Soligenix Investor Relations

Soligenix Announces Positive Top-line Results for its Pivotal Phase 3 FLASH Trial Evaluating SGX301 in Treatment of Cutaneous T-Cell Lymphoma

- Statistically Significant Treatment Response Achieved in Primary Endpoint

- Company to Host Investor Conference Call Today at 8:30AM EDT

PRINCETON, N.J., March 19, 2020 /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 positive preliminary top-line results for its pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial evaluating SGX301 (Synthetic Hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL). The study enrolled 169 patients randomized 2:1 to receive either SGX301 or placebo, demonstrating statistically significant treatment response (p=0.04) in the Composite Assessment of Index Lesion Score (CAILS) primary endpoint assessment at 8 weeks for Cycle 1. In addition, preliminary assessment of the open-label Cycle 2 results suggest a significantly more robust response rate after 12 weeks of SGX301 treatment. These data are expected to be announced in June 2020.

"This is an important outcome for patients suffering from CTCL. SGX301 has successfully demonstrated efficacy in this challenging chronic cancer, with no safety concerns, making it a potentially preferred first-line option for the treatment of early stage CTCL, which is the large majority of patients suffering from this disease," stated Ellen Kim, MD, Director of the Dermatology Clinic, Perelman Center for Advanced Medicine and Lead Investigator of the FLASH study. "The treatment showed a statistically significant improvement after just 6 weeks of treatment. This successfully proves that the drug has biologic activity in combating this disease in a relatively short time window, with preliminary data suggesting that the improvement continues to increase with extended treatment. In addition to the efficacy demonstrated, SGX301 was well-tolerated and its mechanism of action is not associated with DNA damage like other currently available therapies."

"On behalf of everyone at Soligenix, I would like to extend my sincere appreciation to the patients, families, investigators, and advisors involved in the pivotal Phase 3 FLASH study," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We are extremely pleased with the results, which demonstrate successful treatment with SGX301 and reinforces its potential to be an important new treatment for early stage CTCL. We will now look to move as quickly as possible to complete a full analysis of the data for publication, as well as begin preparations for a robust discussion with the FDA regarding this important dataset."

Dr. Schaber continued, "With approximately $7.6M in cash, not including the anticipated sale of our New Jersey net operating loss carryovers and United Kingdom tax incentive receivable of approximately $1.0M or our non-dilutive government funding, we will evaluate the potential need for a larger capital raise only after top-line results from our Phase 3 study in oral mucositis. This will afford us the opportunity to more thoroughly assess commercialization and/or partnership of SGX301 in tandem with preparing for the New Drug Application submission to FDA. These results support our long-standing belief that 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."

Conference Call Thursday, March 19 at 8:30 AM Eastern Time

The Company will share trial results on Thursday, March 19, 2020 during an investor conference call. Investors may submit questions electronically at: ir@soligenix.com at least 15 minutes prior to the scheduled start of the call.

U.S. toll free: 1-866-652-5200
International: 1-412-317-6060
Please request to be entered into the Soligenix call.

A transcript of the conference call will be archived for 30 days following the event.

The Phase 3 FLASH trial enrolled 169 patients (166 evaluable) with Stage IA, IB or IIA CTCL. The trial consists of three treatment cycles, each of 8 weeks duration. Treatments were administered twice weekly for the first 6 weeks and treatment response was determined at the end of the 8th week of each cycle. In the first double-blind treatment cycle, 116 subjects received SGX301 treatment (0.25% synthetic hypericin) and 50 received placebo treatment of their index lesions. A total of 16% of the patients receiving SGX301 achieved at least a 50% reduction in their lesions (graded using a standard measurement of dermatologic lesions, the CAILS score) compared to only 4% of patients in the placebo group at 8 weeks ($p=0.04$). SGX301 treatment in the first cycle was safe and well tolerated. In the second open-label treatment cycle (Cycle 2), all patients received SGX301 treatment. Of note, preliminary results from blinded data to date suggest more than a 35% response rate (inclusive of patients receiving both 12 weeks and 6 weeks of therapy), indicating the response increases with continued treatment. Further independent review of lesion photographs may be conducted to provide for a more uniform confirmation of response. Results from Cycle 2 are expected to be announced in June 2020.

In the third (optional) treatment cycle (Cycle 3), all subjects could receive SGX301 treatment of all their lesions. Of note, the majority of patients enrolled have elected to continue with this optional cycle of the study. Moreover, in a subset of patients evaluated in this cycle, it was demonstrated that SGX301 is not systemically available, consistent with the general safety of this topical product observed to date. Results from Cycle 3 and the subsequent 6-month follow-up after completion of treatment will be further announced as the final patients continue to complete their designated visits.

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 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=0.04) improvement with topical hypericin treatment whereas the placebo was ineffective. 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).

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 targeted to enroll 160 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 will be determined at the end of Week 8. In the first treatment cycle, 116 subjects received SGX301 and 50 subjects received placebo treatment of their index lesions. In the second cycle, all subjects received SGX301 treatment of their index lesions and in the third cycle all subjects could receive SGX301 treatment of *all* their lesions. Subjects are followed for an additional 6 months after the completion of treatment. The primary efficacy endpoint was 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 three index lesions at the Cycle 1 evaluation visit (Week 8) compared to the total CAILS score at baseline. Assessment of the primary endpoint revealed that 16% patients receiving SGX301 responded (i.e., had ≥ 50% reduction in index lesion size) while only 4% receiving placebo responded (p=0.04). Preliminary results from blinded data to date suggest more than a 35% response rate (inclusive of patients receiving both 12 weeks and 6 weeks of therapy), indicating the response increases with continued treatment.

Other secondary measures assessed are treatment response (including duration), degree of improvement, time to relapse and safety, and will be available as the subsequent cycles and follow-up visits are completed for all subjects.

Overall safety of SGX301 is a critical attribute of this treatment and will continue to be monitored throughout the additional treatment cycles and the 6-month follow-up period. SGX301's mechanism of action is not associated with DNA damage, making it a safer alternative than currently available therapies, all of which are associated with significant and sometimes fatal, side effects. Predominantly these include the risk of melanoma and other malignancies, as well as the risk of significant skin damage and premature skin aging. Currently available treatments are only approved in the context of previous treatment failure with other modalities and there is no approved front-line therapy available. Within this landscape, treatment of CTCL is strongly motivated by the safety risk of each product. SGX301 potentially represents the safest available efficacious treatment for CTCL. With no systemic absorption, a compound that is not mutagenic and a light source that is not carcinogenic, there is no evidence to date of any potential safety issues.

The Phase 3 CTCL clinical study was partially funded by the National Cancer Institute via a 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 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 any of our other clinical/preclinical trials. 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.

SOURCE Soligenix, Inc.

For further information: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200 | www.soligenix.com, Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540

https://ir.soligenix.com/2020-03-19-Soligenix-Announces-Positive-Top-line-Results-for-its-Pivotal-Phase-3-FLASH-Trial-Evaluating-SGX301-in-Treatment-of-Cutaneous-T-Cell-Lymphoma