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Nanotherapeutics Files Investigational New Drug Application for NanoDOX™ Hydrogel to Treat Lower Extremity Diabetic Ulcers

ALACHUA, Fla.--([BUSINESS WIRE](#))--Nanotherapeutics, a privately held specialty biopharmaceutical company, announced today that it has submitted its first Investigational New Drug (IND) application to the FDA for a phase IIa clinical study for its product NanoDOX™ Hydrogel, a topical doxycycline hydrogel for chronic wounds. The randomized double-blind study will assess the safety and efficacy of the product on the healing rates of non-infected diabetic ulcers of the lower extremity. Assuming FDA approval, the Company expects to complete enrollment in early 2009.

The phase IIa study will be conducted at Veterans' Administration hospitals in Florida. The Company will enroll diabetics, 18 and older, who have diabetic ulcers of the foot and lower limbs at the Gainesville and Lake City VA hospitals. The primary endpoint to evaluate the hydrogel's efficacy will be the rate of complete (100%) wound closure during a 20-week treatment period.

"Diabetic ulcers are the primary cause of amputations of the leg, foot, or toe. Two-thirds of all lower extremity amputations in the United States are directly linked to diabetes. We believe that NanoDOX™ is a unique formulation that holds significant promise for the millions of people suffering from diabetic ulcers," said Weaver H. Gaines, Chairman of the Board. "Filing the IND for the phase II study is a major step forward in our clinical program and demonstrates the strength of our technology and our capability to generate unique new product opportunities."

NanoDOX™ Hydrogel, the company's leading pharmaceutical product in development, is an alternative topical formulation of doxycycline. Nanotherapeutics developed the product with its proprietary particle stabilization technology and formulated it to improve the topical delivery of doxycycline to increase local efficacy of the drug.

Jim Talton, Ph.D., President of Nanotherapeutics, said, "The Company is also exploring the use of NanoDOX™ Hydrogel for treating traumatic open wounds incurred in combat. In collaboration with Walter Reed Army Medical Center, we plan a clinical trial to evaluate safety and efficacy in treatment of deep trauma wounds. A separate IND will be filed for this indication."

NanoDOX™ 1% Doxycycline Monohydrate Hydrogel

NanoDOX™ Hydrogel is a topical hydrogel applied directly to the entire surface of the wound. A gauze dressing or a non-adhering dressing is applied to cover the hydrogel and wound. This allows the hydrogel to provide a moist healing environment. NanoDOX™ Hydrogel is composed of doxycycline monohydrate, a currently marketed antibiotic available in tablet and injectable forms.

Lower Extremity Diabetic Ulcers

There are more than 18 million people diagnosed with diabetes in the United States and about 5% of them will develop foot and lower limb ulcers. There are, however, about another 7 million diabetics who are undiagnosed. Foot and lower leg ulcers are the primary cause of the approximately 80,000 amputations of toes, feet, and lower legs each year. It is estimated that up to 30% of diabetics with foot ulcers will eventually require amputation. (National Institutes of Health and CDC data)

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. 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.

Contacts

Nanotherapeutics
Weaver H. Gaines, 386-462-3961 or 917-862-2274
Chairman of the Board
Weaver.Gaines@att.net

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