Soligenix Investor Relations

Soligenix Receives European Patent for Therapeutic Use of Synthetic Hypericin to Treat Cutaneous T-Cell Lymphoma

PRINCETON, N.J., April 6, 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 the European patent office has granted the divisional patent application titled "Formulations and Methods of Treatment of Skin Conditions" (No. 2932973). The granted claims are directed to the therapeutic use of synthetic hypericin in the treatment of cutaneous T-cell lymphoma (CTCL). Synthetic hypericin is the active pharmaceutical ingredient in SGX301, the Company's photodynamic therapy, for which positive primary endpoint results in a pivotal Phase 3 study for the treatment of CTCL were recently announced (available here). This new patent expands on Soligenix's comprehensive patent estate, which includes protection on the composition of the purified synthetic hypericin, methods of synthesis and therapeutic methods of use in both CTCL and psoriasis, and is being pursued worldwide.

SGX301 is a novel, first-in-class, photodynamic therapy that combines synthetic hypericin, a potent photosensitizer that is applied to the cancerous CTCL 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 ultraviolet A and B exposure. In the double-blind, placebo-controlled Phase 3 "FLASH" (Fluorescent Light Activated Synthetic Hypericin) trial, SGX301 demonstrated a statistically significant improvement ($p=0.04$) in its primary endpoint after just 6 weeks of therapy (Cycle 1). The open-label extended treatment (Cycles 2 and 3) and 6–month safety follow-up remain ongoing, with data from Cycle 2 expected to be available in June 2020. Preliminary assessment of the blinded Cycle 2 results suggest a more robust response rate after 12 weeks of SGX301 treatment.

"This recently issued patent continues to expand, strengthen and protect our synthetic hypericin patent estate," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With the support of the National Cancer Institute (NCI), most recently providing $1.5 million of non-dilutive funding under a two year Small Business Innovative Research (SBIR) grant, as well as important contributions from key patient advocacy organizations, such as the Cutaneous Lymphoma Foundation, we look forward to completing the ongoing pivotal Phase 3 CTCL study to potentially address the unmet medical need that currently exists in this orphan disease.

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 Synthetic Hypericin

Synthetic hypericin, the active ingredient in SGX301, is 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, 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.

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 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. Despite the statistically significant result achieved in the SGX301 Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma, there can be no assurance that a marketing authorization from the FDA or EMA will be successful. 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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