Soligenix Investor Relations

NIH selects Soligenix's SGX942 in the Treatment of Oral Mucositis for the Commercialization Accelerator Program

Princeton, NJ – September 13, 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 the National Institutes of Health (NIH) selected Soligenix's SGX942 (dusquetide) development program for the treatment of oral mucositis in head and neck cancer (HNC) patients as a Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Commercialization Accelerator Program (CAP) Phase II awardee for 2018-2019. The SGX942 program has been specifically selected by the NIH for the Commercialization Transition Track, which provides technical assistance to awardee companies to advance NIH-funded technologies towards commercialization and market readiness.

Soligenix applied for the CAP as part of its $1.5 million Phase II SBIR/STTR NIH grant to develop SGX942 as a treatment for oral mucositis in HNC patients receiving chemoradiation therapy (CRT). Only a select number of SBIR Phase II awarded companies are accepted into the CAP by the NIH.

"We are appreciative of the NIH for selection into the Commercialization Accelerator Program and for their continued support of Soligenix and the SGX942 development program," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We believe that this NIH CAP has the potential to accelerate the commercialization strategy for the oral mucositis program, in parallel with the ongoing pivotal, multi-national Phase 3 study. Oral mucositis remains an extremely debilitating side effect of cancer treatment and is particularly severe and prevalent in HNC patients. Soligenix looks forward to continuing work with NIH as we participate in this respected program."

Dusquetide (the active ingredient in SGX942) is an innate defense regulator (IDR), a new class of short, synthetic peptides with a novel mechanism of action modulating the body's reaction to both injury and infection towards a simultaneously anti-inflammatory and anti-infective response. By altering the response of the innate immune system, IDRs increase survival after infections caused by a broad range of bacterial Gram-negative and Gram-positive pathogens. They also accelerate resolution of tissue damage (including oral mucositis) following exposure to a variety of agents including bacterial pathogens, trauma and chemo- and/or radiation therapy.

Soligenix is working with leading oncology centers to advance dusquetide with the conduct of a Phase 3 clinical trial referred to as the "DOM–INNATE" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity). Top-line results from this trial are targeted for the second half of 2019.

About Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa by anticancer therapies. It can occur in any mucosal region, but is most commonly associated with the mouth, followed by the small intestine. It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of mucositis, that mucositis affects approximately 500,000 people in the US per year and occurs in 40% of patients receiving chemotherapy. Mucositis can be severely debilitating and can lead to infection, sepsis, the need for parenteral nutrition and narcotic analgesia. The gastrointestinal damage causes severe diarrhea. These symptoms can limit the doses and duration of cancer treatment, leading to sub-optimal treatment outcomes.

The mechanisms of mucositis have been extensively studied and have been recently linked to the interaction of chemotherapy and/or radiation therapy with the innate defense system. Bacterial infection of the ulcerative lesions is now regarded as a secondary consequence of dysregulated local inflammation triggered by therapy-induced cell death, rather than as the primary cause of the lesions.

It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of oral mucositis, that oral mucositis in HNC is a subpopulation of approximately 90,000 patients in the US, with a comparable number in Europe. Oral mucositis almost always occurs in patients with HNC treated with CRT and is severe, causing inability to eat and/or drink, in >80% of patients. It is common (40-100% incidence) in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

Oral mucositis in HNC remains an area of unmet medical need where there are currently no approved drug therapies.

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 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 and positive results in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to CRT for HNC. 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 from the Phase 2 study further indicated the safety and tolerability of SGX942. The long-term follow-up results 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 is working with leading oncology centers in the US and Europe to advance SGX942 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).

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.

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 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.
