Soligenix Investor Relations

Soligenix Announces Publication of Positive Pre-clinical Results for a Novel COVID-19 Vaccine

- Rapid Immune Responses Demonstrated with CoVaccine HT™ Adjuvant in a Prototype Vaccine
- Key Attributes including Generation of Neutralizing Antibodies, Th1 Antibody and Cell Mediated Responses Established

PRINCETON, N.J., July 28, 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 pre-clinical immunogenicity studies for its CiVax™ program (heat stable COVID-19 vaccine), demonstrating immunity of both broad-spectrum antibody and cell-mediated, rapid onset immunity is possible using the CoVaccine HT™ (CoVaccine) adjuvant. The article, authored by collaborators at the University of Hawai'i at Mānoa (UHM), is titled, "CoVaccine HT™ adjuvant potentiates robust immune responses to recombinant SARS-CoV-2 spike-S1 immunization," and has been submitted for peer-review to the journal *npj Vaccines.* An accelerated preprint of the manuscript has been made available here.

CiVax™ is the Company's heat stable subunit vaccine candidate for the prevention of COVID-19, the infection caused by SARS-CoV-2. Ongoing collaborations with Axel Lehrer, PhD, Assistant Professor in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), UHM have demonstrated the feasibility of developing a broadly immunogenic vaccine for COVID-19. With significant research dedicated worldwide to the generation of COVID-19 vaccines, it is noteworthy that the essential attributes of a vaccine successful in controlling the ongoing pandemic are believed to include the ability to rapidly stimulate a balanced antibody response, including an enhanced Th1 response, which includes raising significant virus neutralizing antibodies and potent cell-mediated immunity, demonstrated by T-cell activation. Previous work with the CoVaccine adjuvant, which Soligenix licensed from BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation, has indicated that CoVaccine has these critical characteristics. In these results, Lehrer and his colleagues now demonstrate these attributes of CoVaccine, specifically in the context of SARS-CoV-2. Moreover, these results, using a prototype antigen, also demonstrate a rapid onset of immunity with antibody responses detected within 14 days after the first vaccination.

Many programs have been initiated seeking a vaccine for COVID-19, but the novelty of the virus and previous challenges developing potent vaccines for the related SARS-CoV (Severe Acute Respiratory Syndrome Coronavirus) and MERS-CoV (Middle East Respiratory Syndrome Coronavirus), suggest that a timely solution requires parallel approaches. The total number of vaccine doses required to control the ongoing pandemic also suggests that multiple vaccines, based on different manufacturing platforms, will be necessary to efficiently vaccinate the worldwide population. Subunit vaccines are considered the gold standard for vaccine safety, but are relatively under-represented in fast-tracked COVID-19 vaccine candidates to date. Unlike virally vectored vaccines, there is no limit to the number of times the adjuvant and antigen can be used and the typical safety profile of a subunit vaccine results in a vaccine that is suitable for immune compromised or elderly populations as well. In contrast, while RNA and DNA vaccines are rapid to manufacture, there is a lack of regulatory precedent (no RNA or DNA vaccine has been approved to date).

"Our work to date has demonstrated not only the feasibility of rapid and efficient manufacturing of the required vaccine antigens, but also the potential for a broadly applicable and easily distributed vaccine," stated Dr. Lehrer. "We are delighted with our earlier successes on development of filovirus and flavivirus vaccines with this platform. The results in our latest manuscript confirm that the advantages of our vaccine platform with the CoVaccine adjuvant can also be realized in the context of SARS-CoV-2, while we continue our work to rapidly advance development of a heat stable subunit COVID-19 vaccine in collaboration with Soligenix."

"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 COVID-19 vaccines currently in development and simplifies worldwide distribution," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Our approach appears to be unique in its use of a well-established, well-understood, and safe, subunit platform coupled with a novel adjuvant and a thermostabilizing formulation. We are very encouraged with the latest results and look forward to continuing to advance development of CiVax™."

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 a suspected 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 urgent need for robust technology platforms to rapidly develop new vaccines for novel diseases. The only FDA sanctioned treatments for COVID-19 are available under "Emergency Use Authorization." There is currently no 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 UHM 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, 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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