

DFB Soria Completes a Phase 2 Clinical Trial of Submicron Particle Paclitaxel Anhydrous Ointment for Actinic Keratosis

Soria investigational drug provides evidence of actinic keratosis (AK) lesion reduction without the local irritation of approved topical AK treatment products

FT.WORTH/DALLAS (September 18, 2018) – [DFB Soria](#), a [DFB Pharmaceuticals](#) company, today announced completion of a dose-rising clinical trial of a topically applied submicron particle paclitaxel suspended in a pharmaceutically elegant, preservative-free anhydrous base. The trial was designed to evaluate safety and preliminary efficacy of four strengths of the product applied twice daily for 28 days. Results from the trial show evidence of AK lesion reduction in size and count, dose response, and minimal local irritation or other side effects.

AK affects 58 million Americans and is caused by exposure to the sun and other sources of UV radiation. The condition is responsible for 8 million visits to dermatologists or primary care physicians in the US annually. Left untreated, AK can progress to squamous cell carcinoma (SCC), the second most common form of skin cancer. Each year, more than one million people are diagnosed with SCC and as many as 9,000 people die from the disease. IV Paclitaxel is approved by FDA for the treatment of advanced SCC, which provided Soria the rationale for developing its topical product for AK.

“The most widely prescribed topical treatment for AK contains 5-fluorouracil, which causes severe dermal irritation and significantly decreases quality of life for several weeks during use.” said Gere diZerega, MD, VP of Medical Affairs. “Our goal was to demonstrate our product would result in AK lesion reduction without the severe irritation that limits other topical products. We now may identify a pharma partner or proceed ourselves as the results from this trial allow us to move forward with a dose confirmation trial followed by a pivotal phase 3 trial if successful.”

The submicron particle paclitaxel contained in the Soria product is produced by a proprietary production technology that reduces the size of unprocessed paclitaxel API crystals up to 400 times into stable, uncoated particles of pure drug with exponentially increased surface area and unique geometry. The particles are so unique they have been granted a composition of matter patent ([US 9,814,685](#)) that is valid until 2036. This provides the product new molecular entity-like IP advantages with a streamlined 505(b)2 FDA regulatory pathway.

NanOlogy, LLC, a company related to Soria, is also underway on a phase 1/2 clinical trial of a similar topical product for the treatment of cutaneous metastases, which is expected to complete in early 2019. Cutaneous metastases are skin lesions secondary to certain metastatic cancers and represents an unmet medical need because no approved topical treatments exist for common forms of the condition.

Soria

The company is evaluating options for bringing both products to regulatory approval including sale or license to a dermatology-focused company or continued internal investment.

NanOlogy has an exclusive license for the [submicron particle production technology](#) with investigational drugs currently in [clinical trials](#) for peritoneal malignancies (with orphan drug status), prostate cancer, pancreatic cancer, and pancreatic mucinous cysts. In addition, clinical trials are planned by NanOlogy in bladder cancer in late 2018 and in lung cancer and renal cancer in 2019.

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About Soria and NanOlogy

DFB Soria, LLC (www.dfbsoria.com) is owned and operated by [DFB Pharmaceuticals LLC](#). Soria developed its submicron particle paclitaxel anhydrous ointment under an exclusive worldwide license from [Critech, Inc.](#) for dermatology. [NanOlogy, LLC](#) is a private clinical stage pharmaceutical company formed in 2015 to finance and clinically develop the submicron particle technology platform for local, sustained delivery of chemotherapeutic agents aimed at increasing their safety and efficacy in the treatment of cancer and related conditions.

Disclaimer

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 and Soria investigational drugs have not been proven to be safe and effective in accordance with the requirements of the U.S. FDCA and have not been approved by U.S. FDA for commercial distribution.

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