Soligenix Investor Relations

Soligenix Announces Publication Demonstrating Thermostabilization of Filovirus Vaccine Antigens

- Protein antigen stability after lyophilization demonstrated
- Key analytical assays identified

PRINCETON, N.J., Sept. 15, 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 publication of nonclinical results characterizing filovirus protein antigens (including for Ebola and Marburg viruses) and their thermostabilization. The article, authored by collaborators at the University of Colorado, University of Hawai'i at Mānoa (UHM) and Soligenix, is titled, "Preservation of Quaternary Structure in Thermostable, Lyophilized Filovirus Glycoprotein Vaccines: A Search for Stability-Indicating Assays" and has been accepted for publication in the *Journal of Pharmaceutical Sciences.* A copy of manuscript has been made available here.

Under the Company's Public Health Solutions business segment, ongoing collaborations with Axel Lehrer, PhD, Associate Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), UHM and Hawaii Biotech Inc. (HBI), as well as work conducted by Theodore Randolph, PhD, Professor, Center for Pharmaceutical Biotechnology, Department of Chemical and Biological Engineering at the University of Colorado, Boulder have demonstrated the feasibility of developing heat stable subunit protein vaccine formulations for filovirus vaccines. Protective efficacy has been demonstrated in non-human primates against infection with Ebola virus, Sudan virus, and Marburg virus. 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). These most recent results demonstrate the thermostabilization of three virus glycoproteins (from *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg marburgvirus*), and the identification of key stability-indicating assays to further support mono-, bi- and tri-valent vaccine formulations.

"Filoviruses are endemic in areas of the world where the power supply can be uncertain, making a thermostable vaccine particularly valuable," stated Dr. Lehrer, "Our work to date has demonstrated not only the feasibility of rapid and efficient manufacturing, but also the applicability of thermostabilization and 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."

"The continued advances in the filovirus program demonstrates the program's maturity and overall developability," noted Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix. "The compatibility with thermostabilization, and the identification of key stability indicating assays, are both hallmarks of a potentially broadly applicable vaccine platform. Using this platform, we also continue to accelerate our joint COVID-19 vaccine effort, called CiVax™, with Dr. Lehrer and look forward to further developments for both programs."

About Filovirus Infection

Ebola Virus Disease is caused by one of six species of Ebolavirus, four of which are known to 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. Filoviruses are believed to be harbored in various animal species in Africa, particularly bats, although the specific reservoir host for many of these viruses 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 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, SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and vaccine programs targeting both filoviruses (such as Marburg and Ebola) and coronaviruses. 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 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, such as experienced with the COVID-19 outbreak. 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 the 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 any of our other clinical/preclinical trials. Despite the statistically significant result achieved in the SGX301 Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that a marketing authorization from the FDA or EMA will be successful. 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®. Also, no assurance can be provided that the Company will receive or continue to receive non-dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. 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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