Soligenix Receives US Patent for Improved Production of Synthetic Hypericin

Active Ingredient in SGX301 for the Treatment of Cutaneous T-Cell Lymphoma

PRINCETON, NJ – August 22, 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 the United States (US) Patent Office has granted the patent titled "Systems and Methods for Producing Synthetic Hypericin". The newly issued patent's claims are directed to a novel, highly purified form of synthetic hypericin manufactured through a unique proprietary process. Synthetic hypericin is the active pharmaceutical ingredient in SGX301, the Company's photodynamic therapy for the treatment of cutaneous T-cell lymphoma (CTCL), currently the subject of an actively recruiting pivotal Phase 3 clinical trial with an interim analysis anticipated in the October 2018 timeframe. This new patent (No. 10,053,413), expected to expire in 2036, broadens the protection around synthetic hypericin, in addition to the previously granted US patents covering methods of use (No. 7,122,518) and methods of synthesis (No. 8,629,302).

SGX301 is a novel, first-in-class, photodynamic therapy that combines synthetic hypericin, a potent photosensitizer that is applied to the cancerous CTCL skin lesions and activated using a brief safe, fluorescent light treatment. This treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with the frequently employed DNA-damaging chemotherapeutic drugs and other photodynamic therapies that are dependent on ultraviolet exposure.

Based on the positive results demonstrated in the Phase 2 study of SGX301, the Phase 3 protocol is a highly powered, double-blind, randomized, placebo-controlled, multicenter trial seeking to enroll 120 evaluable subjects. The Phase 3 study is referred to as the FLASH (Fluorescent Light Activated Synthetic Hypericin) trial. The trial consists of three treatment cycles, each of 8 weeks duration. Treatments are administered twice weekly for the first 6 weeks and treatment response is determined at the end of Week 8. In the first treatment cycle, approximately 80 subjects will receive SGX301 treatment and 40 will receive placebo treatment of their index lesions. In the second cycle, all subjects will receive SGX301 treatment of their index lesions and in the third (optional) cycle all subjects will receive SGX301 treatment of *all* their lesions. Subjects will be followed for an additional 6 months after the completion of treatment. To date, the majority of patients enrolled have elected to continue on with the optional, open-label component of the study.

A blinded interim analysis for the study is anticipated in the October 2018 timeframe, with final topline results for the trial targeted for the first half of 2019.

"This recently issued patent continues to expand, strengthen and protect our synthetic hypericin patent estate," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With the support of the National Cancer Institute (NCI), most recently providing $1.5 million of funding under a two year Small Business Innovative Research (SBIR) grant, as well as important contributions from key patient advocacy organizations, such as the Cutaneous Lymphoma Foundation, we look forward to completing the ongoing Phase 3 CTCL study to potentially address the unmet medical need that currently exists in this orphan disease."

About Cutaneous T-Cell Lymphoma (CTCL)

CTCL is a class of non-Hodgkin's lymphoma (NHL), a type of cancer of the white blood cells that are an integral part of the immune system. Unlike most NHLs which generally involve B-cell lymphocytes (involved in producing antibodies), CTCL is caused by an expansion of malignant T-cell lymphocytes (involved in cell-mediated immunity) normally programmed to migrate to the skin. These malignant cells migrate to the skin where they form various lesions, typically beginning as a rash and eventually forming raised plaques and tumors as the disease progresses. Mortality is related to the stage of CTCL, with median survival generally ranging from about 12 years in the early stages to only 2.5 years when the disease has advanced. There is currently no cure for CTCL. Typically, CTCL lesions are treated and regress but usually return either in the same part of the body or in new areas.

CTCL constitutes a rare group of NHLs, occurring in about 4% of the approximate 500,000 individuals living with the disease. It is estimated, based upon review of historic published studies and reports and an interpolation of data on the incidence of CTCL that it affects over 20,000 individuals in the US, with approximately 2,800 new cases seen annually.

About SGX301

SGX301 is a novel first-in-class photodynamic therapy utilizing safe visible light for activation. The active ingredient in SGX301 is synthetic hypericin, a potent photosensitizer that is topically applied to skin lesions, is taken up by the malignant T-cells, and then activated by fluorescent light 16 to 24 hours later. This treatment approach avoids the risk of secondary malignancies (including melanoma) inherent with the frequently employed DNA-damaging chemotherapeutic drugs and other photodynamic therapies that are dependent on ultraviolet exposure. Combined with photoactivation, hypericin has demonstrated significant anti-proliferative effects on activated normal human lymphoid cells and inhibited growth of malignant T-cells isolated from CTCL patients. In a published Phase 2 clinical study in CTCL, patients experienced a statistically significant ($p \leq 0.04$) improvement

with topical hypericin treatment whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively. SGX301 has received orphan drug and fast track designations from the US Food and Drug Administration (FDA), as well as orphan designation from the European Medicines Agency (EMA).

The Phase 3 CTCL clinical study is partially funded with this NCI Phase II SBIR grant (#1R44CA210848-01A1) awarded to Soligenix, Inc.

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 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 the 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. Further, there can be no assurance that RiVax® will qualify for a biodefense Priority Review Voucher (PRV) or that the prior sales of PRVs will be indicative of any potential sales price for a PRV for RiVax®. Also, no assurance can be provided that the Company will receive or continue to receive non-dilutive government funding from grants and contracts that have been or may be awarded or for which the Company will apply in the future. 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.
