Soligenix Investor Relations

Soligenix Announces $150,000 NIH Small Business Innovation Research Award Supporting Evaluation of SGX942 in Pediatric Indications

Exploring Dusquetide in Broader Populations

PRINCETON, N.J., Aug. 15, 2019 /PRNewswire/ -- 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 the National Institute of Dental and Craniofacial Research (NIDCR), part of the National Institutes of Health (NIH), has awarded Soligenix a Phase I Small Business Innovation Research (SBIR) of approximately $150,000 to support the evaluation of SGX942 (dusquetide) in pediatric indications. This award will facilitate the assessment of SGX942 safety in juvenile animals, supporting future studies in pediatric populations, including oral mucositis indications in pediatric patients undergoing stem cell transplants and treatments for head and neck cancer.

Innate Defense Regulators (IDRs) regulate the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. Dusquetide is Soligenix's lead clinical IDR candidate. IDRs have no direct antibiotic activity but modulate host responses, increasing survival after infections with a broad range of bacterial Gram-negative and Gram-positive pathogens including both antibiotic sensitive and resistant strains, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- or radiation-therapy. Soligenix has previously reported the results of a Phase 2 clinical study using dusquetide in the treatment of oral mucositis in head and neck cancer (HNC) patients undergoing chemoradiation therapy (CRT). In addition to demonstrating a reduction in the median duration of severe oral mucositis in these patients, dusquetide treatment was also associated with a reduced incidence of reported infections and an increased rate of tumor resolution. A pivotal, Phase 3, multinational study in oral mucositis is currently underway in the US and Europe, with an interim analysis expected in theSeptember 2019 timeframe.

"We are appreciative of the continued support provided by NIDCR for the SGX942 development program," statedChristopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We believe this SBIR grant award further validates dusquetide's novel mechanism of action, as well as the positive clinical data generated to date. Oral mucositis remains an extremely debilitating side effect of cancer treatment in both adults and children. This funding will allow us to further evaluate the safety of IDRs in juvenile animals, allowing for the conduct of pediatric clinical studies, and the potential to expand future use in the pediatric patient population.

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.

In the pediatric population, head and neck cancer is a rarer occurrence and is caused by different underlying pathologies. The major types of HNC in children are lymphoma, sarcomas (including rhabdomyosarcomas), and neuroblastoma rather than squamous cell carcinoma, the major type of adult HNC cancers. Hematopoietic stem cell transplantation (HSCT), especially allogeneic transplantation with higher risk of oral mucositis, is more frequently used in the pediatric population than in adults when treating a number of primary tumor types, as seen in leukemia and lymphoma. Both treatment of HNC and HSCT are associated with high risk of oral mucositis in the pediatric population.

Oral mucositis remains an area of unmet medical need where there are currently no approved drug therapies in the context of any solid tissue tumors.

About Innate Defense Regulators

IDRs are a new class of short, synthetic peptides. They have a novel mechanism of action whereby they modulate the body's reaction to both injury and infection towards an anti-inflammatory, anti-infective and tissue healing 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. They also accelerate 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, macrophage activation syndrome (MAS) as well as bacterial infections, including melioidosis.

SGX942 (the lead clinical IDR candidate containing the active ingredient dusquetide) has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers. Positive efficacy results were demonstrated in a Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation therapy for head and neck cancer. Soligenix is working with leading oncology centers in the US and Europe to advance SGX942 in oral mucositis with the conduct of a pivotal Phase 3 clinical trial referred to as the "DOM–INNATE" study (Dusquetide treatment in Oral Mucositis – by modulating INNATE immunity).

Soligenix has a strong intellectual property position in the IDR technology platform, including composition of matter for dusquetide and related analogs. IDRs were developed pursuant to discoveries made by Professors B. Brett Finlay, PhD and Robert Hancock, PhD of the University of British Columbia, Canada. Soligenix has received partial funding from NIH for its oral mucositis clinical studies. The Phase 2 study was supported with a Phase I SBIR grant (#R43DE024032) award, with the Phase 3 study being supported by a Phase II SBIR grant (#R44DE024032) award. In addition, support for pediatric studies, including a juvenile toxicology study, has also been provided by a Phase I SBIR grant (#R43DE028769).

Key findings can be found in the following publications:

- "Targeting Innate Immunity to Treat Disease: Potential Therapeutic Applications" at https://www.drugtargetreview.com/article/37410/targeting-innate-immunity/.
- "A novel approach for emerging and antibiotic resistant infections: Innate defense regulators as an agnostic therapy" at http://dx.doi.org/10.1016/j.jbiotec.2016.03.032 .
- "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" at https://www.sciencedirect.com/science/article/pii/S0168165616315668

In addition, a high level review of the IDR technology platform is availablehere.

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 Specialized 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 Public Health Solutions business segment includes active development programs for RiVax®, our ricin toxin vaccine 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 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 U.S. 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 U.S. Congress may not pass any legislation that would provide additional funding for the Project BioShield program. In addition, there can be no assurance as to timing or success of the Phase 3 clinical trial of SGX942 (dusquetide) as a treatment for oral mucositis in patients with head and neck cancer receiving chemoradiation therapy or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. There also can be no assurance as to timing or success of the preclinical/clinical trials of RiVax®, that RiVax® will be approved for the PRV program or the amount for which a PRV for RiVax® can be sold. 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.

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For further information: Karen Krumeich, Chief Financial Officer, (609) 538-8200 | www.soligenix.com; Soligenix, Inc. 29 Emmons Drive, Suite B-10 Princeton, NJ 08540
