

Applied Biomedical Science

AUTOIMMUNE TECHNOLOGIES ANNOUNCES DEVELOPMENT OF NEW VIRAL HEMORRHAGIC FEVER TEST FOR USE IN AFRICA AND AGAINST DOMESTIC BIOTERRORISM THREAT

New recombinant proteins and monoclonal antibodies make effective diagnostic tests possible and may lead to a vaccine

NEW ORLEANS, October 15, 2007 - Autoimmune Technologies, LLC, a New Orleans biomedical company, announced that its ELISA test kits utilizing new recombinant viral proteins and monoclonal antibodies have successfully completed initial clinical testing in Sierra Leone, where the kits were used to diagnose Lassa hemorrhagic fever. Lassa fever is a disease that is endemic in West Africa, where every year it is estimated to routinely infect 300,000 to 500,000 people and cause approximately 5,000 deaths. During some seasons, the case-fatality rate can reach 50%.

The Lassa fever virus, which is normally spread by a single species of West African rodent, is considered to be a potential bioweapon which could be used against countries on other continents. The new ELISA test kit and other tests and related products are being developed by Autoimmune Technologies and its consortium partners under a \$3.8 million biodefense challenge grant awarded by the National Institutes of Health (NIH) in 2005. Together with Autoimmune, the consortium partners are Tulane University School of Medicine, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), BioFactura, Inc., and Corgenix Medical Corporation.

To manufacture the new test kits, recombinant proteins developed by the consortium are used in place of the potentially deadly Lassa fever virus itself. This breakthrough allows the kits to be made less expensively in ordinary laboratories instead of in the high-containment "spacesuit" facilities which are required for the manufacture of current Lassa tests. In addition, the consortium tests work faster and provide more information concerning the patient's condition if he or she has indeed contracted the Lassa fever virus.

Dr. Russell B. Wilson, president and chief science officer of Autoimmune, said "The work of the consortium has significantly advanced the state of the art in protecting humans from the dangers of arenaviruses such as Lassa. The extensive panel of recombinant arenavirus proteins and monoclonal antibodies to those recombinant proteins which the consortium has produced constitutes a unique and highly valuable set of tools for the continuing development of new methods to diagnose, prevent, and potentially treat viral hemorrhagic fevers."

The clinical studies of the new test kits are being conducted through the Mano River Union Lassa Fever Network in Sierra Leone. Under a contract with the World Health Organization, Tulane manages a program in the Mano River Union countries - Sierra Leone, Liberia and Guinea - which aims to assist in the development of national and regional prevention and control strategies for Lassa fever and other regional diseases. "The newly developed assays continue to show remarkable results in Sierra Leone," said Joseph Fair, a Tulane doctoral candidate who is conducting the field testing.

Dr. Robert F. Garry of Tulane, the principle investigator under the NIH challenge grant, was instrumental in assembling the consortium. "We believe this remarkable collaboration will not only result in diagnostic and detection products that will truly have a meaningful impact on the healthcare in West

Africa, but will also fill a critical gap in bioterrorism defense," Dr. Garry said. The new proteins, antibodies, and methods for the design, production, and use of soluble and membrane-anchored forms of the proteins already developed by the consortium represent significant scientific advances, he noted, and raise the expectations of the consortium members that these and related proteins will lead to a vaccine for Lassa virus and other arenaviruses. The consortium intends to pursue this vaccine work and to expand its program to address other important infectious agents which pose both clinical health issues and a threat of bioterrorism, such as Ebola fever and Marburg fever viruses.

Autoimmune Technologies is a privately held biomedical company. In has licensed several breakthrough research discoveries from Tulane University School of Medicine and has made exciting discoveries of its own. Autoimmune is working to offer new diagnostic tests and new anti-viral therapeutics to the medical community based on this proprietary research.

USAMRIID, located at Fort Detrick, Maryland, is the lead medical research laboratory for the U.S. Biological Defense Research Program and plays a leading role in national defense and in infectious disease research. The Institute's mission is to conduct basic and applied research on biological threats resulting in medical solutions, such as vaccines, drugs and diagnostics, to protect the warfighter. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command.

BioFactura, of Rockville, Maryland, is a biopharmaceutical development company focused on solving unmet medical and national security needs in the infectious disease arena. Its product pipeline includes therapeutics, vaccines, diagnostics, and bio-manufacturing technologies.

Corgenix is a leader in the development and manufacturing of specialized diagnostic kits for immunology disorders, vascular diseases and bone and joint disorders. Corgenix's diagnostic products are commercialized for use in clinical laboratories throughout the world, and the company currently sells more than fifty diagnostic products through a global distribution network.

For further information, please visit www.autoimmune.com.

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