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Nanotherapeutics Advances Two Clinical Programs

- *Investigational New Drug Application (IND) filed with FDA for NanoBUP™*
- *NanoBUP™ - Oral Capsule for Opiate Addiction Targeted for Phase I Clinical Trial*
- *NanoDOX™ for Diabetic Foot Ulcers Enrolling Patients at Florida VA Hospital*
- *Collaboration with Walter Reed Army Medical Center - Study on Dehisced Surgical Wounds*

ALACHUA, Fla.--([BUSINESS WIRE](#))--Nanotherapeutics, Inc., a privately held specialty biopharmaceutical company, announced that it has submitted an Investigational New Drug (IND) application to the FDA for a Phase I clinical studies to assess the safety and pharmacokinetics of NanoBUP™ buprenorphine / naloxone capsule for the treatment of opiate addiction. NanoBUP™ is a stable, oral swallowed capsule containing buprenorphine / naloxone developed with the company's proprietary NanoDRY® particle delivery system. This new product is an immediate release capsule that allows buprenorphine to be absorbed more efficiently from the upper gastrointestinal tract upon ingestion, offering a less invasive route of administration and potentially reducing patient-to-patient variability.

Development has been funded through a National Institutes of Health – National Institute of Drug Addiction (NIH-NIDA) small business innovative research (SBIR) contract #HHSN271200577414C.

Buprenorphine is used in the treatment of moderate and severe acute and chronic pain as well as opioid addiction. Naloxone is a drug used to counter the effects of opioid overdose and is intended to render the product less able to be abused by deterring intravenous injection. Sublingual delivery is currently available using Suboxone® (buprenorphine HCl/naloxone HCl dihydrate), but absorption may be variable and lowered if swallowed too early.

Nanotherapeutics has entered a manufacturing and supply agreement for opioid-based active pharmaceutical ingredients with Noramco, Inc., The agreement includes the supply of buprenorphine hydrochloride, one of the active ingredients in NanoBUP™. Noramco, Inc. is a leading supplier of opioid-based active ingredients for generic and branded pharmaceutical products.

NanoDOX™ for Diabetic Foot Ulcers and Wound Care Advances in Clinical Studies

Advances in the clinical program of NanoDOX™, the company's lead product in development, include recruitment of patients in a Phase IIa clinical study at the North Florida/South Georgia Veteran's Health System and a collaboration with Walter Reed Army Medical Center.

The company has begun recruiting patients for a phase IIa clinical study of NanoDOX™ 1% Doxycycline Monohydrate Hydrogel, a topical formulation of doxycycline for chronic wounds. The randomized double-blind study will assess the safety and efficacy of the product on healing of non-infected diabetic ulcers of the lower extremities. The study is being conducted at the Gainesville, Florida Veteran's Administration Hospital under the direction of the study's principal

investigator, Robert Feezor, MD. The study is partially funded by an NIH grant 1R15NR009377-01 (Joyce Stechmiller, Ph.D. ARNP FAAN, grant PI).

Nanotherapeutics has entered into a Cooperative Research and Development Agreement (CRADA) with the North Florida/South Georgia Veterans Health System to conduct the phase IIa clinical trial, *"A Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of NanoDOX™ 1.0% Doxycycline Monohydrate Hydrogel in Diabetic Adult Subjects with Lower Extremity Ulcers Compared to Placebo Hydrogel,"* at the Malcom Randall VA Medical Center in Gainesville, Florida. Recruitment for this clinical trial began in February 2009.

A pilot study with NanoDOX™ to treat dehisced surgical wounds is being developed in collaboration with Walter Reed Army Medical Center through a Cooperative Research and Development Agreement (CRADA). The study, *"Double-Blinded, Single-Site, Pilot Study of NanoDOX™ versus Placebo Hydrogel for Dehisced Surgical Wounds,"* is expected to begin this summer, supported by funding included in the Fiscal Year 2009 Department of Defense Appropriations Act.

About Nanotherapeutics

Nanotherapeutics is a privately held specialty biopharmaceutical company with full product development and cGMP manufacturing capabilities and a proprietary pipeline. The Company's technologies can be used with all drug types ranging from small molecules to proteins and peptides. These technologies can be employed with new chemical entities or with generic drugs and can be used with the spectrum of existing drug types ranging from small synthetic molecules to large recombinant macromolecules. Nanotherapeutics is focused on drug development, not early-stage discovery. Its first FDA approved product, Origen™ DBM with Bioactive Glass, is an injectable bone graft for orthopedic applications. For more information, visit www.nanotherapeutics.com.

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