



# Hawaii Biotech, Inc.

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### **Hawaii Biotech's West Nile Vaccine Shows 100% Protection in Durability Study**

*Third Study Confirms Vaccine Candidate's Protective Efficacy*

**Honolulu, Hawaii—August 16, 2005**—Hawaii Biotech, Inc., a privately held biopharmaceutical company engaged in the research and development of human pharmaceuticals, announced today that in a third study its West Nile vaccine protected 100 percent of test animals from both illness and death after six months when challenged with live West Nile Virus. In contrast, 53.3 percent of the control animals died, and surviving control animals all showed signs of illness. Two previous studies, in which longer term durability was not assessed, also demonstrated 100 percent protection from both illness and death following live West Nile Virus challenge. An additional study examining protection at one year is underway.

The latest vaccine efficacy durability study was conducted in a well-validated model of human West Nile disease, the golden hamster, developed at the University of Texas Medical Branch. The study consisted of three groups of fifteen animals each: one control group and two groups immunized with Hawaii Biotech proprietary vaccine formulations. Each group was vaccinated on day one, boosted on day 28 (controls were vaccinated and boosted with adjuvant only), and then challenged six months post boost with a lethal dose of live West Nile Virus. Morbidity and mortality were monitored for 30 days. The results showed that all 30 animals that received Hawaii Biotech's vaccine remained alive and healthy, with no signs of illness at any time during the study. In contrast, all 15 control animals, or animals that did not receive the vaccine became ill and eight died with encephalitis.

The durability study was conducted by Dr. Douglas Watts, Professor in the Department of Pathology, University of Texas Medical Branch at Galveston, and complements two previous studies conducted at the same university by Dr. Robert Tesh. "Vaccination is likely to be the most effective measure against an infectious disease such as West Nile," said Dr. Watts. "Hawaii Biotech's West Nile vaccine candidate has demonstrated strong protective efficacy and good durability extending out to at least six months."

Hawaii Biotech's genetically engineered, sub-unit vaccine technology represents a potentially safer, non-infectious alternative to live virus vaccines, which have an inherent risk of causing severe disease in some people. Hawaii Biotech's proprietary sub-unit vaccine, which combines a

modern adjuvant with genetically engineered viral proteins designed to eliminate the possibility of viral disease, may confer a substantial safety advantage.

“We are very encouraged by the efficacy, durability and safety profile of our West Nile vaccine candidate in these animal models,” said David G. Watumull, President and CEO of Hawaii Biotech. “While much work remains, these results support our goal of providing a non-infectious vaccine that generates safe and effective protection against West Nile Virus infection across all age groups.

### **About West Nile Virus**

Virtually unknown in the U.S. prior to 1999, the West Nile virus is now established throughout the U.S., Canada and Mexico (or North America). Approximately 20 percent of those infected develop systemic febrile illness, while about one out of 150 progress to develop severe neurological symptoms. Approximately 5-14 percent of the latter cases are fatal. Moreover, in a high percentage of the non-fatal cases, permanent neurological disabilities result. These clinical findings are significantly worse in elderly patients. The CDC reported 2,539 cases and 100 deaths in 2004, with 1,141 (45 percent) of the 2,539 cases reporting neuroinvasive symptoms (meningitis, encephalitis, or a poliomyelitis-like syndrome).

### **About Hawaii Biotech**

Hawaii Biotech, Inc. is a privately held biopharmaceutical company engaged in the research and development of human pharmaceuticals. It is currently developing products from two broad product platforms:

- Small molecules with potent anti-inflammatory activity but without the side effects of steroids, aspirin, ibuprofen, Vioxx, and Celebrex. First applications include: the reduction of peri-procedural damage in angioplasty patients; and a treatment for macular degeneration.
- Targeted and rapid responses to emerging disease and bioterrorism. First applications include safer, highly protective vaccines for West Nile, dengue, and flu as well as small molecule therapeutics for anthrax and dengue.

For more information, please visit <http://www.hibiotech.com>

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