



FOR IMMEDIATE RELEASE
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NanOlogy™ Announces First Patient Enrolled in a Phase 2 Clinical Trial of NanoPac® for Treatment of Mucinous Cysts of the Pancreas

NanOlogy may offer a nonsurgical treatment option for patients at high cancer risk

FORT WORTH/DALLAS, (November 7, 2017) — [NanOlogy LLC](#), a clinical-stage pharmaceutical development company, today announced the first patient has been enrolled in a [clinical trial](#) of NanoPac® (nanoparticle paclitaxel) sterile suspension for treatment of mucinous cystic neoplasms (MCNs) of the pancreas. The Phase 2 dose-rising trial will evaluate the safety and preliminary efficacy of NanoPac delivered directly into MCNs by endoscopic ultrasound-guided fine needle injection.

NanoPac is part of an extensive [submicron technology platform](#) developed by NanOlogy. Gere diZerega, MD, VP of Medical Affairs, will present an overview of the platform and an update of the clinical program during the [Biotech Showcase™](#), January 8-10, 2018, in San Francisco.

“There is no approved drug treatment for patients with MCNs who are at high risk for progression to cancer,” said Dr. diZerega. “This clinical trial is the first study in humans to examine whether NanoPac injected intracystically will safely chemically ablate the cyst with a high locally sustained concentration of the drug.”

Pancreatic cysts are diagnosed in more than a 500,000 people annually in the US and their diagnoses are increasing as advances in imaging technology have made abdominal imaging more common. MCNs are a subset of neoplastic pancreatic cysts and may progress to pancreatic cancer, which kills 90% of patients within five years of diagnosis. Patients with MCNs deemed at high risk for progression may undergo surgical resection of the pancreas to remove the cyst. This surgical procedure is complicated, however, and is associated with mortality and morbidity rates of 2% and 30% respectively. If successful, intracystic injection of NanoPac would represent an alternative to surgery for these patients.

“If we are successful, we may offer the first drug treatment for high-risk MCNs, which would help fill an unmet need in this increasingly diagnosed condition,” said Marc Iacobucci, a Managing Director of NanOlogy.

NanOlogy has a broad clinical development program underway for NanoPac sterile suspension, including clinical trials in ovarian cancer (with orphan drug designation), prostate cancer, pancreatic cancer, and pancreatic mucinous cysts. In addition, NanOlogy and affiliate, DFB Soria, are progressing clinical trials for Soria-developed SOR007 (nanoparticle paclitaxel) ointment in cutaneous metastases and actinic keratosis. Clinical trials for NanoDoce® (nanoparticle docetaxel) are planned in 2018 pending IND approval. An inhaled version of

NanoPac is in a preclinical pharmacology study for lung cancer after pharmacokinetic studies demonstrated retention of drug in lung tissues for more than 14 days following nebulized inhalation. In addition, no abnormalities were seen within the trachea or lung upon gross and histologic exam.

Starting with the world's most prescribed systemic chemotherapeutic agents, the patented NanOlogy submicron particle production technology reduces the size of paclitaxel and docetaxel API crystals by up to 400 times into patent-pending, stable, naked submicron particles with exponentially increased surface area and unique geometry. Unlike nanoparticles, which use coating or carrier agents for stability, NanoPac and NanoDoce are stable in their naked form and suspended prior to use without such agents for local delivery to the site of disease.

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About NanOlogy

NanOlogy, LLC (www.nanology.us) is a collaboration of [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 production 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 NanOlogy and Soria 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 and Soria investigational new drugs have not yet been proven to be safe and effective in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act and are not approved by FDA for commercial distribution.

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