NanOlogy™ Announces First Patient Enrolled in a Pancreatic Cancer Phase 2 Clinical Trial of NanoPac® Adding to Trials in Prostate and Ovarian Cancers

NanOlogy chemotherapy drug injected directly into pancreatic tumor

FT.WORTH/DALLAS, (December 18, 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 administered intratumorally in patients with locally advanced pancreatic adenocarcinoma. The Phase 2a dose-rising trial will evaluate the safety and preliminary efficacy of NanoPac delivered directly into the tumor by endoscopic ultrasound-guided fine needle injection in patients who have completed current standard of care treatment prior to trial entry.

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 at Biotech Showcase™, on January 8, 2018 at 3:45PM in Franciscan room D (Ballroom Level) of the Hilton San Francisco Union Square.

In 2017, an estimated 54,000 new cases of pancreatic cancer will be diagnosed in the U.S. and 43,000 people will die from the disease. Despite being relatively rare, pancreatic cancer is the third leading cause of cancer death in the USA with a survival rate of only 25% at one year and less than 10% at five years. Pancreatic cancer is so deadly because it is rarely diagnosed at an early stage while it is still local and the disease tends to be aggressive and resistant to systemic chemotherapy. Recent advances in abdominal imaging techniques hold the promise for earlier diagnosis of pancreatic cancer and the ability to treat the disease before it spreads to other parts of the body.

“The advanced endoscopy team at Baylor College of Medicine and St Luke’s Medical Center performed the first endoscopic ultrasound-guided intratumoral injection of NanoPac for locally advanced pancreatic cancer last Friday”, said Dr. Mohamed Othman, MD, Director of Advanced Endoscopy and Associate Professor of Medicine at Baylor College of Medicine in Houston, TX.

“The team is hopeful that this approach may offer a more potent and less toxic alternative for patients with locally advanced disease”.

“The targeted administration of submicron particle paclitaxel sterile suspension [NanoPac] by endoscopic ultrasound (EUS) represents an important step in the fight against pancreatic cancer,” says Jacques Van Dam, MD, PhD, Professor of Medicine and Clinical Scholar at the University of Southern California’s Keck School of Medicine, and Principle Investigator for this multicenter trial. “Pancreatic cancer patients, their families, and their physicians recognize all too well the limitations of current therapies. Delivering NanoPac directly into the tumor may eliminate many
of the toxic side effects of standard chemotherapy, while providing a higher concentration of drug directly to its intended target.”

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 has shown evidence of tumor reduction in a preclinical lung cancer study after PK studies demonstrated retention of drug in lung tissues for more than 14 days following nebulized inhalation and no abnormalities 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 patented, stable, naked submicron particles with exponentially increased surface area and unique geometry. Unlike conventional nanoparticles, which use coating or carrier agents for stability, NanoPac and NanoDoce particles 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, CritiTech, 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 illnesses.

**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 and Soria 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.

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