Soligenix Investor Relations

Soligenix Announces Successful Demonstration of Heat Stabilization for Filovirus Vaccine Platform

Focus on Marburg Virus in Response to Government Priorities

PRINCETON, N.J., Feb. 27, 2020 /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 its ongoing collaboration with the University of Hawai'i at Manoa (UHM) and Hawaii Biotech Inc. (HBI) has resulted in what the Company believes is a significant milestone in the development of heat stable filovirus vaccines, in which the platform has demonstrated feasible thermostable formulations and protection in non-human primate models with both monovalent and bivalent vaccine candidates in the three most deadly human pathogenic filoviruses (Ebola virus, Sudan virus and Marburg virus).

Under the Company's Public Health Solutions business segment, ongoing collaborations with Axel Lehrer, PhD of the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), UHM and HBI have demonstrated the feasibility of developing heat stable subunit protein vaccines for filovirus. Protective efficacy has been demonstrated in non-human primates against infection with Ebola virus, Sudan virus, and Marburg virus. Protection has been achieved with both monovalent and bivalent vaccine combinations. Formulation conditions have been identified to enable heat stabilization of each antigen, alone or in combination, for at least 12 weeks at 40 degrees Celsius (104 degrees Fahrenheit). Soligenix and its collaborators are now focusing specifically on accelerating development of a Marburg virus (MARV) vaccine, which is one of the most deadly viruses and has caused multiple disease outbreaks with significant mortality since the 1960s and for which there exists no approved vaccine or treatment.

"Filoviruses are endemic in areas of the world where the power supply can be uncertain, making a thermostable vaccine particularly valuable," stated Dr. Lehrer, Assistant Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology at the JABSOM. "Our work to date has demonstrated not only the feasibility of rapid and efficient manufacturing, but also the potential for a broadly applicable and easily distributed vaccine. With Marburg virus continuing to be an unmet medical need of priority to the US government, we are now focusing and accelerating evaluations of the Marburg virus vaccine specifically."

"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 vaccines currently in development," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "In concert with US government feedback, we will now look to focus specifically on Marburg virus."

About Filovirus Infection

Ebola Virus Disease 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 Marburg virus. 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 Ebola and Marburg virus disease outbreaks since 1967, with the largest outbreak starting in 2014 in Western Africa, 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.

Transmission of filoviruses requires direct contact with bodily fluids from an infected person or contact with infected animals. The mortality rate from filovirus infections are extremely high, and can sometimes be affected by the quality of supportive care available with a focus on early initiation of treatment. Resolution of the disease largely depends on the patient's own immune system. There is no approved treatment for Ebola or Marburg although research into both has accelerated since the onset of the 2014 outbreak and significant progress has been made in advanced clinical testing of immunotherapeutics for *Zaire ebolavirus*. There is an approved vaccine, requiring storage at less than -60 °C for Ebola virus (*Zaire ebolavirus*), but no protection is yet available for Marburg virus (*Marburg Marburgvirus*) or Sudan virus (*Sudan ebolavirus*).

About John A. Burns School of Medicine, University of Hawai'i at Manoa

The University of Hawai'i at Manoa 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 $40 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 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, OrbeShield®, our GI acute radiation syndrome therapeutic 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 Defense Threat Reduction Agents (DTRA) 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.

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 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. 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 (including the outcome of the interim analysis) or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. Further, there can be no assurance that RiVax® will qualify for a biodefense Priority Review Voucher (PRV) or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. 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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