Soligenix Investor Relations

Soligenix Announces Accelerated Publication Demonstrating Efficacy and Broad Neutralizing Activity of its COVID-19 Vaccine in Non-Human Primates

- Vaccination yields broad neutralizing antibody responses against original strain and Beta, Gamma and Delta variants

- Durable response demonstrated against original strain and all variants for several months after vaccination

- Stronger neutralizing antibodies observed after infection, unlike the unvaccinated, naturally infected animals

PRINCETON, N.J., Sept. 28, 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 durable broad-spectrum neutralizing antibody responses, including against the Beta, Gamma and Delta variants of concern. The article, titled "Protein Vaccine Induces a Durable, More Broadly Neutralizing Antibody Response in Macaques than Natural Infection with SARS-CoV-2 P.1," has been posted as an accelerated preprint on bioRxiv (available here). The manuscript is part of the ongoing collaboration with Axel Lehrer, PhD, Associate Professor at the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), University of Hawai'i at Mānoa (UHM). Development continues under a non-dilutive $1.5M Small Business Innovation Research (SBIR) grant from the National Institute of Allergy and Infectious Diseases (NIAID) awarded to Soligenix in December 2020.

"This technology platform has previously demonstrated an encouraging ability to generate vaccines that are stable at ambient temperature, potentially avoiding the need for refrigerated or frozen storage and distribution," said Jerome Kim, MD, Director General of the International Vaccine Institute. "The encouraging development of a broadly neutralizing and efficacious subunit vaccine specifically for SARS-CoV-2, including the variants of concern, using the same heat stable technology platform offers greater promise for achieving worldwide vaccination in the current pandemic."

"We continue to advance our work using our vaccine platform, consisting of a robust protein manufacturing process and a thermostabilizing formulation, using the Soligenix ThermoVax® process and the CoVaccine HT™ adjuvant. The CiVax™ vaccine has demonstrated broad and robust immune responses in mice, which is recapitulated here in NHPs and further shown to yield protection against infection with COVID-19 variants of concern. Our work with CiVax™ emerged from our ongoing efforts to develop heat-stable, single-vial format vaccines for filoviruses. The ability to rapidly pivot from filovirus to SARS-CoV-2 demonstrates the broad applicability of this platform and our productive collaboration with Soligenix," stated Dr. Lehrer. "A single-vial subunit vaccine that can be shipped at ambient temperatures and that need only be reconstituted with sterile water immediately prior to use has the potential to bolster the global vaccination efforts by simplifying storage and distribution logistics."

"We believe that creating a COVID-19 vaccine, like CiVax™, with enhanced stability at elevated temperatures has the potential to lead to a faster resolution of this global pandemic, curtailing the further evolution of the virus," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Moreover, the introduction of a subunit vaccine that has been built on years of proven vaccine technology may also encourage the vaccine-hesitant. This platform not only has the potential to aid in the current worldwide pandemic; but the technology platform, with its broad applicability, may also aid in the preparation for future pandemics. With these latest results, we will be expanding discussions with various funding agencies in the coming weeks."

CiVax™ is the Company's heat stable subunit vaccine candidate for the prevention of COVID-19, the disease caused by infection with SARS-CoV-2. Ongoing collaborations with Dr. Lehrer have confirmed the feasibility of developing a broadly immunogenic vaccine for COVID-19. A full-length Spike protein antigen coupled with liquid or lyophilized (thermostabilized) CoVaccine HT™ adjuvant has been tested for immunogenicity and efficacy in the context of Gamma variant challenge in non-human primates (NHPs). NHPs were vaccinated twice, three weeks apart, and were subsequently challenged with Gamma variant both intranasally and intratracheally 12 weeks later. While most vaccines tested in NHPs use a challenge date only four weeks post-vaccination when antibody levels are peaking, the use of a later challenge time in this study demonstrates the durable response elicited by this vaccine candidate. While the vaccine antigen is developed based on the Spike protein of the original SARS-CoV-2 strain, it elicited cross-neutralizing antibodies against Beta, Gamma and Delta variants of concerns. After challenge, vaccinated animals had a lower peak viral load and more rapid resolution of infectious virus, coupled with reduced lung damage. After challenge with Gamma variant, animals that were *not* vaccinated with CiVax™ generated a neutralizing antibody response to Beta and Gamma variants but not to the original strain and the Delta variant, demonstrating that natural infection may not yield sufficiently robust

immunity. In stark contrast, CiVax™-vaccinated animals subsequently challenged with Gamma variant had enhanced neutralizing antibody responses against the original strain, as well as the Beta, Gamma and Delta variants.

While a number of vaccines are available worldwide, 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 has indicated that it can be thermostabilized both alone and in combination with antigens, potentially yielding a single-vial presentation of CiVax™, which would not require cold chain distribution or storage.

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 requirement 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 expansion of synthetic hypericin (SGX302) into psoriasis, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, 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).

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 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 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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