Soligenix Investor Relations

# Soligenix Receives US Patent for Dusquetide Related Analogs

**Patent broadens protection in infectious disease and oral mucositis, including composition of matter claims**

**Princeton, NJ – April 04, 2019 –** 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 the US Patent Office will issue the patent titled "Novel Peptides for Treating and Preventing Immune-Related Disorders, Including Treating and Preventing Infection by Modulating Innate Immunity" on April 9, 2019. The new patent (#10,253,068) claims composition of matter for novel innate defense regulator (IDR) analogs, expanding patent protection to more diverse analog structures. Therapeutic use claims in oral mucositis, colitis, and infectious disease, both alone and in conjunction with antibiotics, will also issue.

Dusquetide (the active ingredient in SGX942) is a novel, first-in-class IDR. 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 demonstrated positive results in a Phase 2 study in the treatment of oral mucositis in head and neck cancer (HNC) patients. SGX942 at a dose of 1.5 mg/kg successfully reduced the median duration of severe oral mucositis by 67% in patients receiving the most aggressive chemoradiation therapy for treatment of their cancer. In addition to the oral mucositis findings, an increased incidence of "complete response" of tumor at the one month and 12-month follow-up visits were observed. Decreases in infection rate and an increase in the 12-month survival rate were also observed with SGX942 treatment.

SGX942 is currently being evaluated in a pivotal, Phase 3, randomized, double-blind, placebo-controlled, multinational clinical study for the treatment of oral mucositis in HNC patients. The ongoing Phase 3 trial, referred to as the "DOM–INNATE" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity), is actively enrolling patients in the US and Europe.

"Soligenix continues to pursue broad patent coverage for dusquetide and its library of related IDR analogs, first with composition of matter claims followed by therapeutic use claims, such as in oral mucositis," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The composition of matter patents are generally valid until 2028."

**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, 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 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:

- “Targeting Innate Immunity to Treat Disease: Potential Therapeutic Applications” at https://www.drugtargetreview.com/article/37410/targeting-innate-immunity/.
- “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.

In addition, a high level review of the dusquetide technology platform is available here.

**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 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 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 or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the PRV program or the amount for which a PRV for RiVax® can be sold. 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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