Soligenix Investor Relations

Thermostable Vaccine Technology Platform to be Presented at the 6th International Conference on Vaccines Research and Development

PRINCETON, N.J., Nov. 1, 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 that Oreola Donini, PhD, Chief Scientific Officer, will be presenting key data from the Company's thermostable vaccine technology platform, including results from the Company's programs for ricin toxin vaccine (RiVax®), COVID-19 vaccine (CiVax™) and filovirus vaccines (targeting Ebola, Sudan, and Marburg viruses). The presentation will be given at the upcoming 6th International Conference on Vaccines Research and Development, Online, on November 1-3, 2021.

Oral Presentation:
A Thermal Stabilization Platform for Subunit Proteins Compatible with Multiple Adjuvants, with Data from Ricin Toxin, Filovirus and COVID-19 Vaccine Candidates presented by Oreola Donini, PhD, Chief Scientific Officer, on November 2, 2021 from 9:30 – 10:00 AM EST. The official program is here.

Under the Company's Public Health Solutions business segment, Soligenix is developing thermostabilized subunit vaccines. Thermostabilization is achieved by using a combination of Generally Recognized as Safe (GRAS) excipients and lyophilization (freeze-drying) to yield a single-vial presentation of vaccine that is stable at ambient and higher temperatures and that can be reconstituted with water for injection immediately prior to use. The most advanced program is RiVax®, a ricin toxin vaccine utilizing an alum adjuvant. The thermostabilized RiVax® product has been demonstrated to achieve up to 100% protection, even after lethal aerosol exposure to ricin in non-human primates, and to be fully potent even after at least 12 months storage at 40 degrees Celsius (104 degrees Fahrenheit).

The filovirus and CiVax™ programs use similar formulation conditions in combination with a novel nano-emulsion adjuvant, CoVaccine HT™. Ongoing collaborations have demonstrated the feasibility of developing thermally-stable single-vial presentation vaccines for all three filoviruses, as well as combination vaccines in a single-vial formulation (mono-, bi- and tri-valent vaccines) that has the potential to enable generation of broader protective vaccines. Most recently, the antigen and adjuvant manufacturing advances demonstrated in the filovirus program have been found to be similarly effective in the CiVax™ program. This simple delivery format, as well as the compatibility with ambient storage, enables vaccines that significantly reduce the logistical hurdles that have been required for addressing both filovirus and COVID-19 pandemics. The filovirus and CiVax™ vaccine programs are continuing to advance with the support of a National Institute of Health (NIH) grant R01-AI132323 (awarded to the University of Hawaii) and a Small Business Innovation Research grant (#1R44AI157593-01; awarded to Soligenix, Inc.).

About the 6th International Conference on Vaccines Research and Development
The Conference is designed to facilitate an inspiring interdisciplinary exchange. Talks will be presented over the course of 3 days by internationally renowned speakers. More information about the conference, and registration to attend the talk, can be found here.

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 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
