Soligenix Investor Relations

Soligenix Announces Publication Describing Long-Term High Temperature Stability of Protein Subunit Vaccines for Ebola and Related Viruses

Two Year Stability demonstrated in both bivalent and trivalent configurations at temperatures of 40°C / 104°F

PRINCETON, N.J., Sept. 4, 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 extended stability of ebolavirus vaccines using its ThermoVax® platform. Bivalent and trivalent vaccines, constructed from antigens against *Zaire ebolavirus*, *Sudan ebolavirus* and *Marburg marburgvirus* and the CoVaccine HT™ antigen, were formulated in a single vial and subjected to long-term storage at up to 40°C (104°F). After two years of storage, all vaccines were unchanged and had equivalent potency as when initially manufactured. 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 "*Thermostable Bivalent & Trivalent Filovirus Vaccines from Insect Cells: Potency Demonstrated after 3 Months and 2 Years*", has been accepted for publication and is available online in *Vaccine*.

"Our filovirus vaccines have demonstrated broad and robust immune responses in mice and up to 100% protection in non-human primates," stated Dr. Lehrer. "This further demonstration of extended stability is particularly relevant for the use of these vaccines in virus-endemic countries in Africa, as well as in the context of strategic national stockpiles and preparations for potential larger outbreaks and pandemics. 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 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 long-standing protein subunit vaccination technology. We believe this enhancement makes protein subunit vaccines, the gold standard for safe vaccines, competitive with other vaccine technologies, which have much more stringent cold-storage requirements," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The ability of these vaccines to induce rapid broad immune coverage, even when administered after other primary vaccination series, is another marked advantage. Moreover, the use of subunit vaccines that have 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 Filovirus Vaccines

These proprietary filovirus vaccines are subunit protein vaccines of recombinantly expressed*Sudan orthoebolavirus* glycoprotein, *Zaire orthoebolavirus* glycoprotein and *Marburg orthomarburgvirus* glycoprotein developed in partnership with Dr. Axel Lehrer at the University of Hawai'i at Mānoa. The vaccines include a protein found on the surface of each virus, to engender an appropriate immune response without posing a risk of infection, as well as a novel adjuvant which stimulates both humoral and cell mediated immune responses, in combination with Generally Regarded As Safe (GRAS) excipients that enable lyophilization (i.e., freeze-drying) of the vaccines. The resulting products are manufactured as a heat stable powder in a vial which is reconstituted with widely available water for injection immediately prior to use. Alone or in combination, these heat stable protein subunit vaccines, have protected up to100% of non-human primates exposed to a lethal injection of the corresponding virus. Stability studies have demonstrated that these vaccines are heat stable for at least 2 years at temperatures of at least 40 degrees Celsius (104 degrees Fahrenheit).

Manufacture of the recombinant proteins utilizes a robust protein manufacturing process, developed and tested in other subunit vaccines advanced through clinical testing. Similarly, the selected adjuvant, while novel, has also been independently tested in Phase 1 and Phase 2 clinical studies.

Soligenix has been granted Orphan Drug Designation by the United States Food and Drug Administration (FDA) for the prevention and post-exposure prophylaxis against *Sudan orthoebolavirus* and *Marburg orthomarburgvirus* infection. In addition to providing a seven-year term of market exclusivity upon final FDA approval, orphan drug designations also position Soligenix to be able to leverage a wide range of financial and regulatory benefits, including government grants for conducting clinical trials, waiver of expensive FDA user fees for the potential submission of a Biologics License Application (BLA), and certain tax credits.

About Filovirus Infection

Ebola Virus Disease is caused by one of six species of Ebolavirus, four of which are known to cause disease in humans, including its best-known member, *Zaire ebolavirus* (Ebola virus), with *Sudan orthoebolavirus* being the second-most common cause of human infection in this family. All species of orthoebolavirus belong to the Filoviridae family, a family that further

contains the equally human pathogenic Marburg virus. Filoviruses are believed to be harbored in various animal species in Africa, particularly bats, although the specific reservoir host for many of these viruses is still unknown. There have been several known Ebola, Sudan and Marburg Virus Disease outbreaks since 1967. The most recent SUDV outbreak occurred in January – April, 2025 in Uganda according to the Centers for Disease Control and Prevention (CDC). The most recent MARV outbreaks occurred in January – March 2025 in Tanzania, according to the CDC.

Transmission of filoviruses requires direct contact with bodily fluids from an infected person or contact with infected animals. The mortality rates following filovirus infections are extremely high, and, in the absence of wide availability of effective therapeutics, are affected by the quality of supportive care available with a focus on early initiation of treatment. Resolution of the disease largely depends on the patient's own immune system. There are limited treatment options for Ebola Virus Disease and no available treatments for Sudan Virus or Marburg Virus Disease, although steady progress has also been made in development of immunotherapeutics for filoviruses beyond *Zaire orthoebolavirus*. There are approved vaccines for Ebola virus, requiring stringent ultra-low cold-chain storage, but no efficacious vaccines are yet available for Marburg virus or Sudan virus.

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

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 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 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® 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 (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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