Soligenix Investor Relations

FDA Grants Soligenix “Fast Track” Designation for SGX943 for the Treatment of Melioidosis

Princeton, NJ – May 31, 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 its SGX943 (dusquetide) development program has received “Fast Track” designation from the US Food and Drug Administration (FDA) as adjunctive therapy with other antibacterial drugs, for the treatment of melioidosis, a serious and potentially life-threatening condition.

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 SGX943 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.

“We are very pleased to have been granted fast track designation from the FDA,” stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. “We believe that the FDA’s action in granting fast track designation validates the unmet medical need that currently exists for the treatment of melioidosis and for the potential key role SGX943 can serve as a therapy in this rare, life-threatening disease. We look forward to working with the federal government to advance this biodefense development program.”

About Melioidosis

Melioidosis is a potentially fatal infection caused by the Gram-negative bacillus, Burkholderia pseudomallei (Bps). Highly resistant to many antibiotics, Bps can cause an acute disease characterized by a fulminant pneumonia and a chronic condition that can recrudesce. There is no preventive vaccine or effective immunotherapy for melioidosis. Therefore, there is a significant medical need for improved prevention and therapy.

Bps and the closely related Burkholderia mallei (Bm) are considered possible biological warfare agents by the Department of Health and Human Services (DHHS) because of the potential for widespread dissemination through aerosol. Bps is classified as a Tier 1 biothreat and a category B priority pathogen by the NIAID and is a top 5 priority in the most recent Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Strategy document.

Bps infection (melioidosis) is a major public health concern in the endemic regions of Southeast Asia and Northern Australia. Moreover, the organism has a worldwide distribution and the full extent of global spread is likely underestimated. Bps activity is seen in Southeast Asia, South America, Africa, the Middle East, India, and Northern Australia. The highest pockets of disease activity occur in Northern Australia and Northeast Thailand, Burma and Vietnam, and is likely under-reported in China. In Northeast Thailand, the mortality rate associated with Bps infection is over 40%, making it the third most common cause of death from infectious disease in that region after HIV/AIDS and tuberculosis.

About SGX943

SGX943 is the drug product designation for the active ingredient dusquetide in the treatment of melioidosis. Dusquetide is an IDR, a new class of short, synthetic peptides that has a novel mechanism of action in that it has simultaneous anti-inflammatory and anti-infective activity. 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, as well as accelerating resolution of tissue damage following exposure to a variety of agents including bacterial pathogens, trauma and chemo- and/or radiation-therapy. Dusquetide has demonstrated safety in a Phase 1 clinical study in 84 healthy human volunteers and preliminary efficacy and safety in an exploratory Phase 2 clinical study in 111 patients with oral mucositis due to chemoradiation therapy for head and neck cancer. Dusquetide has also previously demonstrated efficacy in numerous animal disease models including melioidosis, mucositis, colitis, skin infection and other bacterial infections. 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.

The testing of SGX943 in melioidosis has been supported by a NIAID Small Business Innovation Research (SBIR) grant valued at approximately $300,000 over one year.

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 dusquetide (SGX942) for the treatment of oral mucositis.

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.

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," "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 dusquetide (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.
