News

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HHS funds drug for bioterrorism, antimicrobial-resistant infections

A new drug to help protect the public against two bioterrorism threats and provide a new option to treat antibiotic-resistant infections will advance in development under a public-private partnership, the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) (http://www.phe.gov/about/aspr/Pages/default.aspx) announced today.

" Antibiotic resistance adversely impacts our nation' s ability to respond effectively to a bioterrorism attack and to everyday public health threats," said Robin Robinson, Ph.D., director of ASPR' s Biomedical Advanced Research and Development Authority (BARDA) (http://www.phe.gov/about/barda/Pages/default.aspx), which will oversee the project. " By partnering with industry to develop novel antimicrobial drugs against biothreats that also treat drug-resistant bacteria, we can address health security and public health needs efficiently."

BARDA will support the development of Carbavance under a five-year cost-sharing agreement with Rempex Pharmaceuticals Inc. (a wholly owned subsidiary of The Medicines Company) in San Diego. The agreement includes an initial commitment from BARDA of $19.8 million and can be extended to provide up to $90 million over the five years.

The two bioterrorism threats are melioidosis and glanders. With existing antibiotic treatments, approximately 40 percent of people who become ill from these bacteria die from the illness, and up to 90 percent die if not treated.

Melioidosis, also called Whitmore's disease, can be mistaken for other diseases such as tuberculosis and common forms of pneumonia. The bacteria that cause melioidosis can be found in water and soil, and cause infection when a person touches or inhales the bacteria. The infection is common in parts of Southeast Asia and Australia.

Glanders is a respiratory disease that can affect people, although it is primarily found in animals. The bacteria that cause glanders can affect skin, blood, lungs, or muscles, and may be transmitted through direct contact with infected animals or by inhaling contaminated aerosols or dust.

Melioidosis and glanders can become resistant to existing antibiotics.

In addition to showing promise as a treatment for melioidosis and glanders in a bioterrorism event, Carbavance potentially could be used commercially to treat complicated urinary tract infections, hospital-acquired pneumonia, ventilator-acquired pneumonia, and carbapenem-resistant Enterobacteriaceae (CRE) (http://www.cdc.gov/HAI/organisms/cre/), all of which can be resistant to existing antibiotics.

CRE are a family of bacteria that have been called nightmare bacteria (http://www.cdc.gov/media/releases/2013/t0305_lethal_cre.html) because the bacteria are resistant to all or nearly all antibiotics, kill up to half of people who get serious infections with them, and can spread their resistance to other bacteria. CRE infections have been detected in nearly every state, and the incidence has risen sharply over the past five years.

Patients whose care requires devices such as ventilators, urinary (bladder) catheters, or intravenous (vein) catheters, and patients who are taking long courses of certain antibiotics are most at risk for CRE infections.

The project includes preclinical and clinical studies, manufacture of enough of the drug for clinical studies, and other manufacturing-related activities needed to apply for U.S. Food and Drug Administration approval of the drug.

The project with Rempex is the latest in a BARDA program that supports development of broad-spectrum antimicrobials, technologies and platforms for biodefense needs that simultaneously address other public health challenges, such antibiotic-resistant infections.

BARDA is seeking additional proposals for advanced development of novel antimicrobials to treat illness caused by biological threat agents and that also could address the growing threat of antimicrobial resistance. Proposals are accepted through the Broad Agency Announcement BARDA-BAA-13-100-SOL-00013 at https://www.fbo.gov.

BARDA utilizes a comprehensive, integrated portfolio approach to support the advanced research and development, innovation, acquisition, and manufacturing of vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products for public health emergency threats. These threats include chemical, biological, radiological, nuclear threats, pandemic influenza, and emerging infectious diseases.

HHS (http://www.hhs.gov/) is the principal federal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. ASPR (http://www.phe.gov/about/aspr/Pages/default.aspx) is an HHS leader in preparing the nation to respond to and recover from adverse health effects of emergencies, supporting communities' ability to withstand adversity, strengthening health and response systems, and enhancing national health security.

For more information on national public health and medical preparedness, visit www.phe.gov and to learn more about partnering with BARDA in public health preparedness visit www.medicalcountermeasures.gov.

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