

## Soligenix Announces Interim Results from the Phase 3 FLASH2 Trial Evaluating HyBryte™ in Treatment of Cutaneous T-Cell Lymphoma

PRINCETON, N.J., April 28, 2026 /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 Data Monitoring Committee completed the interim efficacy analysis of its pivotal Phase 3 FLASH2 (Fluorescent Light Activated Synthetic Hypericin 2) trial evaluating HyBryte™ (Synthetic Hypericin) in the treatment of cutaneous T-cell lymphoma (CTCL). Under the terms of the interim analysis, the study was recommended to halt for futility.

"We are obviously very disappointed with the unanticipated outcome of the study," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "Despite the fact that HyBryte™ demonstrated statistically significant reductions in CTCL lesions after 6 weeks treatment in the first FLASH study, a similar signal was not observed with 18 weeks of treatment in this study. Over the coming weeks, we will analyze the data to better determine why the study did not meet expectations. If there is any clarity gained from further analysis of the dataset, especially with respect to specific subsets of patients that may benefit from HyBryte™ therapy, then we intend to communicate our findings and explore follow-up discussions with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA)."

Dr. Schaber continued, "With approximately \$5.9 million of cash, we will evaluate all strategic options moving forward, including but not limited to merger and acquisition opportunities as well as the potential of advancing dusquetide for the treatment of Behçet's Disease, which demonstrated promising biological efficacy in a [Phase 2 study last year using the intravenous formulation](#) and [has received orphan drug designation](#) most recently from the EMA."

### About HyBryte™

HyBryte™ (research name 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 safe, visible light approximately 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 [published 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 (Cycle 1), 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 modified Composite Assessment of Index Lesion Severity [mCAILS] 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 this 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 responses also revealed a statistically significant improvement ( $p<0.0001$ ) between the two timepoints, 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.

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 positive 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. HyBryte'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. HyBryte™ potentially represents the safest available efficacious treatment for CTCL. With very limited 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.

Following the first Phase 3 study of HyBryte™ for the treatment of CTCL, the FDA and the EMA indicated that they would require a second successful Phase 3 trial to support marketing approval. With agreement from the EMA on the key design components, the second, confirmatory study, called FLASH2, has demonstrated a good safety profile in the pre-specific safety evaluations by the Data Monitoring Committee. This study is a randomized, double-blind, placebo-controlled, multicenter study that replicates the double-blind, placebo-controlled design used in the first successful Phase 3 FLASH study that consisted of three 6-week treatment cycles (18 weeks total), with the primary efficacy assessment occurring at the end of the initial 6-week double-blind, placebo-controlled treatment cycle (Cycle 1). However, this second study extends the double-blind, placebo-controlled assessment to 18 weeks of *continuous* treatment (no "between-Cycle" treatment breaks) with the primary endpoint assessment occurring at the end of the 18-week timepoint. In the first Phase 3 study, a treatment response of 49% ( $p < 0.0001$  vs patients receiving placebo in Cycle 1) was observed in patients completing 18 weeks (3 cycles) of therapy. In this second study, all important clinical study design components remain the same as in the first FLASH study, including the primary endpoint and key inclusion-exclusion criteria.

In light of the interim analysis results, the Company will evaluate all available data and assess potential next steps, if any, with respect to the HyBryte™ development program.

Additional supportive studies have demonstrated the [utility of longer treatment times](#) (Study RW-HPN-MF-01), the [lack of significant systemic exposure](#) to hypericin after topical application (Study HPN-CTCL-02) and its relative efficacy and tolerability [compared to Valchlor®](#) (Study HPN-CTCL-04).

In addition, the FDA awarded an Orphan Products Development grant to support the investigator-initiated study evaluation of HyBryte™ for expanded treatment in patients with early-stage CTCL, including in the home use setting. The grant, totaling \$2.6 million over 4 years, was awarded to the University of Pennsylvania that was a leading enroller in the Phase 3 FLASH study.

### **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 more than 1.7 million individuals living with the disease in the U.S. and Europe (European Union and United Kingdom). 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 approximately 31,000 individuals in the U.S. (based on SEER [Surveillance, Epidemiology, and End Results] data, with approximately 3,200 new cases seen annually) and approximately 38,000 individuals in Europe (based on ECIS [European Cancer Information System] prevalence estimates, with approximately 3,800 new cases 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 HyBryte™ (SGX301 or synthetic hypericin sodium) as a novel photodynamic therapy utilizing safe visible light for the treatment of cutaneous T-cell lymphoma (CTCL). 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, including oral mucositis in head and neck cancer, and (SGX945) in Behçet's Disease.

Our Public Health Solutions business segment includes development programs for RiVax®, our ricin toxin vaccine candidate, as well as our vaccine programs targeting filoviruses (such as Marburg and Ebola) and CiVax™, our vaccine candidate for the prevention of COVID-19 (caused by SARS-CoV-2). 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 X at [@Soligenix\\_Inc.](#)

This press release may contain forward-looking statements that reflect Soligenix'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, and include the expected timing and results of clinical trials and the expected timing of regulatory submissions and approvals. In light of the discontinuation of the FLASH2 study, the Company's ability to continue as a going concern will be dependent upon its ability to develop and commercialize its remaining pipeline assets, including dusquetide for the treatment of Behçet's Disease, to identify and acquire or in-license additional product candidates or technologies, and to raise sufficient capital to fund such development and any such acquisitions. There can be no assurance that the Company will be able to obtain financing on acceptable terms, if at all, that suitable acquisition or in-licensing opportunities will be available, or that any of its remaining or future development programs will be successful. If the Company is unable to raise sufficient capital or otherwise advance its remaining assets, it may be required to significantly curtail or cease its operations, sell or otherwise dispose of its assets, or pursue dissolution and liquidation. 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 first HyBryte™ (SGX301) Phase 3 clinical trial for the treatment of cutaneous T-cell lymphoma or any other studies (including the open-label, investigator-initiated study) and the overall blinded study response rate observed in the second HyBryte™ (SGX301) Phase 3 clinical trial, notwithstanding any prior observations regarding such blinded response rate, the second HyBryte™ (SGX301) Phase 3 clinical trial did not demonstrate sufficient efficacy at the interim analysis to support continuation of the study, and no assurance can be given that any further development of HyBryte™ (SGX301) will be pursued or that a marketing authorization from the FDA or EMA will be sought or granted. Notwithstanding the result of HyBryte™ (SGX301) in the first Phase 3 clinical trial (or any other studies) for the treatment of cutaneous T-cell lymphoma and the Phase 2a 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. Additionally, despite the biologic activity observed in aphthous ulcers induced by chemotherapy and radiation, there can be no assurance as to the timing or success of the clinical trials of SGX945 for the treatment of Behçet's Disease. 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 (the "SEC"), 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: Jonathan Guarino, CPA, CGMA, Senior Vice President and Chief Financial Officer, (609) 538-8200 | [www.soligenix.com](http://www.soligenix.com) | Soligenix, Inc., 29 Emmons Drive, Suite B-10, Princeton, NJ 08540

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