Soligenix Investor Relations

Soligenix Announces Publication Demonstrating Positive Correlates of Protection with RiVax® in Non-Human Primate Survival after Ricin Challenge

- **RiVax®-Vaccinated NHP survival was statistically significantly correlated with an epitope-specific serum assay ("EPICC") prior to challenge**
- **Correlates of protection are essential to support approval via the FDA "Animal Rule"**

PRINCETON, N.J., Dec. 20, 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 publication of preclinical immunogenicity challenge studies for RiVax® (heat stable ricin toxin vaccine) demonstrating statistically significant correlates of protection predicting survival after lethal aerosolized ricin challenge in non-human primates (NHPs). The article titled "Serum antibody profiling identifies vaccine-induced correlates of protection against aerosolized ricin toxin in rhesus macaques" has been accepted for publication in the journal npj Vaccines (available here). The article results from collaborative work lead by the Wadsworth Center of the New York State Department of Health. This same thermostabilization approach is also being advanced in the development of Soligenix's CiVax™ vaccine for COVID-19 and SuVax™ and MarVax™ vaccines for ebola type filovirus infections.

"These published results identifying correlates of protection between NHPs and humans are essential to advancing RiVax® under the U.S. Food and Drug Administration (FDA) Animal Rule," stated Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix. "This, and other ongoing work, has continued to corroborate the efficacy of RiVax® and will facilitate its potential approval."

RiVax® is the Company's vaccine candidate for the prevention of death following exposure to a lethal dose of ricin toxin using a unique antigen that is completely devoid of the toxic activity of ricin. Formulated by Soligenix to have enhanced thermostability, RiVax® has demonstrated up to 100% protection in mice and NHPs subsequently exposed to lethal doses of ricin toxin either systemically or by aerosol. RiVax® has been demonstrated to be stable for at least 12 months of storage at temperatures up to 40 degrees Celsius (104 degrees Fahrenheit). Moreover, mice have been shown to be protected from ricin challenge at 10 times the lethal dose for at least 12 months post-vaccination. These results, coupled with the recent demonstration of statistically significant correlates of protection via the EPICC assay, position RiVax® for additional clinical and pivotal non-clinical studies under the FDA Animal Rule.

About RiVax®

RiVax® is Soligenix's proprietary heat stable recombinant subunit vaccine developed to protect against exposure to ricin toxin, the threat of which has been highlighted in the news with an envelope addressed to President Trump that was thought to contain this potent and potentially lethal toxin. With RiVax®, Soligenix is a world leader in the area of ricin toxin vaccine research.

RiVax® contains a genetically altered version of a Ricin Toxin A (RTA) chain containing two mutations that inactivate the toxicity of the ricin molecule which was originally invented at the University of Texas Southwestern. Phase 1 clinical studies to date have demonstrated the safety of the antigen and adjuvant, as well as the generation of ricin neutralizing antibodies which are increased in the presence of the alum adjuvant. In animal studies, the alum formulation of RiVax® also induced higher titers and longer-lasting antibodies than the adjuvant-free vaccine. Vaccination with the thermostabilized alum-adjuvanted RiVax® formulation in a NHP animal model provided 100% protection ($p<0.0001$) against acute exposure to aerosolized ricin, the most lethal route of exposure for ricin. The protected animals also had no signs of gross lung damage, a serious and enduring ramification with long-term consequences for survivors of ricin exposure. These results are described in a publication available here.

Heat stabilization of RiVax® is achieved with the Company's proprietary ThermoVax® technology, designed to eliminate the cold-chain production, distribution and storage logistics required for most vaccines. The technology utilizes precise lyophilization of protein immunogens with conventional aluminum adjuvants in combination with secondary adjuvants for rapid onset of protective immunity with the fewest number of vaccinations. By employing ThermoVax® during the final formulation of RiVax®, the vaccine has demonstrated enhanced stability and the ability to withstand temperatures at least as high as 40 degrees Celsius (104 degrees Fahrenheit) for up to one year. These results are described in a publication available here.

The development of RiVax® has been funded through a series of grants from both the NIAID (NIAID contract #HHSN272201400039C) and the FDA Recent NHP work has also been supported by an NIH grant (#AI125190) awarded to Dr. Nicholas Mantis, Wadsworth Center of the State of New York Department of Health. Non-dilutive funding for the development of RiVax® has exceeded $40 million to date. RiVax® is being developed under the FDA "Animal Rule" and potentially would be added to the Strategic National Stockpile and dispensed in the event of a terrorist threat. RiVax® has received orphan drug designation in the U.S. and in Europe.

RiVax® has received Orphan Drug and Fast Track designations from the FDA, and, upon approval, has the potential to qualify for a biodefense Priority Review Voucher (PRV). In addition, RiVax® has received Orphan Drug designation from the European Medicines Agency (EMA).

Approval for RiVax® will be pursued under the FDA "Animal Rule," which is applied to products where testing in clinical efficacy trials would be unethical. In the case of a ricin toxin vaccine, clinical efficacy testing of the vaccine is unethical since it would require intentionally exposing humans to ricin toxin. The Animal Rule is generally associated with the approval of medical countermeasures for biodefense purposes. The Animal Rule requires the evaluation of efficacy in animals (RiVax® has demonstrated up to 100% protection in NHPs exposed to lethal aerosolized ricin), safety in humans (the RiVax® antigen has been demonstrated to be well-tolerated in human Phase 1 clinical studies) and immunogenicity correlated between animal models and humans.

As a new chemical entity, an FDA approved RiVax® vaccine has the potential to qualify for a biodefense PRV, which allows the holder accelerated review of a drug application. Approved under the 21st Century Health Cures Act in late 2016, the biodefense PRV is awarded upon approval as a medical countermeasure when the active ingredient(s) have not been otherwise approved for use in any context. PRVs are transferable and can be sold, with sales in recent years of approximately $100 million. When redeemed, PRVs entitle the user to an accelerated review period of six months, saving a median of seven months' review time as calculated in 2009. However, the FDA must be advised 90 days in advance of the use of the PRV and the use of a PRV is associated with an additional user fee ($2.1 million in 2020).

About Ricin Toxin

Ricin toxin is a lethal plant-derived toxin and is considered both a bioterrorism agent and a chemical warfare agent because of its stability and high potency, and the fact that it is readily extracted from by-products of castor oil production. Ricin comes in many forms including powder, mist or pellet. Ricin can also be dissolved in water and other liquids. The U.S. Centers for Disease Control and Prevention estimates that the lethal dose in humans is about the size of a grain of salt. Ricin toxin illness causes tissue necrosis and general organ failure leading to death within several days of exposure. Ricin is especially toxic when inhaled. Ricin works by entering cells of the body and preventing the cells from making the proteins they need. Without the proteins, cells die, which is eventually harmful to the entire body.

There are currently no effective treatments for ricin poisoning. The successful development of an effective vaccine against ricin toxin may act as a deterrent against the actual use of ricin as a biological weapon and could be used to vaccinate military personnel and civilian emergency responders at high risk of potential exposure in the event of a biological attack.

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).

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.

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For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200
