NanOlogy

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# NanOlogy™ Announces First Patient Enrolled in a Phase 2 Clinical Trial for Cutaneous Metastases and DFB Soria Provides an Update on AK Trial

- *New study of submicron particle paclitaxel topical product seeks to address unmet medical need in treatment of cutaneous metastases*
- *Affiliate, DFB Soria, completes enrollment of Phase 2 actinic keratosis (AK) trial with evidence of lesion reduction and minimal side effects*
- *Company Representatives in San Diego during AAD annual meeting*

DALLAS/FT.WORTH, (February 14, 2018) —NanOlogy™, a clinical-stage pharmaceutical development company and affiliate of DFB Pharmaceuticals, today announced enrollment of the first patient in a Phase 1/2 clinical trial of a submicron particle paclitaxel topical anhydrous ointment for the treatment of cutaneous metastases. The open label dose escalating trial of three different strengths of the product will be followed by dose confirmation to evaluate safety and preliminary safety. NanOlogy has licensed the topical formulation for use in oncology from DFB Soria, which is owned and operated by DFB.

Cutaneous metastases occur when cells from cancer elsewhere in the body spread or metastasize to the skin. These metastatic skin lesions can appear as firm round or oval nodules, or red patches, which may ulcerate through the skin causing discomfort and disfigurement. Affecting as many as 700,000 late-stage cancer patients, the condition may originate from breast, lung, colon, or other types of cancers and adds to the distress faced by these patients.

“Treatment of metastatic skin lesions is widely seen as an unmet medical need as no approved topical treatments exist for lesions caused by the most common metastatic diseases.” said Dr. Sant Chawla of Sarcoma Oncology Research Center. “There is a strong scientific rationale for local treatment with a topical formulation because systemic paclitaxel is often used to treat the underlying cancer. We are hopeful that topical use of the formulation will be effective without causing the debilitating side effects of systemic chemotherapy.”

Because no other topical treatment options exist for many patients suffering from cutaneous metastases, the company will seek to gain FDA fast track status if the results of this trial are successful.

Separately, Soria has completed enrollment in a Phase 2 actinic keratosis (AK) clinical trial that is evaluating different strengths of the topical formulation for safety and efficacy. Results from

the randomized, double-blind, placebo-controlled trial are expected in April but preliminary blinded observations are promising.

AK is a precancerous condition caused by exposure to the sun, affecting an estimated 58 million Americans. AK can progress to cutaneous squamous cell carcinoma (CSCC), the second most common form of skin cancer. More than 1 million people are diagnosed with CSCC each year, and as many as 9,000 people die from the disease. The most widely prescribed topical treatment for AK contains 5-fluorouracil, which can cause severe local irritation and inflammation.

"Our topical product has caused minimal local irritation and negligible systemic absorption in clinical trials." said Managing Director, Marc Iacobucci. "Confirmation of lesion reduction in this clinical trial will allow selection of the most efficacious strength to move forward into pivotal trials."

The key advance of the proprietary production technology is a patented process that reduces the size of taxane API crystals by up to 400 times into stable, naked submicron particles with exponentially increased surface area and unique geometry. The submicron particles, which are so unique they have recently been granted a composition of matter patent, are then suspended in a patent-pending topical anhydrous base, which has successfully shown penetration of drug through the epidermis into the dermis.

NanOlogy is also advancing four clinical trials of another product, NanoPac® (submicron particle paclitaxel sterile suspension), for evaluation in 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 expected to begin in bladder cancer in mid-2018.

Preclinical studies of a form of NanoPac delivered via nebulized inhalation for lung cancer have demonstrated significant tumor reduction and greater than 14-day retention in lung tissue with no gross or histological abnormalities.

Representatives from the company will be in San Diego during the American Academy of Dermatology Annual Meeting to meet with companies interested in partnering opportunities.

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**About NanOlogy and DFB Soria**

NanOlogy, LLC (www.nanology.us) is a company formed between DFB Pharmaceuticals, LLC, CritiTech Inc., and US Biotest, Inc. to finance and develop a submicron particle technology platform to transform systemic chemotherapy through local delivery to improve the lives of patients with cancer and other serious illnesses. DFB Soria, LLC is owned and operated by DFB. Soria developed the topical formula under an exclusive worldwide license of the submicron particle production technology from CritiTech for certain fields outside of oncology including dermatology.

**Disclaimer**

This announcement contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding NanOlogy and Soria product development, business, and other activities. Such statements are subject to risks and uncertainties inherent in any pharmaceutical development program which may cause actual results to differ materially due to developmental, clinical, regulatory, market, competitive, technological, or other factors. All forward-looking statements are made as of the date of this announcement and NanOlogy disclaims any intent or obligation to update these statements. The Soria and NanOlogy investigational new drugs have not yet been proven to be safe and effective in accordance with the requirements of the U.S. FDCA and are not approved by FDA for commercial distribution.

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