



FOR IMMEDIATE RELEASE  
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## NanOlogy Presents Updated Clinical Data on Targeted Injections of NanoPac<sup>®</sup> for Pancreatic Cancer and Mucinous Cystic Neoplasms on DDW2020 Site

*Updated clinical data from both trials available through Digestive Disease Week<sup>®</sup> (DDW) Online Education Site*

FT. WORTH, (May 14, 2020) — [NanOlogy, LLC](#), a clinical-stage oncology company, announced today that updated data from two of its ongoing clinical trials were presented as abstracts last week through the [DDW ePosters and ePresentations site](#). The clinical trials are evaluating endoscopic ultrasound guided fine needle injection (EUS-FNI) of NanoPac<sup>®</sup> (submicron particle paclitaxel) suspension for treatment of [locally advanced pancreatic cancer \(LAPC\)](#) and [mucinous cystic neoplasms \(MCNs/IPMNs\) of the pancreas](#).

The lead author of the abstract on intratumoral NanoPac for LAPC is [Neil Sharma, MD](#) (Parkview Cancer Institute – Fort Wayne, IN). The lead author of the abstract on intracystic NanoPac for MCNs/IPMNs is [Mohamed O. Othman, MD](#) (Baylor College of Medicine – Houston, TX).

### **Pancreatic Cancer**

The Phase 2a dose-rising and expansion trial is evaluating over 6 months the safety and preliminary efficacy of NanoPac delivered intratumorally by EUS-FNI in patients with LAPC, concurrent with or following SOC therapy for the disease. After completing the dose-rising cohort (n=11), a dose expansion cohort has now fully enrolled (n=22) in which patients receive 2 monthly intratumoral (IT) injections of NanoPac. FDA has also recently allowed expansion of up to 30 additional patients who will receive up to 4 monthly IT injections.

Dr. Sharma's [abstract](#) submitted to DDW in December 2019 reports data from the first 7 evaluable subjects from the dose expansion cohort. No drug-related local or systemic SAEs were reported including no reports of acute pancreatitis in any subject, 4 subjects had a partial response, 2 had stable disease, and 1 had progressive disease. Encouraging data has continued to accrue from the fully enrolled dose expansion (2- injection) cohort, which are expected to be presented later in 2020.

### **Pancreatic Cyst**

The Phase 2a dose rising and expansion trial is evaluating over 6 months the safety and preliminary efficacy of NanoPac delivered intracystically by EUS-FNI following aspiration in patients with MCNs/IPMNs. The study has now completed enrollment (n=19) with patients in the dose expansion phase (n=8) receiving two intracystic injections of NanoPac 12 weeks apart.

Dr. Othman's [abstract](#) also submitted in December reports data from the first 9 subjects who had completed the trial. No confirmed drug-related local or systemic SAEs were reported including no reports of acute pancreatitis. Plasma paclitaxel levels have not exceeded 1 ng/mL indicating that NanoPac particles are retained in the cyst over time. Evaluation of cyst volume showed decreases ranging from 8% to 89% in 8 subjects, 6 of whom showed a volume decrease > 50%. Cyst volume increased in 1 subject.

Based on encouraging results from both trials, NanOlogy is designing follow-on clinical protocols for evaluation by FDA.

In 2020, about 57,600 new cases of pancreatic cancer will be diagnosed in the U.S. and 47,050 people will die from the disease. Pancreatic cancer is currently the third most frequent cause of cancer related death in western countries and is predicted to become the second leading cause of death from cancer within the next 10 years. It is one of the few cancers for which no meaningful improvement in survival has been achieved over recent time with only an 8% survival rate at 5 years.

MCNs/IPMNs are a subset of pancreatic cysts that risk progression to pancreatic cancer. While estimates vary widely, as many as 30,000 new cases of high risk MCNs/IPMNs are diagnosed annually in the U.S. These patients may ultimately be required to undergo surgical resection of the pancreas to remove the lesion, a complicated procedure associated with high morbidity. No approved drug therapy exists in the U.S to treat the condition.

In addition to pancreatic neoplasms, NanOlogy [clinical programs](#) are advancing in genitourinary, peritoneal, lung, and dermal cancers.

The NanOlogy submicron particle therapeutic platform is based on a proprietary production technology that converts taxane API crystals into stable submicron particles of pure drug with disproportionate size to surface area ratio. The particles are covered by two composition of matter patents ([US 9,814,685](#)) and ([10,507,195](#)) both valid until 2036 in the US 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 formed in 2015 to finance and clinically develop a patented submicron particle technology platform for targeted, sustained delivery of proven drugs aimed at increasing their value in the treatment of cancer and other serious diseases.

### **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 to be safe and effective as required by U.S. FDA and have not been approved for commercial distribution. NanOlogy and NanoPac are trademarks of NanOlogy LLC.

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