

## **HyBryte™ FLASH Study Selected as a 'Top Poster' Winner for Presentation at the National Organization for Rare Disorders' Rare Diseases and Orphan Products Breakthrough Summit** **HyBryte™ filling a Critical Need in the CTCL Treatment Landscape**

PRINCETON, N.J., Oct. 12, 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 their poster abstract was selected as a "top abstract winner" and has been accepted for display and presentation at the 2021 National Organization for Rare Disorders (NORD) Rare Diseases and Orphan Products Breakthrough Summit to be held virtually on October 18-19, 2021. Christopher Pullion, DO, Soligenix's Medical Director, will present the positive Phase 3 results with [HyBryte™](#) (hypericin ointment 0.25%) in the context of the broader cutaneous T-cell lymphoma (CTCL) treatment landscape. The FLASH (Fluorescent Light Activated Synthetic Hypericin) trial is the largest multicenter, randomized, double-blind, placebo-controlled, skin-directed therapy study in CTCL to date, enrolling a total of 169 evaluable patients.

### **Oral/Poster Presentation:**

***Phase 3 Efficacy with a Novel, First in Class, Well-Tolerated Photodynamic Therapy (HyBryte™) for Early Stage Cutaneous T-Cell Lymphoma.*** Dr. Pullion's presentation will be available to view starting on October 18, 2021 and will remain available to view until November 19, 2021. Attendees will also be able to meet with Dr. Pullion to discuss the presentation live at several times during the two-day event. Only registered attendees can view and participate in this virtual conference. Attendees can [register for the NORD Summit here](#).

"To be selected to present our clinical trial data and review it in the context of its potential impact to patients at this year's NORD summit is a true honor," noted Dr. Pullion. "Conducting research in the rare disease landscape is only possible through close collaboration with patient advocacy groups, such as NORD and the Cutaneous Lymphoma Foundation, and the patients they serve. It is wonderful to be able to share with them the results of such a successful collaboration and detail why we think HyBryte, with its positive safety and efficacy profile, will represent a promising new treatment option in this difficult to treat and chronic cancer. I would like to thank all our participating patients and physicians who made this groundbreaking study possible."

### **About the National Organization for Rare Disorders**

The Rare Diseases and Orphan Products Breakthrough Summit brings together members of the rare disease community. The purpose is to allow disease experts and leaders from patient advocacy groups, government, industry, and academia to unlock new insights, network in a positive virtual environment, and discuss critical topics in the rare diseases and orphan products field. NORD, is a patient advocacy organization dedicated to individuals with rare diseases and the organizations that serve them. NORD, along with its more than 300 patient organization members, is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

### **About HyBryte™**

HyBryte™ (SGX301) is a novel, first-in-class, photodynamic therapy utilizing safe, visible light for activation. The active ingredient in HyBryte™ is synthetic hypericin, a potent photosensitizer that is topically applied to skin lesions that is taken up by the malignant T-cells, and then activated by visible 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 plaques and 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. HyBryte™ 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 consisted 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 HyBryte™ treatment (0.25% synthetic hypericin) and 50 received placebo treatment of their index lesions. A total of 16% of the patients receiving HyBryte™ 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). HyBryte™ treatment in the first cycle was safe and well tolerated.

In the second open-label treatment cycle (Cycle 2), all patients received HyBryte™ treatment of their index lesions. Evaluation of 155 patients in this cycle (110 receiving 12 weeks of HyBryte™ treatment and 45 receiving 6 weeks of placebo treatment followed by 6 weeks of HyBryte™ 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. HyBryte™ continued to be safe and well tolerated. Additional analyses also indicated that HyBryte™ 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 [HyBryte™ 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 HyBryte™ 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 HyBryte™ is not systemically available, consistent with the general safety of this topical product observed to date. At the end of Cycle 3, HyBryte™ continued to be well tolerated despite extended and increased use of the product to treat multiple lesions.

Overall safety of HyBryte™ 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. Its 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. HyBryte™ 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 Small Business Innovation Research (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 and commercializing SGX301 (synthetic hypericin) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma. With a successful Phase 3 study completed, regulatory approval and commercialization for this product is being advanced initially in the U.S. Development programs in this business segment also include expansion of synthetic hypericin (SGX302) into psoriasis, our first-in-class innate defense regulator (IDR) technology, dusquetide (SGX942) for the treatment of inflammatory diseases, 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).

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 Agency (DTRA) and the Biomedical Advanced Research and Development Authority (BARDA).

For further information regarding Soligenix, Inc., please visit the Company's website at <https://www.soligenix.com> and follow us on [LinkedIn](#) and Twitter at [@Soligenix\\_Inc.](#)

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 its clinical/preclinical trials. Despite the statistically significant result achieved in the HyBryte™ (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. Notwithstanding the result in the HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma and the Phase 1/2 proof-of-concept clinical trial of SGX302 for the treatment of psoriasis, there can be no assurance as to the timing or success of the clinical trials of SGX302 for the treatment of psoriasis. 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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