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Nanotherapeutics Awarded \$30.9 Million NIAID Contract to Develop Inhaled Antiviral for Prophylaxis and Treatment of Smallpox

ALACHUA, Fla.--(BUSINESS WIRE)--Nanotherapeutics, Inc., today announced that it has been awarded a \$30.9 Million, 5-year contract from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to develop an inhaled version of the injectable antiviral drug, cidofovir, for non-invasive, post-exposure prophylaxis and treatment of the Category A bioterrorism agent smallpox (*Variola major*). Since transmission of smallpox occurs through inhalation of airborne *variola* virus, usually droplets expressed from the oral, nasal, or pharyngeal mucosa of an infected person, non-invasive anti-viral treatment alternatives with proven agents (cidofovir) are needed. Development of inhaled cidofovir will also provide an alternative for those who have contraindications to the currently approved smallpox vaccination such as severe exfoliative skin diseases, immunosuppression from many sources, and pregnancy. Inhaled cidofovir could decrease the proportion of the population that would remain susceptible to smallpox due to their inability to be vaccinated, and has been shown in multiple studies to be highly efficacious against various pox models compared to injectable administration, which results in lower pulmonary levels, possible nephrotoxicity, and requires a health-care worker to implement treatment.

Nanotherapeutics has assembled a highly-esteemed consortium of experts and organizations to support the preclinical development program including Tulane National Primate Research Center, Respirics, Next Breath, and Lovelace Respiratory Research Institute. David L. Gardner, Ph.D., an expert with over 30 years experience in inhalation and delivery technologies, will lead the program at Nanotherapeutics as the new Director of Inhalation Product Development. Cidofovir will be provided under an agreement with Gilead Sciences, Inc. This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) under Contract No. HHSN272200900015C.

About Nanotherapeutics

Nanotherapeutics, Inc. is a privately held specialty biopharmaceutical company. Its product pipeline includes, an FDA-approved injectable biologic product (OrigenTM DBM, marketing partner Orthofix), an FDA filed product (NanoFUSETM bone graft), and two products in clinical trials (NanoDOXTM and NanoBUPTM). The company also has in-house GMP manufacturing to support additional products. Nanotherapeutics was previously awarded a \$20 million contract in 2007 to develop an inhaled version of gentamicin for the post-exposure prophylaxis and treatment of tularemia and plague, both Category A bioterrorism agents. The 10-year old company employs several platform technologies to manipulate and enhance the properties of drugs, has an experienced management and development team, and a pipeline of clinical and pre-clinical pharmaceutical and biologic products. For more information, visit the company website at www.nanotherapeutics.com.

About Tulane University

The Tulane National Primate Research Center (TNPRC) is a unit of Tulane University's Health Sciences Center located in the greater New Orleans area. The TNPRC, among the largest of the eight NIH-funded primate research centers in the nation, has been heavily engaged in infectious disease research involving nonhuman primates for over three decades. Housing over 5,000 nonhuman primates comprising nine species, the TNPRC has unparalleled technical expertise and specialized resources to perform nonhuman primate-related biomedical research. The TNPRC is the only NPRC with an NIH-funded high containment Regional Biosafety Laboratory focused on research with emerging infectious disease and biodefense agents. For more information, visit www.tpc.tulane.edu.

About Respirics

Respirics Inc. is a pulmonary drug delivery and development company located in Raleigh, North Carolina. The company is developing a line of branded inhalation drug products in its patented Acu-Breathe™ dry powder inhalers, and is working with pharmaceutical clients to enhance the delivery of their own compounds or formulations. Respirics combines proprietary inhalation technology with powder drug formulation expertise to develop unique drug delivery solutions. The company is committed to bringing effective, easy-to-use and affordable inhalation drug products to the patients who need them. For more information, visit www.respirics.com.

About Next Breath LLC

Located in Baltimore, MD, Next Breath is a contract services provider for pharmaceutical, biotech and medical device companies that bring new inhalation and nasal products to market. Next Breath has broad experience with drug delivery devices including nasal pumps, metered dose inhalers, dry power inhalers, nebulizers and spacers. Next Breath is a GMP laboratory providing an array of in vitro services ranging from pre-clinical formulation development to analytical testing, in support of submissions made to regulatory agencies. For more information, visit www.nextbreath.net.

About Lovelace Respiratory Research Institute

Lovelace Respiratory Research Institute (LRRI), through its wholly owned subsidiary, Lovelace Biomedical and Environmental Research Institute (LBERI), is a private biomedical research organization with a broad range of research capabilities and alliances with government, industry, universities, health advocacy organizations, and the public. LBERI offers this team its 50+ years of internationally recognized expertise in aerosol science and inhalation exposure technology, including aerosol generation and delivery techniques, sampling instrumentation and strategies, exposures, dosimetry of inhaled particles, and characterization and behavior of airborne particles. LBERI also provides safety, pharmacokinetic and toxicology support for products requiring FDA oversight. LBERI has a strong focus in virology, immunology, and infectious disease along with a complementary focus in the pharmaceutical and biopharmaceutical contract arena. LBERI supports national security, law enforcement, industry, and medical communities by improving the understanding of the possible use of biological weapons, biological agent pathogenesis, dissemination principles, and bio-threat prevention.

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