NanOlogy

DFB Pharmaceuticals Forms NanOlogy™ and Soria for Clinical Development of Naked Nanoparticle Platform to treat Cancer and Related Illnesses

Demand for new cancer drugs is enormous with public and private investment skyrocketing for new technologies. Immunotherapies have captured much of the attention in recent years. However, the first generation of these drugs has not delivered the hoped for panacea and development of more effective, safer immunotherapies is still years from reaching patients. In addition, immunotherapy is extremely expensive with treatment costs easily reaching $100,000 or more annually per patient.

Despite the promise of these drugs, many experts also believe that the most effective treatment strategies will continue to involve the combination of immunotherapies with traditional chemotherapy for many years to come. In the near term, increasing the safety and effectiveness of proven chemotherapies, such as paclitaxel and docetaxel, have the potential more quickly and cost effectively to improve the outlook for cancer patients.

DFB Pharmaceuticals, a privately held investment and development group in Ft. Worth, TX, has taken on this challenge by forming NanOlogy, in collaboration with CritiTech and US Biotest, to finance and develop a breakthrough technology platform for producing unique, patented, naked nanoparticles of paclitaxel and docetaxel. NanoPac® (nanoparticle paclitaxel) and NanoDoce® (nanoparticle docetaxel) are the first investigational drugs based on this platform and are aimed at transforming the safety and efficacy of these proven therapeutic agents for multiple indications in oncology and related illnesses.

“The NanOlogy nanoparticle technology platform has the potential to quickly bring proven chemotherapeutic agents to patients in a significantly safer and more effective form and at reasonable prices compared to the newer immunotherapy agents.” remarks Maurie Markman, MD, President of Medicine and Science, Cancer Treatment Centers of America®. “In the longer term, NanoPac and NanoDoce not only have the potential to be breakthrough first line treatments, but may prove to be extremely beneficial in combination with immunotherapies.”

The key scientific advance of the NanOlogy technology platform is a patented manufacturing process that uses sonic energy and super critical carbon dioxide to reduce the size of unprocessed paclitaxel and docetaxel crystals by up to 400 times into stable, naked nanoparticles with an exponential increase in surface area and unique geometry.

NanoPac and NanoDoce Sterile Suspension

Unlike other nanoparticles, which require coating agents to keep them stable, our nanoparticles are stable in their naked form and are suspended prior to use in simple vehicles without coating agents. The suspended nanoparticles then can be injected directly into tumors, cysts, the peritoneum, or other body cavities, where studies have demonstrated the nanoparticles remain and slowly release at therapeutic levels for at least four weeks, resulting in prolonged local exposure. In contrast, systemic forms of taxanes remain at the treatment site only for a short time as they are rapidly cleared from the body.

Moreover, systemic administration of paclitaxel and docetaxel is associated with significant adverse effects, some of which are attributed to solvents used in the formulations. Since both drugs have short half-lives and typically remain at therapeutic levels for less than 48 hours, effectiveness may be suboptimal because of the short time the site of treatment is exposed to drug. Remarkably, however, local administration of NanoPac or NanoDoce remains at the treatment site for weeks, over multiple cancer cell division cycles, and provides a much better opportunity for treatment success.

Physicians and scientists have known for years that paclitaxel and docetaxel are effective cancer killing agents, and have long searched for ways to retain high concentrations of drug at the treatment site for a longer period of time in order to increase their effectiveness. This is not possible with traditional IV chemotherapy due to the limitations of systemic delivery, associated adverse events, and rapid clearance. NanoPac and NanoDoce delivered directly to the area of disease, are designed to solve this problem, by allowing for local delivery of higher, sustained concentrations of drug, and also by eliminating the side effects caused by systemic administration.

Nebulized inhalation delivery

Nanology's technology platform also includes NanoPac for nebulized inhalation that is showing promise in lung cancer. The inhaled version of NanoPac is in process of a nonclinical efficacy study in lung cancer after successful PK studies.

DFB Soria develops topical version of NanoPac

DFB Soria is an affiliate of NanOlogy and also owned and operated by DFB Pharmaceuticals. In 2015, Soria gained an exclusive worldwide license from CritiTech for its nanoparticle production technology for use in certain fields outside of oncology. Soria then developed SOR007 (uncoated nanoparticle paclitaxel) Ointment, which has demonstrated dermal penetration *in vitro* and successful results from an *in vivo* dermal toxicity study in support of an IND. After completing a phase 1 clinical trial in psoriasis in 2016 which further demonstrated the safety of SOR007, Soria is progressing nonclinical and clinical development across a number of indications.

Broad Clinical Program

NanOlogy has planned a broad clinical development program for NanoPac sterile suspension in 2017 with clinical trials underway in ovarian cancer (with orphan drug designation), prostate cancer, pancreatic cancer, and pancreatic mucinous cysts. In addition, NanOlogy is evaluating SOR007 in a clinical trial for treatment of cutaneous metastases. At the same time, Soria is also evaluating SOR007 for treatment of actinic keratosis. Also planned for 2018 are clinical trials in various cancers for NanoDoce pending successful nonclinical development and IND approval.

In an encouraging Phase 1 clinical trial, NanoPac was delivered directly into the peritoneal cavity of patients with cancer predominantly confined to the peritoneal cavity with no curative systemic treatment options. The data, reported in the March 24, 2015 issue of *Cancer Chemotherapy Pharmacology*, revealed that compared with intravenous administration of the

paclitaxel, NanoPac provided "higher and prolonged levels of paclitaxel" at the tumor site in the peritoneum "with minimal systemic exposure and reduced toxicity." In addition, of the 21 patients enrolled in the Phase 1 trial, five of these seriously ill patients survived at least 400 days after receiving NanoPac.

The significance of the NanOlogy naked nanoparticle technology is particularly evident when compared to traditional and nanoparticle chemotherapy agents that are approved for systemic administration, and forms the basis for an extensive IP portfolio. In addition, the technology represents a platform for transforming other molecules into nanoparticles, unlocking the potential for safer and more effective local treatments.

NanoPac and NanoDoce are being developed under FDA's streamlined 505(b) (2) regulatory pathway. This designation is applied to new embodiments of approved drugs, and is designed to reduce the overall development time for advancing successful product candidates through the development process to regulatory approval.

About NanOlogy
NanOlogy, LLC (www.nanology.us) is a company formed by DFB Pharmaceuticals, LLC of Fort Worth, TX, CritiTech, Inc. of Lawrence, KS, and US Biotest, Inc. of San Luis Obispo, CA, to finance and clinically develop a patented nanoparticle technology platform for local, sustained delivery of proven drugs aimed at increasing their safety and efficacy in the treatment of cancer and related conditions.

About DFB Pharmaceuticals
DFB Pharmaceuticals, LLC (www.dfb.com) is a private Texas investment group with an entrepreneurial drive for developing new healthcare products and businesses. Founded in 1990, DFB and its principals have realized more than $1.5 billion in value through startups, strategic acquisition and sale of companies and technologies, internal product development, brand optimization, and operations in the healthcare industry.

About CritiTech
CritiTech, Inc. (www.crititech.com) is private Kansas particle engineering company focused on developing new drugs and improving existing drugs. Using the company's proprietary Supercritical Precipitation Technology (SCP Technology) CritiTech specializes in optimizing the delivery of challenging drug substances, potent molecules and poorly soluble compounds. In addition, CritiTech uses its SCP Technology to improve the efficacy, drug delivery options, dosing regimen and pharmacokinetics of a wide variety of drugs, including oral, injectable, and inhaled drugs.

About US Biotest
US Biotest, Inc. is a private California company dedicated to the development of therapeutics to address serious unmet medical needs. Building on strong relationships with industry experts, academic institutions, and leading physicians, the company provides product development strategy and support. US Biotest manages efficient delivery of programs from nonclinical through late-stage clinical trials.

Disclaimer

This announcement contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding NanOlogy's 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 NanOlogy disclaims any intent or obligation to update these statements. 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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