

## **Dusquetide as a Potential Solution to Antimicrobial Resistant Bacteria to be Presented at the 2017 World Anti-Microbial Resistance Congress**

**PRINCETON, NJ – September 11, 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 anti-infective activity of the dusquetide (SGX94) technology platform and its utility in anti-microbial resistance on September 14, 2017 at the World Anti-Microbial Resistance Congress taking place in Washington, DC from September 14 – 15, 2017. The presentation will address dusquetide’s novel mechanism of anti-inflammatory, anti-infective and tissue-healing action, including effectiveness data from the SGX942 Phase 2 clinical trial in oral mucositis.

### Details of the Oral Presentation:

Innate Defense Regulators (IDRs) as an Agnostic Therapy to Treat Bacterial Infections and Fight Resistance presented by Dr. Oreola Donini, Chief Scientific Officer on September 14, 2017 at 3:30 pm Eastern Daylight Time. The abstract is available [here](#).

Dusquetide is an Innate Defense Regulator (IDR) which has demonstrated preclinical activity in bacterial infection models as both a stand-alone agent and as a synergistic treatment with antibiotics. Dusquetide is equally effective irrespective of the bacterial pathogen, with efficacy demonstrated with gram-positive and gram-negative bacteria as well as with bacteria occupying intracellular or extracellular niches and bacteria with antibacterial resistance mechanisms. The IDRs leverage a unique mechanism of action, acting at a key intracellular convergence point in the innate immune pathways, facilitating a multi-dimensional impact on the response of the innate immune system to any stimulus, ameliorating tissue damage and increasing survival following exposure to a variety of agents, including a broad range of bacterial pathogens, trauma and radiation or chemotherapy.

Dusquetide has been demonstrated to be clinically effective in modulating the innate immune system. In a Phase 2 clinical trial in oral mucositis in which SGX942, the drug product 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. Building upon positive Phase 2 data, Soligenix has recently initiated a pivotal Phase 3 clinical trial with SGX942 in this patient population.

### **About the World Anti-Microbial Resistance Congress**

Starting in 2015, the annual World Anti-Microbial Resistance Congress brings together stakeholders from government, funding agencies, pharma, academia, hospitals, and payers. The meeting focuses on both the scientific and economic sides of the antimicrobial resistance space. Details on the congress 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/m<sup>2</sup> 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 the National Institute of Dental and Craniofacial Research, part of the National Institutes of Health, for its oral mucositis clinical studies. The Phase 2 study was supported with a Phase I SBIR grant (#1R43 DE024032-01) 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](http://www.soligenix.com).

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*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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