Soligenix Announces Positive Long-Term Follow-up Results from its Phase 2 Clinical Trial of SGX942 for the Treatment of Oral Mucositis in Head and Neck Cancer Patients

Study data supports advancing development to pivotal Phase 2b/3 program

Princeton, NJ – December 8, 2016 – Soligenix, Inc. (OTCQB: 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 the long-term follow-up data from its Phase 2 clinical trial with SGX942 (dusquetide), a first-in-class Innate Defense Regulator (IDR), in the treatment of oral mucositis (OM) in head and neck cancer patients undergoing chemoradiation therapy (CRT). The additional 12-month safety data remains consistent with the preliminary positive safety and efficacy findings from the Phase 2 study and provide further support for advancing SGX942 into a pivotal Phase 2b/3 clinical trial. Following the positive results announced in December 2015, in which SGX942 at a dose of 1.5 mg/kg, successfully reduced the median duration of severe OM by 50% in all patients and by 67% in patients at highest risk of developing severe OM, long-term follow-up visits conducted throughout 2016 further demonstrated that SGX942 was safe, well-tolerated, and did not interfere with CRT as demonstrated by improved survival and tumor resolution at one and 12 months. Overall, there were no drug-related toxicities identified in this study.

While the placebo population experienced the expected 12-month survival rate of approximately 80%, as defined in the Surveillance, Epidemiology, and End Results (SEER) statistics 1975-2012 from the National Cancer Institute, the SGX942 1.5 mg/kg treatment group reported a 12-month survival rate of 93% (7% mortality in the SGX942 1.5 mg/kg group compared to 19% in the placebo group). Similarly, tumor resolution (complete response) at 12 months was better in the SGX942 1.5 mg/kg treatment group relative to the placebo population (80% in the 1.5 mg/kg group compared to 74% in the placebo group).

In addition to safety, evaluations of other secondary efficacy endpoints, such as the utilization of opioid pain medication, indicated that the SGX942 1.5 mg/kg treatment group had a 40% decrease in the use of opioids at the later stage of the treatment phase of the trial, when OM is usually most severe and expected to increase pain medication use. This was in contrast to the placebo group, which demonstrated a 10% increase in use of opioids over this same period. These results are consistent with the observed significant decrease in the duration of severe OM. There were no differences observed in the rates of xerostomia (dry mouth) and trismus (limited jaw range of motion) across the SGX942 and placebo dose groups in the study.

“We are extremely pleased with the findings from the Phase 2 study of SGX942. The study met all of its objectives including defining a clinically effective dose of SGX942 – specifically the 1.5 mg/kg as seen in both the acute and long-term follow-up phases of the trial. We also identified the most appropriate clinical endpoint and patient population to use in a future pivotal study,” stated Richard Straube, MD, Senior Vice President and Chief Medical Officer of Soligenix. “The positive and clinically meaningful effect observed on the duration of ulcerative and severe OM clearly demonstrates the significant biologic activity that SGX942 exerts on this catastrophic side effect of cancer treatment. Additionally, the positive impact of the drug on the reported infection rates as well as the trends in improved survival rates and complete tumor responses at both one and 12 months following CRT is consistent with preclinical findings, not only confirming the long-term safety and tolerability of SGX942 in a sick patient population, but the drug’s exciting potential as an effective treatment in OM.”

“Given the positive and compelling data generated in OM, where there is a substantial unmet medical need and market potential, we are engaging the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) on the design of a pivotal Phase 2b/3 clinical program,” stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. “In parallel, we continue to pursue partnership opportunities to support ongoing SGX942 clinical development. With the biologic activity of the IDR technology now confirmed in humans, we are also looking to expand its potential utility in the infectious disease space.”

The Phase 2 exploratory study enrolled 111 patients across three SGX942 dose groups (i.e., 1.5, 3.0, and 6.0 mg/kg) and a placebo group and evaluated patients undergoing CRT for head and neck cancer. This study achieved all objectives, including identifying the best dose of 1.5 mg/kg. In the 1.5 mg/kg treatment group, the median duration of severe OM was decreased by 50%, from 18 days to 9 days ($p=0.099$), meeting the prospectively defined statistical threshold of $p<0.1$ in the study protocol. Further, patients receiving the most aggressive CRT in this dose group had even more striking reductions in their median duration of severe OM of 67%, from 30 days to 10 days ($p=0.040$). Clinicians are most concerned about severe OM, which includes patients who cannot eat and/or drink due to their mouth ulcers. All dose levels of SGX942 were found to be safe and well tolerated.

In addition to the OM findings and safety assessments, a decrease in infection rate was also observed with

SGX942 treatment, particularly with infections of bacterial origin. Top-line data from this study was recently published in the *Journal of Biotechnology*, available at: http://dx.doi.org/10.1016/j.jbiotec.2016.10.010. The long-term (12 month) follow-up data from the trial is also expected to be submitted for future presentation and publication.

About Oral Mucositis

Mucositis is the clinical term for damage done to the mucosa of the entire gastrointestinal tract 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, intravenous rehydration, and narcotic analgesia. The intestinal damage can cause 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 anti-cancer 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 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 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 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://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 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 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 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 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 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.
