Soligenix Investor Relations

Soligenix Announces Publication of Preclinical Efficacy Results with Dusquetide in Infectious Disease

Preclinical Results Supported by Recent Positive Phase 2 Clinical Trial

Princeton, NJ – March 29, 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 the publication of data demonstrating the mechanism and broad-spectrum activity of dusquetide in preclinical bacterial infection models. Dusquetide, also known by the research name SGX94, is a novel Innate Defense Regulator (IDR) composed of 5 amino acids and is the active ingredient in the lead IDR drug product, SGX942. Recently, SGX942 demonstrated positive results in a Phase 2 clinical trial of oral mucositis in head and neck cancer patients receiving chemoradiation therapy, not only reducing the duration of severe oral mucositis, but also reducing the incidence of infection as well as potentially enhancing the anti-tumor response. The preclinical results were published online in the *Journal of Biotechnology* and are available at the following link:http://dx.doi.org/10.1016/j.jbiotec.2016.03.032.

As an IDR, dusquetide modulates the innate immune system by interacting at an intracellular integration point, operating downstream of most innate immune receptors and upstream of most cytokine and chemokine effectors. IDRs directly interact with an important protein known as p62, or sequestosome-1, thereby enhancing anti-infective mechanisms of the innate immune system and decreasing the often deleterious inflammatory responses. Because IDRs such as dusquetide target the host innate immune system, and not the bacteria directly, they are effective irrespective of the specific biological characteristics of the bacteria, whether antibiotic sensitive or resistant, gram-positive or gram-negative, intracellular or extracellular. IDRs are also complementary to antibiotics, and may provide an important tool in the fight against antibiotic-resistant and emerging infectious diseases.

Innate immunity is not only triggered by infection, but also by tissue damage. As such, IDRs also provide an ability to modulate inflammatory reactions to tissue damage, such as in the pathogenesis of oral mucositis. In a Phase 2 clinical trial, SGX942, containing dusquetide at a dose of 1.5 mg/kg, successfully reduced the median duration of severe oral mucositis by 50% in all patients and by 67% in patients receiving the most aggressive chemoradiation therapy for treatment of their head and neck cancer. In addition to the oral mucositis findings, an increased incidence of “complete response” of tumor at the one month follow-up visit was observed (47% in placebo versus 63% in SGX942 at 1.5 mg/kg). Decreases in infection rate were also observed with SGX942 treatment.

“The IDR technology was initially discovered in the context of infectious disease. Because IDRs target the host innate immune system, and not the bacteria, they are effective even when the bacteria are antibiotic resistant. Extensive testing has been done in the context of methicillin-resistant *Staphylococcus aureus* (MRSA) and has demonstrated that IDRs not only are effective as stand-alone therapy, but also are complementary to antibiotics, allowing a “two-pronged” attack on the bacterial infection,” stated Oreola Donini, PhD, Senior Vice President and Chief Scientific Officer of Soligenix. “The Phase 2 results not only confirm the potential efficacy of IDRs in the context of oral mucositis, but also prove that the unique biology of IDRs translates well into the human clinical setting. The multiple modes of efficacy observed in the Phase 2 study and the demonstrated safety in both the Phase 1 and Phase 2 clinical trials were very consistent with the preclinical findings and the highly conserved nature of the innate immune system.”

“These data demonstrate the broad and promising potential of our IDR technology platform,” stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. “While we continue to actively develop dusquetide for the treatment of oral mucositis, we are also poised to expand the platform to the infectious disease space and hope to fund these advancements through both partnerships and government grants/contracts, such as we have done to date with *Burkholderia pseudomallei* infection, a category B biothreat agent and the causative agent in melioidosis, an endemic tropical disease which is poorly treated by antibiotics.”

These studies were partially funded with grants from the National Research Council of Canada Industrial Research Assistance Program, agreement #703724, the National Institutes of Allergy and Infectious Diseases Small Business Innovation Research grant # 1R43 AI108175-01A1 and grant # 1R43DE024032-01.

About SGX942

SGX942 is an innate defense regulator (IDR), which contains a new class of short, synthetic peptide, having the chemical name dusquetide. 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 and other bacterial infections.

SGX942 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 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 (47% in placebo versus 63% in SGX942 at 1.5 mg/kg), 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.

SGX942 has received fast track designation 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. Fast track is a designation that the FDA reserves for a drug intended to treat a serious or life-threatening condition and one that demonstrates the potential to address an unmet medical need for the condition. Fast track designation is designed to facilitate the development and expedite the review of new drugs. For instance, should events warrant, Soligenix will be eligible to submit a new drug application (NDA) for SGX942 on a rolling basis, permitting the FDA to review sections of the NDA prior to receiving the complete submission. Additionally, NDAs for fast track development programs ordinarily will be eligible for priority review, which imparts an abbreviated review time of approximately six months.

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 first-in-class photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma, 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), and our novel innate defense regulator technology (SGX942) for the treatment of oral mucositis and infectious disease.

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 $57 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.

T*his 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," "intends," "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, including SGX942, particularly in light of the significant uncertainty inherent in developing vaccines against bioterror threats conducting preclinical and clinical trials of vaccines, obtaining regulatory approvals and manufacturing 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. Positive results from the Phase 2 study evaluating SGX942 does not ensure that the follow-on Phase 2/3 clinical study will be successful. 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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