Soligenix Investor Relations

Soligenix Announces $1.5 Million NCI SBIR Grant Award Supporting the Pivotal Phase 3 Clinical Trial of SGX301 for the Treatment of Cutaneous T-Cell Lymphoma

2017 Non-Dilutive Funding Climbs to $6 Million

PRINCETON, NJ – September 18, 2017 – 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 National Cancer Institute (NCI), part of the National Institutes of Health (NIH), has awarded Soligenix a Small Business Innovation Research (SBIR) grant of approximately $1.5 million over two years to support the conduct of its pivotal, Phase 3, randomized, double-blind, placebo-controlled study evaluating SGX301 (synthetic hypericin) as a treatment for cutaneous T-cell lymphoma (CTCL).

“We are appreciative of the financial support provided by NCI for our pivotal Phase 3 clinical study of SGX301 in the treatment of CTCL,” stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. “With the assistance of NCI, as well as important collaborators such as the National Organization for Rare Disorders and the Cutaneous Lymphoma Foundation, we look forward to completing this study in order to potentially address the unmet medical need that currently exists in this patient population.”

Dr. Schaber continued, “We would like to thank NIH for its continued support and for its recognition of the merits of the important work we are doing in orphan diseases and areas of unmet medical need, as demonstrated by the approximate $6 million of additional non-dilutive funding it has awarded to Soligenix in 2017 across both our biotherapeutics and biodefense business segments. We will continue to be aggressive in our pursuit of government grants and contracts across our entire pipeline as a way to secure non-dilutive funding to support multiple development programs, while effectively managing our cash position.”

SGX301 is a novel, first-in-class, photodynamic therapy that combines synthetic hypericin, a potent photosensitizer that is applied to the cancerous skin lesions and activated using a brief treatment with safe fluorescent light. 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 trial consists of three treatment cycles, each of eight weeks duration. Treatments are administered twice weekly for the first six weeks and treatment response is determined at the end of Week 8. In the first treatment cycle, approximately 80 subjects will receive SGX301 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 cycle all subjects will receive SGX301 treatment of *all* their lesions. Subjects will be followed for an additional six months after the completion of treatment. The primary efficacy endpoint will be assessed on the percent of patients in each of the two treatment groups (i.e., SGX301 and placebo) achieving a Partial or Complete Response (yes/no) of the treated lesions defined as a ≥ 50% reduction in the total Composite Assessment of Index Lesion Disease Severity (CAILS) score for 3 index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline.

Soligenix has been working with leading CTCL centers, as well as with the National Organization for Rare Disorders and the Cutaneous Lymphoma Foundation to conduct this pivotal Phase 3 clinical trial with SGX301, referred to as the FLASH study (Fluorescent Light Activated Synthetic Hypericin).

About Cutaneous T-Cell Lymphoma

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, causing various lesions to appear that may change shape as the disease progresses, typically beginning as a rash and eventually forming plaques and tumors. 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.

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 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, as well as orphan designation from the European Medicines Agency.

The Phase 3 CTCL clinical study is partially funded with a NCI Phase II SBIR grant (#R44CA210848) award 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 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. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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. 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 and the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. 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.

https://ir.soligenix.com/2017-09-18-soligenix-announces-1-5-million-nci-sbir-grant-award-supporting-the-pivotal-phase-3-clinical-trial-of-sgx301-for-the-treatment-of-cutaneous-t-cell-lymphoma