



Hawaii Biotech, Inc.

**Soligenix Announces Collaboration with the  
University of Hawai'i at Mānoa and  
Hawaii Biotech to Develop Heat Stable Ebola Vaccine**

**ThermoVax™ Development Expands into Pandemic Infectious Disease**

**Princeton, NJ – May 28, 2015** – Soligenix, Inc. (OTCQB: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company developing products that address unmet medical needs in the areas of inflammation, oncology and biodefense, announced today a collaboration agreement with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), University of Hawai'i at Mānoa (UH Mānoa ) and Hawaii Biotech, Inc. (HBI) to develop a heat stable subunit Ebola vaccine. Dr. Lehrer, a co-inventor of the Ebola vaccine with HBI, has shown proof of concept efficacy with subunit Ebola vaccines in non-human primates. Under the terms of the feasibility agreement, Soligenix will evaluate its proprietary vaccine thermostabilization technology, ThermoVax™, licensed from the University of Colorado, to stabilize components of the vaccine. Ultimately, the objective is to produce a thermostable Ebola vaccine for worldwide distribution that does not require cold storage. ThermoVax™ has been previously demonstrated to enhance thermostability of both ricin (RiVax™) and anthrax (VeloThrax™) subunit vaccines. The initial work on the potential Ebola vaccine will focus on a single protein subunit antigen.

The most advanced Ebola vaccines involve the use of vesicular stomatitis virus (VSV) and adenovirus vectors – live, viral vectors which complicate the manufacturing, stability and storage requirements. Dr. Lehrer's vaccine is based on highly purified recombinant protein antigens, circumventing many of these manufacturing difficulties. Dr. Lehrer and HBI, have developed a robust manufacturing process for the required proteins. Application of ThermoVax™ may allow for a product that can avoid the need for cold-chain distribution and storage, yielding a vaccine ideal for use in both the developed and developing world.

"There is a great need for a thermostable Ebola vaccine, particularly in areas of the world where Filoviruses are endemic and the power supply uncertain," stated Dr. Lehrer, Assistant Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology at the JABSOM. "We are delighted to pursue this feasibility work with Soligenix and look forward to a long and productive collaboration."

"Coupling Soligenix's thermostabilization technology with Hawaii Biotech's robust manufacturing processes has the potential to yield a much needed vaccine to add to the world's arsenal against infectious disease and we look forward to working with both Soligenix and the JABSOM, UH Mānoa," said D. Elliot Parks, PhD, President and Chief Executive Officer of Hawaii Biotech.

"We believe that creating a vaccine with enhanced stability at elevated temperatures, which can obviate the costs and logistical burdens associated with cold chain storage and distribution, has the potential to provide a distinct advantage over other Ebola vaccines currently in development," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We are continuing to develop ThermoVax™ using RiVax™, our proprietary ricin

vaccine, under a recent National Institute of Allergy and Infectious Diseases (NIAID) contract award of up to \$24.7M over 6 years. We intend to apply this same technology beyond biodefense to emerging infectious diseases and see this collaboration with UH Manoa and Hawaii Biotech to be an important next step in demonstrating the broad applicability of this technology.”

### **About Ebola**

Ebola Virus Disease (EVD) is caused by one of five species of *Ebolavirus*, four of which cause disease in humans, including its best-known member, *Zaire Ebolavirus* (Ebola virus). All species of *Ebolavirus* belong to the *Filoviridae* family, a family that further contains the equally human pathogenic *Marburgvirus*. The Ebola virus is believed to be harbored in various animal species in Africa, although the specific reservoir host is still unknown. There have been several known EVD outbreaks in Africa since 1976, with the most recent and largest outbreak starting in 2014 in Western Africa.

Transmission of Ebola requires direct contact of bodily fluids from an infected person or contact with infected animals. The mortality rate from Ebola infection is extremely high, and can sometimes be affected by the quality of supportive care available with a focus on early initiation of treatment. Symptoms of Ebola virus infection include high fever, severe headache, muscle pain, weakness, fatigue, diarrhea, vomiting, abdominal pain and unexplained hemorrhage. Resolution of the disease largely depends on the patient’s own immune system. There is no approved treatment and no approved vaccine for Ebola, although research into both has accelerated since the onset of the 2014 outbreak.

The Ebola outbreak in 2014 primarily spanned three West African countries, and involved over 26,000 confirmed/probable/suspected cases with an estimated death toll of 10,892 people as of May 1, 2015 according to the Centers for Disease Control and Prevention (CDC), including some cases in Europe and the United States. The widespread nature of the infection and its devastating impact has further illustrated the need to develop an Ebola vaccine to prevent future and possibly more significant outbreaks.

### **About ThermoVax™**

ThermoVax™ is a technology that is designed to eliminate the standard cold chain production, distribution and storage logistics required for most vaccines. Cold chain requirements add considerable cost to the production and storage of current conventional vaccines. According to the Biopharma Cold Chain Sourcebook of 2010, 98% of all vaccines (with a total value of \$20.6 billion) require shipment through cold chain. Elimination of the cold chain would also enhance the utility of these vaccines for emerging markets and for other applications requiring but lacking reliable cold chain capabilities. Further, the World Health Organization (WHO) reports that 50% of all global vaccine doses are wasted because they are not kept within required temperature ranges. NIAID has also highlighted the priority of technologies for biodefense vaccines that focus on broad spectrum approaches including vaccine adjuvants and temperature stabilization for long shelf life, rapid onset of immunity, and surge capacity for production. For vaccines that are intended for long-term stockpiling, such as for use in biodefense or in pandemic situations, the utilization of ThermoVax™ has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency situations.

The technology utilizes precise lyophilization of protein immunogens with conventional aluminum adjuvants in combination with secondary adjuvants for rapid onset of protective

immunity with the fewest number of vaccinations. RiVax™ and VeloThrax™ are extremely labile in their liquid form requiring careful management under refrigerated conditions at 4 degrees Celsius (39 degrees Fahrenheit). By employing ThermoVax™ during their final formulation, it is possible to produce stable and potent vaccines that are capable of withstanding temperatures at least as high as 40 degrees Celsius (104 degrees Fahrenheit) for up to one year.

The underlying technology has been developed by Drs. John Carpenter and Theodore Randolph at the University of Colorado. The vaccine technology has been developed to date in collaboration with SRI International, the University of Kansas, the Wadsworth Center of the New York State Department of Health, and the Tulane National Primate Research Center under the sponsorship of a cooperative grant from NIAID.

### **About John A. Burns School of Medicine, University of Hawai'i at Mānoa**

The University of Hawai'i at Mānoa is one of the most ethnically diverse institutions of higher education. Hawai'i's cultural diversity and geographical setting affords the John A. Burns School of Medicine (JABSOM) a unique research environment to excel in health disparity research. JABSOM faculty bring external funding of about \$42 million annually into Hawai'i.

### **About Hawaii Biotech, Inc.**

Hawaii Biotech (HBI) 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. HBI completed successful first-in-human Phase 1 clinical studies with both West Nile virus and dengue vaccines in healthy human subjects. HBI has developed a product pipeline of recombinant subunit vaccines, including vaccine candidates for West Nile virus, tick-borne flavivirus, malaria, Crimean-Congo hemorrhagic fever, and Ebola. The company is also continuing the development of small molecule anti-toxin drugs for anthrax and botulism. HBI, founded in Hawaii in 1982, is headquartered in suburban Honolulu. For more information, please visit: [www.hibiotech.com](http://www.hibiotech.com)

### **About Soligenix, Inc.**

Soligenix is a late-stage biopharmaceutical company developing products that address unmet medical needs in the areas of inflammation, oncology and biodefense. Our BioTherapeutics business segment is developing SGX301 as a first-in-class photo-dynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, proprietary formulations of oral beclomethasone 17,21-dipropionate (BDP) for the prevention/treatment of gastrointestinal (GI) disorders characterized by severe inflammation including pediatric Crohn's disease (SGX203) and acute radiation enteritis (SGX201), and our novel innate defense regulator technology (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, VeloThrax™, our anthrax vaccine candidate, OrbeShield™, our GI acute radiation syndrome therapeutic candidate and SGX101 and SGX943, our melioidosis therapeutic candidates. The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax™. Currently, this business segment is supported with up to \$57 million in

government grant and contract funding from the National Institute of Allergy and Infectious Diseases (NIAID) and the Biomedical Advanced Research and Development Authority (BARDA). Additionally, Soligenix has an exclusive worldwide collaboration with Intrexon Corporation (NYSE: XON) focused on the joint development of SGX101 for the treatment for melioidosis.

For further information regarding Soligenix, Inc., please visit the Company's website at [www.soligenix.com](http://www.soligenix.com).

This press release contains forward-looking statements that reflect Soligenix, Inc.'s current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations and clinical trial enrollment. Statements that are not historical facts, such as "anticipates," "estimates," "believes," "intends," "potential," or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual events or results in future periods to differ materially from what is expressed in, or implied by, these statements. Soligenix cannot assure you that it will be able to successfully develop, achieve regulatory approval for or commercialize products based on its technologies, particularly in light of the significant uncertainty inherent in developing vaccines against bioterror threats conducting preclinical and clinical trials of vaccines, obtaining regulatory approvals and manufacturing vaccines, that product development and commercialization efforts will not be reduced or discontinued due to difficulties or delays in clinical trials or due to lack of progress or positive results from research and development efforts, that it will be able to successfully obtain any further funding to support product development and commercialization efforts, including grants and awards, maintain its existing grants which are subject to performance requirements, enter into any biodefense procurement contracts with the US Government or other countries, that it will be able to compete with larger and better financed competitors in the biotechnology industry, that changes in health care practice, third party reimbursement limitations and Federal and/or state health care reform initiatives will not negatively affect its business, or that the US Congress may not pass any legislation that would provide additional funding for the Project BioShield program. These and other risk factors are described from time to time in filings with the Securities and Exchange Commission, including, but not limited to, Soligenix's reports on Forms 10-Q and 10-K. Unless required by law, Soligenix assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

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