Soligenix Investor Relations

Soligenix Announces Positive Phase 3 FLASH Study Demonstrates Increased Efficacy with Continued Treatment in Patients with Cutaneous T-Cell Lymphoma

- SGX301 treatment response continues to demonstrate highly statistically significant improvement after 12 weeks of therapy
- Response rate in patients receiving a total of 12 weeks treatment increased two and a half-fold
- Reinforces positive SGX301 primary endpoint treatment response demonstrating statistical significance after 6 weeks of therapy

PRINCETON, N.J., April 30, 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 that continued treatment with SGX301 (synthetic hypericin) twice weekly for 12 weeks increased the positive response rate to 40% ($p<0.0001$ compared to placebo and $p<0.0001$ compared to 6-weeks treatment) in the open-label treatment cycle (referred to as Cycle 2) of its pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study for the treatment of early-stage cutaneous T-cell lymphoma (CTCL). These highly statistically significant results confirm the benefit of continued SGX301 treatment in CTCL patients.

Soligenix previously announced positive top-line results when the study achieved statistical significance ($p=0.04$) in its primary endpoint over the first 6 week double-blind treatment cycle (referred to as Cycle 1) (available here). The study enrolled 169 patients randomized 2:1 to receive either SGX301 or placebo in Cycle 1. After the subsequent additional 6-week treatment in the open-label Cycle 2, the response rate in patients receiving a total of 12 weeks treatment increased two and a half-fold. Treatment responses for each cycle were assessed at Week 8 (after 6 weeks of treatment) and at Week 16 (after 12 weeks of treatment). A positive response was defined as an improvement of at least 50% in the Composite Assessment of Index Lesion Score (CAILS) for three index lesions evaluated in both Cycles 1 and 2. The data continues to indicate that SGX301 is safe and well tolerated.

"As anticipated, the data continues to become more compelling with extended SGX301 treatment," stated Ellen Kim, MD, Director of the Dermatology Clinic, Perelman Center for Advanced Medicine and Lead Investigator of the FLASH study. "This treatment response is comparable to other, less safe, treatment alternatives, showing a statistically significant response at just 6 weeks, which continues to significantly increase with more treatment. The response rate at 12 weeks is similar to other therapies, some of which patients must take for more than a year. In addition to the efficacy demonstrated, SGX301 remains well tolerated with a unique mechanism of action that is not associated with DNA damage like other currently available therapies. I look forward to working with Soligenix to move this important new therapy forward with US Food and Drug Administration (FDA) so that patients may access it as soon as possible."

"The availability of a safe, rapid-acting, treatment for CTCL is extremely important to patients," stated Ms. Susan Thornton, Chief Executive Officer of the Cutaneous Lymphoma Foundation, the largest patient advocacy organization for CTCL. "From the patient perspective, you want a treatment that is safe and effective with the least amount of side effects. Many of the therapies available today either don't work for all patients, don't work for long-periods of time, can't be used by some because of their concerning side effects, or are used off-label creating access issues. As the leader of the patient organization and a patient myself, I know first-hand the importance of developing more therapies and options to support people living with this rare cancer."

"On behalf of everyone at Soligenix, I would like to again 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 study results, which demonstrate successful continued treatment with SGX301 and reinforces its potential to be a valuable and life-changing new therapy for patients suffering from early-stage CTCL, which is an orphan disease and area of unmet medical need."

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 patches and may progress to raised 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. 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 drugs and other phototherapy 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 FDA, as well as orphan designation from the European Medicines Agency (EMA).

The Phase 3 FLASH trial enrolled a total of 169 patients (166 evaluable) with Stage IA, IB or IIA CTCL. The trial consists of three treatment cycles. 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 ($p=0.04$) during the first treatment cycle (primary endpoint). 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 their index lesions. Evaluation of 155 patients in this cycle (110 receiving 12 weeks of SGX301 treatment and 45 receiving 6 weeks of placebo treatment followed by 6 weeks of SGX301 treatment), demonstrated that the response rate among the 12-week treatment group was 40% ($p<0.0001$ vs the placebo treatment rate in Cycle 1). Comparison of the 12-week and 6-week treatment groups also revealed a statistically significant improvement ($p<0.0001$) between the two groups, indicating that continued treatment results in better outcomes. SGX301 continued to be safe and well tolerated.

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. Other secondary measures assessed are treatment response (including duration), degree of improvement, and time to relapse and safety. 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.

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, SGX943, our therapeutic candidate for antibiotic resistant and emerging infectious disease, and our research programs to identify and develop novel vaccine candidates targeting viral infection including Ebola, Marburg and SARS-CoV-2 (the cause of COVID-19). 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.

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