

Soligenix and University of Hawai'i at Mānoa Initiate Work on Novel Coronavirus Vaccine for COVID-19

Leverage existing research collaboration in Ebola and Marburg to assess potential coronavirus vaccines

PRINCETON, N.J., March 23, 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 Mānoa (UH Mānoa) is being expanded to assess potential coronavirus vaccines (including COVID-19).

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), UH Mānoa have demonstrated the feasibility of developing heat stable subunit filovirus vaccines, including Ebola virus disease caused by either Zaire or Sudan ebolavirus variants, as well as Marburg virus disease, 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 expanding the technology platform to assess compatibility with coronaviruses including SARS-CoV-2, the cause of COVID-19.

The vaccine platform includes three essential components:

- 1) a protein antigen, specifically a viral surface glycoprotein, which mediates entry and fusion of the virus with host cells and is manufactured with a proprietary insect cell expression system coupled with protein-specific affinity purification;
- 2) an adjuvant which has been shown to enhance both cell mediated and humoral immunity; and
- 3) a formulation which enables thermostabilization of the resulting mixture, avoiding the need for cold chain storage and shipping.

The resulting vaccine is broadly applicable, including to individuals often excluded from common viral vector vaccine approaches such as children, the elderly and the immunocompromised. These same components can now be applied to coronavirus vaccine, using well-defined surface glycoprotein(s) from one or more coronaviruses, which will include key antigens expected to be protective for COVID-19. The protection of elderly and immunocompromised populations are particularly important in the context of COVID-19.

"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. We are delighted with our successes on development of filovirus and flavivirus vaccines using our platform and look forward to accelerated studies with the coronaviruses," stated Dr. Lehrer, Assistant Professor, Department of Tropical Medicine, Medical Microbiology and Pharmacology at the JABSOM.

"It is rewarding to see ongoing work by JABSOM investigators and collaborators expanding on successful research on filovirus vaccines (protecting against viruses such as Ebola and Marburg virus) that may help us make unique life-saving contributions during this difficult time in healthcare. The prospect of a science lab in Hawai'i helping develop a vaccine amid the COVID-19 pandemic is a testament to the importance of local research in Hawai'i," stated JABSOM Dean Jerris R. Hedges, MD, MS, MMM.

"We believe that creating a vaccine with enhanced stability at elevated temperatures that 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 and simplifies worldwide distribution," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With the rapid advancement of the filovirus vaccine platform, we feel the program is optimally poised to look at other viruses and infections, including COVID-19."

About Coronavirus Infection

Coronavirus infections can cause a wide spectrum of disease in humans, ranging from a common cold to a more severe respiratory infection, such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), which have a case mortality rate of approximately 10% and 30%, respectively. Similar to filoviruses, coronaviruses also are endemic in wildlife populations and can be transmitted to humans with close contact. The COVID-19 outbreak, caused by SARS-COV-2, is the most recent example of species crossover seen with this virus family. Although the case fatality rate of COVID-19 is still under investigation, COVID-19 has been declared a global pandemic by the World Health Organization. The global impact of this emerging infection demonstrates the need for robust technology platforms to rapidly develop new vaccines for novel diseases. There is currently no approved treatment for any coronavirus infection, nor any approved vaccine.

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

The John A. Burns School of Medicine (JABSOM) at the University of Hawai'i at Mānoa is one of the leading medical education institutions in the United States. For the last three years, JABSOM has been a leader in National Institutes of Health research awards among community-based public medical schools (i.e., public medical schools without a university hospital). JABSOM has also been a leader in the rate of MD graduates (who are also residency trained in state) retained as practitioners in-state. In addition, Hawai'i's cultural diversity and geographical setting affords JABSOM a unique research environment to excel in health disparity research. JABSOM faculty bring external funding of about \$40 million annually into the state.

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, or any of our other clinical/preclinical trial. 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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