Soligenix Investor Relations

Soligenix Announces Conference Presentations Demonstrating Formulations of Single and Multivalent Ebola Subunit Vaccines

PRINCETON, N.J., July 31, 2019 /PRNewswire/ -- Soligenix, Inc. (Nasdaq: 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 that two posters outlining ongoing formulation efforts to develop a trivalent thermostabilized Ebola vaccine will be presented on Wednesday July 31 at the 2019 Colorado Protein Stability Conference in Breckenridge, CO.

Poster Presentations:

> ***Preservation of Quaternary Structure in Thermostable, Lyophilized Ebola Glycoprotein Vaccines*** presented by Kendall Preston, University of Colorado, Boulder.
>
> ***Preliminary Stability Assays for a Thermostable, Trivalent Filovirus Vaccine*** presented by Kendall Preston, University of Colorado, Boulder.

Previous collaborations 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 and Hawaii Biotech, Inc. (HBI) demonstrated the feasibility of developing a heat stable subunit Ebola vaccine. Soligenix, together with collaborators at the University of Colorado's Center for Pharmaceutical Biotechnology including Dr. Theodore Randolph and Kendall Preston, have been continuing to develop thermostable formulations with JABSOM and HBI under a 5-year National Institute of Health (NIH) subaward, initially awarded in 2017. The ultimate objective of the collaboration is to produce a thermostable trivalent filovirus vaccine for protection against Ebola and related diseases, allowing worldwide distribution without the need for cold storage. The first poster outlines the stability of the lyophilized formulations of the Ebola virus glycoprotein upon lyophilization and storage at temperatures as high as 40°C (104°F) and identifies potential stability assays while the second poster further demonstrates the ability to co-lyophilize multiple antigens in the presence of an emulsion forming adjuvant, facilitating the development of a thermostable trivalent vaccine.

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. Thermostabilization techniques initially developed by Dr. Randolph in collaboration with Soligenix may allow for a product that can avoid the need for cold-chain distribution and storage, yielding a vaccine suitable for use in both the developed and developing world.

"Filoviruses are endemic in areas of the world where the power supply can be uncertain, making a thermostable Ebola vaccine particularly valuable," stated Dr. Lehrer, Assistant Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology at the JABSOM.

"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.

About 2019 Colorado Protein Stability Conference

The Colorado Protein Stability Conference is a highly successful recurring conference focused exclusively on the study of protein stability. Specific topics for this year's conference include protein folding, dynamics, stability and self-assembly; amyloidosis and protein aggregation; and stability, formulation, analysis and processing of therapeutic proteins. The conference runs from July 30 through August 1, 2019 in Breckenridge, Colorado. Additional details can be found here.

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 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 over 11,000 people according to the Centers for Disease Control and Prevention (CDC), including some cases in Europe and the United States. A more recent outbreak, which began in 2018, is still ongoing in the Democratic Republic of Congo. Due to sustained transmission chains with this most recent outbreak, it is now considered the second largest Ebola outbreak in history. 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 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 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.

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 Specialized BioTherapeutics business segment is developing SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of oral mucositis in head and neck cancer, and 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).

Our Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. To date, this business segment has been supported with government grant and contract funding from the National Institute of Allergy and Infectious Diseases (NIAID), the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Threat Reduction Agency (DTRA).

For further information regarding Soligenix, Inc., please visit the Company's website atwww.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," "hopes," "intends," "plans," "expects," "goal," "may," "suggest," "will," "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 therapeutics and vaccines against bioterror threats, conducting preclinical and clinical trials of therapeutics and vaccines, obtaining regulatory approvals and manufacturing therapeutics and 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 U.S. 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 U.S. Congress may not pass any legislation that would provide additional funding for the Project BioShield program. In addition, there can be no assurance as to timing or success of the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy or the Phase 3 clinical trial of SGX301 (synthetic

hypericin) for the treatment of cutaneous T-cell lymphoma. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax^{Ò}, that RiVax^{Ò} will be approved for the Priority Review Voucher (PRV) program or the amount for which a PRV for RiVax^{Ò} can be sold. 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.

SOURCE Soligenix, Inc.

For further information: Karen Krumeich, Chief Financial Officer, (609) 538-8200 | www.soligenix.com, Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540
