Soligenix Investor Relations

Soligenix Announces $600,000 Subaward Supporting Evaluation of Innate Defense Regulator Platform Technology as a Medical Countermeasure for Bacterial Threat Agents

PRINCETON, NJ – May 28, 2019 – 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 Soligenix will be participating in a biodefense contract for the development of medical countermeasures against bacterial threat agents, with Soligenix awarded a subcontract of approximately $600,000 over 3 years.

Innate Defense Regulators (IDRs) regulate the innate immune system to simultaneously reduce inflammation, eliminate infection and enhance tissue healing. 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. IDRs are also effective in conjunction with antibiotics, enhancing efficacy of sub-optimal antibiotic regimens and reducing the required antibiotic dose, thereby potentially minimizing the generation of antibiotic resistance. Soligenix has previously reported the results of a Phase 2 clinical study using dusquetide, its lead IDR, in the treatment of oral mucositis in head and neck cancer patients undergoing chemoradiation therapy. 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. A pivotal Phase 3 multinational study in oral mucositis is currently underway in the U.S. and Europe, with an interim analysis expected in the September 2019 timeframe.

The proposed work will further evaluate the efficacy of the IDR platform in animal models of disease caused by bacterial biothreat agents, such as *B. pseudomallei* and *F. tularensis*, among others. Previous animal studies have demonstrated efficacy against *B. pseudomallei* infection.

About Bacterial Threat Agents

Bioterrorism agents are characterized by the Centers for Disease Control and Prevention (CDC) as having significant potential to be utilized as a biowarfare weapon. The classification is based on the ease of dissemination and the potential consequent impact on society. Such diseases can be caused by viruses, bacteria and toxins. Bacterial threat agents, including *Bacillus anthracis* (Anthrax), *Burkholderia mallei* (Glanders), *Burkholderia pseudomallei* (Melioidosis), *Francisella tularensis* (Tularemia), *Yersinia pestis* (Plague) and *Coxiella burnetti* (Q-fever) and are considered either Category A (high priority) or B (second priority) threat agents. More information can be found at the CDC website.

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.

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.

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 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 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.
