



Biodefense solutions to protect our nation

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USAMRIID's Next Generation Anthrax Vaccine Acquired for Advanced Development

An anthrax vaccine discovered and initially developed by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has been acquired by a Maryland-based firm for advanced development that could lead to eventual licensure of the product by the Food and Drug Administration.

According to company officials, Emergent BioSolutions Inc. has acquired the next generation anthrax vaccine, as well as the technology on which it is based. This vaccine candidate was patented by USAMRIID and previously licensed to a company called VaxGen, which had pursued advanced development since 2002 under a contract from the U.S. Department of Health and Human Services.

The vaccine uses recombinant protective antigen, or rPA, a protein secreted by the anthrax bacterium, *Bacillus anthracis*. This protein induces the body's immune system to produce antibodies against the bacteria's toxins. In several nonhuman primate studies conducted at USAMRIID, rPA has demonstrated the ability to induce a high level of protection against inhalational anthrax—the type most likely to occur following a bioterrorist event.

“We believe this acquisition will facilitate the continued development of this promising anthrax vaccine candidate,” said Colonel George W. Korch, Jr., commander of USAMRIID. “We are excited about the future prospects for rPA as an effective medical countermeasure for the nation's biodefense.”

Anthrax is caused by spores and most commonly occurs in wild and domestic mammals, although it has the potential to be used as a biological threat agent. Symptoms vary depending on the route of exposure; however, sore throat, mild fever, and muscle aches usually begin within 7 days of exposure. Severe breathing difficulty, shock, and meningitis can follow, and as the bacteria multiply in the lymph nodes, toxemia progresses and the potential for widespread tissue destruction and organ failure increases. Up to 90 percent of untreated cases of inhalational anthrax result in death. Obtaining an alternative for the currently licensed anthrax vaccine would provide the Department of Defense—and the nation—with additional options in protecting against this threat.

USAMRIID's proprietary technology also has a number of potential manufacturing advantages, including the ability to express full-length soluble anthrax PA in a non-toxic, non

spore-forming strain of the anthrax bacterium. When full-length rPA is expressed in anthrax bacteria, it is secreted into the culture fluid, from which it can be isolated in a highly purified form. This material also has the potential to provide broader protection against anthrax.

“By acquiring this particular vaccine candidate, Emergent will be able to leverage over a decade of development work conducted at USAMRIID and 5 years of experience and advanced development work conducted by VaxGen, in order to continue the development of this vaccine through to licensure,” said Fuad El-Hibri, chairman and chief executive officer of Emergent BioSolutions Inc.

USAMRIID, located at Fort Detrick, Maryland, is the lead medical research laboratory for the U.S. Department of Defense Biological Defense Research Program, and plays a key role in national defense and in infectious disease research. The Institute conducts basic and applied research on biological threats resulting in medical solutions (such as vaccines, drugs and diagnostics) to protect the warfighter. While USAMRIID’s primary mission is focused on the military, its research often has applications that benefit society as a whole. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command. For more information, visit www.usamriid.army.mil

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