Soligenix Announces Positive Preclinical Data with Multiple Heat Stable Filovirus Vaccine Candidates

- Potent efficacy data using purified antigens and CoVaccine HT™ adjuvant demonstrated in non-human primates (NHPs) published in Frontiers in Immunology
- Thermostabilized vaccine formulations have additionally shown efficacy in NHPs when combined in a single-vial platform presentation
- Thermostable vaccine platform may be an important contributor to addressing the next potential pandemic and developing "prototype" vaccines for future health emergencies

PRINCETON, N.J., Aug. 18, 2021 /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 positive data demonstrating the efficacy of multiple filovirus vaccine candidates in NHPs, including thermostabilized multivalent vaccines in a single vial platform presentation. Collaborators at the at the University of Hawai'i at Mānoa (UHM) describe the potent efficacy of vaccine candidates protecting against three life-threatening filoviruses, *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg Marburgvirus* in an article titled "Recombinant Protein Filovirus Vaccines Protect Cynomolgus Macaques from Ebola, Sudan, and Marburg Viruses", published *in Frontiers in Immunology*. These vaccine candidates contain highly purified protein antigens combined with the novel CoVaccine HT™ adjuvant, in both monovalent (single antigen) and bivalent (two antigen) formulations. Most recently, efforts to formulate all three antigens and adjuvant into a thermostable single-vial vaccine platform has also been shown to protect 75% of vaccinated NHPs against subsequent *Sudan ebolavirus* challenge, with further development to test efficacy against other filovirus infections ongoing.

"Filoviruses are endemic in areas of the world where the power supply can be uncertain, making a thermostable vaccine particularly valuable," stated Axel Lehrer, PhD, Associate Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), UHM, "Our work to date has demonstrated not only the feasibility of rapid and efficient manufacturing, but also the applicability of thermostabilization of multiple antigens with the potential for a broadly applicable and easily distributed vaccine. Once developed, such a vaccine may be able to address emerging outbreaks, such as the Marburg virus infection that appeared in Guinea recently. We feel that this technology may be an important contribution to Dr. Fauci's proposed idea to develop prototype vaccines against the top 20 viral families that may also cause pandemics. Having such a platform available would likely enable broader and faster worldwide vaccination campaigns addressing future health emergencies. In addition, the ability to combine antigens in the formulation also enables generation of potentially broader protective vaccines."

"The continued advances in the filovirus program demonstrates the program's maturity and overall ability to successfully develop vaccines against these lethal viral threats," 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. This most recent demonstration of protective efficacy against subsequent challenge continues to advance the overall platform, as well as the *Sudan ebolavirus* program specifically. Using this platform, we also continue to accelerate our joint COVID-19 vaccine effort, called CiVax™, with Dr. Lehrer and look forward to discussing further developments for both programs in the near future."

Under the Company's Public Health Solutions business segment, ongoing collaborations with Dr. Lehrer, 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 filoviruses. The thermostabilized filovirus vaccine program is continuing to advance with the support of a National Institute of Health (NIH) grant R01-AI132323 (awarded to the University of Hawaii) and a Small Business Innovation Research grant (#1R44AI157593-01; awarded to Soligenix). Work to date has demonstrated the compatibility of lyophilizing both antigen and adjuvant in the same vial, with reconstitution with sterile water for injection immediately prior to use. This simple delivery format, as well as the compatibility with ambient storage, enables vaccines that significantly reduce the logistical hurdles that have been required for addressing the current pandemic or deployment of other Ebola virus vaccines in recent outbreaks in Central and West Africa.

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), and *Sudan ebolavirus* being the second-most common cause of human infection in this family. 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). These numbers also include some cases of virus introduction and limited

spread 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 rates following filovirus infections are extremely high, and, in the absence of wide availability of effective therapeutics, are 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 are limited treatment options for Ebola Virus Disease and no available treatments for Sudan Virus or Marburg Virus Disease, although steady progress has also been made in development of immunotherapeutics for filoviruses beyond *Zaire ebolavirus*. There are approved vaccines for Ebola virus (*Zaire ebolavirus*), both requiring stringent ultra-low cold-chain storage, but no efficacious vaccines are 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 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 and moving toward potential commercialization of HyBryte™ (SGX301 or synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With a successful Phase 3 study completed, regulatory approval is being sought and commercialization activities for this product candidate are being advanced initially in the U.S. Development programs in this business segment also include our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, including 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, and our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). 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 Agency (DTRA) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website at https://www.soligenix.com and follow us on LinkedIn and Twitter at @Soligenix_Inc.

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 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 the timing or success of any of its clinical/preclinical trials. Despite the statistically significant result achieved in the HyBryte™ (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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