



FOR IMMEDIATE RELEASE  
September 26, 2017

## DFB Soria Gives Update on Enrollment in Phase 2 Clinical Trial of SOR007 (Nanoparticle Paclitaxel) Ointment for Actinic Keratosis (AK)

*AK can lead to the second most common form of skin cancer*

DALLAS/FT.WORTH, (September 26, 2017) —[DFB Soria](#), a clinical-stage pharmaceutical development company, and an affiliate of [NanOlogy™](#), today announced completion of the second of four patient cohorts enrolled in a [Phase 2 actinic keratosis \(AK\) clinical trial](#) of a topical ointment containing nanoparticle paclitaxel formed by a proprietary production process. Identified as SOR007, the ointment is being evaluated topically in a dose escalating trial for safety and preliminary efficacy.

“The most widely prescribed topical treatment for AK is 5-fluorouracil, which causes severe dermal irritation and significantly decreases the patient’s quality of life for several weeks.” said Gere diZerega, MD, Soria VP of Medical Affairs. “Preclinical dermal irritation studies and a Phase 1 clinical trial of SOR007 showed minimal dermal irritation and negligible systemic absorption, and formed the basis for FDA approving the clinical protocol for our AK trial.”

AK is a precancerous condition caused primarily by exposure to the sun, and affects an estimated 58 million Americans. If left untreated, AK can progress to cutaneous squamous cell carcinoma (CSCC), the second most common form of skin cancer. More than one million people are diagnosed with CSCC each year, and as many as 9,000 people die from the disease. Paclitaxel administered systemically is effective in the treatment of advanced CSCC but can cause systemic adverse effects.

“Our goal is to demonstrate that SOR007 is effective without the severe topical irritation that limits other AK products.” said Maxwell Lea of Soria. “Successful results from this clinical trial will allow selection of the most efficacious SOR007 concentration to move forward into phase 3-enabling clinical trials.”

Nanoparticle paclitaxel contained in SOR007 is produced by a proprietary nanoparticle production technology that reduces the size of unprocessed paclitaxel API crystals up to 400 times into patented, stable, naked nanoparticles with exponentially increased surface area and unique geometry. NanoPac is then suspended in a topical anhydrous base, which has successfully shown penetration of the drug through the epidermis into the dermis. Both the nanoparticle and the ointment are patent pending.

Nanology and Soria share a common [nanoparticle technology platform](#) that is currently in [six clinical trials](#) for evaluation in ovarian cancer (with orphan drug status), prostate cancer,

# Soria

pancreatic cancer, pancreatic mucinous cysts, cutaneous metastases, and actinic keratosis. In addition, preclinical studies are underway for lung cancer and bladder cancer.

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## **About Soria and NanOlogy**

DFB Soria, LLC ([www.dfbsoria.com](http://www.dfbsoria.com)) is owned and operated by [DFB Pharmaceuticals, LLC](#). Soria, an affiliate of NanOlogy, developed SOR007 under an exclusive worldwide license of the nanoparticle production technology from [Critech, Inc.](#) for certain fields outside of oncology including dermatology. NanOlogy, LLC ([www.nanology.us](http://www.nanology.us)) is a company formed between DFB, Critech, and [US Biotest, Inc.](#) to finance and develop a nanoparticle technology platform to transform systemic chemotherapy through local delivery to improve the lives of patients with cancer and other serious illnesses.

## **Disclaimer**

This announcement contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding Soria and NanOlogy 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 Federal Food, Drug, and Cosmetic Act and are not approved by FDA for commercial distribution.

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