



FOR IMMEDIATE RELEASE
February 13, 2019

NanOlogy to Present Positive Preclinical Data for NanoDoce® in Treatment of Uro-Oncologic Cancers at 2019 Genitourinary Cancers (ASCO-GU) Symposium

- *Intratumoral delivery of NanoDoce in multiple murine xenograft studies resulted in prolonged, high concentration of drug in tumor tissue, significant tumor regression, and immune cell infiltration*

FT. WORTH/DALLAS, (February 13, 2019) [NanOlogy](#), a clinical-stage oncology company, will present an abstract at the [2019 Genitourinary Cancer Symposium](#), co-sponsored by the American Society of Clinical Oncology (ASCO), held February 14-16, 2019 in the Moscone West Building, San Francisco.

Data from preclinical studies of NanoDoce (submicron particle docetaxel suspension) administered via intratumoral injection will be presented showing prolonged, high concentration of drug at the tumor site and significant tumor regression in multiple xenograft animal models including clear cell renal carcinoma (768-O cell line), transitional cell bladder carcinoma (UM-UC-3 cell line), and prostate carcinoma (PC-3 cell line). Abstract title, location, and times follow:

Title: Evaluation of submicron particle docetaxel directly injected into uro-oncologic xenografts
Poster Session: B – Prostate Cancer; Urothelial Carcinoma; Penile, Urethral, Testicular, and Adrenal Cancers
Where: Board E17 Abstract #360, West Building Moscone, San Francisco
When: Friday, February 15, 2019, 12:15 to 1:45 PM and 5:15 to 6:15 PM

Data from the preclinical studies showed that tumor volume decreases with two and three intratumoral doses of NanoDoce were significantly greater than or similar to IV docetaxel. Immunohistochemistry evaluations for the renal and bladder cancer models revealed immune cell infiltration in NanoDoce-treated animals. Drug was detected in NanoDoce-treated tumor tissue up to 50 days after administration, and at levels far greater than IV-treated animals.

Persistent, therapeutic levels of docetaxel from intratumoral NanoDoce appear to kill tumor cells through direct and indirect means. NanoDoce is known to directly inhibit tumor cell mitosis, and its persistence results in prolonged release of tumor antigen, which appears to promote indirect immune cell-mediated tumor kill.

A [clinical trial](#) in high-risk non-muscle invasive (NMIBC) and muscle invasive bladder cancer (MIBC) will begin enrollment in the first quarter of this year. Following transurethral resection of bladder tumor, subjects will receive direct injections of NanoDoce into the base of the index tumor resection site in combination with intravesical instillations of NanoDoce.

In addition, IND-enabling studies are nearing completion on NanoDoce for renal cell carcinoma to allow for a clinical trial via intratumoral injection in the second half of 2019. This work is part of an extensive preclinical and [clinical development program](#) underway by NanOlogy in peritoneal cancers, prostate cancer, pancreatic cancer, pancreatic mucinous cysts, breast cancer, non-small cell lung cancer, and 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 in the US, which provides new molecular entity-like advantages without the risks and timeline associated with NME drug development.

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About NanOlogy

NanOlogy, LLC (www.nanology.us) is a private clinical stage oncology company formed in 2015 to finance and clinically develop a patented submicron particle technology platform for local, sustained delivery of proven drugs aimed at increasing value 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 by FDA and have not been approved by FDA for commercial distribution.

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