Soligenix Investor Relations

Soligenix Completes Enrollment in its Pivotal Phase 3 Clinical Trial of SGX301 in the Treatment of Cutaneous T-cell Lymphoma

Final top-line results expected Q1 2020

PRINCETON, N.J., Dec. 3, 2019 /PRNewswire/ -- 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 it has completed patient enrollment in its Phase 3 "Fluorescent Light Activated Synthetic Hypericin" (FLASH) study for SGX301 (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL). The study successfully enrolled 169 subjects, following positive interim analysis, which included a prospectively defined, unblinded assessment of the study's primary efficacy endpoint by an independent Data Monitoring Committee (DMC). With enrollment completed, top-line results are expected in the first quarter of 2020.

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

"We are pleased to have completed enrollment and look forward to the top-line results in the first quarter of next year, particularly in light of the DMC recommendation at the interim analysis which observed a beneficial drug effect," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We have invested a significant amount of the Company's resources into the CTCL development program and continue to positively position this fast-tracked program for approval. We believe SGX301 has the potential to be a valuable therapy in the front-line treatment of early stage CTCL, which is an orphan disease and area of unmet medical need."

"SGX301 has the potential to have a significant impact on the lives of CTCL patients while minimizing their exposure to potential secondary cancers," stated Richard Straube, MD, Senior Vice President and Chief Medical Officer of Soligenix. "We would like to thank the DMC members, our esteemed medical advisory board and our dedicated clinical investigators for their ongoing efforts in the design and conduct of this important clinical trial, as well as all the subjects that are participating in the trial. Our focus is now to complete the treatments for all subjects and to lock the study database, facilitating top-line results in the first quarter of 2020."

Based on the positive results demonstrated in the Phase 2 study of SGX301, the Phase 3 trial is a highly powered, double-blind, randomized, placebo-controlled, multicenter trial. The primary efficacy endpoint is assessed as the percent of patients in each of the two treatment groups (i.e., SGX301 and placebo) achieving a successful response of the treated lesions at the end of Cycle 1 (Week 8) compared to baseline. A successful treatment response is defined as a 50% or greater reduction of the three index lesions treated as determined by the cumulative Composite Assessment of Index Lesion Severity (CAILS) scoring system. Other secondary measures, including treatment response (including duration), degree of improvement, time to relapse and safety, are further determined by data collected throughout the follow-on open-label portions of the trial in Cycle 2 (index lesions treated in all patients) and Cycle 3 (all lesions treated in all patients), as well as the six-month follow-up period.

A prospectively defined interim analysis was conducted inOctober 2018 by an independent DMC and was used to verify the underlying assumptions defining the required sample size of the study to maintain its rigorous 90% statistical power. The DMC identified a beneficial SGX301 effect and accordingly adjusted the study sample size to approximately 160. The DMC did not identify any safety concerns. The interim recommendation is described in the October 2018 press release here.

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 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 107 subjects receive SGX301 treatment (0.25% synthetic hypericin) and 53 receive placebo treatment of their index lesions. In the second cycle, all subjects

receive SGX301 treatment of their index lesions and in the third (optional) cycle all subjects receive SGX301 treatment of *all* their lesions. Subjects are followed for an additional 6 months after the completion of treatment. The majority of patients enrolled have elected to continue with the optional, open-label component of the study.

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

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 700,000 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 25,000 individuals in the US, with approximately 3,000 new cases seen annually.

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 Specialized 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 Public Health Solutions 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), the Defense Threat Reduction Agents (DTRA) 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 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.

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