Soligenix Investor Relations

Soligenix Announces Issuance of New Composition of Matter Patent for Dusquetide Analogs

Princeton, NJ – September 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 the United States (US) Patent Office granted the patent entitled "Peptides for Treating and Preventing Immune-Related Disorders, Including Treating and Preventing Infection by Modulating Innate Immunity." The newly issued patent claims composition of matter of analogs of dusquetide (research name: SGX94), the Company's lead development compound. Dusquetide recently demonstrated positive preliminary results in a Phase 2 clinical trial for the treatment of oral mucositis in head and neck cancer patients. The recently issued patent broadens the protection around dusquetide and provides further protection for the underlying innate defense regulator (IDR) technology platform. Similar claims have been granted and/or are being pursued in jurisdictions worldwide.

IDRs are first-in-class small peptides with a novel mechanism of action. IDRs function by modulating the response of the innate immune system at a key convergence point in the intracellular signaling pathways. The innate immune system is a non-specific system which responds to a variety of insults, including infections and tissue damage. Because IDRs act by modulating the response of the innate immune system, they are agnostic as to either the cause of tissue damage (e.g., chemotherapy, radiation or trauma) or infection (e.g., antibiotic sensitive or antibiotic resistant infections). A summary of the IDR technology can be found in the following audio presentation entitled, "Dusquetide: Innate Defense Regulation as a Novel Approach to Antibiotic-Resistant Infection": https://www.youtube.com/watch?v=ef0-wQod-2E&feature=youtu.be

Patent number 9,416,157 was granted on August 16, 2016.

"Soligenix continues to pursue broad patent coverage for its dusquetide technology, first with composition of matter claims followed by therapeutic use claims in various indications, including infectious disease and oral mucositis," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "The IDR technology utilizes a novel mechanism, and first-in-class compounds, to address the underlying role of innate immune dysregulation in a broad spectrum of disease indications, including many areas of unmet medical need. The patent estate, including this most recent patent granted in the US, establishes a platform to pursue or partner these indications, as circumstances allow."

About Dusquetide

Dusquetide is an innate defense regulator (IDR), a new class of short, synthetic peptide. 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.

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 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, and as an adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis. Orphan Drug Designation for use of dusquetide in the treatment of MAS has also been granted.

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 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 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.

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