Soligenix Investor Relations

Soligenix COVID-19 Vaccine, CiVax™, Boosts Neutralizing Activity against SARS-CoV-2, including Delta and Omicron

- **CiVax™ booster vaccine administered seven months after primary vaccination with COVID-19 adenovirus vaccine shows rapid enhancement of neutralizing antibody responses in non-human primates**
- **Neutralizing antibodies against Delta and original strain increased by up to 27-fold within one week and up to 243-fold within three weeks**
- **Omicron neutralizing antibody levels were undetectable prior to booster vaccination, and attained presumed protective levels within one week of vaccination**

PRINCETON, N.J., March 17, 2022 /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 the results of a booster vaccination study using CiVax™ (heat stable COVID-19 subunit vaccine program) in non-human primates (NHPs) demonstrating rapid enhancement of neutralizing antibody responses to SARS-CoV-2, including against Delta and Omicron variants. The NHPs had been double vaccinated with an adenovirus vaccine for COVID-19 seven months previously. Prior to administration of the booster vaccine, neutralizing antibody levels against the original and Delta strains of SARS-CoV-2 were low, but detectable, and were undetectable for the Omicron strain. Within one week of receiving booster, neutralizing antibody levels increased as much as 27-fold against the original and Delta strains. By three weeks this increased up to 243-fold. Protective neutralizing antibody levels were also rapidly raised against Omicron by one-week post-vaccination. These results are consistent with the broad-spectrum activity observed to date with CiVax™ on primary vaccination, as described in an article recently published by ACS Infectious Diseases.

These most recent results are part of the ongoing collaboration withAxel 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). CiVax™ 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. "Published data have shown the ability of the CiVax™ vaccine, developed using this platform, to induce a neutralizing response to SARS-CoV-2, including the variants of concern. The extension of these findings in the context of a booster vaccination shows the broad potential applicability of this vaccine and this platform."

"The CiVax™ vaccine has demonstrated broad and robust immune responses in mice, which has been recapitulated in NHPs and further shown to yield protection against infection with COVID-19 variants of concern," stated Dr. Lehrer. "The multi-variant booster response in a heterologous prime-boost approach further supports the broad-spectrum utility of our vaccine candidate. 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, like Ebola, to SARS-CoV-2 demonstrates the broad applicability of this novel platform and our productive collaboration with Soligenix. "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 improve vaccination efforts globally by simplifying storage and distribution logistics not only as a stand-alone vaccine, but also as a practical add-on booster in persons previously vaccinated with other COVID-19 vaccines."

"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 may also aid in the preparation for future pandemics, as emphasized in the Biden-Harris Administration's American Pandemic Preparedness white paper."

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 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 demonstrated 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. Further, utilizing CiVax™ as a booster vaccine, after previous vaccination with an adenovirus-based SARS-CoV-2 vaccine, also demonstrated a rapid and broad-spectrum boost response, including against highly infectious Delta and Omicron 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 number of vaccines administered worldwide. 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 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 expansion of synthetic hypericin (SGX302) into psoriasis, 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. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 1/2 proof-of-concept clinical trial of SGX302 for the treatment of psoriasis, there can be no assurance as to the timing or success of the clinical trials of SGX302 for the treatment of psoriasis. 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.

SOURCE Soligenix, Inc.

For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200, www.soligenix.com, Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540
