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CONTACT: Caree Vander Linden
(301) 619-2285
teresa.l.vanderlinden.civ@mail.mil

USAMRIID Receives Technology Transfer Award for Experimental Ebola Treatment

CHICAGO – Scientists from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) were recognized for their work on ZMapp, a therapeutic monoclonal antibody "cocktail" designed to treat Ebola virus infection, at the Federal Laboratory Consortium for Technology Transfer (FLC) national meeting held this week.

According to the consortium, the Excellence in Technology Transfer Award is presented annually by the FLC to recognize "laboratory employees who have accomplished outstanding work in the process of transferring federally developed technology." Dr. Mark Dertzbaugh, chief of USAMRIID's Business Plans and Programs Office, accepted the award on behalf of the Institute.

In August 2014, within days of being infected with the Ebola hemorrhagic fever raging around them, two American missionaries serving as medical workers in Liberia received an antibody cocktail called ZMapp and were flown back to the United States to fight for their lives. This experimental treatment had never been tested on humans, but had demonstrated considerable success in nonhuman primate studies at USAMRIID—and there were few other options. Physician Kent Brantly showed improvement after just one dose, and aid worker Nancy Writebol recovered after receiving two doses of ZMapp.

This dramatic story highlights the critical research done at USAMRIID, according to Dertzbaugh. While the Institute's primary mission is to develop medical countermeasures to protect U.S. service members, its work often benefits civilian and global public health as well. In the case of ZMapp, USAMRIID scientists had developed one of the three monoclonal antibodies used in the cocktail, and it was licensed to Mapp Biopharmaceutical (MappBio) of San Diego in October 2009—five years before the unprecedented Ebola outbreak in Western Africa.

"The license agreement between the Army and MappBio was the first in the Department of Defense, and perhaps in the nation, to leverage the Tropical Disease Priority Review Voucher (PRV) Program of the Food and Drug Administration," said Barry M. Datlof, director of Medical

Technology Transfer at the U.S. Army Medical Research and Materiel Command (USAMRMC), which manages license agreements for USAMRIID.

Launched in 2007, the PRV program provides incentives for pharmaceutical companies to find effective treatments where no adequate therapy exists. Under the program, the first company that receives FDA approval for a treatment or vaccine targeting certain tropical diseases can request a PRV, which can be used by the company to speed FDA review of one of its own drugs or be sold to another pharmaceutical company. A priority review designation by the FDA brings additional agency resources to bear during the drug review process, with the FDA goal of completing it within six months rather than the ten-month goal of standard review designation.

"By incorporating FDA's voucher program into licensing negotiations, we have seen a surge of interest throughout the pharmaceutical industry in investing in the research and development of viable treatments for infectious diseases of all kinds," Datlof said. "It also serves as a source of potential financial windfalls for the companies involved and for the laboratories."

Terms originally developed for the MappBio agreement regarding a potential PRV are now standard in all tropical disease licenses negotiated by USAMRMC, according to Datlof.

Former USAMRIID scientists Mary Kate Hart, Ph.D., Alan Schmaljohn, Ph.D., and Julie A. Wilson, Ph.D., were credited with the original invention of the monoclonal antibody. The team produced the antibody by first injecting mice with the Ebola glycoprotein gene, which enables the virus to attach to human cells. Each antibody-producing plasma cell generated by the mice was fused with a cancer cell, producing a hybridoma that continues to divide in the culture, creating a single type of antibody.

After extensive screening, the team identified Ebola-specific antibodies that adhere to the Ebola glycoprotein and stop reproduction of the virus. One of these became part of the ZMapp cocktail after being "humanized" to prevent rejection by the human body. The antibodies in the cocktail are manufactured in tobacco plants. Currently, Phase I, Class II clinical trials of ZMapp are underway in Western Africa.

Ebola virus causes severe hemorrhagic fever in humans and nonhuman primates with high mortality rates and continues to emerge in new geographic locations, including Western Africa, the site of the largest recorded outbreak to date. Over 28,000 confirmed, probable and suspected cases have been reported in Guinea, Liberia and Sierra Leone, with over 11,000 reported deaths, according to the World Health Organization.

USAMRIID scientists began seeking therapeutic interventions soon after the disease was identified in 1976, but there was little interest among the pharmaceutical industry, Dertzbaugh noted. Pursuing treatment was costly and the market for an Ebola drug was limited. Not only were Ebola outbreaks rare, they occurred primarily in underdeveloped countries with minimal

health care resources. The unprecedented outbreak in Western Africa brought worldwide attention to the disease—and to the critical need for medical solutions.

"At the end of the day, the transfer of USAMRIID technology is always about saving lives," Datlof commented. "Thanks to the excellence of this technology transfer effort, patients and healthcare providers now have hope of bringing an end to future outbreaks of Ebola."

USAMRIID's mission is to provide leading-edge medical capabilities to deter and defend against current and emerging biological threat agents. Research conducted at USAMRIID leads to medical solutions—vaccines, drugs, diagnostics, and information—that benefit both military personnel and civilians. The Institute plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense. 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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