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USU Researchers to support NIAID in US-Liberia Ebola Clinical Trial Partnership

Initial study will evaluate experimental drug cocktail ZMapp

Bethesda, MD -- A new clinical trial to obtain safety and efficacy data on the investigational drug, ZMapp, as a treatment for the Ebola virus, was launched today by the National Institute of Allergy and Infectious Diseases (NIAID), in partnership with the Liberian government. Scientists from the Uniformed Services University of the Health Sciences (USU) will play a role in the evaluation.

Dr. Mark Kortepeter, the Associate Dean for Research, and Dr. Scott Miller, Director of the Infectious Disease Clinical Research Program (IDCRP) in USU's F. Edward Hebert School of Medicine, are associate investigators for the study, which partners the IDCRP with NIAID, U.S. Ebola treatment units, and now sites in Liberia to conduct a randomized, controlled trial to evaluate potentially beneficial Ebola therapeutics. The FDA-regulated research protocol for the study is currently under ethical review at the infectious disease Institutional Review Board (IRB) at USU.

The research is designed to test best available therapies in an adaptive trial design, starting with a comparison of ZMapp monoclonal antibodies to an enhanced standard of supportive care. ZMapp, developed by San Diego-based Mapp Biopharmaceutical Inc., is designed to prevent the progression of Ebola virus disease within the body by targeting the main surface protein of the Ebola virus. The antibodies comprising ZMapp are produced in tobacco plants specially bioengineered to produce large quantities of these proteins. Studies in non-human primates demonstrated that ZMapp has strong antiviral activity and rescued the animals from death as late as five days after infection with Zaire ebolavirus. The drug has not yet been tested in human clinical trials, but was administered under emergency use authorization to nine infected patients in Africa, the U.S. and Western Europe.

The trial will be led by co-principal investigators Richard T. Davey, Jr., MD, deputy clinical director of NIAID's Division of Intramural Research, and Moses Massaquoi, M.D., National Chair for Case Management at the Ebola Incident Management System in Monrovia. The trial will enroll adults and children of any age who have been admitted to Ebola treatment units in Liberia, and health care workers who were infected through secondary transmission with Ebola virus in West Africa and have returned to the U.S.

Treatment centers in Monrovia, Liberia, will include the ELWA 2 Ebola treatment unit and the Monrovia Medical Unit – staffed by the Commissioned Corps of the U.S. Public Health Service. The NIH Clinical Center in Bethesda, Maryland will serve as a treatment center in the U.S. Additional trial sites under consideration in the U.S. include the Walter Reed National Military Medical Center in Bethesda, Md., Emory University Hospital in Atlanta, and the University of Nebraska Medical Center in Omaha, Neb.

“The use of the USU's central IRB and the IDCRP network would allow a rapid approval of additional sites within the DoD health system, if needed, and allow military beneficiaries access to state-of-the-art research,” said Kortepeter.

Learning to Care for Those in Harm's Way

The trial is expected to conclude in December 2016. Given the current decline in the number of new Ebola cases in Liberia, study investigators anticipate the need for flexibility in the conduct and design of the trial to address the changing nature of the outbreak in West Africa. Consideration will also be given to other sites in the outbreak region that express interest.

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About USU

The Uniformed Services University of the Health Sciences, founded by an act of Congress in 1972, is the nation's federal health sciences university and the academic heart of the Military Health System. USU students are primarily active duty uniformed officers in the Army, Navy, Air Force and Public Health Service who receive specialized education in tropical and infectious diseases, TBI and PTSD, disaster response and humanitarian assistance, global health, and acute trauma care. A large percentage of the university's more than 5,000 physician and 1,000 advanced practice nursing alumni are supporting operations around the world, offering their leadership and expertise. USU also has graduate programs in biomedical sciences and public health committed to excellence in research, and in oral biology. The University's research program covers a wide range of clinical and other topics important to both the military and public health. For more information about USU and its programs, visit www.usuhs.edu.