Soligenix Investor Relations

Efficacy Results from Soligenix's Ricin Toxin Vaccine Program to be Presented at the 20th Annual Conference on Vaccine Research

PRINCETON, NJ – April 19, 2017 – 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 results from its ricin toxin vaccine (RiVax™) development program will be presented at the 20th Annual Conference on Vaccine Research, being held April 24-26 in Bethesda, Md.

"Serum Antibody Profiling following Vaccination Reveals a Correlate of Immunity to Ricin Toxin" will be presented by Jennifer Yates, Ph.D., New York State Department of Health, Wadsworth Center and attended by Oreola Donini, Ph.D., Chief Scientific Officer of Soligenix, on April 25 at 2:15 p.m. Eastern time.

RiVax™ is the Company's proprietary vaccine candidate for the prevention of exposure to ricin toxin that utilizes a unique antigen that is completely devoid of the toxic activity of ricin. When formulated with ThermoVax®, Soligenix's proprietary vaccine heat stabilization technology, RiVax™ has demonstrated significantly enhanced thermostability and 100% protection in preclinical ricin aerosol challenge models.

In collaboration with the New York State Department of Health and the laboratory of Nicholas Mantis, Ph.D., Soligenix has been investigating immune correlates of protection in sera of animals vaccinated with RiVax™. The findings demonstrate that: 1) the ThermoVax® thermostabilization process significantly enhances the stability of the RiVax™ antigen; 2) degradation in the antigen can be measured with specific monoclonal antibodies; and 3) these same monoclonal antibodies can be used to probe the immune profile of vaccinated mice and primates and predict their survival to subsequent ricin exposure challenge.

These findings are expected to facilitate the potential approval of the RiVax™ product under the U.S. Food and Drug Administration (FDA) "Animal Rule" and represent a significant step forward in the understanding of ricin toxin immunology. This work was funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, via Contract #HHSN272201400039C.

About the Annual Conference on Vaccine Research

In its 20th year, the Annual Conference on Vaccine Research is offered by the National Foundation of Infectious Diseases and brings together experts from around the world, including healthcare professionals, researchers, public health experts and industry. The 2017 conference includes a diverse range of topics including therapeutic vaccines and the use of novel technologies to fight emerging infectious diseases. Details regarding the annual conference can be found here.

About Ricin Toxin

Ricin toxin is a lethal plant-derived toxin and potential biological weapon because of its stability and high potency, and the fact 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 (CDC) estimates 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 it needs. 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 in rapid deployment scenarios in the event of a biological attack.

About RiVax™

RiVax™ is Soligenix's proprietary heat stable recombinant subunit vaccine developed to protect against exposure to ricin 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. A Phase 1A clinical trial was conducted with a formulation of RiVax™ that did not contain an adjuvant. This trial revealed dose dependent seroconversion as well as lack of toxicity of the molecule when administered intramuscularly to human volunteers. The adjuvant-free formulation of RiVax™ induced toxin neutralizing antibodies that lasted up to 127 days after the third vaccination in several individuals.

To increase the longevity and magnitude of toxin neutralizing antibodies, RiVax™ was subsequently formulated with an adjuvant of aluminum salts (known colloquially as Alum) for a Phase 1B clinical trial. Alum is an adjuvant that is used in many human vaccines, including most vaccines used in infants. The results of the Phase 1B study indicated that Alum-adjuvanted RiVax™ was safe and well tolerated, and induced greater ricin neutralizing antibody levels in humans than adjuvant-free RiVax™. In preclinical 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 large 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.

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.

The development of RiVax™ has been sponsored through a series of grants from both the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and the FDA, which were granted to Soligenix and to the University of Texas Southwestern (UTSW) where the vaccine protein originated. To date, Soligenix, Ellen Vitetta, Ph.D. and her colleagues at UTSW have collectively received approximately $25 million in funding from NIAID for development of RiVax™ and related vaccine technologies. RiVax™ potentially would be added to the Strategic National Stockpile and dispensed in the event of a terrorist attack. RiVax™ has received orphan drug designation from the FDA.

As a new chemical entity, an FDA approved RiVax™ vaccine has the potential to qualify for a biodefense Priority Review Voucher, 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 varying from between $125 million to $350 million.

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 BioTherapeutics business segment is developing SGX301 as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of 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 Vaccines/BioDefense business segment includes active development programs for RiVax™, our ricin toxin vaccine candidate, OrbeShield®, our GI acute radiation syndrome therapeutic candidate and SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease. 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) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website at www.soligenix.com.

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. 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 timing or success of the preclinical/clinical trials of RiVax™, that RiVax™ will be approved for the PRV program or the amount for which a PRV for RiVax™ can be sold. 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.
