FOR IMMEDIATE RELEASE
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NanOlogy announces First Patient Enrolled in a Phase 1/2 Clinical Trial of NanoDoce® for Treatment of Bladder Cancer

- *NanOlogy may offer an alternative treatment option for patients with bladder cancer*
- *Investigational drug, NanoDoce, is injected locally into tumor resection bed via cystoscope guidance followed by intravesical instillation*

FT. WORTH (April 9, 2019) — NanOlogy, a clinical-stage oncology company, today announced the first patient has been enrolled in a clinical trial of NanoDoce (sterile submicron particle docetaxel suspension) for treatment of bladder cancer. The Phase 1/2 dose-rising trial will evaluate the safety and preliminary efficacy of NanoDoce for patients with high-risk non-muscle invasive bladder cancer (NMIBC) and muscle invasive bladder cancer (MIBC).

In 2019, an estimated 80,000 new cases of bladder cancer will be diagnosed in the United States and an estimated 18,000 will die from the disease. Despite being one of the top five cancer diagnoses in the U.S., the last drug FDA approved for NMIBC was more than a decade ago. Of all cancers, bladder cancer tends to have the highest lifetime treatment costs due to the frequency of recurrence, progression to MIBC often requiring removal of the bladder (cystectomy), and lifetime cost of care thereafter.

In the NanOlogy clinical trial, following transurethral resection of the bladder tumor, subjects will receive direct injections of NanoDoce into the base of the index tumor resection site in combination with an intravesical instillation of NanoDoce. Additional intravesical instillations of NanoDoce will be administered to NMIBC subjects while MIBC subjects will follow institutional standard of care.

The local delivery of submicron particle docetaxel suspension [NanoDoce] represents an important step in evaluating new therapies for the treatment bladder cancer", said Dr. Donald Lamm, MD, President of BCG Oncology and principal investigator on the trial. "Preclinical studies suggest the submicron particle technology improves both the penetration of drug into the bladder wall and its duration of activity. If this investigational drug can be proven to delay or prevent disease progression and need for cystectomy, it would contribute significantly to the quality of life of patients with this disease."

An abstract from preclinical studies of NanoDoce was presented in February at the 2019 Genitourinary Cancer Symposium. In one of the studies, NanoDoce administered via intratumoral injection resulted in prolonged, high concentration of drug in tumor tissue, significant tumor regression, and immune cell infiltration in a xenograft animal model of transitional cell bladder carcinoma. The immune cell infiltration is of particular interest to

NanOlogy for future research into the role NanoDoce may play in combination with immunoncology therapy for the treatment of advanced disease.

This work is in addition to extensive preclinical and clinical development programs underway by NanOlogy in peritoneal/ovarian cancers, prostate cancer, pancreatic cancer, pancreatic mucinous cysts, renal cell carcinoma, 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 they are protected under a composition of matter patent (US 9,814,685) valid until 2036, 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 their safety and efficacy in the treatment of cancer and related conditions.

Disclaimers

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.

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