

## Soligenix Announces Publication Demonstrating CiVax™ Booster Induces Rapid Broad Protection Against COVID-19 Variants

***Broader protection induced by combination of COVID adenovirus vaccine plus CiVax™ compared to 2-shot mRNA vaccination series***

PRINCETON, N.J., March 25, 2025 /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 a publication describing the preclinical efficacy of CiVax™, a thermostabilized subunit vaccine against SARS-CoV-2. Using custom-developed immunoassays, the combination of a primary adenovirus vaccine (COVID-19 Vaccine AstraZeneca) coupled with a CiVax™ booster was shown to induce broader protection against COVID-19 variants in non-human primates than a 2-shot mRNA series (such as the Moderna vaccine Spikevax® or the Pfizer vaccine Cominarty®) in humans. In collaboration with Axel Lehrer, PhD, Professor at the Department of Tropical Medicine, Medical Microbiology and Pharmacology, John A. Burns School of Medicine, University of Hawai'i at Mānoa, the manuscript entitled "[Use of a Multiplex Immunoassay Platform to Investigate Multifaceted Antibody Responses in SARS-CoV-2 Vaccinees with and Without Prior Infection](#)", has been published in *COVID*.

"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 rapid-onset multi-variant booster response with CiVax™ in a heterologous or mixed 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 filoviruses, 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 then needs only to 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."

"Our ThermoVax® platform has successfully thermostabilized vaccines for ricin toxin, for filoviruses such as Ebola, Sudan and Marburg, and for COVID, and as such is a well-established thermostabilization strategy that enhances the standard protein subunit vaccination technology. We believe this enhancement makes protein subunit vaccines, the gold standard for safe vaccines, competitive with other vaccine technologies, such as mRNA, which have much more stringent cold-storage requirements," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The ability of CiVax™ to induce rapid broad immune coverage, including against SARS-CoV-2 variants, even when administered after other primary vaccination series, is another marked advantage. Moreover, the use of subunit vaccines that has been built on years of proven vaccine technology may also provide a very safe option for people of all ages. This platform may also aid in the preparation for future pandemics."

### About CiVax™

CiVax™ is the Company's heat stable subunit vaccine candidate for the prevention of COVID-19, the infection caused by SARS-CoV-2. 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, University of Hawai'i at Mānoa have demonstrated the feasibility of developing heat stable subunit filovirus vaccines, including hemorrhagic disease caused by Zaire ebolavirus, Sudan ebolavirus as well as Marburg marburgvirus, 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 months at 40 degrees Celsius (104 degrees Fahrenheit). Soligenix and its collaborators expanded the technology platform to assess compatibility with vaccine candidates targeting SARS-CoV-2, the cause of COVID-19.

CiVax™ has been previously demonstrated to be heat-stable for at least one year when formulated as a lyophilized single vial dose and reconstituted immediately prior to use with water for injection. Previous efficacy studies have demonstrated the novel protein antigen and adjuvant (CoVaccine HT™) combination yields [broad spectrum immune responses in mice](#) and in [non-human primates](#). This subunit vaccine has also shown efficacy as a [booster](#) after other primary vaccinations against COVID and in particular, appears to yield [broad immune coverage](#).

CiVax™ development was partially funded under a non-dilutive \$1.5 million Small Business Innovation Research (SBIR) grant from the National Institute of Allergy and Infectious Diseases (NIAID) awarded to Soligenix in December 2020.

### 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 limited the ability to vaccinate individuals worldwide, a requirement to curtail further viral mutations and rapidly stop the pandemic.

### **About John A. Burns School of Medicine, University of Hawai'i at Mānoa**

Established in 1965, the John A. Burns School of Medicine (JABSOM) is one of the degree-granting schools of the University of Hawai'i at Mānoa. Named in honor of the visionary former governor, JABSOM trains the next generation of outstanding physicians, scientists, medical technologists, and speech pathologists to improve the health and wellness of our diverse communities throughout Hawai'i and the Pacific. Our impactful research focuses on understanding and addressing health disparities, particularly in Native Hawaiian, Pacific Islander, and Filipinos. JABSOM is home to the first clinical department in an accredited medical school in the nation that is focused on health disparities of an indigenous population, Native Hawaiians.

### **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 sodium) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). With successful completion of the second Phase 3 study, regulatory approvals will be sought to support potential commercialization worldwide. 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 (SGX945) in Behçet's Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate, as well as 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's current expectations about its future results, performance, prospects and opportunities, including but not limited to, potential market sizes, patient populations, clinical trial enrollment, the expected timing for closing the offering described herein and the intended use of proceeds therefrom. 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, and include the expected amount and use of proceeds from the offering and the expected closing date of the offering. Soligenix cannot assure 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 first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that the second HyBryte™ (SGX301) Phase 3 clinical trial will be successful or that a marketing authorization from the FDA or EMA will be granted. Additionally, although the EMA has agreed to the key design components of the second HyBryte™ (SGX301) Phase 3 clinical trial, no assurance can be given that the Company will be able to modify the development path to adequately address the FDA's concerns or that the FDA will not require a longer duration comparative study. Notwithstanding the result in the first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 2a 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. Additionally, despite the biologic activity observed in aphthous ulcers induced by chemotherapy and radiation, there can be no assurance as

to the timing or success of the clinical trials of SGX945 for the treatment of Behçet's Disease. Further, there can be no assurance that RiVax<sup>®</sup> 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<sup>®</sup>. 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 (the "SEC"), 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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