Soligenix Investor Relations

Soligenix Announces Publication of its Phase 2 Long-Term Follow-Up Results of SGX942 for the Treatment of Oral Mucositis in Head and Neck Cancer Patients

At 12 Months SGX942 Found to be Safe and Well Tolerated with Multiple Potential Ancillary Benefits

PRINCETON, NJ – May 18, 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 long-term follow-up data from its recent positive Phase 2 clinical trial, in which SGX942 (dusquetide) demonstrated a significant reduction in the median duration of severe oral mucositis in patients with head and neck cancer (HNC), have been published in the peer-reviewed journal *Biotechnology Reports*. These 12-month data further support the safety and tolerability of SGX942, with the 1.5 mg/kg treatment group demonstrating accelerated tumor resolution and a decreased mortality rate relative to the placebo group. The results were published online and are available here.

As a first-in-class innate defense regulator (IDR), dusquetide modulates the innate immune system, enhancing its tissue-healing and anti-infective mechanisms and decreasing the often deleterious inflammatory responses. The pathogenesis of oral mucositis involves the dysregulation of the innate immune system. In a randomized, double-blind, placebo-controlled Phase 2 clinical trial in 111 patients, SGX942 (1.5 mg/kg dusquetide) 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 (CRT) for treatment of their HNC. In addition to the oral mucositis findings, decreases in the bacterial infection rate were observed with SGX942 treatment, along with an increased incidence of “complete response” of tumor (i.e., disappearance) at the one month follow-up visit and a reduction in opioid pain medication use.

Long-term follow-up data indicate that the tumor resolution was enduring and, moreover, that the mortality rate in the SGX942 1.5 mg/kg treatment group was lower ($p=0.08$) than the placebo group over the 12 months following completion of CRT. These data further support the safety and tolerability of SGX942 in this patient population. Potential ancillary benefits of utilizing SGX942 for the treatment of oral mucositis include the reduction of infection, the accelerated tumor resolution and the decreased mortality rate.

Soligenix recently announced that it has received US Food and Drug Administration (FDA) clearance to advance the pivotal Phase 3 clinical trial and released the protocol study design for SGX942, following the completion of the Phase 2 follow-up visits late last year. The Phase 3 study utilizes the patient population at highest risk of severe oral mucositis as identified in the Phase 2 study (i.e., those receiving the most aggressive CRT). While the drug effect was 67% in the Phase 2 study, a much more conservative estimate was utilized in planning the Phase 3 study, yielding a study size of approximately 190 subjects. SGX942 will be administered in conjunction with the CRT, as a treatment for oral mucositis.

“The long-term follow-up data further support the safety and tolerability of SGX942, consistent with the results from the previous Phase 1 study,” stated Richard Straube, MD, Senior Vice President and Chief Medical Officer of Soligenix. “The Phase 2 study also enabled a highly powered and efficient Phase 3 study to be designed, which will use duration of severe oral mucositis as the primary endpoint, while continuing to assess incidence of infection, tumor resolution status and survival as important safety endpoints. We look forward to starting the pivotal Phase 3 study this year.”

“The primary objective of the Phase 2 study was to demonstrate the safety and explore the efficacy of SGX942,” stated Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix. “The results from the follow-up evaluations indicate that SGX942 is safe and well tolerated and may have a number of additional benefits. The consistency between the clinical findings and the earlier nonclinical studies further demonstrates the applicability of dusquetide to a human clinical population in multiple indications, including reduction of infection. Accordingly, we will continue to explore expanding the IDR technology across additional indications, including 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.).

About SGX942

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 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/m2 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.

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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.

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.

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 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.

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