Soligenix Investor Relations

Soligenix to Present at the 2018 ESCMID/ASM Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance

Princeton, NJ – August 29, 2018 – 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 Dr. Oreola Donini, Chief Scientific Officer, will be presenting preclinical and clinical data illustrating the potential utility of the Innate Defense Regulator technology in the treatment of infectious disease in a poster session at the upcoming European Society of Clinical Microbiology and Infectious Diseases / American Society of Microbiology Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance on September 4 – 7, 2018 to be held in Lisbon, Portugal.

Poster Presentation:

Innate Defense Regulators (IDRs) – Agnostic Therapy to Treat Bacterial Infections and Fight Resistance presented by Dr. Oreola Donini, Chief Scientific Officer, Soligenix, Inc., on September 4-5, 2018.

Dusquetide is an Innate Defense Regulator (IDR) that regulates 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 reported the results of a Phase 2 clinical study using dusquetide 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.

The presented results will address recent preclinical and clinical efficacy findings supported, in part, by the National Institute of Dental and Craniofacial Research (NIDCR; grants 1R43DE024032-01 and 2R44DE024032-02A1) and the National Institute of Allergy and Infectious Diseases (NIAID; grant 1R43 AI108175-01A1). These results are solely the responsibility of Soligenix and do not necessarily represent the official views of the National Institutes of Health.

About the 2018 ESCMID/ASM Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance

ESCMID/ASM conference is focused on the need to develop new antimicrobial drugs for the treatment of increasingly resistant pathogens. With a growing emphasis placed on the development of antimicrobial resistance by National and International bodies, the multidisciplinary meeting will look at the challenges, opportunities and current requirements for antimicrobial drug development.

For more information about the ESCMID/ASM 2018 conference, please refer to the conference website here.

About Dusquetide

Dusquetide (the active ingredient in both SGX942 and SGX943) 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.

Dusquetide has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers and positive results in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation therapy (CRT) for HNC. 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 from the Phase 2 study further indicated the safety and tolerability of dusquetide treatment. The long-term follow-up results 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.

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.

Soligenix has a strong intellectual property position in the IDR technology platform, including composition of matter for dusquetide and related analogs. 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 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.

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. 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.
