



## Hawaii Biotech, Inc.

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Contact:

David G. Watumull

President and CEO

Hawaii Biotech, Inc.

99-193 Aiea Heights Drive Suite 200

Aiea, Hawaii 96701

Tel: (808) 486-5333 Fax (808) 792-1343

E-mail: [dwatumull@hibiotech.com](mailto:dwatumull@hibiotech.com)

### **Hawaii Biotech Launches Vaccine Program to Protect Native Hawaiian Birds from West Nile**

*Likely West Nile Virus Spread Could Devastate Native Bird Population*

**Honolulu, Hawaii (June 1, 2005) – Hawaii Biotech, Inc.** announced today that, in collaboration with the University of Hawaii, the National Wildlife Center, and the National Park Service, it has launched a vaccine program designed to protect Native Hawaiian bird species from lethal West Nile virus. The spread of West Nile virus from the U.S. to Hawaii could decimate the Native Hawaiian bird population.

The program will first test the Company's vaccine's ability to protect U.S. mainland geese from infection by West Nile virus. If successful in these and other tests, the vaccine could be used to protect native Hawaiian birds, including the state bird, the Hawaiian Nene goose.

“West Nile virus is a real and imminent threat to the native Hawaiian bird population,” stated Duane Gubler, ScD, former director of the Department of Viral Born and Infectious Disease (DVBID) at the Centers for Disease Control (CDC) and now Director of the Asian-Pacific Institute of Tropical Medicine and Infectious Diseases at the John A. Burns School of Medicine at the University of Hawaii. “While we need to increase our surveillance and prevention methods for this mosquito born disease, a vaccine offers the best hope for protection of our native bird population.”

“Our West Nile vaccine has protected all of the nearly 200 animals tested to date,” said Carolyn Weeks-Levy, Ph.D., VP, Research, Development and Regulatory Affairs for Hawaii Biotech, Inc. “The goal of this new initiative is to extend this protection to Hawaii's native bird population.”

“This program helps demonstrate how biotechnology can help our community,” said David G. Watumull, President and CEO of Hawaii Biotech, Inc., “and is reflective of Hawaii Biotech's commitment to improving Hawaii.”

## **Program Overview**

Younger birds are most susceptible to West Nile morbidity and mortality and the first study will include six groups of ten young domestic U.S. geese. The sixty animals will be vaccinated at the University of Hawaii, Hilo with a first immunization at three weeks of age followed by a booster at six weeks. Five vaccinated individuals from each group will then be transported from Hawaii to the BSL-3 facility at the National Wildlife Center in Madison, WI for challenge with live West Nile virus at a maximum age of 3 months.

If the safety and efficacy of the vaccine is demonstrated in these animals, additional studies that could result in vaccination of Nene and other native Hawaiian birds will be pursued.

## **Program Collaborators**

The program is a collaboration among scientists at Hawaii Biotech, Inc. and

- University of Hawaii Hilo:
  - Susan Jarvi, MS, PhD, Assistant Professor and Principal Investigator (PI)
  - Mark Haines, DVM, MS, MPH, Assistant Professor, co-PI, veterinarian
- University of Hawaii Manoa
  - Vivek Neurakar, PhD, Professor, Retrovirology Research Lab
- U.S. Geological Survey, National Wildlife Center, Madison, WI
  - Christopher Brand, Branch Chief, Field and Laboratory Research
  - Eric Hofmeister, Veterinary Medical Officer
- National Park Service
  - Darcy Hu, Wildlife Biologist

## **West Nile Background**

Virtually unknown in the U.S. prior to 1999, the West Nile virus is now established throughout the U.S. and Canada. Approximately 20 % of those infected develop systemic febrile illness, while about 1 out of 150 progress to develop severe neurological symptoms. Approximately 5-14 % 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 Center for Disease Control reported 2,470 cases and 88 deaths in 2004, with 900 (36%) of the 2,470 cases reporting neuroinvasive symptoms (meningitis or encephalitis).

## **Hawaii Biotech's West Nile Vaccine**

Unlike most human viral diseases, West Nile causes both disease and death in animals. A well-validated model of human West Nile disease, the golden hamster, has been developed by Robert B. Tesh, M.D., of the University of Texas Medical Branch--Galveston and one of the leading researchers in this field. Dr. Tesh has completed a series of three efficacy studies in this model evaluating several formulations of Hawaii Biotech's West Nile vaccine. The studies consisted of groups of fifteen to thirty animals each depending on the study. In all cases the Hawaii Biotech candidate vaccine efficacy was compared to a naïve or adjuvant control. Each group received two doses of vaccine at approximately a one month interval and was challenged two-three weeks later with live West Nile virus. In one representative study, following challenge with live West Nile virus, 23 (77%) of control animals died and all others showed signs of illness. 100% of the animals in Hawaii Biotech's two vaccine groups remained alive and healthy with no evidence of virus replication in the blood. These results were highly statistically significant ( $p < 0.00001$ ). In addition, serological and immune parameters, such as hemagglutination-inhibition (HI), complement-fixation (CF), and *in vitro* virus neutralization (PRNT) tests clearly supported the efficacy.

## **Hawaii Biotech Overview**

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 (the “TRED” program). First applications include safer, highly protective vaccines for West Nile, dengue, and avian flu as well as small molecule therapeutics for anthrax and dengue. Hawaii Biotech’s vaccine technology was featured on the cover of the January 22, 2004 edition of *Nature* magazine.

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

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