



FOR IMMEDIATE RELEASE
November 4, 2020

NanOlogy Enrolls First Patient in Phase 2 Clinical Trial of NanoPac[®] for Intratumoral Treatment of Prostate Cancer

- *Follows completion of a first-in-human dose-rising study of a single focal injection of NanoPac in patients with local prostate cancer*
- *Evaluates multiple intratumoral injections of NanoPac for safety, tumor response, and immune effect*

DALLAS (November 4, 2020) — [NanOlogy LLC](#), a clinical-stage oncology company advancing intratumoral therapy for solid tumors, has enrolled the first patient in a Phase 2 clinical trial of NanoPac[®] (sterile nanoparticulate paclitaxel) for suspension via intratumoral injection for local prostate cancer. The single arm trial is evaluating up to 3 monthly injections of the investigational drug in patients scheduled for prostatectomy approximately 90 days after the first injection. Patients will be followed for safety and tumor response. Immune effects will be evaluated via multiplex immunohistochemistry and flow cytometry.

[Craig G. Rogers, MD \(Henry Ford Cancer Institute\)](#), a clinical investigator for the Phase 2 trial, commented: “NanoPac completed a first-in-human clinical safety trial in 2019. In this innovative second trial, we will be evaluating both safety and efficacy of multiple intratumoral injections of NanoPac in patients with prostate cancer. We will also be analyzing tissue and blood for immune response and what therapeutic potential NanoPac may offer patients suffering from local disease. This trial aligns with our vision of offering precision medicine approaches along with cutting edge clinical trials at Henry Ford Cancer Institute.”

The multicenter Phase 2 trial expects to enroll up to 18 patients with localized prostate cancer (tumors classified as <T3 and Gleason \geq 6) scheduled for prostatectomy three months after enrollment. In the trial, subjects will receive up to 3 monthly intratumoral injections (days 1, 29, 57) of NanoPac at a dose determined by lesion size. The primary outcome measures will be safety, tolerability, and tumor response. Tumor response will be measured by change in tumor dimension and volume, PSA, PSA-density, and PI-RADS compared to baseline. Prostate and related tissues will be evaluated after biopsy or post-surgery for tumor cell regression via histology and presence of drug in lymph nodes. Immune effects will be analyzed by multiplex immunohistochemistry (IHC) on tissue samples and flow cytometry on blood samples obtained in the study. Drug plasma levels of paclitaxel will also be measured during the trial. The trial is identified as [NCT04221828](#) in [clinicaltrials.gov](#).

This second clinical trial follows completion of a first-in-human phase 2a dose-rising trial (NCT03077659) at a single institution to establish the safety of a single focal injection of

NanoPac into the tumor-bearing lobe of patients scheduled for prostatectomy. Selected findings from the first trial:

- No drug related SAEs including no prostatitis reported
- Highest dose up to 75mg of NanoPac well tolerated
- Mean reductions in tumor volume, PSA-density, and percent adenocarcinoma in biopsy
- Peak paclitaxel plasma concentration was well below toxicity threshold at all timepoints, while drug was detected in all prostatectomy tissue specimens following prostatectomy.

A summary of study findings submitted to FDA can be found under [NCT03077659](https://clinicaltrials.gov/ct2/show/study/NCT03077659) in the clinicaltrials.gov database.

Prostate cancer affects about 3 million men in the USA with 191,930 new cases and 33,330 deaths estimated for 2020 by the American Cancer Society[®]. Patients at higher risk for disease progression may face surgical removal of the prostate or radiation therapy. Unfortunately, these patients may suffer incontinence or impotence, which significantly decreases quality of life. If the cancer becomes metastatic, patients have an estimated 5-year survival rate of only 31%.

In addition to prostate cancer, NanOlogy [clinical programs](#) are advancing in other genitourinary cancers, as well as gastrointestinal, peritoneal, lung, and dermal cancers. Data from preclinical and clinical studies in a variety of solid tumors have shown persistent tumor kill, antitumoral immune response, and minimal local or systemic toxicity.

The NanOlogy large surface area particle therapeutic platform is based on a proprietary supercritical precipitation technology that converts taxane API crystals into stable particles of pure drug with disproportionate size to surface area ratio. The particles are covered by two composition of matter patents ([US 9,814,685](#)) and ([10,507,195](#)) both valid until 2036 in the US and pending globally, forming the foundation of an extensive intellectual property portfolio protecting the investigational drugs and technology.

###

About NanOlogy

NanOlogy, LLC (www.nanology.us) is a private clinical stage oncology company formed in 2015 to finance and clinically advance intratumoral therapy for solid tumors based on a proprietary supercritical precipitation particle technology platform.

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 as required by U.S. FDA and have not been approved by FDA or any other jurisdiction for commercial distribution. NanOlogy and NanoPac are trademarks of NanOlogy LLC.

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