Soligenix Investor Relations

## Soligenix to Present Data on Dusquetide at the 19th Annual Superbugs & Superdrugs Conference

**PRINCETON, NJ – March 15, 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 Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix will present preclinical and clinical results on the use of dusquetide (SGX94) in the treatment of emerging and antibiotic resistant infectious diseases at Superbugs & Superdrugs – A Focus on Antibacterials. The conference is being held in London March 20-21, 2017.

Details of the Oral Presentation:

- Innate Defense Regulators: Agnostic Therapy For Antibiotic Resistant Disease – "Supercharging existing and new antibiotic therapies," presented by Dr. Oreola Donini, Chief Scientific Officer of Soligenix, on March 20, 2017 at 1:20 pm local time. Conference details are available here.

Dr. Donini will present key data from mechanistic studies, multiple animal models and the Company's Phase 2 oral mucositis study.

Last month, the European Food Safety Authority and European Center for Disease Prevention and Control estimated that superbugs kill 25,000 Europeans each year; the US Centers for Disease Control and Prevention estimates that they kill at least 23,000 Americans a year. The World Health Organization also has warned that a dozen antibiotic-resistant superbugs pose an enormous threat to human health.

Dusquetide, also known by the research name SGX94, is an Innate Defense Regulator (IDR) and the active ingredient in the drug SGX942, which yielded positive results in a Phase 2 clinical trial in oral mucositis. In that trial, a significant decrease in the rate of infections was also observed in the group treated with SGX942, a finding that is consistent with preclinical data supporting the broad-spectrum activity of IDRs in the treatment of bacterial infections. Preclinical data demonstrate that dusquetide can be used prophylactically (before infection), pre-emptively (after infection but prior to significant symptoms) and therapeutically (after symptoms appear) to treat bacterial infections, whether caused by Gram-positive or Gram-negative bacteria and regardless of resistance to antibiotic treatment. Moreover, dusquetide treatment is complementary with antibiotic action; this holds potential for a very effective combination treatment, which is particularly relevant for the treatment of antibiotic-resistant bacterial infections.

**About the Superbugs & Superdrugs Conference**

The Superbugs & Superdrugs Conference is an annual industry meeting bringing together international experts and project decision makers to discuss antimicrobial resistance. Details on the conference are available here.

**About Dusquetide**

Dusquetide (the active ingredient in the SGX942 drug product) is an 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 anti-inflammatory and anti-infective responses. IDRs have no direct antibiotic activity, but by modulating the host's innate immune system responses, they increase survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens. They also accelerate 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," and are available at the following link: http://www.sciencedirect.com/science/article/pii/S0168165616301390.

SGX942 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 $p<0.1$ in the study protocol. Additional observations included an improved tumor response to CRT therapy at the one month follow-up visit, as well as decreases in 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 2a Clinical Study" published online in the *Journal of Biotechnology* and are available at the following link: http://www.sciencedirect.com/science/article/pii/S0168165616315668. Long-term (12 months) follow-up data further indicated the safety and tolerability of SGX942 treatment, with a trend towards reduced mortality and

increased tumor resolution in the 1.5 mg/kg SGX942 treatment 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.

The Phase 2 oral mucositis clinical study was partially funded with a grant from the National Institute of Dental and Craniofacial Research Small Business Innovation Research grant #1R43 DE024032-01 (Soligenix, Inc.).

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 US Food and Drug Administration (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 Designations from the FDA 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, the UK Medicines and Healthcare Products Regulatory Agency has granted the Promising Innovative Medicine (PIM) designation to SGX942 in oral mucositis.

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

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