

Soligenix Announces Strategic Partnership with Daavlin for Supply and Distribution of the SGX301 Companion Light Device in the Treatment of Cutaneous T-Cell Lymphoma

-- Providing an end-to-end business solution for our customers

-- Ensuring seamless integration of drug and light combination for both physicians and patients

PRINCETON, N.J., Jan. 7, 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 it has signed an exclusive Supply, Distribution and Services Agreement with Daavlin. Securing long-term supply and distribution of a commercially ready light device is an integral component of the regulatory and commercial strategy for SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma (CTCL).

Daavlin has a 40-year history of innovation and development in the field of phototherapy, providing an extensive line of products and services to health care providers and patients worldwide for the purposes of treating photoresponsive skin disorders such as psoriasis, vitiligo and now CTCL. The company's corporate headquarters and manufacturing plant are located in Bryan, Ohio.

Pursuant to the Agreement, Daavlin will exclusively manufacture the proprietary light device for use with SGX301 for the treatment of CTCL. Upon approval of SGX301 by the US Food and Drug Administration (FDA), Soligenix will promote SGX301 and the companion light device, and facilitate the direct purchase of the device from Daavlin; and Daavlin will exclusively distribute and sell the SGX301 light device to Soligenix, physicians and patients.

"We are pleased to be partnering with a company like Soligenix that has such deep expertise in development of products for treating rare diseases such as CTCL," said Dave Swanson, Founder and Chief Executive Officer of Daavlin, "Our extensive history in the commercialization of phototherapy medical devices in both the US and Europe complements Soligenix as they bring SGX301 to CTCL patients in need."

"Daavlin brings technical, manufacturing and commercial capabilities in both the US and Europe that will assist us in rapidly and efficiently distributing the SGX301 companion light device upon approval by FDA," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Seamless integration of the drug product and companion light device for physicians and patients is critical to the commercial success of SGX301 and working with Daavlin will help us achieve that operational excellence."

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 (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 Daavlin

Daavlin is a privately held company founded in 1981 by David Swanson, and has developed into a leading manufacturer of phototherapeutic products with a world-wide presence. The company's corporate headquarters and manufacturing plant are located in Bryan, Ohio. A network of international distributors offers Daavlin products in more than sixty countries around the world. Daavlin has a long tradition of development and innovation in the field of phototherapy with an extensive line of products and services offered in the field of dermatology. Daavlin products are used world-wide by dermatologists and by patients in their homes to treat photoresponsive skin disorders such as psoriasis, vitiligo, and eczema (atopic dermatitis).

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 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 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.

SOURCE Soligenix, Inc.

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