FOR IMMEDIATE RELEASE
June 9, 2020

NanOlogy Announces Initiation of a Lung Cancer Clinical Trial Following FDA Allowances of Two IND Applications for NanoPac® in Lung Cancer

- *First-in-human clinical trial of intratumoral (IT) injections of NanoPac in non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC) is expected to begin enrollment in August*
- *The clinical trial follows FDA allowance of IT NanoPac in neoplasms of the lung*
- *FDA also allowed a second IND for nebulized inhalation of NanoPac in NSCLC*

FT. WORTH, (June 9, 2020) — NanOlogy, LLC, a clinical-stage oncology company, announced today initiation of a clinical trial of IT NanoPac® (submicron particle paclitaxel) for suspension via endobronchial ultrasound-guided transbronchial needle injection (EBUS-TBNI) in NSCLC and SCLC. The trial follows FDA allowance of an investigational new drug (IND) application for IT NanoPac in neoplasms of the lung. A second IND was also allowed by FDA for a nebulized inhaled form of NanoPac in NSCLC. Five INDs have been established for NanoPac allowing progress of clinical trials via multiple routes of targeted administration for a variety of solid tumors including pancreatic, prostate, ovarian, peritoneal, and now lung.

Clinical Trial of NanoPac in Lung Cancer

The first study to proceed will be a Phase 2a dose-rising and expansion trial (NCT04314895) evaluating the safety and tolerability of up to 3 monthly IT injections of NanoPac delivered via EBUS-TBNI, concurrent with standard of care therapy, in patients with primary or recurrent NSCLC or SCLC. In addition to safety and pharmacokinetics (PK), the study will measure progression free survival, overall survival, and tumor response determined from CT scan imaging. Blood and biopsy samples will be evaluated for immune effect through flow cytometry and multiplex immunohistochemistry analysis. The trial will begin at two clinical sites: Parkview Healthcare Institute in Fort Wayne, Indiana and University of Florida Health Cancer Center in Gainesville, Florida. More clinical sites will follow. The first subject is expected to be enrolled in August 2020.

Preclinically, a nebulized inhaled form of NanoPac was retained in lung tissue for more than 14 days in a PK model and caused tumor regression and immune cell infiltration in an orthotopic model of NSCLC. Clinical plans for inhaled NanoPac are under development.

Other Clinical Experience with Targeted Delivery of NanoPac

To date, approximately 70 patients have received targeted injections of NanoPac across clinical trials in the prostate and pancreas. Another 30 patients have received intraperitoneal NanoPac for peritoneal and ovarian cancers. NanoPac has been well tolerated in these study subjects with no confirmed drug-related serious adverse events reported. Along with safety and tolerability, signs of activity have also been observed across the clinical programs.

NanOlogy Submicron Particle Therapeutic Platform

The NanOlogy submicron particle therapeutic platform is based on a proprietary production technology that converts taxane API crystals into stable submicron 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 (US 10,507,195) both valid until 2036 in the US and pending globally. In addition to lung cancer, NanOlogy clinical programs are advancing in pancreatic, genitourinary, peritoneal, ovarian, and dermal cancers.

About Lung Cancer

In 2020, an estimated 228,820 new cases of lung cancer will be diagnosed in the U.S. and 135,720 people will die from the disease. Lung cancer is by far the leading cause of cancer deaths in the U.S. responsible last year for 22% of all cancer-related deaths (SEER). Globally, lung cancer is also the most common form of cancer and the deadliest accounting for an estimated 2.1 million annual new cases and 1.8 million deaths (GLOBOCAN 2018).

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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 targeted, sustained delivery of proven drugs aimed at increasing their value in the treatment of cancer and other serious diseases.

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 for commercial distribution. NanOlogy and NanoPac are trademarks of NanOlogy LLC.

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