



FOR IMMEDIATE RELEASE
October 16, 2017

NanOlogy™ Announces First Patient Enrolled in a Phase 2 Clinical Trial of NanoPac® for Treatment of Prostate Cancer

NanOlogy to Present at BIO Investor Forum on October 17 in San Francisco

FT.WORTH/DALLAS, (October 16, 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 into the prostate for treatment of prostate cancer. Part of a broad [nanoparticle technology platform](#) developed by the company, NanoPac will be evaluated for safety and preliminary efficacy in a dose-rising Phase 2(a) clinical trial following intratumoral injection of the prostate via transrectal ultrasound guidance in patients four weeks prior to radical prostatectomy. Gere diZerega, MD, VP of Medical Affairs, will present an overview of the NanOlogy platform and clinical program at [BIO Investor Forum](#), October 17, 2017 9:45AM, at the San Francisco Westin St. Francis Hotel in Elizabethan D presentation room.

“Systemically administered paclitaxel has been shown to be effective for prostate cancer but is limited to metastatic disease,” said Dr. diZerega. “This clinical trial is the first study in humans to examine whether NanoPac injected intratumorally will effectively and safely treat the tumor with a high locally sustained concentration of the drug.”

Prostate cancer affects an estimated 3 million men in the US and about 27,000 die annually from the disease. In 2017, about 161,000 new cases of prostate cancer will be diagnosed and newly diagnosed patients considered at low risk may undergo “watchful waiting” or “active surveillance” to monitor but not treat the disease. Patients at higher risk for disease progression or those in whom the cancer has spread have a number of treatment options including prostatectomy. Unfortunately, prostatectomy can cause side effects like incontinence or impotence, which significantly decrease the patient’s quality of life.

“If we are successful, we may offer a treatment option for moderate or high risk patients with localized or non-metastatic disease without a negative impact on quality of life,” said Shelagh Verco, Clinical Director of NanOlogy.

NanOlogy has an extensive 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 efficacy study for lung cancer after pharmacokinetics studies demonstrated retention of drug in lung tissues for more than 14 days following nebulized delivery and no abnormalities were seen within the trachea or lung upon gross and histologic exam.

The NanOlogy nanoparticle technology platform is based on a patented production process that reduces the size of paclitaxel and docetaxel API crystals by up to 400 times into patent-pending, stable, naked nanoparticles with exponentially increased surface area and unique geometry. Unlike other nanoparticles, which use coating agents for stability, NanoPac and NanoDoce are stable in their naked form and suspended prior to use in simple vehicles without coating agents.

This open-label, dose-rising, Phase 2a trial will enroll up to 30 patients with local prostate cancer scheduled for prostatectomy. Four weeks prior to scheduled radical prostatectomy, patients will receive NanoPac injected under transrectal ultrasound guidance directly into the lobe of the prostate with the dominant tumor. In addition to assessing safety and tolerability of NanoPac, tumor size change and histologic changes will be evaluated. In addition, local lymph nodes will be analyzed to investigate potential lymphatic transport of NanoPac.

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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 nanoparticle technology platform for local, sustained delivery of proven drugs aimed at increasing their safety and efficacy in the treatment of cancer and related conditions.

About DFB Pharmaceuticals

DFB Pharmaceuticals, LLC (www.dfb.com) is a private Texas investment group with an entrepreneurial drive for developing new healthcare products and businesses. Founded in 1990, DFB and its principals have realized more than \$1.5 billion in value through startups, strategic acquisition and sale of companies and technologies, internal product development, brand optimization, and operations in the healthcare industry.

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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