Soligenix Investor Relations

Broad-Spectrum Innate Defense Regulator Platform Technology to be Presented at the Peptide Therapeutics Foundation Symposium

PRINCETON, NJ – October 24, 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 it will be presenting the Innate Defense Regulator (IDR) technology platform and its potential utility in various therapeutic applications on October 27, 2017 at the Peptide Therapeutics Foundation Symposium taking place at the Salk Institute for Biological Studies, La Jolla, CA from October 26 – 27, 2017. The presentation will address the IDR mechanism of action as well as the preclinical and clinical data obtained with the Company's lead IDR peptide, dusquetide.

Details of the Oral Presentation:

Innate Defense Regulator Peptides: A Novel Mechanism with Broad Applicability in Multiple Disease Indications presented by Dr. Oreola Donini, Chief Scientific Officer on October 27, 2017 at 11 am Pacific Daylight Time.

IDRs modulate the innate immune response, down-modulating the inflammatory response and augmenting the tissue-healing and anti-infective immune response pathways. IDRs have potential utility in a broad spectrum of diseases including acute inflammatory conditions (e.g., intestinal bowel disease), infectious disease (e.g., bacterial infection, including infection caused by antibiotic resistant microbes), immune perturbation (e.g., oncology) and tissue damage (e.g., oral mucositis). Dusquetide has demonstrated preclinical activity in bacterial infection models both as a stand-alone agent and as a synergistic treatment with antibiotics. Other preclinical models have demonstrated activity in oral and gastrointestinal mucositis, gastrointestinal inflammation, and modulation of tumor growth.

In a Phase 2 clinical trial in oral mucositis in which SGX942, Soligenix's product candidate containing dusquetide, not only reduced the duration of severe oral mucositis in response to chemotherapy and radiation therapy induced tissue damage in head and neck cancer patients, but also reduced the incidence of infections in patients treated with SGX942. In addition, patients receiving SGX942 were found to have an accelerated resolution of tumor burden and a decreased mortality rate. Building upon positive Phase 2 data, Soligenix has recently initiated a pivotal Phase 3 clinical trial with SGX942 in this patient population.

About the Peptide Therapeutics Foundation Symposium

The Peptide Therapeutics Foundation was established in 2008 to promote research and development of peptide therapeutics. The Annual Peptide Therapeutics Symposium is held every year in San Diego, California and includes world leaders from academia, the biopharmaceutical industry, contract research and manufacturing organizations, and investors. Focused discussion topics include drug discovery, safety and toxicology, clinical development, manufacturing, pharmaceutical development, formulation, drug delivery and regulatory affairs. Details on the symposium can be found here.

About Dusquetide

Dusquetide (the active ingredient in SGX942) is an 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 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 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, melioidosis, macrophage activation syndrome (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," available at the following link: http://dx.doi.org/10.1016/j.jbiotec.2016.03.032.

SGX942 has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers. Recently, SGX942 had positive results in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation therapy (CRT) for HNC. 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 the highest risk of developing severe oral mucositis (i.e., those receiving concomitant cisplatin chemotherapy of 80-100 mg/m2 every third week), 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 met the prospectively defined statistical threshold of p<0.1 in the study protocol. Additional observations included an improved tumor response to CRT at the one month follow-up visit, as well as decreases in mortality and infection rate. The study results are reviewed in "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," published online in the *Journal of Biotechnology* and available at the following link: http://dx.doi.org/10.1016/j.jbiotec.2016.10.010.

Long-term (12 month) follow-up data further indicated the safety and tolerability of SGX942 treatment, with a sustained trend towards reduced mortality and increased tumor resolution in the 1.5 mg/kg SGX942 treatment group compared to the placebo group. Opioid pain medication use was also seen to decrease over the course of CRT in the 1.5 mg/kg SGX942 treatment group at the point of highest oral mucositis risk, while it increased in the placebo group. Detailed clinical results from the Phase 2 study, as well as a review of the pathogenesis of oral mucositis and the mechanism of action of SGX942, are discussed here. The long-term follow-up results from the Phase 2 study are reviewed in, "Dusquetide: Reduction in Oral Mucositis associated with Enduring Ancillary Benefits in Tumor Resolution and Decreased Mortality in Head and Neck Cancer Patients", published online in *Biotechnology Reports* and available at the following link: https://doi.org/10.1016/j.btre.2017.05.002.

Soligenix has received partial funding from NIDCR 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.

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 HNC patients, and as an adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis. Orphan Drug Designations for use of dusquetide in the treatment of MAS as well as for the treatment of acute radiation syndrome have also been granted. In addition, dusquetide has been granted 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.

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.

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 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 and the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. 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.
