



FOR IMMEDIATE RELEASE
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NanOlogy™ to Unveil Positive Preclinical Data for Inhaled NanoPac® In Treatment of Lung Cancer at 2018 ASCO Annual Meeting

- *Studies Demonstrate Inhaled NanoPac Shows Prolonged Retention in the Lung, Decreased Primitive Tumor cells, and Increased Tumor Regression*

FT. WORTH/DALLAS, (May 16, 2018) — [NanOlogy LLC](#), a clinical-stage pharmaceutical development company, will present data from preclinical studies of inhaled NanoPac (submicron particle paclitaxel) showing prolonged retention of drug in lung tissue and significant tumor regression without adverse drug-related observations in an orthotopic animal model of non-small cell lung cancer (NSCLC).

The data will be presented in an abstract entitled [“NanoPac Inhalation Treatment of NSCLC in a Nude Rat Orthotopic Lung Cancer Model”](#) during the [American Society of Clinical Oncology \(ASCO\) Annual Meeting](#) on Sunday, June 3rd, from 8:00 AM to 11:30 AM in Hall A of McCormick Place in Chicago.

An initial preclinical pharmacokinetic (PK) study examined the retention of NanoPac in rat lung tissue following a single inhalation via a nose-only exposure chamber. Data showed measurable amounts of drug in the lung at the end of the 14-day study with examined tissue being microscopically indistinguishable from normal lung tissue.

A preclinical study followed to examine the therapeutic effect of inhaled NanoPac using an orthotopic model of NSCLC. Histologic analysis revealed NanoPac achieved a significant decrease in primitive tumor cell population as well as significant tumor regression.

Gere diZerega, MD, VP of Medical Affairs, said, “In our initial PK study, inhaled NanoPac resulted in longer lung retention of drug at a higher concentration compared to systemically administered paclitaxel. The evidence seen in our preclinical PK and efficacy studies has given us the confidence to move forward with IND-enabling studies in preparation for clinical trials.”

Lung cancer is by far the leading cause of cancer death according to the American Cancer Society with more than 154,000 deaths expected this year. More people die of lung cancer every year than breast, prostate, and colon cancers combined.

The preclinical lung cancer studies are in addition to 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), prostate cancer, pancreatic

cancer, and pancreatic mucinous cysts. A clinical trial of NanoDoce® (submicron particle docetaxel sterile suspension) is planned to begin in September for bladder cancer.

NanOlogy is also progressing a clinical trial of a submicron particle paclitaxel topical anhydrous ointment for cutaneous metastases.

All NanOlogy investigational drugs 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 submicron particles of pure drug with exponentially increased surface area and unique geometry. The submicron particles are so unique that they are protected under a composition of matter patent ([US 9,814,685](#)) valid until 2036, 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 and the company disclaims any intent or obligation to update these statements. NanOlogy 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.

Media Contact

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

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