

## NanOlogy Clinical Updates on Local Injection of NanoPac<sup>®</sup> for Pancreatic Cancer and Mucinous Cystic Neoplasms of the Pancreas

*Interim data from both clinical trials presented at the 2019 American College of Gastroenterology (ACG) Conference in San Antonio*

FT. WORTH (November 7, 2019) — [NanOlogy LLC](#), a clinical-stage oncology company, announced today that interim data were presented last week at the 2019 ACG annual meeting from two of its clinical trials each evaluating endoscopic ultrasound guided fine needle injection (EUS-FNI) of NanoPac (submicron particle paclitaxel): one for treatment of [locally advanced pancreatic cancer](#) (LAPC) and the other for treatment of [mucinous cystic neoplasms of the pancreas](#) (MCNs).

The pancreatic cancer clinical update of intratumoral NanoPac for treatment of LAPC was presented by [Simon K. Lo, MD](#) (Cedars-Sinai) as part of the Pancreatic Cancer/Esophagus plenary session.

The Phase 2a dose-rising and expansion pancreatic cancer trial is evaluating the safety and preliminary efficacy of NanoPac delivered intratumorally by EUS-FNI over 6 months in patients with nonresectable LAPC. After completion of the dose-rising phase, the trial has now enrolled 16 of 22 subjects into the dose expansion phase of the trial in which patients are receiving two intratumoral injections of NanoPac 4 weeks apart.

Highlights from Dr. Lo's [presentation](#) on the dose expansion phase of the trial:

- No drug-related local or systemic serious adverse events have been reported to date (n=25) including no reports of acute pancreatitis.
- Of 7 subjects who have completed the 6-month study to date, one subject had a partial response with restaging from nonresectable to resectable ([see video](#)), 3 had stable disease, 1 had progressive disease, and 2 were withdrawn from the study.
- Tumor volume decreases ranging from 7% to 76% have been seen in 7 of 11 subjects upon latest mpMRI to date at either the 3- or 6-month time point.
- CA19-9 reductions of greater than 20% have been seen in 5 of 11 subjects upon latest measure to date at either the 3- or 6-month time point.

The pancreatic cyst clinical update on intracystic NanoPac for treatment of MCNs of the pancreas was presented during the poster sessions by [Mohamed O. Othman, MD](#) (Baylor College of Medicine). Dr Othman's poster was recognized as a Presidential Poster, a distinction given to fewer than 5% of accepted abstracts each year, and was ultimately named co-winner for high quality, novel, unique and interesting research.

The Phase 2a dose rising and expansion pancreatic cyst trial is evaluating the safety and preliminary efficacy of NanoPac delivered intracystically by EUS-FNI following aspiration in patients with MCNs. The study is also enrolling in the dose expansion phase of the study and patients are receiving two intracystic injections of NanoPac 12 weeks apart.

Highlights from Dr. Othman's [poster presentation](#) on the trial:

- No drug-related local or systemic serious adverse events (SAE) have been reported to date (n=15) including no reports of acute pancreatitis. One case of gastric outlet obstruction that was possibly drug-related occurred in a subject who had a recent unrelated endoscopic procedure for hepatobiliary dysfunction. This condition was subsequently added as an exclusion criterion for the trial.
- Plasma paclitaxel levels for all subjects analyzed have not exceed 1ng/mL suggesting that NanoPac particles are retained in the cyst over time.
- Cyst volume decreases ranging from 8% to 89% have been seen in 9 of 11 subjects at last available imaging at either the 3- or 6-month time point.

Nanology plans to design follow-on clinical trials for both pancreatic cancer and pancreatic cysts in 2020 to further advance the programs toward regulatory submission.

In 2019, an estimated 57,000 new cases of pancreatic cancer will be diagnosed in the U.S. and 46,000 people will die from the disease. Pancreatic cancer is among the deadliest cancers with 9% survival rate at 5 years. It is also one of the few cancers for which no meaningful improvement in survival has been achieved in the last two decades. MCNs are a subset of pancreatic cysts that risk progression to pancreatic cancer. Patients with high risk MCNs may undergo surgical resection of the pancreas to remove the lesion, a complicated procedure associated with mortality and morbidity rates of 2% and 30% respectively. For both the disease itself and one of its common precursors, Nanology investigational drugs may offer a new way to help prevent or treat pancreatic cancer.

In addition to these trials, NanOlogy is advancing its therapeutic platform in [preclinical and clinical programs](#) across genitourinary, peritoneal, lung, and dermal cancers. The NanOlogy therapeutic platform is based on a proprietary submicron particle production technology that reduces the size of taxane API crystals by up to 400 times into stable submicron particles of pure drug with exponentially increased surface area and unique geometry. The characteristics of the particles have recently been granted a composition of matter patent valid in the US ([9,814,685](#)) and Australia until 2036, and pending globally.

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### **About NanOlogy**

NanOlogy, LLC ([www.nanology.us](http://www.nanology.us)) is a private clinical-stage oncology company developing a submicron particle therapeutic platform designed for local delivery to increase the effectiveness of cancer treatment while reducing the serious adverse effects normally associated with systemic chemotherapy.

### **Disclaimers**

This announcement contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements about our product development, business, and other activities. Such statements are subject to the risks and uncertainties inherent in any pharmaceutical development program which may

cause actual results to differ materially due to developmental, clinical trial, regulatory, market, competitive, technological, or other factors. All forward-looking statements are made as of the date of this announcement and the company disclaims any intent or obligation to update these statements. NanOlogy investigational drugs have not been proven safe and effective as required by U.S. FDA and have not been approved for commercial distribution.

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