



For Immediate Release
August 8, 2018

NanOlogy™ Adds Clinical Trial Sites for Phase 2 Clinical Trials of NanoPac® in Pancreatic Cancer and Pancreatic Mucinous Cysts

*Preliminary Data from Both Trials Show NanoPac Well-Tolerated
via Intratumoral and Intracystic Injection*

FORT WORTH/DALLAS, (August 8, 2018) — [NanOlogy LLC](#), a clinical-stage pharmaceutical development company, today announced the adding of three new sites for its Phase 2 clinical trials of NanoPac (submicron particle paclitaxel) sterile suspension in the treatment of [pancreatic adenocarcinoma](#) and [mucinous cystic neoplasms \(MCNs\) of the pancreas](#).

The new sites for the pancreatic cancer trial are Parkview Regional Medical Center in Fort Wayne, IN with Neil Sharma, MD serving as principal investigator (PI) and Texas Tech University Health Sciences Center in El Paso with Antonio Mendoza-Ladd, MD the PI. Parkview will also be a new site for the Phase 2 MCN trial with Dr. Sharma serving as PI.

Parkview and Texas Tech join two other sites for the pancreatic cancer trial: Baylor St. Luke's Medical Center in Houston, TX and Cedars-Sinai Medical Center in Los Angeles. The PIs for the Baylor and Cedars-Sinai sites are Mohamed Othman, MD and Simon Lo, MD, respectively.

In addition to Parkview, the other sites for the Phase 2 MCN trial are Baylor St. Luke's Medical Center with Dr. Othman as the PI and University of Chicago Medical Center with Irving Waxman, MD, serving as PI.

To date, the independent Data and Safety Monitoring Boards for both trials have found no drug-related safety concerns and both studies have dose-escalated in accordance with their clinical protocols.

NanoPac is part of a broad [submicron particle technology platform](#) developed by NanOlogy. The technology reduces paclitaxel crystals to submicron particles for direct injection into the pancreatic cancer tumors and MCNs. The particles are so unique in terms of size and surface area that they have recently been granted a composition of matter patent valid until 2036.

Intratumoral injection of NanoPac, rather than systemic infusion of paclitaxel, enables local delivery of a more concentrated dose at the site of disease that kills pancreatic cancer cells over a longer period without adverse systemic side effects.

If successful in clinical trials, intracystic delivery of a high, locally sustained concentration of NanoPac for patients with high risk MCN's could serve as an alternative to surgery, which is the primary treatment.

An estimated 55,000 new cases of pancreatic cancer will be diagnosed in 2018 and 44,000 people will die from the disease. Despite being relatively rare, pancreatic cancer is the third leading cause of cancer death in the US with a survival rate of only 25% at one year and less than 10% at five years.

Pancreatic cysts affect an estimated 3 million Americans, and most are benign. However, a subset of pancreatic cysts called MCN's are deemed to be at high risk for progression to pancreatic cancer and prevalence estimates range from 60,000 to 180,000 people.

The Phase 2 trials in pancreatic cancer and pancreatic mucinous cysts are part of an extensive [clinical development program](#) underway by NanOlogy. Local administration of NanoPac also is being evaluated in Phase 2 clinical trials for ovarian cancer (with orphan drug designation) and prostate cancer. A clinical trial of NanoDoce (submicron particle docetaxel sterile suspension) is planned to begin in in late 2018 for bladder cancer and in 2019 for renal cancer.

In addition, NanOlogy is progressing a clinical trial of a submicron particle paclitaxel topical anhydrous ointment for cutaneous metastases. An inhaled version of NanoPac in preclinical lung cancer studies demonstrated prolonged retention of drug in lung tissue and significant tumor regression without adverse drug-related observations. The positive findings will be used to support an IND to begin clinical trials of inhaled NanoPac for treatment of non-small cell lung cancer.

###

About NanOlogy

NanOlogy, LLC (www.nanology.us) is a clinical stage pharmaceutical company formed by [DFB Pharmaceuticals, LLC](#) of Fort Worth, TX, [Critech, Inc.](#) of Lawrence, KS, and [US Biotest, Inc.](#) of San Luis Obispo, CA, to finance and clinically develop a patented submicron particle technology platform for local, sustained delivery of proven drugs aimed at increasing their safety and efficacy in the treatment of cancer and related conditions.

Disclaimer

This announcement contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding our product development, business, and other activities. Such statements are subject to risks and uncertainties inherent in any pharmaceutical development program which may cause actual results to differ materially due to developmental, clinical, regulatory, market, competitive, technological, or other factors. All forward-looking statements are made as of the date of this announcement and NanOlogy disclaims any intent or obligation to update these statements. NanOlogy investigational drugs have not been proven safe and effective in accordance with the requirements of the FDCA and are not approved by FDA for commercial distribution.

Contacts

Dan Eramian
Opus Biotech Communications
danieleramian@comcast.net
425-306-8716

Charles Craig
Opus Biotech Communications
charles.s.craig@gmail.com
404-245-0591