Soligenix Investor Relations

Soligenix Announces Investor Webcast Event: Origins of Innate Defense Regulators and Review of the SGX942 Phase 2 Study Results in Oral Mucositis

Friday, December 16, 2016, from 8:30-9:30 am ET

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 that it will be hosting an Investor Webcast Event Friday, December 16, 2016, from 8:30-9:30 am ET on the origins of innate defense regulators (IDRs) as a new drug class, as well as a review of oral mucositis and the recently announced and published Phase 2 clinical data for SGX942 (dusquetide) in the treatment of oral mucositis in head and neck cancer patients, available online in the *Journal of Biotechnology* at the following link: http://www.sciencedirect.com/science/article/pii/S0168165616315668.

The live webcast event can be accessed at: https://engage.vevent.com/rt/soligenixinc~121616, with replay of the event to be made accessible on the Soligenix corporate website. A question and answer (Q&A) session with the featured experts and management will follow the presentations. If you would like to ask a question during the live Q&A, please submit your request via email to ir@soligenix.com. For a more detailed technical response, you are encouraged to e-mail questions no later than December 14, 2016. Alternatively, audio can be accessed by dialing Toll-Free 866-563-6458, Conference ID: 33796918.

The Investor Event will include presentations from the following:

Dr. Oreola Donini, Chief Scientific Officer of Soligenix and an inventor of Soligenix's IDR technology:*"Origins of IDRs, dusquetide and their unique mechanism of action as demonstrated in preclinical animal models of oral mucositis and infection."*

Dr. Steve Sonis, Senior Surgeon, Brigham and Women's Hospital and Dana Farber Cancer Institute, Chief Scientific Officer, Biomodels, LLC, and Chair of Soligenix's Oral Mucositis Medical Advisory Board, and an expert in the field of oral mucositis: *"Overview of oral mucositis as a significant complication in head and neck cancer and the unmet medical need that exists in its effective treatment."*

Dr. Richard Straube, Chief Medical Officer of Soligenix and Medical Monitor for the Oral Mucositis Clinical Program:*"Review of the recently published SGX942 (dusquetide) clinical results, including the acute and long-term Phase 2 study data (IDR-OM-01) for the treatment of oral mucositis in head and neck cancer patients."*

Dr. Mahesh Kudrimoti, Professor of Radiation Medicine, University of Kentucky and Principal Investigator for the IDR-OM-01 clinical trial will also contribute to the meeting.

Featured Clinical Experts Biographical Background

Stephen Sonis, DMD, DMSc

Dr. Sonis is a Clinical Professor of Oral Medicine at Harvard School of Dental Medicine and Senior Surgeon, Divisions of Oral Medicine at Brigham and Women's Hospital and the Dana-Farber Cancer Institute, and Chief Scientific Officer, BioModels, LLC. He is also a consultant to a number of biotechnology and pharmaceutical companies, advising directly on the conduct of clinical trials in oral mucositis. Throughout his career, Dr. Sonis has focused on the biology and clinical significance of cancer regimen-related mucosal toxicities. In particular, Dr. Sonis was pivotal in identifying the crucial role of innate immunity in the generation of severe oral mucositis. The results of his studies have provided treatment targets for biological and pharmaceutical development. Dr. Sonis and his collaborators have identified specific pathways that are critical in toxicity development and have used these to form the basis for models of gene-based risk prediction. Dr. Sonis has published and lectured extensively on the clinical, biological, and health economic aspects of cancer and complications associated with its treatment. He serves on a number of editorial boards, and is a founding member of the International Society of Oral Oncology and the International Academy of Oral Oncology. Dr. Sonis received his Doctor of Dental Medicine (DMD) from Tufts University, his Doctor of Medical Sciences (DMSc) from Harvard University and was a Knox Fellow at Oxford University.

Mahesh Kudrimoti, MD

Dr. Kudrimoti is a Professor of Radiation Medicine at the University of Kentucky. Dr. Kudrimoti received his medical degree from Osmania Medical College, Andhra Pradesh, India, and completed residencies at the University of Kentucky in Lexington, Robert Parker Hospital in Sayre, PA and Post Graduate Institute of Medical Education and Research in Chandigarh, India. He is board-certified by the American Board of Radiology in Radiation Oncology. Dr. Kudrimoti treats cancer patients, including many with head and neck cancer and has participated in multiple clinical trials in oral mucositis and trials in head and neck cancer.

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. 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 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 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.
