Soligenix Investor Relations

Soligenix Announces Positive Progress in the Pre-clinical Development of its COVID-19 Vaccine

- Broad and potent immune responses demonstrated with full length Spike protein antigen
- Large animal studies and COVID variant testing planned
- Facilitates development of a heat-stable vaccine candidate, avoiding refrigeration or freezing

PRINCETON, N.J., March 4, 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 publication of pre-clinical immunogenicity studies for CiVax™ (heat stable COVID-19 vaccine program) demonstrating rapid-onset, broad-spectrum, neutralizing antibody and cell-mediated immunity is confirmed using full-length Spike protein antigens. The article titled, "Recombinant protein subunit SARS-CoV-2 vaccines formulated with CoVaccine HT adjuvant induce broad, Th1 biased, humoral and cellular immune responses in mice," has been posted as an accelerated preprint on bioRxiv (available here). This work will continue under a $1.5M Small Business Innovation Research (SBIR) grant awarded to Soligenix in December 2020.

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, Associate Professor in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), University of Hawai'i at Mānoa, have confirmed the feasibility of developing a broadly immunogenic vaccine for COVID-19. Using an efficient expression system in *Drosophila* S2 cells developed by Hawaii Biotech Inc., full-length Spike protein antigens have been produced and tested for immunogenicity in this latest work. These latest results demonstrate the immunogenic potential of the full-length CiVax™ antigen in combination with CoVaccine HT™, specifically in the context of SARS-CoV-2.

While a number of vaccines are available worldwide under Emergency Use Authorization, the requirement for cold chain shipping and timely administration, coupled with manufacturing scale up logistics, have limited the world's supply. Rapid vaccine administration worldwide is necessary to curtail disease spread and slow or pre-empt evolution of mutations, which may abrogate the effectiveness of current vaccine approaches. Previous work with the novel CoVaccine HT™ adjuvant, which Soligenix licensed from BTG Specialty Pharmaceuticals, a division of Boston Scientific Corporation, has indicated that CoVaccine HT™ can be thermostabilized both alone and in combination with antigens, potentially yielding a single vial presentation of the vaccine, which would not require cold chain distribution or storage.

"Our work to date has demonstrated not only the feasibility of rapidly adaptable and cost-effective 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 HT™ 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. Next steps will include evaluation of immunogenicity in a non-human primate model and assessment of antibody coverage with key variants of concern."

"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 simplify worldwide distribution, leading to a faster resolution of this pandemic and curtailing the further evolution of the virus," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Once fully developed, we anticipate that our platform would be easily updated to address specific variants directly. 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™ in larger animal models and human clinical trials."

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. 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. Despite vaccines approved under Emergency Use Authorization, the logistical challenges of cold chain distribution and manufacturing scale up are limiting the

ability to vaccinate individuals worldwide, a required to curtail further viral mutations and stop the pandemic. More rapid distribution of vaccines worldwide will also curtail the emergence of new variants.

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 and commercializing SGX301 (synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma. With a successful Phase 3 study completed, regulatory approval and commercialization for this product is 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, SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and our research programs to identify and develop novel vaccine candidates targeting viral infection including Ebola, Marburg and SARS-CoV-2 (the cause of COVID-19). 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, 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 our 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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