NanOlogy

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# NanOlogy Presents Results of SOR007 (Topical Submicron Particle Paclitaxel) Phase 1/2 Clinical Trial in the Treatment of Cutaneous Metastases at 2020 SABCS®

FT. WORTH, (December 29, 2020) — NanOlogy, LLC, a clinical-stage oncology company, today announced that results from its Phase 1/2 clinical trial of SOR007 (topical submicron particle paclitaxel) in the treatment of cutaneous metastases were presented during the 2020 San Antonio Breast Cancer Symposium by Mario Lacouture, MD, Director of Oncodermatology, Memorial Sloan Kettering Cancer Center. The dose escalation/expansion trial enrolled 23 subjects across three clinical sites, 21 of whom had cutaneous metastases of breast cancer (CMOBC). In addition to Dr. Lacouture, clinical investigators included Julie Lang, MD (USC Norris Comprehensive Cancer Center, Los Angeles, CA) and Sant Chawla, MD (Sarcoma Oncology Research Center, Santa Monica, CA).

Three concentrations of SOR007 were evaluated (0.15%, 1.0% and 2.0%) applied twice daily to one or more 50 $cm^2$ treatment areas per subject for 28 or 56 days. The primary endpoint of the study was safety and tolerability. Secondary endpoints included lesion response, pain reduction, and pharmacokinetic (PK) analysis.

SOR007 was well tolerated at all concentrations allowing the 2.0% concentration to continue to the dose expansion phase of the trial. No confirmed drug-related severe adverse events were recorded, local skin reactions were limited and minor, and PK analysis confirmed negligible systemic absorption of paclitaxel.

Lesion response was evaluated by individual lesion and subject for both dimension and surface area under RECIST 1.1. Response was superior with 56 days of treatment versus 28 days of treatment indicating a doses response/duration relationship. Best overall response in evaluable subjects for the 56-day treatment group (n=11) was 54% versus 27% for the 28-day treatment group (n=11). Preliminary signs in lesion pain reduction were observed in half of the subjects reporting lesion pain at baseline. Please click on this link for a copy of the poster presentation with more details on trial results.

In 2020, an estimated 276,480 people will be diagnosed with breast cancer in the United States, of whom 6%-10% (16,600-27,700) will be diagnosed with metastatic breast cancer (MBC). Approximately 168,000 people are currently living with MBC in the United States and cutaneous metastases may develop in up to a quarter of those (c. 40,000) with MBC. CMOBC are progressive malignant skin lesions that can cause severe local pain, skin ulceration, disfigurement, discharge, malodor, bleeding, and infection. The negative impact to quality of life (QOL) for these patients can be severe.

In addition to SOR007, NanOlogy is advancing clinical programs aimed at solid tumor-directed therapy with investigational drugs NanoPac® (LSAM paclitaxel) for suspension

and NanoDoce® (LSAM docetaxel) in pancreatic, peritoneal, ovarian, prostate, bladder, and lung cancers. The NanOlogy large surface area microparticle (LSAM) drug platform is based on a proprietary supercritical precipitation technology that converts API crystals into stable LSAMs of pure drug with disproportionate surface area to particle size ratio. The taxane particles are covered by composition of matter patents issued in the US (US 9,814,685) and (US 10,507,195), Europe, Japan, and Australia all valid until 2036, and applications pending globally.

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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 advance tumor-directed drug therapy for solid tumors based on a proprietary supercritical precipitation 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 regulatory authority for commercial distribution. NanOlogy, NanoDoce, and NanoPac are trademarks of NanOlogy LLC.

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