Hawaii Biotech, Inc.

HAWAII BIOTECH RECEIVES CONTRACT TO DEVELOP DENGUE VACCINE

FOR IMMEDIATE RELEASE
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(Honolulu, Dec. 03, 2015) -- Hawaii Biotech, Inc. (HBI), announced today that the US Army SBIR Program awarded the company a Small Business Innovation Research (SBIR) Phase I contract to develop an effective dengue vaccine to protect military personnel against this potentially mission-aborting disease.

Current leading dengue vaccine candidates in clinical trails offer only partial protection and long immunization periods. International travelers and military personnel being deployed to tropical or subtropical regions require more immediate and more complete immunity.

Specifically, HBI will develop and test novel adjuvants to enhance the immunogenicity of an inactivated dengue vaccine candidate. This effort takes the initial steps toward developing the world's first vaccine capable of rapidly generating complete, lasting protection from dengue fever.

"The growing outbreak of dengue fever in Hawaii highlights the need for stronger containment efforts now, and a commitment to preventing additional outbreaks in the future. This vaccine has the potential to seriously improve the response to dengue fever both in Hawaii, and around the world, and I am pleased that the Army has awarded this important research and development contract to a local Hawaii business," said Tulsi Gabbard.

"This contract will enable Hawaii Biotech to apply our many years of experience in viral vaccine development and our knowledge of the challenges in developing a dengue vaccine to this important mission," said Elliot Parks, CEO.

In Phase I, HBI will select suitable adjuvant formulations and then demonstrate protective efficacy in a mouse model with a single dengue serotype. Upon successful completion of Phase I, HBI will be eligible to apply for Phase II funding that will continue development of the inactivated dengue vaccine candidate. This will include expanding the work to all four dengue serotypes to establish feasibility of the required tetravalent vaccine for dengue and additional preclinical efficacy studies. A successful Phase II outcome will provide the basis for advancement of the dengue vaccine into clinical trials needed for regulatory approval and commercialization.

This contract was funded by the Army SBIR Program. The work is managed by the US Army Medical Research and Materiel Command under Contract No. W81XWH-15-C-0120 and will be managed and done in collaboration with the Viral and Rickettsial Diseases Department at the Naval Medical Research Center.

The views, opinions and/or findings contained in this report are those of the author and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation. In conducting research using animals, the investigator will adhere to the Animal Welfare Act Regulations and other Federal statutes relating to animals and experiments involving animals and the principles set forth in the current version of the Guide for Care and Use of Laboratory Animals, National Research Council.

About Hawaii Biotech, Inc. (HBI):

Hawaii Biotech is a privately held biotechnology company focused on the development of prophylactic vaccines for established and emerging infectious diseases and anti-toxin drugs for biological threats. HBI has developed proprietary expertise in the production of recombinant proteins that have application to the manufacture of safe and effective vaccines, diagnostic kits, and as research tools. The company has developed a product pipeline of recombinant subunit vaccines, including vaccine candidates for dengue fever, West Nile virus, tick-borne flavivirus, malaria, Crimean-Congo hemorrhagic fever, and Ebola. HBI completed successful first-in-human Phase 1 clinical studies with both West Nile virus and dengue vaccines in healthy human subjects. The company is also continuing the development of small molecule anti-toxin drugs for anthrax and botulism. HBI, founded in Hawaii in 1982, is currently headquartered in suburban Honolulu. For more information, please visit: www.hibiotech.com

About Dengue:

Dengue, also known as "break-bone fever," is a prevalent disease in tropical and subtropical countries throughout the world. Approximately 3.5 billion people live in endemic countries and about 100 million people are infected with dengue every year. It is currently ranked 2nd in the Infectious Disease Threats to the U.S. Military Prioritization Panel (*DoD Memo: 23 April 2010*). Dengue infections result in an estimated 20,000 deaths.

There are currently no licensed vaccines to prevent dengue, nor drugs to treat dengue illness. Vaccination offers the most effective method of protecting at-risk individuals. Dengue is caused by one of four closely related, but distinct, virus serotypes (DEN1, DEN2, DEN3, and DEN4), of the family Flaviviridae, which also includes, yellow fever, West Nile, Japanese encephalitis, and tick-borne encephalitis viruses. Dengue is transmitted by the bite of a mosquito infected with any one of the four dengue viruses. Infection with dengue virus results in severe flu-like symptoms that can lead to a life-threatening hemorrhagic fever.

During the last quarter century, many tropical regions of the world have seen an increase in dengue cases. The southern United States is potentially susceptible to dengue epidemics as the types of mosquitoes that transmit dengue virus are prevalent there. Hawaii experiences intermittent, limited Dengue outbreaks. More than 100 cases of dengue fever have been reported in the most recent outbreak on Hawaii Island.

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