Soligenix Investor Relations

Soligenix Announces Positive Recommendation by Independent Data Monitoring Committee on its Phase 3 Clinical Trial of SGX301 for the Treatment of Cutaneous T-cell Lymphoma

Princeton, NJ – October 15, 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 it has received a positive recommendation from the independent Data Monitoring Committee (DMC) to continue enrolling into the Company's Phase 3 "Fluorescent Light Activated Synthetic Hypericin" (FLASH) study for SGX301 (synthetic hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL). Following its unblinded interim analysis with data from approximately 100 subjects, including assessment of the study's primary efficacy endpoint, the DMC recommended that approximately 40 additional subjects be randomized into the trial to maintain the rigorous assumption of 90% statistical power for the primary efficacy endpoint. No safety concerns were reported by the DMC based on the interim analysis.

"We are pleased to have received the DMC's recommendation to continue enrolling to the adjusted target of 160 evaluable subjects in order to maintain our conservative power calculation," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We have invested a significant amount of the Company's resources over the last three years into the CTCL development program and it is gratifying to have received this feedback from the DMC indicating sufficient potential efficacy to warrant enrolling additional subjects into the trial. With this new level of clarity from the DMC's analysis of the interim Phase 3 study data and given our current enrollment status of approximately 120 subjects, we anticipate completing the study before the end of 2019 with topline results coming no later than the first quarter of 2020. Given our current cash resources, we anticipate that the available funds are sufficient to cover the additional study patients needed. We believe SGX301 has the potential to be a valuable therapy in the treatment of early stage CTCL, which is an orphan disease and area of unmet medical need."

"The DMC's recommendation is very encouraging and will allow us to aggressively pursue completing the trial, demonstrating SGX301's potential to successfully treat the CTCL index lesions using a combination therapy (SGX301 and the proprietary fluorescent light panel) that minimizes the long-term risks of treatment-associated secondary cancers," stated Richard Straube, MD, Senior Vice President and Chief Medical Officer of Soligenix. "SGX301 truly has the potential to have a significant impact on the lives of CTCL patients. We would like to thank the DMC members for their assistance, as well as our esteemed medical advisory board and our dedicated clinical investigators for their ongoing efforts in the design and conduct of this important clinical trial."

Based on the positive results demonstrated in the Phase 2 study of SGX301, the pivotal Phase 3 protocol is a highly powered, double-blind, randomized, placebo-controlled, multicenter trial originally targeted to enroll 120 evaluable subjects. 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 two-thirds of the subjects receive SGX301 (0.25% synthetic hypericin) and one-third of the subjects receive placebo treatment of their index lesions. In the second cycle, all subjects receive SGX301 treatment of their index lesions and in the optional third cycle all subjects receive SGX301 treatment of *all* their lesions. Subjects are followed for an additional 6 months after the completion of treatment. The primary efficacy endpoint is assessed on the percent of patients in each of the two treatment groups (i.e., SGX301 and placebo) achieving a successful response of the treated lesions, defined as an overall ≥50% reduction as assessed by the Composite Assessment of Index Lesion Severity (CAILS) scoring system across the three index lesions at the Cycle 1 evaluation visit (week 8) compared to

the total CAILS score at baseline. Other secondary measures assessed are treatment response (including duration), degree of improvement, time to relapse and safety.

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

The Phase 3 CTCL clinical study is partially funded with a National Cancer Institute 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 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 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 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®. 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.
