



FOR IMMEDIATE RELEASE
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NanOlogy™ Completes Dose Escalation Portion of Phase 2 Clinical Trial of NanoPac® for Treatment of Prostate Cancer

- *Intratumoral injection of three concentrations of NanoPac successfully completed across a total of 9 patients*
- *Highest concentration of NanoPac continues into dose confirmation phase of trial as no drug-related local or systemic side effects observed*
- *Histologic examination of prostate tissue shows tumor regression*

FT.WORTH/DALLAS, (April 30, 2018) — [NanOlogy LLC](#), a clinical-stage pharmaceutical development company, has completed the dose escalation phase of an open-label [clinical trial](#) of NanoPac (submicron particle paclitaxel sterile suspension) injected directly into the tumor area for treatment of prostate cancer. Successful completion of the dose escalation phase has allowed the highest concentration of NanoPac to begin the dose confirmation phase of the trial, which will continue to generate data on safety and tumor response.

The Phase 2a trial is enrolling patients with local prostate cancer scheduled for prostatectomy. In the trial, patients receive intratumoral injection of NanoPac 28 days before surgery. Tumor volume and prostate tissue biopsy taken prior to NanoPac administration is compared to tumor volume and tissue after surgery.

In the dose escalation phase to determine highest concentration of drug which can be safely administered, 6 mg/mL, 10 mg/mL, 15 mg/mL concentrations of NanoPac were each injected into three patient cohorts followed by safety review for each cohort. No drug related serious adverse events were reported in any of the cohorts and preliminary data show evidence of tumor reduction and tumor cell death.

“NanoPac is injected directly into the cancerous lobe of the prostate under MRI/TRUS fusion guidance”, said Andre Abreu, MD, Assistant Professor of Clinical Urology, Co-director of Image-Guided Surgery & Focal Therapy of Prostate and Kidney Cancer at the University of Southern California’s Institute of Urology. “The drug injected locally has been well tolerated to date and we have progressed into the dose confirmation phase of the trial to further assess safety and tumor response.”

The dose confirmation phase has begun and will enroll 9 additional patients for a total of 18 patients who received direct injection of NanoPac 28 days prior to their scheduled prostatectomy. In addition to assessing safety and tolerability, tumor size and histologic evidence of tumor response will be evaluated, and local lymph nodes will be analyzed to investigate potential

lymphatic transport of NanoPac. Completion of the clinical trial and final report are expected in the third quarter of 2018.

Prostate cancer affects an estimated 3 million men in the US with about 160,000 new cases and 27,000 deaths annually. Patients at higher risk for disease progression or those in whom the cancer has spread may face surgical removal of the prostate or radiation therapy. Unfortunately, these patients often suffer incontinence or impotence, which significantly decrease quality of life.

Dr. Abreu added, “If we are successful, we may offer a treatment option for moderate or high-risk patients with localized or non-metastatic disease potentially providing better oncologic outcomes while minimizing side-effects of chemotherapy, and therefore maintaining quality of life.”

The prostate cancer study is part of an extensive [clinical development program](#) underway by NanOlogy. Local administration of NanoPac is also being evaluated in Phase 2 clinical trials for ovarian cancer (with orphan drug designation), pancreatic cancer, and pancreatic mucinous cysts.

An inhaled version of NanoPac for lung cancer has demonstrated prolonged lung tissue residence time and tumor regression in preclinical studies and a clinical trial of NanoDoce[®] (submicron particle docetaxel sterile suspension) is planned to begin in September for bladder cancer.

In addition, NanOlogy is progressing a clinical trial of a submicron particle paclitaxel topical anhydrous ointment for cutaneous metastases. The topical product was developed by NanOlogy affiliate DFB Soria, who has also recently completed a Phase 2 clinical trial of the product in actinic keratosis, which showed lesion reduction and no drug-related local or systemic adverse events.

All the NanOlogy and Soria products are progressing under FDA’s streamlined 505(b)(2) regulatory pathway. The NanOlogy submicron particle 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 stable, naked submicron particles of pure drug with exponentially increased surface area and unique geometry. The particles are so unique they have recently been granted a composition of matter patent ([US 9,814,685](#)) which provides NME-like advantages without the risk and timeline associated with new molecular entity drug development.

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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 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. DFB disclaims any intent or obligation to update these statements. NanOlogy and Soria investigational drugs have not been proven to be safe and effective in accordance with the requirements of the U.S. FDCA and have not been approved by FDA for commercial distribution.

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