HHS, DoD, VenatoRx Pharmaceuticals to Co-Develop Novel Antibiotic to Treat Drug-Resistant Infections

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WASHINGTON & MALVERN, Pa.--(BUSINESS WIRE)--The U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) will collaborate with the U.S. Department of Defense's Defense Threat Reduction Agency (DTRA) and VenatoRx Pharmaceuticals, Inc. of Malvern, Pennsylvania, to develop a novel antibiotic to treat infections caused by bacteria resistant to currently available agents.

The U.S. Centers for Disease Control and Prevention designated antibiotic-resistant infections, including infections such as carbapenem-resistant Enterobacteriaceae (CRE), as urgent public health threats. CDC estimates that antibiotic-resistant infections affect at least two million people in the United States each year and drive $35 billion in healthcare system costs annually.

VenatoRx's clinical-stage candidate includes a novel compound, VNRX-5133, which when combined with cefepime, a currently marketed antibiotic, may overcome certain forms of antibiotic resistance. This approach could enable cefepime/VNRX-5133 to treat infections caused by some drug-resistant bacteria not susceptible to currently available antibiotics.

Cefepime/VNRX-5133 holds potential as an intravenous treatment for drug-resistant gram-negative infections that cause complicated urinary tract infections (cUTI), hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, as well as the potential bioterrorism pathogens that cause glanders and melioidosis.

ASPR's interest in antibiotic-resistant infections stems from the need for biodefense preparedness. Terrorists or nation states can develop antibiotic-resistant pathogens for use in bioterrorism. In addition, after chemical, biological, radiological or nuclear emergencies, survivors can develop secondary infections that are resistant to antibiotics. In this way, antibiotic resistance complicates any emergency response, particularly those to biothreats.

"Developing new antibiotics that represent an improvement over standard of care antibiotics is essential to national health security and global health efforts to combat antibiotic-resistant infections," explained Rick Bright, Ph.D., director of the Biomedical Advanced Research and Development Authority (BARDA), within ASPR. "This unique public-private partnership will focus on adding a new tool to healthcare providers' toolkits and to help them save lives in an incident involving some of the serious bioterrorism threats our country faces."

BARDA will provide up to $20.7 million over two years to VenatoRx under a cost-sharing contract to support the development and studies needed for submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing authorization of cefepime/VNRX-5133 to treat cUTI. The contract can be extended to provide up to a total cost-share of $86.8 million over six years.

BARDA and VenatoRx will share the costs of all studies needed to bring the drug to market, including planned pivotal Phase 3 clinical trials to treat cUTI, hospital-acquired and ventilator-associated bacterial pneumonia, carbapenem-resistant pathogens, and a data package to potentially support the use of cefepime/VNRX-5133 in the treatment of melioidosis and glanders. VenatoRx will lead all regulatory activities needed to seek FDA approval of cefepime/VNRX-5133 under this cost-sharing contract.

In parallel with the BARDA-supported work, DTRA will provide up to $10 million through its bacterial Rapid Acquisition Platform program to fund the nonclinical biodefense aspects of the inter-agency collaboration. This work includes execution of non-clinical potency and efficacy studies to test cefepime/VNRX-5133 against biothreat bacterial pathogens, beginning with *Burkholderia pseudomallei,* which causes melioidosis.

“DTRA is thrilled to expand the interagency strategic partnership with BARDA to ensure critical public health and defense medical needs are met with an eye toward both civilian and military utility,” according to Dr. Ron Hann, director of the Chemical Biological Technologies Department in DTRA’s Research and Development Directorate. “These joint programs will ensure that we deliver FDA-approved therapies to the U.S. military forces to combat the threat of antibiotic resistant bioterrorism.”

If successful, this therapy would increase treatment options for patients with antibiotic-resistant gram-negative infections, potentially reducing the cost and complications associated with extended hospital stays.

This project is the second under an ASPR-DTRA partnership agreement signed in October 2018. With cefepime/VNRX-5133, BARDA’s development portfolio includes 15 products to combat antimicrobial resistant infections that pose bioterrorism and urgent public health threats, in addition to 29 therapeutics, one vaccine, and five diagnostics being developed with BARDA funding under the CARB-X partnership.

BARDA continues to seek proposals for the development of effective products to diagnose and treat antimicrobial-resistant infections and other biothreats. Proposals are accepted through the Broad Agency Announcement 18-100-SOL-00003 at the Federal Business Opportunities website, www.fbo.gov.

About HHS, ASPR and BARDA

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of the Office of the Assistant Secretary for Preparedness and Response (ASPR) is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats.

For more about ASPR and BARDA, visit www.phe.gov/aspr; and to learn more about partnering with BARDA, visit www.medicalcountermeasures.gov.

About DTRA

The Defense Threat Reduction Agency (DTRA), an agency within the United States Department of Defense (DoD), is the official Combat Support Agency for countering weapons of mass destruction (chemical, biological, radiological, nuclear, and high explosives). The Defense Threat Reduction Agency enables DoD, the U.S. government, and international partners to counter and deter weapons of mass destruction and improvised threat networks. Under the auspice of the Chemical and Biological Defense Program, DTRA has the responsibility to manage and integrate the DoD chemical and biological defense science and technology programs. DTRA's continued effort to enhance the combat support mission also advances public health services by developing innovative technologies that protect against biological threats. For more information, visit www.dtra.mil.

About VenatoRx Pharmaceuticals, Inc.

VenatoRx Pharmaceuticals is a private, clinical-stage pharmaceutical company dedicated to the discovery and development of new medicines to treat drug-resistant infections. More information is available at www.venatorx.com.

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