Soligenix Announces Publication of its Phase 2 Clinical Trial Results of SGX942 for the Treatment of Oral Mucositis in Head and Neck Cancer Patients

Positive Clinical Results Consistent with Preclinical Data

Princeton, NJ – October 18, 2016 –Soligenix, Inc. (OTCQB: SNGXD) (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 the publication of the positive interim results from its recent Phase 2 clinical trial in which SGX942 (dusquetide) demonstrated a statistically significant reduction in the median duration of severe oral mucositis by 50% in all patients and by 67% in patients at the highest risk for developing severe oral mucositis. Other important findings in the study included a reduction in the incidence of infection and an increase in tumor resolution at one month post-radiation. The publication also delineates the supportive nonclinical data in this indication, demonstrating consistency in the qualitative and quantitative biological response, including dose response, across the nonclinical and clinical data sets. The results were published online in the *Journal of Biotechnology* and are available at the following link: http://authors.elsevier.com/sd/article/S0168165616315668.

As a first-in-class innate defense regulator (IDR), dusquetide modulates the innate immune system by interacting at an intracellular integration point, operating downstream of most innate immune receptors and upstream of most cytokine and chemokine effectors. IDRs directly interact with an important protein known as p62, or sequestosome-1, thereby enhancing the tissue-healing and anti-infective mechanisms of the innate immune system and decreasing the often deleterious inflammatory responses. The pathogenesis of oral mucositis is believed to be related to a dysregulation of the innate immune system. In a randomized, double-blind, placebo-controlled Phase 2 clinical trial, SGX942, containing dusquetide at a dose of 1.5 mg/kg, successfully reduced the median duration of severe oral mucositis when compared to placebo by 50% in all patients and by 67% in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. In addition to the oral mucositis findings, decreases in the non-fungal (i.e., bacterial) infection rate were observed with SGX942 treatment (45% in placebo versus 28% in SGX942 at 1.5 mg/kg), along with an increased incidence of “complete response” of tumor (i.e., disappearance) at the one month follow-up visit (47% in placebo versus 63% in SGX942 at 1.5 mg/kg). Preclinical data supporting the anti-infective activity of dusquetide has also been previously published (http://dx.doi.org/10.1016/j.jbiotec.2016.03.032).

“The IDR technology was initially discovered in the context of infectious disease and later extended to indications involving tissue damage and concomitant inflammation. The Phase 2 results not only confirmed that the unique biology of IDRs seen in preclinical animal models translates well into the human clinical setting, but also validated the important role that innate immunity plays in the pathogenesis of oral mucositis,” stated Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix. “With positive proof of concept demonstrated in humans, the IDR technology may now be applied across a range of potential indications, including antibiotic resistant and emerging infectious disease, gastrointestinal inflammation and acute radiation injury.”

“These data demonstrate the broad and promising potential of our IDR technology platform,” stated Richard Straube, MD, Senior Vice President and Chief Medical Officer of Soligenix. “While we continue to actively develop dusquetide for the treatment of oral mucositis, an area of unmet medical need where there is currently no approved drug therapy, we are also poised to expand the IDR platform into other potential indications, such as infectious disease. The broad-spectrum activity of IDRs against bacterial infectious disease makes them promising candidates for the treatment of antibiotic resistant and emerging infectious disease.”

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). Long-term follow-up visits remain ongoing in the study with further data expected by the end of 2016.

About Dusquetide

Dusquetide is an innate defense regulator (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 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 with 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” and are available at the following link: http://dx.doi.org/10.1016/j.jbiotec.2016.03.032.

SGX942 (the drug product containing dusquetide) 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.

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 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 for use of dusquetide in the treatment of MAS as well as for the treatment of acute radiation syndrome have also been granted.

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 head and neck cancer 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 head and neck cancer treated with chemoradiation therapy 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 head and neck cancer remains an area of unmet medical need where there are currently no approved drug therapies

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®. Currently, this business segment is supported with up to $58 million in 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 atwww.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 US 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 US Congress may not pass any legislation that would provide additional funding for the Project BioShield program. 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.
