

Soligenix Announces Poster Presentation of its Ricin Vaccine and Dusquetide Orphan Programs at the 2016 NORD Rare Diseases and Orphan Products Breakthrough Summit

Princeton, NJ - October 11, 2016 - Soligenix, Inc. (OTCQB: SNGXD) (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 it has been invited to present preliminary results from two programs at National Organization for Rare Disorders' (NORD's) Rare Diseases and Orphan Products Breakthrough Summit on October 17-18, 2016 in Arlington, VA.

The presented results will be available for viewing throughout the conference and will address preclinical efficacy findings in two programs that have previously been granted orphan drug designation by the US Food and Drug Administration (FDA) meaning it can be used as treatment by [Licensed Pharmaceutical Distributors](#):

- Dusquetide in the treatment of macrophage activation syndrome (MAS); and
- RiVax™, a proprietary thermostable ricin toxin vaccine, for the prevention of ricin intoxication.

Dusquetide (the active ingredient in SGX942) is a first-in-class Innate Defense Regulator. It modulates the response of the innate immune system in response to various stimuli, including infection, tissue damage and inflammation. Dusquetide has shown preclinical efficacy in an extensive array of preclinical models emphasizing all 3 aspects of its activity. As will be presented, the drug is effective in a preclinical model of MAS. This finding is supported by dusquetide's ability to improve survival in models of bacteremia which also feature excess innate immune pro-inflammatory signaling. Clinical activity, highlighting the anti-inflammatory action of dusquetide, has also been obtained in both Phase 1 and Phase 2 clinical studies. Results from the Phase 2 study recently demonstrated that dusquetide can reduce the duration of severe oral mucositis, caused by the excessive inflammatory response of the innate immune system to damage caused by chemoradiation, in head and neck cancer patients.

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

Poster Presentation Titles:

- ***An Innate Defense Regulator for the Treatment of Macrophage Activation Syndrome: Preclinical Studies in an Orphan Indication***
- ***Orphan Disease, Biodefense and the Animal Rule: A Thermostabilized Ricin Toxin Vaccine***

About the NORD Rare Disease and Orphan Products Breakthrough Summit

NORD's Rare Diseases and Orphan Products Breakthrough Summit features speakers from the FDA, participation of patient organizations and the Pharma/Biotech industry's foremost experts in orphan product innovation, investment and commercialization. More details about the conference can be found at <http://rarediseases.org/summit-overview/>.

About Dusquetide

Dusquetide is an innate defense regulator (IDR), a new class of short, synthetic peptides. It has a novel mechanism of action in that it modulates the body's reaction to both injury and infection towards an anti-inflammatory and an anti-infective response. IDRs have no direct antibiotic activity but, by modulating the host's innate immune system responses, increase survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens. It also accelerates resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- and/or radiation therapy. Preclinical efficacy and safety has been demonstrated in numerous animal disease models including mucositis, colitis, melioidosis, MAS and other bacterial infections. Some of these preclinical findings have been published in an article entitled "A novel approach for emerging and antibiotic resistant infections: Innate defense regulators as an agnostic therapy" and are available at the following link: <http://dx.doi.org/10.1016/j.jbiotec.2016.03.032>.

SGX942 (the drug product containing dusquetide) has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers. Recently, SGX942 has demonstrated preliminary efficacy and safety in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation (CRT) therapy for

head and neck cancer. Consistent with preclinical findings, SGX942 at a dose of 1.5 mg/kg demonstrated positive improvements in decreasing the duration of severe oral mucositis by 50% overall compared to the placebo group, from 18 days to 9 days ($p=0.099$). In patients at highest risk of oral mucositis (e.g., those exposed to the most aggressive concomitant chemotherapy), the reduction in the duration of severe oral mucositis was even more significant at 67% when treated with SGX942 1.5 mg/kg, from 30 days to 10 days ($p=0.04$). The p-values meet the prospectively defined statistical threshold of p

Dusquetide and related analogs have a strong intellectual property position, including composition of matter. Dusquetide was developed pursuant to discoveries made by Professors B. Brett Finlay, PhD and Robert Hancock, PhD of the University of British Columbia, Canada.

Drug products containing dusquetide have also received Fast Track Designations from the FDA for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients, and as an adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis. Orphan Drug Designation for use of dusquetide in the treatment of MAS has also been granted.

About RiVax™

RiVax™ is Soligenix's proprietary 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 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 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 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. 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 originated. To date, Soligenix and Dr. Ellen Vitetta and colleagues at UTSW have collectively received approximately \$25 million in grant funding from NIAID for development of RiVax™ and related vaccine technologies. RiVax™ would potentially be added to the Strategic National Stockpile and dispensed in the event of a terrorist attack. **About ThermoVax®**

ThermoVax® is a technology that is designed to eliminate the standard cold chain production, distribution and storage logistics required for most vaccines. Cold chain requirements add considerable cost to the production and storage of current conventional vaccines. According to the Biopharma Cold Chain Sourcebook of 2010, more than 90% of all vaccines (with a total value of \$20.6 billion) require shipment through cold chain. Elimination of the cold chain would also enhance the utility of these vaccines for emerging markets and for other applications requiring but lacking reliable cold chain capabilities. Further, the World Health Organization (WHO) reports that as much as 50% of all global vaccine doses are wasted due, in part, to excursions outside required temperature ranges. NIAID has also highlighted the priority of technologies for biodefense vaccines that focus on broad spectrum approaches including vaccine adjuvants and temperature stabilization for long shelf life, rapid onset of immunity, and surge capacity for production. For vaccines that are intended for long-term stockpiling, such as for use in biodefense or in pandemic situations, the utilization of ThermoVax® has the potential to facilitate easier storage and distribution of strategic national stockpile vaccines in emergency situations.

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. RiVax™ is extremely labile in liquid form requiring careful management under refrigerated conditions at 4 degrees Celsius (39 degrees Fahrenheit). By employing ThermoVax® during the final formulation, it is possible to produce stable and potent vaccines that are capable of withstanding temperatures at least as high as 40 degrees Celsius (104 degrees Fahrenheit) for up to one year.

The underlying technology has been developed by Drs. John Carpenter and Theodore Randolph at the University of Colorado. The vaccine technology has been developed to date in collaboration with SRI International, the

University of Kansas, the Wadsworth Center of the New York State Department of Health, and the Tulane National Primate Research Center under the sponsorship of the cooperative grant from NIAID.

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 melioidosis therapeutic candidate. The development of our vaccine programs incorporates the use of our proprietary heat stabilization platform technology, known as ThermoVax®. Currently, this business segment is supported with up to \$58 million in 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 US 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 US Congress may not pass any legislation that would provide additional funding for the Project BioShield program. 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.

<https://ir.soligenix.com/2016-10-11-soligenix-announces-poster-presentation-of-its-ricin-vaccine-and-dusquetide-orphan-programs-at-the-2016-nord-rare-diseases-and-orphan-products-breakthrough-summit>