

## **Soligenix Announces Presentation of Positive Preliminary Results of a Heat Stable Ebola Vaccine Formulation**

**Princeton, NJ - July 18, 2016** – Soligenix, Inc. (OTCQB: SNGX) (Soligenix or the Company), a late-stage biopharmaceutical company focused on developing and commercializing products to treat rare diseases where there is an unmet medical need, announced today positive preliminary proof-of-concept results from its collaboration 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. Thermostabilization formulation studies, conducted with Theodore Randolph, PhD at the University of Colorado Boulder, have identified a formulation that enhances the physical stability of the protein and may be dose sparing (i.e., allowing immunization to potentially be achieved with fewer vaccinations).

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. Soligenix evaluated its proprietary vaccine thermostabilization technology, ThermoVax®, licensed from the University of Colorado, to stabilize components of the vaccine. These studies identified a formulation that maintained the physical state of the Ebola subunit protein despite incubation at 40 degrees Celsius (104 degrees Fahrenheit) for 12 weeks. Moreover, initial testing revealed that two doses of this new formulation is as effective as three doses of a non-stabilized vaccine in generating antibodies to Ebola, even after storage at 40 degrees Celsius for 12 weeks. Further studies evaluating the protective ability of the vaccines are planned. Ultimately, the objective is to produce a thermostable Ebola vaccine for worldwide distribution that does not require cold storage. In preclinical studies, ThermoVax® has been previously demonstrated to enhance thermostability of ricin (RiVax™), anthrax and human papillomavirus (HPV) subunit vaccines.

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.

"None of the other Ebola vaccines under development have the ability to withstand high temperatures, which is an ongoing concern in areas of the world where Filoviruses are endemic," stated Dr. Lehrer, Assistant Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology at the JABSOM. "The ability to stabilize our vaccine candidate to retain immunogenicity may not only have an impact on logistics, but also has the potential to reach more persons in need with fewer vaccine doses. This would be a tremendous advantage, especially in endemic areas, increasing the number of people receiving sufficient doses of the vaccine to protect them from disease. We are very encouraged by these preliminary results and look forward to our continuing collaboration with Soligenix and HBI to further develop our Ebola and multivalent filovirus vaccines."

Results from the Ebola development studies will be presented by Dr. Carly Chisholm and Dr. Theodore Randolph in a poster entitled "Thermostable Lyophilized Ebola Vaccine Formulations" at the 2016 Workshop on Protein Aggregation and Immunogenicity, on August 2-4, 2016 in Breckenridge, Colorado.

"We continue to demonstrate the broad applicability of the ThermoVax® heat stabilization platform," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "These latest results join other successful endeavors with ricin, anthrax and HPV vaccines. We look forward to expanding the use of this proprietary technology, while continuing to develop ThermoVax® using RiVax™, our novel subunit ricin vaccine, under an active National Institute of Allergy and Infectious Diseases (NIAID) contract award of up to \$24.7M over 6 years."

### **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 of 2014 primarily spanned three West African countries, and involved over 28,000 confirmed/probable/suspected cases with an estimated death toll of more than 11,000 persons 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, more than 90% 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 as much as 50% of all global vaccine doses are wasted due, in part, to excursions outside 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™ is extremely labile in liquid form requiring careful management under refrigerated conditions at 4 degrees Celsius (39 degrees Fahrenheit). By employing ThermoVax® during the 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 the cooperative grant from NIAID.

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

The John A. Burns School of Medicine (JABSOM) at the University of Hawai'i Mānoa honors its unique research environment to excel in science-based efforts to eliminate diseases that disproportionately affect people in Hawai'i and the Pacific region. The school obtains some \$50 million annually in external research funding and offers degrees in Medicine, in Biomedical Sciences, Communication Sciences & Disorders, and Medical Technology, and trains physicians in MD Residency programs in partnership with Hawai'i's top community-based medical centers.

### **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 Zika virus, 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 focused on developing and commercializing products to treat rare diseases where there is an unmet medical need. Our BioTherapeutics business segment is developing

SGX301 as a first-in-class photodynamic 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 dusquetide (SGX942) for the treatment of oral mucositis.

Our Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome therapeutic candidate and SGX943, our melioidosis therapeutic candidate. 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).

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

*This press release may contain 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, including dusquetide (SGX942), 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. Positive results from the Phase 2 study evaluating SGX942 does not ensure that the follow-on Phase 2/3 clinical study will be successful. 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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