Soligenix Investor Relations

Soligenix Announces Poster Presentations of its Ricin Vaccine and Dusquetide Oral Mucositis Programs at the 2018 NORD Rare Diseases and Orphan Products Breakthrough Summit

Princeton, NJ – October 4, 2018 – 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 it has been invited to present results from two of its development programs at National Organization for Rare Disorders' (NORD's) Rare Diseases and Orphan Products Breakthrough Summit on October 15-16, 2018 in Washington, DC.

The presented results will be available for viewing throughout the conference and will address efficacy findings in two programs that have previously been granted orphan drug or fast track designation by the U.S. Food and Drug Administration (FDA).

Poster Presentation Titles:

- ***Ricin Toxin Vaccine: Using Monoclonal Antibodies as Biomarkers to Satisfy the FDA's Animal Rule in Orphan Disease***
- ***A Novel Approach to Oral Mucositis: An Unmet Medical Need in Head and Neck Cancer Patients***

RiVax® is the Company's proprietary vaccine candidate for the prevention of death following exposure to ricin toxin using a unique antigen that is completely devoid of the toxic activity of ricin. RiVax® has demonstrated significantly enhanced thermostability and up to 100% protection in preclinical ricin aerosol challenge models. RiVax® potency correlated with the maintenance of protein conformational integrity, as confirmed by evaluating binding potential to monoclonal antibodies; when RiVax® protein conformation was altered, RiVax® potency was shown to be reduced. Moreover, antibody competition with binding to these same monoclonal antibodies was also predictive of survival to subsequent ricin toxin challenge, providing a potential species independent biomarker of RiVax® efficacy, as required under the FDA Animal Rule. The FDA Animal Rule is operative when human clinical efficacy testing is infeasible or unethical, a common issue with medical countermeasures developed for biodefense purposes.

Dusquetide (the active ingredient in SGX942) is a novel, 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 demonstrated efficacy in an extensive array of preclinical models emphasizing all three aspects of its activity. SGX942 is currently being evaluated in a Phase 3, randomized, double-blind, placebo-controlled, multinational clinical study for the treatment of oral mucositis in head and neck cancer patients. Positive results from the completed Phase 2 study evaluating the efficacy and safety of SGX942 will be presented, referencing its anti-infective, tissue healing and anti-inflammatory activity, as well as plans for the ongoing pivotal Phase 3 trial which is actively recruiting in the U.S. and Europe.

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 here.

About RiVax®

RiVax® is Soligenix's proprietary heat stable recombinant subunit vaccine developed to protect against exposure to ricin toxin, the recent threat of which has been highlighted in the news with an envelope addressed to President Trump that may have contained 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. 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 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. 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 sponsored through a series of grants from both National Institute of Allergy and Infectious Diseases (NIAID), and the FDA and ongoing development is sponsored by NIAID contract #HHSN272201400039C. The planned Phase 2 clinical trial is contingent upon exercise of the final option by the U.S. government under NIAID contract #HHSN272201400039C and/or through other funding sources. 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 in the U.S. and in Europe.

As a new chemical entity, an FDA approved RiVax® vaccine has the potential to qualify for a biodefense Priority Review Voucher (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 ranging between $125 million to $350 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 ($2.7 million in 2017).

About SGX942

Dusquetide (the active ingredient in SGX942) is an Innate Defense Regulator (IDR), a new class of short, synthetic peptides. It has a novel mechanism of action whereby it modulates the body's reaction to both injury and infection towards an anti-inflammatory, anti-infective and tissue healing response. IDRs have no direct antibiotic activity but, by modulating the host's innate immune system responses, increase survival after infections caused by 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, macrophage activation syndrome (MAS) as well as bacterial infections, including melioidosis.

SGX942 has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers. Positive efficacy results were demonstrated in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation therapy (CRT) for head and neck cancer (HNC). Soligenix is working with leading oncology centers in the US and Europe to advance SGX942 in oral mucositis with the conduct of a pivotal Phase 3 clinical trial referred to as the "DOM–INNATE" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity).

SGX942 has received Fast Track Designation from the FDA for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in HNC patients, as well as Promising Innovative Medicine designation in the United Kingdom by the Medicines and Healthcare Products Regulatory Agency for the treatment of severe oral mucositis in HNC patients receiving CRT. In addition, products containing the same active ingredient, dusquetide, have been granted Fast Track Designation as an adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis and Orphan Drug Designations in the treatment of MAS and the treatment of acute radiation syndrome.

Soligenix has a strong intellectual property position in the IDR technology platform, including composition of matter for dusquetide and related analogs. Dusquetide was developed pursuant to discoveries made by Professors B. Brett Finlay, PhD and Robert Hancock, PhD of the University of British Columbia, Canada. Soligenix has received partial funding from NIH for its oral mucositis clinical studies. The Phase 2 study was supported with a Phase I SBIR grant (#R43DE024032) award, with the Phase 3 study being supported by a Phase II SBIR grant (#R44DE024032) award.

Key nonclinical and clinical findings from the dusquetide program can be found in the following publications:

- “A novel approach for emerging and antibiotic resistant infections: Innate defense regulators as an agnostic therapy” at http://dx.doi.org/10.1016/j.jbiotec.2016.03.032.
- “Dusquetide: A Novel Innate Defense Regulator Demonstrating a Significant and Consistent Reduction in the Duration of Oral Mucositis in Preclinical Data and a Randomized, Placebo-Controlled Phase 2 Clinical Study” at http://dx.doi.org/10.1016/j.jbiotec.2016.10.010.
- “Dusquetide: Reduction in Oral Mucositis associated with Enduring Ancillary Benefits in Tumor Resolution and Decreased Mortality in Head and Neck Cancer Patients” at https://doi.org/10.1016/j.btre.2017.05.002.

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 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 the timing or success of the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy. 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.
