

Soligenix Announces Presentation of Phase 2 Oral Mucositis Clinical Trial Results at the 2016 Multinational Association for Supportive Care in Cancer Conference

Princeton, NJ – June 6, 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 that it will be presenting preliminary results from its SGX942 Phase 2 clinical trial in oral mucositis on June 25, 2016 at the Multinational Association for Supportive Care in Cancer (MASCC) conference taking place in Adelaide, Australia from June 23 to 25, 2016.

SGX942 is the drug product using dusquetide, an Innate Defense Regulator, for the treatment of oral mucositis. Preliminary data with SGX942 was announced on December 16, 2016. Long-term follow-up visits in the study are ongoing with final results expected by the end of the year. The trial, entitled “A Phase 2, double-blind, randomized, placebo-controlled, dose-escalating, multicenter study of SGX942 for the attenuation of oral mucositis in patients being treated with concomitant chemoradiation for the treatment of squamous cell carcinoma of the head and neck”, was the first evaluation of dusquetide efficacy in a sick patient population and demonstrated a positive, clinically meaningful reduction in the duration of severe oral mucositis. The reduction in duration of severe oral mucositis ranged from 50% in the overall population to 67% in the population with the most severe disease. The incidence of infection and the resolution of tumor burden were also improved with dusquetide treatment. On the basis of these results, Soligenix is currently planning a pivotal Phase 2b/3 clinical program.

Key data from the Phase 2 study will be presented.

Details of the Oral Presentation:

SGX942 Reduced the Duration of Severe Oral Mucositis in Head and Neck Cancer Patients in a Phase 2 Placebo-Controlled, Double-Blinded, Randomized Trial will be presented by Dr. Oreola Donini, Chief Scientific Officer and attended by Dr. Richard Straube, Chief Medical Officer on June 25, 2016 at 9:12 am. The abstract is available [here](#).

About the MASCC Conference

The Multinational Association of Supportive Care in Cancer (MASCC) is an international multidisciplinary organization dedicated to research, practice, and education in all aspects of supportive care for people with cancer, regardless of the stage of their disease. Founded in 1990, MASCC now includes members from more than 60 countries and 5 continents. Details on the MASCC society can be found at <http://www.mascc.org/>. The annual meeting is alternately held on various continents. This year's conference, held in conjunction with the International Society of Oral Oncology in Adelaide Australia, will feature reviews of the progress made in supportive care over the past thirty years as well as disparities in supportive care across the world and will include a special patient symposium.

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 (>80% incidence of severe mucositis) and 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

SGX942 is an innate defense regulator (IDR), which contains a new class of short, synthetic peptide, having the chemical name dusquetide. 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 and other bacterial infections.

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 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 (47% in placebo versus 63% in SGX942 at 1.5 mg/kg), 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.

SGX942 has received fast track designation from the US Food and Drug Administration (FDA) for the treatment of oral mucositis as a result of radiation and/or chemotherapy treatment in head and neck cancer patients. Fast track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, Soligenix will be eligible to submit a new drug application (NDA) for SGX942 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for fast track development programs ordinarily will be eligible for priority review, which imparts an abbreviated review time of approximately six months.

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 first-in-class photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, 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), and our novel innate defense regulator technology dusquetide (SGX942) for the treatment of oral mucositis.

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 \$57 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," "intends," "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, including dusquetide (SGX942), particularly in light of the significant uncertainty inherent in developing vaccines against bioterror threats conducting preclinical and clinical trials of vaccines, obtaining regulatory approvals and manufacturing 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. Positive results from the Phase 2 study evaluating SGX942 does not ensure that the follow-on Phase 2/3 clinical study will be successful. 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.

<https://ir.soligenix.com/2016-06-06-soligenix-announces-presentation-of-phase-2-oral-mucositis-clinical-trial-results-at-the-2016-multinational-association-for-supportive-care-in-cancer-conference>