Soligenix Investor Relations

Soligenix Announces SGX301 Patient Case Study Presentation at the 4th World Congress of Cutaneous Lymphomas

Clinically meaningful response in difficult to treat type of CTCL

PRINCETON, N.J., Feb. 11, 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 Dr. Brian Poligone, clinical investigator and lead enroller in the pivotal Phase 3 FLASH (Fluorescent Light Activated Synthetic Hypericin) study evaluating SGX301 in the treatment of early stage cutaneous T-cell lymphoma (CTCL), will present a patient case study from the trial. The presentation will be given at the upcoming 4th World Congress of Cutaneous Lymphomas on February 12-14, in Barcelona, Spain.

Oral Presentation:

Response in a patient with refractory folliculotropic mycosis fungoides to a topical hypericin ointment activated with fluorescent light presented by Brian Poligone, MD, PhD, an Investigator in the FLASH study and Director of the Rochester Skin Lymphoma Medical Group, Fairport, NY, USA, on February 13th, 2020 at 8:00 AM CET. Abstract will be available on corporate website following the conference.

Folliculotropic mycosis fungoides (FMF) is a type of CTCL that is very difficult to treat. FMF is generally considered more severe and aggressive than other types of CTCL due to its greater risk of disease progression and worse prognosis. Treatment usually includes early consideration of systemic therapies, as topical therapies are often not beneficial. The presented case study focuses on a single patient with FMF who has completed the Phase 3 FLASH trial, including the open-label cycles and 6-month follow-up. The patient had previously failed at least five therapies, including topical treatments, oral medications and phototherapy. While in the study, the patient received at least 12 weeks of SGX301 treatment and experienced significant improvement, eventually leading to complete clearance of disease that has been sustained for at least 4 years.

"I'm happy to be presenting this important case study at the world congress," stated Dr. Brian Poligone, Director of the Rochester Skin Lymphoma Group. "This patient community needs safe, skin directed therapies to treat this difficult lymphoma and I'm very excited that SGX301 may be one such therapy. I know I can speak for the other clinical study sites participating in the FLASH study, when I say, we are eager for the topline results this quarter."

About the 4th World Congress of Cutaneous Lymphomas

The 4th World Congress is designed to promote the exchange of scientific ideas and foster interactions between physicians, researchers and anyone engaged in the field of cutaneous lymphomas. The program will include discussions of basic, translational and clinical research and discuss new developments in the diagnosis, practice and management of cutaneous lymphomas. More information about the Congress is found here and the final programme is available here.

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 ($p \leq 0.04$) improvement with topical hypericin treatment whereas the placebo was ineffective: 58.3% compared to 8.3%, respectively.

The Phase 3 FLASH trial enrolled 169 patients with Stage IA, IB or IIA CTCL. Enrollment of the trial is completed and topline primary endpoint results are expected to be available in Q1 2020. 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 is determined at the end of Week 8. In the first treatment cycle, approximately 107 subjects receive SGX301 treatment (0.25% synthetic hypericin) and 53 receive placebo treatment of their index lesions. In the second cycle, all subjects receive SGX301 treatment of their index lesions and in the third (optional) cycle all subjects receive SGX301 treatment of all their lesions. Subjects are followed for an additional 6 months after the completion of treatment. The majority of patients enrolled have elected to

continue with the optional, open-label component of the study.

The Phase 3 CTCL clinical study was partially funded with this NCI Phase II SBIR grant (#1R44CA210848-01A1) awarded to Soligenix, Inc.

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).

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 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 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 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 (including the outcome of the interim analysis) or the Phase 3 clinical trial of SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma. 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®. 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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For further information: Company Contact: 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
