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Nanotherapeutics Awarded $20 Million NIAID/BARDA Contract to Develop Inhaled Gentamicin for Treatment of Aerosol Exposure to Bioterrorism Agents

ALACHUA, Fla.--(BUSINESS WIRE)--Nanotherapeutics, Inc., today announced that it has been awarded a $20 Million 4-year contract from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA) to develop an inhaled version of the injectable drug, gentamicin, a broad-spectrum antibiotic that is used as a first-line therapy for pneumonic plague and tularemia, Category A bioterrorism agents. Both diseases are highly infectious and could pose a serious danger if used as an aerosolized biological weapon.

Using its novel particle formulation, the company has developed NanoGENT™, an inhaled dry-powder formulation of gentamicin, to provide early treatment for exposure to biological warfare agents, as well as TB and other respiratory infections. In the event of an accidental or deliberate exposure to these agents, noninvasive drug delivery systems, such as improved inhaled and nasal delivery would be especially beneficial for administering wide-spread immediate post-exposure prophylaxis and treatment using disposable multi-dose inhalers with adequate shelf-life stability.

James D. Talton, Ph.D., President and C.E.O. of Nanotherapeutics and co-founder of the company said, “We are very pleased to receive this contract to fund this product development program. The continued support from the NIAID and BARDA of Nanotherapeutics’ proprietary drug delivery systems is a terrific endorsement of our technologies and manufacturing capabilities. The continued development of NanoGENT™ with our partners Respirics, Next Breath, Lovelace Respiratory Research Institute, and i3Research is a strategically important milestone for the company as it demonstrates the utility of our technology to meet a significant medical need. We are confident we will be able to develop a novel improved formulation that can rapidly and effectively provide therapeutic results into a viable product.”

Gentamicin, the front-line therapy for plague and tularemia, is a generic drug approved by the FDA for injection. For many years it has been used in a saline nebulized version to treat *Pseudomonas* respiratory infections, particularly in patients with cystic fibrosis. Nanotherapeutics and its collaborators will continue the clinical development of NanoGENT™ and expect to bring it to human clinical trials to evaluate the safety and pharmacokinetics in the fourth year of its NIAID/BARDA contract.

In 2005, Nanotherapeutics received funding from National Institute on Drug Abuse (NIDA) to develop an oral medication to treat opiate addiction. The company also received funding from the NIAID, as part of the NIH research program on Medical Countermeasures against Radiological and Nuclear Threats, to test the oral delivery of DTPA, an injectable treatment, and from Project Bioshield for preliminary testing of NanoGENT™. Nanotherapeutics has one approved injectable product and several products in advanced development, manufactured in-house under cGMP. This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Disease, National Institutes of Health (NIAID) and the Biomedical Advanced Research and Development Authority (BARDA), Department of Health and Human Services (DHHS), under Contract No. HHSN27220070030C"

About Nanotherapeutics

Nanotherapeutics Inc., an emerging specialty pharmaceutical company with expertise in the early stage development of pharmaceuticals, is a privately held corporation located in Florida. The company is a provider of specialized drug delivery systems that use the company’s discoveries in nanotechnology to

develop novel drug therapies or improved formulations for existing therapies. The company employs several platform technologies to manipulate and enhance the properties of drugs. 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.

Significant advances have been made in the area of nanometer-scale particle delivery, and Nanotherapeutics has created three proprietary drug delivery technologies: NanoQUAD™, NanoDRY™, and NanoCOAT™. These specialized proprietary techniques can improve the release rate and enhance both the rate and extent of drug uptake, thus increasing bioavailability. The consequences of these changes include more consistent drug therapy with potentially reduced dose and dose frequency requirements and fewer side effects.

For more information about Nanotherapeutics visit the company's website at www.nanotherapeutics.com.

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 biothreat prevention.

About i3Research

i3 Research is a full-service, global contract research organization focused on: central nervous system; oncology; respiratory and infectious diseases, cardiology and endocrinology and metabolic disease. i3 Research is experienced in designing, planning and executing studies of all sizes and is driven by its therapeutic specialization; from project staffing and talent management to quality initiatives, such as six sigma, i3 Research relies on thought leaders in each of its therapeutic areas to integrate teams medically, scientifically and operationally, helping to ensure that customer needs are met or exceeded. i3 Research is a business unit of i3, a global Ingenix company, providing integrated scientific strategies and solutions throughout the pharmaceutical product lifecycle. Additional i3 business units are: i3 Drug Safety, engaged in pharmacovigilance and epidemiology; i3 Statprobe, a leader in comprehensive data services; i3 Pharma Resourcing, a world-class staffing partner; and i3 Innovus, delivering the science and solutions to achieve marketplace success. i3 helps companies gain sharper insights that lead to better patient care. For more information, visit www.i3global.com.

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