6 months.

**Results**
- Fourteen subjects have been enrolled to date. Eight completed the study (1 injection). Imaging (EUS, CT, MRI), cyst fluid CEA and amylase concentrations were consistent with branch duct IPMN cysts (BD-IPMN) or MCNs (Table 1).
- No dose limiting toxicities, or clinically significant changes in blood work (hematology, chemistry, coagulation) or urinalysis have been reported. Adverse events have been mainly transient in nature, with one serious event considered probably related to the Investigational Product (see Safety).
- Plasma paclitaxel concentrations did not exceed 1 ng/mL and were undetectable at 2 weeks post SPP injection. Paclitaxel concentrations were below the assay limit of detection at 4 weeks post injection.

**Discussion**
In-dose escalation subjects, treated cysts had reduced volumes at study completion in comparison to screening, one subject’s cyst was increasing volume after Month 3, but remained below baseline at Month 6 (Figure 1a).

The double-injection phase of the study is actively enrolling at the highest dose level (15 mg/mL).

**Conclusion**
- Of the 18 reported adverse events across all cohorts possibly related to SPP include mild, transient and non-serious events. The safety profile was consistent with previous studies of SPP injection and paclitaxel systemic exposure.

**Investigational Product – Submicron Particle Paclitaxel (SPP, NanoPac®)**

**Technology**
Unique non-mechanical process using supercritical CO2 and emulsification to precipitate paclitaxel particles (SPP) in a GMP production environment (CintiTech, Inc, Lawrence, Ks).

**Benefits**
- Submicron particles without need for additives or coatings.
- Submicron particles with narrow size particle distribution (0.8 µm mean) with a large surface area to size ratio.
- SPP has shown sustained drug release and preliminary efficacy in preclinical[1] and clinical studies[3].

**Investigational Site**
- Baylor College of Medicine, Houston, TX
- OSU Wexner Medical Center, Columbus, OH
- Texas Tech University Health Sciences Center, El Paso, TX

**Sponsor**
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