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## **Nanotherapeutics Announces NanoBUP™ Capsule for Treating Opiate Addiction Demonstrated Bioavailability and Safety in Phase Ia Clinical Trial**

### **Progress in other Nanotherapeutics clinical programs**

*NanoDOX™ for Diabetic Foot Ulcers Enrolling Patients at Florida VA Hospital*

*FDA Clearance to start Surgical Wound Healing study with Walter Reed Army Medical Center*

ALACHUA, Fla.--([BUSINESS WIRE](#))--Nanotherapeutics, Inc., a privately held specialty biopharmaceutical company, announced that NanoBUP™ Oral Buprenorphine / Naloxone Capsule, for treating opiate addiction, demonstrated strong oral absorption in a Phase Ia clinical trial. The 2 x 2mg capsule achieved significant oral bioavailability of 60 to 70 percent, in comparison to sublingual administration of buprenorphine/naloxone at a similar dose, as reported in published scientific reports. NanoBUP™ is a stable, swallowed capsule containing buprenorphine / naloxone developed with the Company's proprietary NanoDRY® particle delivery system. The product is an immediate release capsule that allows buprenorphine to be absorbed more efficiently from the upper gastrointestinal tract, offering an improved route of administration over currently available formulations.

The Phase Ia clinical program investigated the absorption of the NanoBUP™ capsule from the upper gastrointestinal tract in healthy volunteers. The results were favorable showing good bioavailability and safety. The peak plasma concentration (Cmax) for buprenorphine was lower for NanoBUP™, but the time to peak concentration (Tmax) was similar to sublingual administration of buprenorphine/naloxone. There were no major side effects. Development has been funded through a National Institutes of Health – National Institute of Drug Addiction (NIH-NIDA) small business innovative research (SBIR) contract.

In other clinical updates, a Phase IIa clinical trial of NanoDOX™ 1% Doxycycline Monohydrate Hydrogel, a topical formulation of doxycycline for chronic wounds, has been enrolling patients since February 2009 and is expected to be completed by fourth quarter 2009. The study, "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", will enroll 40 patients at the Malcom Randall VA Medical Center in Gainesville, Florida.

The FDA has given approval for the Company to conduct a pilot study to treat dehisced surgical wounds with NanoDOX™ Hydrogel. The Company will conduct the clinical trial with investigators at the Walter Reed Army Medical Center. The study, "A Double-Blinded, Single-Site, Pilot Study of NanoDOX™ versus Placebo Hydrogel for Dehisced Surgical Wounds," is expected to begin at the end of 2009. The study is supported by funding included in the Department of Defense FY 2009 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](http://www.nanotherapeutics.com).

## Contacts

Nanotherapeutics, Inc.  
Weaver H. Gaines, 386-462-9663 Ext. 329  
Chairman

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