

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

PRINCETON, N.J., Feb. 1, 2021 /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 Hong Kong Registrar of Patents has granted a patent for the application titled "Formulations and Methods of Treatment of Skin Conditions" (No. 16102842.8), published on January 29, 2021 under Publication No. 1214771 B. The granted claims are directed to the therapeutic use of synthetic hypericin in the treatment of cutaneous T-cell lymphoma (CTCL), similar to those granted in Europe in 2020. 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 is the first granted in Hong Kong and 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 (synthetic hypericin) is a novel first-in-class photodynamic therapy for first-line treatment of early stage CTCL. In the recently completed pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) trial, SGX301 achieved a statistically significant treatment response rate ($p=0.04$) in the primary endpoint after just 6 weeks (Cycle 1) of therapy when compared to placebo. This positive treatment response continued to significantly improve with extended SGX301 treatment in the open-label treatment cycles after 12 weeks ([Cycle 2](#)) and 18 weeks ([Cycle 3](#)) total treatment, reinforcing the positive SGX301 primary endpoint treatment response demonstrated in Cycle 1. In addition, SGX301 has demonstrated a statistically significant response in both patch and plaque lesions through 12 weeks of treatment (Cycle 2), highlighting the unique benefit of using visible light with its deeper skin penetration. SGX301 was well tolerated throughout the study and no mutagenic risks have been identified, unlike other second-line or off-label treatments, including other phototherapies, which utilize ultraviolet light. The Company believes SGX301 has compelling competitive advantages over existing therapies for early stage CTCL and represents a significant near-term commercial opportunity, as recently discussed (see webcast presentation [here](#)).

"This recently issued patent continues to expand, strengthen and protect our worldwide synthetic hypericin patent estate," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "With the recently announced strategic financing with Pontifax and our partnership with Daavlin for supply and distribution of the SGX301 companion light device, as well as important contributions from key patient advocacy organizations, such as the Cutaneous Lymphoma Foundation, we are moving towards SGX301 marketing approval and commercialization in the U.S., while actively pursuing partnership opportunities to leverage ex-U.S. markets."

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 U.S., with approximately 3,000 new cases seen annually.

About SGX301

SGX301 (synthetic hypericin) 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. The use of visible light in the red-yellow spectrum has the advantage of penetrating more deeply into the skin (much more so than ultraviolet light) and therefore potentially treating deeper skin disease and thicker lesions. 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 patients 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. Additional analyses also indicated that SGX301 is equally effective in treating both plaque (response 42%, $p<0.0001$ relative to placebo treatment in Cycle 1) and patch (response 37%, $p=0.0009$ relative to placebo treatment in Cycle 1) lesions of CTCL, a particularly relevant finding given the historical difficulty in treating plaque lesions in particular.

The third (optional) treatment cycle (Cycle 3) was focused on safety and all patients could elect to receive SGX301 treatment of all their lesions. Of note, 66% of patients elected to continue with this optional compassionate use / safety cycle of the study. Of the subset of patients that received SGX301 throughout all 3 cycles of treatment, 49% of them demonstrated a treatment response ($p<0.0001$ vs patients receiving placebo in Cycle 1). 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. At the end of Cycle 3, SGX301 continued to be well tolerated despite extended and increased use of the product to treat multiple lesions. Follow-up visits were completed in Q4 2020, and data lock and final analyses remain ongoing.

Overall safety of SGX301 is a critical attribute of this treatment and was monitored throughout the three treatment cycles (Cycles 1, 2 and 3) 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, such as experienced with the COVID-19 outbreak. 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 any of our 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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<https://ir.soligenix.com/2021-02-01-Soligenix-Receives-Hong-Kong-Patent-for-Therapeutic-Use-of-Synthetic-Hypericin-to-Treat-Cutaneous-T-Cell-Lymphoma>